Quality of life, functional level and needs of care after vascular major lower limb amputation

Riis Madsen, Ulla

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Quality of life, functional level and needs of care after vascular major lower limb amputation

Ulla Riis Madsen
To the patients who were too frail to participate in this project, and whose needs of care we still know far too little about.
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Abstract

This thesis was designed to investigate health-related quality of life, functional level and needs of care the first year after dysvascular major lower limb amputation and consists of four studies with three different designs.

A grounded theory was constructed in Study I. Data collection was guided by theoretical sampling and comprised of observations and interviews with eleven patients. The substantive theory of ‘Pendulating’ was constructed to explain patients' behavior shortly after having a leg amputated due to vascular disease. This theory shows that patients, independent of age and condition, go through a three-phased process as they realize they are experiencing a life-changing event. The results illustrates how cognitively and emotionally vulnerable patients are shortly after leg amputation.

In Study II, a systematic review was conducted in accordance with the Cochrane Handbook for systematic reviews to assess the effects of early mobilisation interventions in dysvascular lower limb amputated patients. With only five studies identified which covered the aim of the study—none of which were high quality—a research evidence gap was identified, and it cannot be concluded whether early mobilisation is beneficial to this vulnerable population. It was found that ambulation of newly amputated patients is complex but possible if the necessary interdisciplinary team is dedicated to the task.

A prospective longitudinal cohort study design was used in Studies III&IV. Short-term functional status was compared with status one month pre-amputation. Factors potentially influencing outcome were evaluated in Study III where characteristics of a consecutive sample of patients having amputation were also reported and participants were compared with non-participants. Effect of time and age on health related quality of life (HRQOL), general self-efficacy and functional level twelve months following dysvascular major lower limb amputation were investigated in Study IV. Data were collected via in-person interviews on functional level (Barthel index 100) at baseline and on Day 21 (Study III) and HRQOL (SF36), functional level (Barthel index 100) and general self-efficacy (GSE) at baseline and after three, six and twelve months respectively (Study IV). Participants were consecutively recruited from patients having amputation at the tibia, knee or femoral level at two Danish hospitals. In all, 60 of 105 eligible patients participated at baseline. Fifty-one patients completed Study III and 38 completed Study IV.
Short-term functional outcome (Study III) was positively associated with lower age and physiotherapy initiated after discharge and indicates that outcome is modifiable by care provided. Non-participants were significantly older than participants and had a high prevalence of dementia, acute confusion and severely deteriorated health and were therefore expected to have worse outcomes than participants.

Unique prospective longitudinal data on patients after dysvascular LLA who survived twelve months post-amputation were reported in Study IV. This study documents that significant improvement in more aspects of HRQOL can be achieved as soon as three months post-amputation. Independent of age, psychosocial problems persist and fluctuate throughout the first twelve months. Significant differences between age groups were identified in physical function over time with loss of physical function almost solely evident among the oldest patients after twelve months.

This thesis provides unique insight into the lives of dysvascularly-amputated patients during the first twelve months after an amputation and shows that, as a group, they are vulnerable in more aspects even though leg amputation can result in better HRQOL in all domains except physical function. Dysvascularly-amputated patients constitute a heterogeneous group with widely different functional levels and psychosocial needs and have a range of complex needs of care not always met by healthcare provided. Quality improvements are required in several areas to optimize quality of life.
Dansk resume

At få amputeret et ben betyder at man skal leve sit liv på en ny måde. Hvis man er ung og mister benet ved en ulykke, har man gode chancer for at få en protese som giver én en virkelig god gangfunktion tilbage. Heldigvis er det sjældent at unge mennesker mister benet i ulykker. De der rammes, er ældre, har ofte flere kroniske sygdomme, og har derfor ikke de samme chancer for at opnå god gangfunktion med en benprotese som de raske unge. Den mest almindelige årsag til benamputation i den vestlige verden er åreforkalkning og diabetes. Dette giver ulidelige smertener og sår som ikke vil hele, på trods af langvarige og specialiserede behandlingsforløb.

Det er kendt at de fleste af de ca. 1300 patienter der hvert år får amputeret et ben i Danmark, er over 70 år, at de har flere kroniske sygdomme, og at omkring halvdelen dør indenfor de første 12 måneder efter amputationen. Vi ved også at det at få amputeret et ben har store konsekvenser for den enkelte og dennes familie, både fysisk, psykisk og socialt. Men vi ved ikke hvordan de der overlever, klarer sig med disse udfordringer. Vi ved heller ikke hvordan patienterne oplever den hjælp, de får af sundhedsvesenet undervejs.

I denne afhandling der består af fire delstudier, er der brugt forskellige forskningsmetoder til at undersøge patienters oplevelse af deres livskvalitet, funktionsevne og behov det første år efter at have fået amputeret et ben på grund af vaskulær sygdom som åreforkalkning eller diabetes.

I det første delstudie (I) blev det med den kvalitative forskningsmetode 'Grounded Theory' undersøgt hvad man som patient særligt er optaget af i de allerførste dage/uger efter man har fået amputeret et ben. I alt elleve patienter deltog i observationer og interviews, og på baggrund af disse data blev den praksisnære teori 'Pendulering' konstrueret. Teorien 'Pendulering’ beskriver hvordan patienterne gennemgår en proces alt imens det går op for dem at de står midt i en stor livsforandring. Teorien forklarer deres reaktioner og underliggende bevæggrunde for at handle som de gør alt imens de først og fremmest er optaget af hvordan de skal komme til at klare sig. Dette studie illustrerer at patienter som får amputeret et ben er både kognitivt og følelsesmæssigt skrøbelige i den første tid, og understreger vigtigheden af at sundhedspersonalet møder dem med dette for øje.

I det andet delstudie (II) blev forskningslitteraturen systematisk gennemgået for at undersøge om tidlig mobilisering efter vaskulært betinget benamputation kan
mindske komplikationer, herunder tab af basale funktioner som f.eks. evne til at forflytte sig selv. På trods af grundige og systematiske søgninger blev kun fem studier fundet, og ingen af dem var af god kvalitet. De fire undersøgte mobilisering med midlertidige proteser, og det sidste målte effekten af at indføre en tværfaglig protokol. Selv om det er forventeligt, så kan det således ikke på baggrund af den forskning der hidtil er lavet, konkluderes at denne patientgruppe vil have glæde af tidlig mobilisering. Til gengæld viste litteraturgennemgangen at tidlig mobilisering er mulig blandt hele denne patientgruppe hvis et tværfagligt team er dedikeret til opgaven, og arbejder sammen med fælles mål for patienten.

I de sidste to del-studier (III&IV) blev alle der fik amputeret et ben på ét af de to deltagende danske hospitaler fra april 2015-april 2016, fulgt de første tolv måneder efter amputationen for at undersøge hvordan de kom til at klare sig. I studie III blev det undersøgt hvordan patienterne klarede sig på kort sigt, sammenlignet med før amputationen, samt hvilke faktorer der havde indflydelse på om de kunne forflytte sig selvstændigt fra stol til seng efter 21 dage. I Studie IV blev det undersøgt hvordan mål for livskvalitet, funktionsevne og self-efficacy ændrede sig over de første tolv måneder, og om der var forskel på hvordan forskellige aldersgrupper klarerede sig.

Patienterne blev interviewet ud fra en række spørgeskemaer om livskvalitet, daglige aktiviteter og self-efficacy. Første gang handlede interviewet om hvordan de havde klaret sig i måneden op til amputationen, og det blev udført indenfor de første tre uger efter operationen. Interviewene blev gentaget efter 21 dage, samt efter tre, seks og tolv måneder. Ved disse opfølgende interviews svarede patienterne på hvordan de klarede sig på det givne tidspunkt. Ud af de i alt 105 patienter som fik amputeret ben på de to deltagende danske hospitaler i studieperioden, deltog i alt 60 ved baseline hvoraf 51 fuldførte studie III og 38 studie IV. De mest almindelige årsager til ikke at deltage var demens, akut konfusion eller svært påvirket helbred.


Resultaterne fra studie IV viser at de patienter som overlever de første tolv måneder efter at have fået amputeret et ben, allerede efter tre måneder har signifikant forbedret livskvalitet på flere områder. Der er stor forskel på dem der klarer sig bedst og dem der klarer sig dårligst, både fysisk og psykosocialt. Der blev rapporteret om
psykosociale problemer gennem hele det første år, uafhængigt af alder. Når det kommer til den fysiske funktion er der stor forskel på hvordan yngre (<65 år), ældre (65-74 år) og de ældste (75+år) klarer sig idet de ældste står for stort set hele funktionstabet efter tolv måneder.

Denne afhandling giver et unikt indblik i patienternes liv det første år efter en vaskulært betinget benamputation, og viser at de benamputerede som gruppe er sårbare på flere områder. Dette er selvom det at få et ben amputeret kan føre til bedre livskvalitet på alle områder på nær den fysiske funktion sammenlignet med hvordan status var en måned inden amputationen. Det er samtidig vigtigt at påpege at patienter som får amputeret ben på grund af vaskulær sygdom er en heterogen gruppe som har meget forskellige funktionsniveauer og psykosociale behov. De har en række komplekse behov for pleje og rehabilitering som ikke altid bliver mødt af sundhedsvæsenet, og der er behov for kvalitetsforbedringer på en række områder for at sikre sig at flere klarer sig bedre.
This thesis is based on the following original papers, referred to in the text by their Roman numerals:


Paper II has been reprinted with kind permission from the publisher.

Paper I and III are available in open access.
Abbreviations

ADL: Activities of daily living
GSE: General Self-efficacy scale
HRQOL: Health related quality of life
ICF: The International Classification of Functioning, Disability and Health
LLA: Lower limb amputation
TFA: Through femur amputation
TKA: Through knee amputation
TTA: Through tibia amputation

Definitions:
Major LLA: a limb amputation at tibia, knee or femoral level.
Functional level is in this thesis used to describe physical function
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Introduction

My interest in patients having leg amputations goes back thirteen years. As the nursing head of an orthopaedic surgery unit, I was part of a group that developed and implemented an evidence-based critical pathway for patients having leg amputations. At that time, however, we did not dare say that what we were developing was evidence-based even though, looking back, it was. Experiencing the positive implications the changed procedures had on our patients became a deep part of each one of us involved in the process. Unfortunately, at the time none of us knew enough about research to document what we did or to evaluate the effect it had on our patients.

Having a leg amputated can have significant physical, psychological and social consequences for the individual\(^1\). Patients having dysvascular leg amputations are some of the frailest and most vulnerable patients in the orthopaedic settings and are characterized by high age\(^2\), multi co-morbidity and low survival prognosis\(^3,4\). Amputation of a leg as a result of vascular disease is a common and often inevitable procedure in orthopaedic departments and is commonly considered the end of a long, failed therapeutic process designed to save the leg. Proper rehabilitation is crucial to these patients’ prognosis. That being said, the need of care among patients having leg amputations as a result of dysvascularity has been very sparsely investigated and finding research on this topic is difficult. This thesis focuses on patients’ lives after leg amputation and looks at the potentially unmet healthcare needs experienced by these patients, and aims to investigate health related quality of life (HRQOL), functional level and needs of care the first year after dysvascular major lower limb amputation.

This Ph.D. project was initiated by the managers of two orthopaedic departments who wanted to raise awareness of patients having leg amputations in order to improve the quality of care level for this patient group. These managers worked with clinical staff and the following questions were asked:

'What kind of a life do we give them?'

'How do they manage after discharge?'

'How do we support them psychologically during their in-hospital stay?'
This thesis aims to answer these three questions and uses different methods to do so while trying to keep focus on patients’ perspective while examining potential unmet care needs. The first two questions 1) ‘What kind of a life do we give them’, and 2) ‘How do they manage after discharge?’ inspired me to look at patients experienced quality of life and functional level in both the short-term and over time as well as factors that could potentially influence these outcomes. The third question—‘How do we support them psychologically during their in-hospital stay?’ — gave the idea to explore the patients’ psychosocial needs immediately after having a leg amputated.
Background

Needs of care

When investigating how the life of a person having had LLA is affected and how improvements in care can contribute to better function and quality of life, it is interesting to explore how needs being met by healthcare is defined. The ultimate goal of health care is ”to provide equitable access for all people to an adequately trained, skilled and supported health workforce to contribute towards the attainment of the highest possible level of health”\(^5\). This definition is applicable whether longer or better quality of life is being discussed\(^6\). Health services should be organized around people's needs and expectations in order to provide person-centered care\(^7\).

The term ‘need’ is subjective and socially constructed\(^8\) and when used as a concept, it is often imprecise\(^9\). As a result, there is a list of considerations that need to be taken into account to identify need of care. These considerations include questions such as 1) What is a need of care? 2) How do you measure needs? 3) How much should a certain problem affect the individual, before the healthcare system should provide a service to relieve the need? 4) Can the need be met by healthcare? and 5) Are the costs reasonable?\(^10\)

Bradshaw’s (1972) taxonomy of needs distinguishes four types of needs within a sociological context which weigh the needs of the person from their own perspective and is a useful framework for identifying need of care after a LLA\(^9\). The framework consists of four perspectives on needs which add to the depth and breadth of understanding of needs. Neither is sufficient to explain the needs on its own but each contributes valuable information that helps with understanding of the concept. Bradshaw’s four needs comprise of normative, felt, expressed and comparative needs\(^9\).

Normative needs are needs defined by the expert. A ‘desirable’ standard for a given symptom is set, and everybody who falls short of this standard is considered in need. These ‘normative standards’ change over time as a result of development in knowledge and changing societal values. An example of this could be post-operative pain alleviation which has changed dramatically with more accessibility to modern medication. The limitation of only using normative needs as a basic identification is the paternalistic view that experts are always correct and that they know what is
best for the population of interest. This perspective fails to take into account the different needs of certain patient groups, personal values of the so-called experts and evolving nature of health care services.

*Felt need* is important as it tells us what the population says it needs. Felt need is limited by the perceptions of the individual, whether they know there is a service available and whether the service available seems feasible as well as a reluctance in many situations to acknowledge the loss of independence. This need is thought (by health care providers) to be inflated by those who ask for help without ‘really needing it’.

*Expressed need* is felt need turned into action by demands. One does not demand a service unless one feels a need, and it is common for felt need not to be expressed by demand.

*Comparative need* is need obtained by studying characteristics of the target population. Where there is a deficit between groups with the same characteristics and services available, there is a need.

To get a comprehensive picture of how improvement in care can contribute to better function and quality of life after having a LLA, potential need of care will be highlighted from more of these perspectives. These will not be limited to identifying needs of nursing care as defined in the International Classification for Nursing Practice (ICNP®)¹¹.

**Patient characteristics**

Complications to vascular disease is the most common cause of patients having major lower limb amputations (LLA) all over the western world with dysvascularity (peripheral artery disease, diabetes & infection) being the underlying cause of more than 90% of the cases²,¹²,¹³. Globally, the reported incidences¹⁴ of patients having dysvascular major lower limb amputations vary from 3.6 – 68.4 per 10⁵ (¹⁴). Differences are explained by ethnicity, social deprivation and by the role of diabetes and its complications. Significant variation in reporting methods makes comparisons difficult. That being said, incidence is expected to rise in coming years due to the rising prevalence of Type 2 diabetes and the increasingly aging population¹⁴,¹⁵. The incidence of major amputations performed in Denmark 2016 was estimated to be 3.0 per 10⁵ (¹⁶).

Patients who have major LLA on dysvascular indication constitute some of the most vulnerable and frail patients in the orthopaedic and vascular departments. The mean age of patients having dysvascular LLA is over 70 years². A slightly higher number of men than woman experience LLA and men are a little younger than the women
when it happens\textsuperscript{2}. Many of the patients have been restricted in mobility prior to amputation as a result of pain and months of treatments designed to save the leg\textsuperscript{17}. When combined with chronic illness and multi-comorbidity\textsuperscript{3,4}, these patients are at high risk of postoperative complications. Thirty-day mortality rates of 30\% have been reported\textsuperscript{3,4} with the main causes of death being cardiovascular and respiratory complications. Wound complications resulting in re-amputation at a higher level has been found in 20-23\% of patients who have transtibial-amputations\textsuperscript{18,19}. In addition to risk of medical complications, these patients are described as being at high risk of functional decline after amputation\textsuperscript{20} and have one-year survival rates of 46-56\%\textsuperscript{3,4}. This rate dips to as low as 25\% after five years\textsuperscript{3} which means it is important to focus on factors which influence the quality of life left for the individual.

**Life before the amputation**

When describing characteristics of patients having leg amputations, it is important to know about medical history and what implication this history has had on the patient's life. For many patients, there have been a series of events, such as suffering from diabetic foot ulcers or peripheral artery disease, that has led to the amputation, Patients who have diabetes are extensively educated in self-care to prevent foot-ulcers\textsuperscript{21}. Once a diabetic foot-ulcer has developed, the patient often needs to follow a strict regime of frequent change of dressings, avoiding weight-bearing on the foot, antibiotic medication and close monitoring by a specialist. This continues for months making it difficult to maintain social daily life activities such as work, leisure activities or housework which consequently leads to impaired Quality of Life (QOL)\textsuperscript{17}. These patients have an immense fear of losing their limp as up to 29.6\% of patients treated for diabetic foot ulcers have major LLA\textsuperscript{22}. One fourth of the patients treated for diabetic wounds in a specialist wound setting in Denmark ended up with major LLA\textsuperscript{23}.

Even if the wound heals, the individual is not out of danger as 50\% of the patients experience relapse wounds within 3 years\textsuperscript{24}. The risk of losing the remaining leg when the first leg is amputated is also high with risk of contralateral amputation being 5.7\% within the first year and 11.5\% within 5 years\textsuperscript{25}. Patients suffering from peripheral artery disease experience similar long and troublesome courses of diagnostic trajectories, vascular surgery, pain and wounds. When treatment fails, these patients are referred to orthopaedic surgeons to have the leg amputated. The procedure is often sub-acute with the aim of ensuring survival for patients with infections or acute embolus and to relive pain and give the best possible level of function for patients afterwards\textsuperscript{15} as they face remarkable physical challenges while recovering from surgery\textsuperscript{26}.
Psychosocial needs of care immediately after having a leg amputated

Losing a leg presents an array of physical, emotional and social challenges for the individual involved\(^2\), and successful adaption to the new life situation after having lost a leg is known to be highly correlated with health related quality of life (HRQOL)\(^2\). Patients’ need of psychosocial care immediately after leg amputation due to vascular disease, however, has only been investigated briefly and post-discharge\(^2\). Studies indicate that healthcare professionals involved in in-hospital care focus on physical and practical issues but often leave patients alone with their emotional and existential suffering\(^3\). Several studies have documented that in the months following an amputation, patients struggle with higher levels of anxiety, depression, restricted mobility and social isolation\(^2\)^. Moreover, themes of low self-esteem, changes in self and a struggle to accept the new identity as disabled are described as dominant during this period\(^3\). In addition to all of this, patients deal with a sense of grief, loss and shock\(^4\). Previous studies have been mostly cross-sectional and include selected populations of patients attending gait-training at rehabilitation facilities\(^2\)^. Consequently, the psychosocial challenges among patients not attending gait-training as well as the immediate reactions to amputation have yet to be investigated\(^2\).

Liu et al.\(^3\) investigated the lived experience after amputation among 22 Taiwanese amputees attending gait-training two months post-discharge and found participants reported suffering in both the physical and psychosocial realms and felt strongly that their lives had completely changed. While they appreciated the amputation intellectually, they simultaneously struggled to accept the decision emotionally and found professional help primarily directed at the physical and practical aspects of the amputation even though their focus was on coping with fear and anxiety. In a Danish study performed one to five months post-discharge, Norlyk et al.\(^3\) found that losing a leg is a radical and existential upheaval which restricts the patients’ lifestyles and changes their lifeworld dramatically. Restrictions to lifeworld was related to a sense of great loss as well as hope of regaining lost territory and personal independence. It is interesting to note that participants felt they were not always supported by healthcare professionals during this process.

Previous research indicates a gap in current care regarding support of patients’ transition towards life as physically-impaired after having a leg amputated\(^3\)^ and leaves the patient experience shortly after having amputation unexplored. Understanding patients’ behavior shortly after amputation could inform healthcare professionals in regard to how these vulnerable patients’ needs at hospital can be met as well as how to plan for post-discharge care which includes psychosocial dimensions.
Functional level

A range of factors influence achievable functional level after having acquired a physical disability such as having a leg amputated. In this section the theoretical framework which guided data collection in a part of this project is presented together with an explanation of functional level and factors related to functional outcome after dysvascular LLA which underpins this thesis.

Factors influencing functional level

The level of function after having acquired a disability (e.g. an amputated leg) is the result of a broad range of factors as described in the International Classification of Functioning, Disability and Health (ICF) model\(^{35}\) (Figure 1). The ICF was developed to create a shared language to analyze, consider and compare disability among individuals or groups with a variety of problems. The model is a bio – psycho – social model which means that it considers factors from bio-medical, psychological and social contexts when analyzing the consequences of disabilities. According to the model, function acquired by an individual (independence in activities at the individual level) after a disease or accident is the result of body-functions and structures on the one hand, and activities and participation on the other hand. Additionally, function is influenced by the disease or the disorder itself as well as by external (environmental) and personal factors\(^{35}\). Functional level achieved after LLA is thus influenced by factors from all parts of the model such as health condition (e.g. amputation level, complications and co-morbidities), body function and structures (e.g. prosthesis or wheelchair mobilisation, pain, cognitive impairments, social network), environmental factors (e.g. rehabilitation and homecare provided), personal factors (e.g. age, gender and adaption to the situation) and participation in leisure activities and degree of outdoor mobility.

![Figure 1. The International Classification of Functioning, Disability and Health (ICF)\(^{35}\).](image-url)
Long term functional outcome

Following major LLA, the focus of rehabilitation is to optimize function especially mobility\textsuperscript{29}. Mobility provides independence which enables the performance of activities of daily living (ADL) and can make the difference between returning home or remaining in a long-term care facility. Walking with a prosthesis is associated with higher HRQOL\textsuperscript{36} and, whether it is realistic or not, regaining walking ability with a prosthesis is the long-term goal for most patients after LLA\textsuperscript{37}.

The provision of prosthesis and gait training is a costly and time-consuming process that cannot be achieved by all patients who have LLA\textsuperscript{29}. Although older age in itself does not prevent prosthetic walking, the comorbidities previously described can stymie the requirements of higher energy, strength and cognitive demands needed for prosthetic walking\textsuperscript{15,29,38}. A more realistic long-term goal for rehabilitation for some patients should be independent transfers and mobility in wheelchair\textsuperscript{29}.

The reported number of patients regaining indoor walking ability after LLA varies from 25-97\%\textsuperscript{39-42}. Despite the fact that an unknown percentage of patients who have dysvascular LLA are never referred for prosthesis rehabilitation, most studies are performed in rehabilitation settings and have only included patients referred for prosthesis rehabilitation. This selection in the populations studied could explain the significant differences in success rates.

Short life expectancy combined with the fact that regaining walking ability on a prosthesis is not a realistic option for a considerable number of patients after dysvascular LLA\textsuperscript{29} makes it vital to measure functional outcome on factors contributing to quality of life even without prosthesis such as HRQOL and independence in ADL activities. Longitudinal studies in functional outcome that have measures of HRQOL and ADL and that include patients not attending gait rehabilitation are lacking.

Short term functional outcome

Autonomy in self-care has been described as one of the most important goals for patients admitted to rehabilitation after LLA\textsuperscript{43}; and independence in (ADL) at admission to rehabilitation after LLA is significantly associated with higher rates of survival after six months\textsuperscript{44}, prosthetic use\textsuperscript{45} and predicts good walking ability\textsuperscript{46}. Previous studies in functional outcome after LLA have mainly focused on factors associated with post-rehabilitation recovery of ambulation and prosthetic use\textsuperscript{39}.

Whether the realistic long-term goal is mobility in wheelchair or prosthetic walking, remaining and regaining personal independence should be highly prioritized as a goal for short-term functional outcome in postoperative care and early rehabilitation.
after LLA\textsuperscript{12,29,38}. Knowledge of factors influencing short-term functional outcome is limited to the population of patients having dysvascular major LLA.

**Early postoperative mobilisation**

It is known that in-hospital immobilisation leads to decline in ADL function among older patients\textsuperscript{47}. In contrast, postoperative early mobilisation starting as early as the day of surgery is known to prevent a range of postoperative complications including loss of basic functions in different settings\textsuperscript{48-51}. Despite this knowledge, it has been established that hospitalized patients spend most of their time in bed or in a chair\textsuperscript{52} and ambulating patients is a care task that is often missed\textsuperscript{53}.

Mobilising patients in the acute care setting is a fundamental care task\textsuperscript{54}. As such, it is the responsibility of nursing staff to mobilise patients\textsuperscript{55} though this care activity can be partially provided by allied health professionals such as physiotherapists. Nurses have been identified as the most capable healthcare professionals to promote functional independence in the chain of care providers surrounding older hospitalized patients to preserve independent walking ability\textsuperscript{55}.

Several factors have been identified that may act as barriers to patients being mobilised while they are hospitalized. Nurses, physicians and older adults themselves are reluctant to carry out mobilisation if the patients have symptoms of weakness, pain, fatigue or are concerned about falls or medical devices. Lack of staff and devices to assist with out-of-bed activity have been identified as further barriers to nurses and physicians when it comes to mobilising older hospitalized patients. This challenge is often combined with lack of motivation from patients\textsuperscript{47}.

In a study of how registered nurses decide to ambulate hospitalized older adults, Doherty-King \textit{et al.}\textsuperscript{57} found that nurses often labeled patients as either ‘community’ or ‘nursing home residents’. The latter label was given patients who had either come from a nursing home or looked as if they should be in a nursing home. Nursing home patients were assessed as patients who fell frequently, required considerable assistance with ADL or were confused. Consequently, patients labeled ‘nursing home residents’ were significantly more limited to the bed or chair, and ambulation was not considered. In the same study, it was also found that nurses were grouped into two categories identified by two specific traits which characterized the nurses’ behavior. One group attributed the responsibility of ambulation to another health care discipline while the second group accepted that ambulation of patients was their responsibility of practice. Nurses who attributed responsibility to another discipline waited to act while those who claimed responsibility for ambulation were more likely to take actions that initiated ambulation\textsuperscript{57}. 


Mobilising patients after major LLA is challenging for more reasons than those already mentioned. The fact that the patient only has one leg is an obvious challenge. Additionally, factors such as low muscle strength, uncertain balance, pain, age, multi-comorbidity, cognitive impairments and emotional distress make the task of mobilizing patients after dysvascular amputation a complex care task that involves an entire multidisciplinary team. Whether early mobilisation can protect patients having dysvascular LLA from complications including loss of basic functions is thus expected but still unknown and knowledge of effective strategies to promote postoperative mobilisation in this population is needed.

Quality of Life & Self- Efficacy

Having a leg amputated not only results in permanent physical changes to the individual involved; it also has an impact on psychological and social well-being\(^5^8\). Leg amputation can therefore have an impact on a range of factors that contribute to quality of life for the individual.

Quality of life (QOL) is considered a multidimensional and subjective concept that can only be understood from the individuals’ point of view\(^5^9\). There are several definitions of quality of life available\(^5^9\). The World Organization quality of life group defines QOL \(^6^0\) as ‘An individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.’ In order to distinguish between QOL in this broader sense and QOL connected with an individual’s health in particular, the concept of Health Related Quality Of Life (HRQOL) is often used\(^5^9\). HRQOL is the subjective and multidimensional concept measured with self-reported instruments and encompasses physical and occupational function, psychological state, social interaction and somatic sensation\(^6^0\) which is defined as ‘the functional effect of a medical condition and/or its consequent therapy upon a patient’\(^6^1\).

Health Related Quality Of Life after LLA

The concepts of QOL and HRQOL have been used interchangeably in the literature of LLA without a clear distinction between definitions\(^6^2\). In this thesis, HRQOL is used when referring to quality of life measured with self-reported instruments, and the term ‘quality of life’ is used when referring to the broader meaning of the concept of QOL.

Overall, HRQOL has been found to be lower among individuals having dysvascular LLA when compared with LLA for other reasons such as trauma or cancer\(^6^3\). When
compared with age and gender matched controls\textsuperscript{58}, it becomes important to investigate HRQOL among the dysvascular population themselves.

In a recent systematic review, walking with a prosthesis was identified as the most notable factor influencing HRQOL after dysvascular LLA \textsuperscript{36}. Other factors that influence HRQOL were found to be age, gender, level of amputation, co-morbidities and social support. All of these are described as indirectly influencing HRQOL through the ability to walk with a prosthesis\textsuperscript{36}. It has also been suggested that the associations between walking and the psychosocial dimensions of HRQOL are due to the positive influence of walking abilities on social interaction\textsuperscript{64} and that even small amounts of walking can result in greater HRQOL\textsuperscript{65}.

That being said, symptoms of perceived loss, changes in body image and social discomfort have been found to be more strongly associated with decreased HRQOL than physical health among older people\textsuperscript{32} which could indicate that the process of adaption may be different in older than younger individuals. While both more, less and no difference in psychological disturbance among older individuals compared with younger individuals with LLA have been reported, it has also been speculated that older people, who have a life of experiences, may have greater ability to adapt psychologically in extreme adverse circumstances\textsuperscript{32}. Despite this, ageism may limit support for all older patients which could affect their ability to make successful psychological adjustment.

Most studies in HRQOL after dysvascular LLA have used a cross sectional design and selected samples of individuals attending prosthesis fitting and could therefore be biased as factors influencing HRQOL among those not attending prosthesis fitting is left unknown. Additionally, HRQOL has been reported to change over time especially during the first twelve months post-amputation\textsuperscript{58,65}. Longitudinal studies including older patients are needed to identify when specific aspects of HRQOL change in order to target rehabilitation and long-term care for person-centered needs.

**Self-efficacy**

One unexplored element that could expand the understanding of the psychosocial consequences of amputation are measures of self-efficacy. Self-efficacy originates from cognitive theory and refers to the extent to which an individual believes that he/she can perform in a specific situation\textsuperscript{66}. Perceived self-efficacy is typically evaluated using self-report instruments which either focus on one specific skill or more general instruments when a wider range of activities, skills and conditions are of interest. Given the relationship between self-efficacy, motivation and improved coping, it is likely that an individual’s self-efficacy would affect his/her adaption and functional outcome and thereby his/her HRQOL.
Rationale

To address the three questions raised in the clinic and to get a comprehensive picture of which care improvements possibly contribute to better function and quality of life after having LLA, potential care needs through the first twelve months after a major LLA will be examined from several perspectives.

Patients’ experiences shortly after leg amputation is mainly unexplored, and previous research indicates a gap in current care regarding support of patients’ psychosocial needs after this kind of procedure. Understanding patients’ behavior shortly after amputation could inform healthcare professionals regarding how vulnerable patients’ psychosocial needs at hospital can be met as well as how to create a post-discharge plan that includes psychosocial needs.

Remaining and regaining personal independence should be highly prioritized as a goal for short-term functional outcome regardless of whether the realistic long-term goal is mobility in wheelchair or prosthetic walking. Previous research in functional outcome after LLA have, however, been mainly focused on factors associated with post-rehabilitation recovery of ambulation and prosthetic use and knowledge of factors influencing short-term functional outcome is limited in the population of patients having major dysvascular LLA.

One such factor could be early post-operative mobilisation. Whether early mobilisation can protect patients having dysvascular LLA from complications including loss of basic functions is expected but unknown. Moreover, knowledge of effective strategies to promote postoperative mobilisation of patients after major LLA is desired.

Longitudinal studies in functional outcome including patients not attending gait rehabilitation and with measures of HRQOL and ADL are also lacking. The majority of studies in HRQOL after dysvascular LLA have used a cross sectional design and have included selected samples of individuals having prosthesis fitting leaving HRQOL among those not having prosthesis fitting unknown. Given the relationship between self-efficacy, motivation and improved coping, it is likely that an individual’s self-efficacy would affect his/her adaption and functional outcome and thereby his/her HRQOL. HRQOL has been reported to change over time especially during the first twelve months post-amputation, and longitudinal studies including older patients are needed to identify when which aspects of HRQOL change in order to target rehabilitation and long-term care to person-centered needs.
Aim

The overall aim was to investigate health related quality of life, functional level and needs of care the first year after a dysvascular major lower limb amputation.

The specific aims of the four studies were to:

I. Construct a grounded theory explaining patients’ behaviour shortly after having a leg amputated because of vascular disease. Research question: What is the main concern of patients shortly after having a leg amputated and how do they resolve it?

II. Assess the effect of early mobilisation of patients after dysvascular lower limb amputation and to compare the effectiveness of different mobilisation regimens.

III. Investigate functional status on Day 21 after dysvascular major lower limb amputation compared with functional level one month pre-amputation and to evaluate factors potentially influencing short-term functional outcome. A second aim of this study was to report characteristics of a consecutive sample of patients having amputations and compare participants with non-participants.

IV. Investigate effect of time and age on HRQOL, general self-efficacy and functional level twelve months following dysvascular major lower limb amputation.
Methods

Design

This project was designed to investigate health-related quality of life, functional level and needs of care the first year after a dysvascular major lower limb amputation. The thesis consists of four studies with three different designs: Study I—a grounded theory design, Study II—a systematic review of the literature, and Studies III-IV—a prospective cohort study design. A chronological presentation of the scope of the four studies as related to the patient pathway is presented in Figure 2, and a schematic overview of designs and methods used are shown in Table 1.

Figure 2. Chronological presentation of the scope of the four studies as they correspond to the patient pathway. Vertical lines indicate time of data collection.
Methodological considerations

In this thesis, a multi-phase mixed method design was applied meaning that a step-by-step process of qualitative and quantitative studies was used concurrently and sequentially aligned with each new approach building on what was previously learnt (Figure 3). The research process started with Study I where a grounded theory design was chosen to answer the research question: ’What is the main concern of patients shortly after having a leg amputated and how do they resolve it?’ Data collection and analysis for this first study was completed and the information obtained during this process was used to form the initial research question and data collection for the cohort study: ’How do patients manage after having had a leg amputated?’ (Studies III+IV) Results and experiences obtained during data collection for Study I, combined with early data from the cohort study, led to the idea of performing a systematic review to assess the effect of early mobilisation of patients after dysvascular lower limb amputation and to compare the effectiveness of different mobilisation regimens. Information obtained from the systematic review (Study II) motivated us to explore the final aims of Study III. Data from all four studies will be integrated in the overall interpretation of data.

Figure 3. A multi-phase mixed method design with concurrent and sequential timing of studies. Arrows indicates where knowledge produced in one study informed another.

Even though it is still considered a research paradigm under development, mixed methods as a distinct concept is increasingly gaining ground. Choosing a mixed method approach is recommended for research of new or badly defined concepts or phenomena and/or when neither method alone answers the study objectives. Both arguments are relevant for the topic of this thesis.
Choosing a mixed method design reflects a pragmatic philosophical approach to science. The pragmatic scientist views science from an ontological stance which states that there are multiple ways of viewing, hearing and understanding the world and sees facts and values as linked rather than separate and truth as relativistic and provisional. The pragmatic epistemology says that knowledge is not neutral but influenced by human interest (ibid); hence, knowledge is formed by both objective and subjective values. The pragmatic scientist is identified by being ‘pragmatic’ in all stages of the research process which means that regardless of philosophy, he will use the methods or approaches which will lead to the best possible evidence.

Though there are several definitions of mixed methods available, there is still not consensus about what mixed methods entails or how to define it. Some of the leading authors in the field (Creswell and Plano Clark) define mixed methods as:

A research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches in many phases in the research process. As a method, it focuses on collecting, analyzing and mixing both quantitative and qualitative data in a single or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides better understanding of research problems than either approach alone.

Thus, mixed methods are characterized by integration of both quantitative and qualitative data in a single or series of studies as applied in this thesis. Integration of data can take place in any part of the research process whether it be in data collection, data analysis or interpretation of data.

**Sampling**

An overview of the specific inclusion and exclusion criteria and samples included in the four studies are presented in Table 1. More details of sampling methods used and samples included are presented in the description of the methods used in each of the studies.

In mixed method studies, it is not unusual (nor is it a prerequisite) that the same sample participate in both the qualitative and quantitative strand. In this thesis, participants were either included in the qualitative (Study I) or in the quantitative strand (Studies III+IV) which were parallel samples where all participants were selected from the population of patients having major lower limb amputations from the same setting and were thus comparable in characteristics and care situation.
Table 1 Overview of designs and methods used.

<table>
<thead>
<tr>
<th>Study</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Grounded theory</td>
<td>Systematic review</td>
<td>Prospective cohort study, follow-up day 21 post amputation</td>
<td>Prospective longitudinal cohort study, follow-up at 3,6 and 12 months post amputation</td>
</tr>
<tr>
<td>Inclusion criteria</td>
<td>Experiencing first major LLA(^a) on dysvascular background</td>
<td>Trials aimed at increasing early in-hospital mobilisation after amputation surgery</td>
<td>First major LLA(^a) in one or both legs</td>
<td>First major LLA(^a) on dysvascular background in one or both legs</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>Dementia and not speaking Danish</td>
<td>Studies describing mobilisation starting &gt;10 days post-surgery</td>
<td>Dementia, severely deteriorated health lasting &gt; Day 21 and not speaking Danish</td>
<td>Dementia, severely deteriorated health lasting &gt; Day 21 and not speaking Danish</td>
</tr>
<tr>
<td>Sample</td>
<td>Included patients (n=11)</td>
<td>Included studies (n=5)</td>
<td>Included patients(^b) (n=51)</td>
<td>Included patients(^b) (n=38)</td>
</tr>
<tr>
<td>Data collection</td>
<td>Observations and interviews</td>
<td>Systematic literature search in: PubMed CINAHL and EMBASE</td>
<td>In-person interviews using structured instruments</td>
<td>In-person interviews using structured instruments</td>
</tr>
<tr>
<td>Analysis</td>
<td>Constant comparative method</td>
<td>EPOC(^c) ‘risk of bias assessment tool’ and ‘data collection checklist’ Qualitative synthesis</td>
<td>Chi-square test Fisher’s exact test Student t-test Paired sample t-test Wilcoxon signed-rank test Logistic regression</td>
<td>Chi-square test Fisher’s exact test Mann-Whitney U-test Wilcoxon signed-rank test Kruskal-Wallis H test Dunn’s (1964) procedure</td>
</tr>
</tbody>
</table>

\(^a\) LLA = lower limb amputation. \(^b\) Patients recruited from the same cohort for Studies III and IV. \(^c\) EPOC: Cochrane Effective Practice and Organization of Care Review Group.

Setting and context

Patients participating in the studies were all recruited at the orthopaedic wards of two hospitals (Slagelse and Holbaek) in Region Zealand in Denmark. In total about 130 major amputations are performed on yearly basis in these two hospitals with approximately 75% performed in Slagelse where the vascular surgical department is located. Patients lived in 12 different municipalities throughout the region.

No national guidelines exist regarding the pathway for patients having LLA. However, local guidelines for care and treatment of amputation patients were available at both departments. An internal audit performed in June 2014 showed that these guidelines were neither updated nor followed in several areas. This discovery led to the establishment of a working group that has worked to prepare a critical
pathway valid for all four hospitals in Region Zealand. This pathway is ready for implementation in autumn 2017.

In Denmark, each patient is entitled by law to a plan for rehabilitation when discharged from the hospital if the physician believes there is a need. The municipality is then responsible for providing the necessary rehabilitation recommended and care is provided for free. The municipality decides how they will provide rehabilitation based on national minimum standards. Prostheses are considered a personal aid and, if the municipality allows, is provided to the patient free of charge. This decision is based on an application filled in by a physician, physiotherapist and prosthetist. The latter is self-employed and manufactures and supplies the necessary prostheses.

Slightly different procedures were followed at the two hospitals concerning referral to rehabilitation and provision of prostheses. For patients discharged from Slagelse Hospital, the prosthetic supply and walking training was given at the hospital. This training consisted of a one hour session twice a week. That is, patients who were assessed to be able to start training on a prosthesis on these grounds, directly after discharge, were referred directly to this specialist function. All others had to be re-referred to the hospital for re-assessment when / if their condition was improved.

For patients discharged from Holbaek Hospital, all rehabilitation was performed in the municipalities and if it was the patient’ wish to aim for a prosthesis, the application was filled in before discharge.

Study I

A constructivist grounded theory approach was used\textsuperscript{71} to construct a grounded theory explaining patients’ behavior shortly after having a leg amputated as a result of vascular disease. The research question was: ‘What is the main concern of patients shortly after having a leg amputated and how do they resolve it?’

Grounded theory

According to Charmaz\textsuperscript{71}, grounded theory are methods that consist of systematic yet flexible guidelines for collecting and analyzing qualitative data to construct theories from the data themselves. Grounded theory was introduced by Glaser and Strauss in 1967\textsuperscript{72} as a reaction to criticism from the predominant positivistic research world about qualitative research not being valid and reliable because of its apparent non-systematic methods. Since then, Glaser and Strauss have taken grounded theory into
somewhat divergent directions, and today researchers use the concept of grounded theory on very different methods.

Charmaz\textsuperscript{71} builds her understanding of grounded theory on a constructivist perspective where the basic assumption is that social reality is multiple, processual, and constructed. The researcher is involved in constructing and interpreting data, and therefore the researchers’ position, privileges, perspective and interactions must be considered as an inherent part of the research reality. According to Charmaz\textsuperscript{71} grounded theory provides a frame for qualitative inquiry and guidelines for conducting it which always begins with inductive logic which subjects data to rigorous comparative analysis with the aim of developing theoretical analysis. By choosing a constructivist grounded theory approach, the researcher aims for an abstract understanding of the life of the patients under study and views her analysis as located in time, place and the situation of inquiry\textsuperscript{71}.

**Sampling**

Sampling was divided into initial and theoretical sampling\textsuperscript{71}. The initial sampling was guided by the research question: ‘What is the main concern of patients shortly after having a leg amputated and how do they resolve it?’ The process was initiated by including participants belonging to the population under study\textsuperscript{71}. Thus, the initial recruitment of participants was based on a desire to investigate concerns and behavior among the heterogeneous population of patients who experienced leg amputation due to vascular disease for the first time (Table 1). A conscious effort to not exclude more frail patients who had not been included in this kind of study previously was made. Thus, the first two patients who were Danish-speaking and did not have a diagnosis of dementia were included based on accessibility.

Having analyzed the first set of data and constructed the first tentative theoretical categories (Table 2), all further inclusion was guided by the principles of theoretical sampling. Theoretical sampling is a deductive process where the researcher seeks people, events or information to illuminate and define properties, boundaries and relevance of the tentative theoretical categories that emerge through analysis\textsuperscript{71}. Thus, choices were made about where to look for data that could expand the emerging categories and concepts. As the study focus was the patients’ immediate reactions, and it was discovered early that observing patients in-hospital gave insight not available when the participants had rationalized their experiences after discharge, it was decided to continue recruiting patients experiencing their first leg amputation based on accessibility. It was also decided that the same data collection process would be used for all participants.
**Participants**

A total of eight men and three women were recruited within three days after having undergone unilateral leg amputation due to vascular disease. The age range of participants was 45-84 years. Two patients only participated in-hospital: one withdrew his consent and one was re-amputated before data collection was completed. Six participants underwent below-knee amputation, one was amputated through the knee and four above the knee. All had at least one comorbidity. Six participants lived with their spouse and the rest lived alone. All participants were retired. All but one was discharged to their former independent living situation with the latter being released to a temporary nursing home.

**Data collection**

Data collected involved a total of 30 informal interviews with participants and ten non-participant observations performed during the participants’ in-hospital stay and was followed by nine in-depth interviews two weeks post-discharge. Data collection was conducted from April 2014 to January 2015. All data were collected by the first author (URM) who met each participant on four occasions (three informal meetings and one planned observation) during the time he or she was admitted to hospital as well as in their homes two weeks post-discharge.

The study was designed to gain insight into the participants’ views, feelings, intentions and actions shortly after leg amputation. In this study, shortly means the first days/few weeks after the amputation. There was no clear, sharp demarcation of time and the insights follow where the patient was in his process.

To avoid influencing the study and recognizing the vulnerability of these patients, ethnographic (informal) interviews and observations were performed during the patients’ hospital stay and observations were expanded through in-depth interviews given 2 weeks post-discharge. In ethnographic interviews and observations, the researcher observed and inquired about behavior. She saw artifacts and objects used and asked about the meaning participants assigned to them. She observed emotional states and asked about what feelings meant. The approach of combining observations and interviews was chosen in order to compare the behavior observed with narratives told by the participants at interviews and, thereby, expand understanding as recommended by Charmaz.

Data collection, analyses and coding were performed simultaneously; and the constant comparative method was used to systematically collect data, code and analyze by constantly comparing incident with incident, incident with categories, and categories with categories while memos were written and theoretical sampling
performed\textsuperscript{71}. When writing memos, the main researcher (URM) stopped and wrote down analytical ideas about codes and the emerging categories as they occurred\textsuperscript{71}.

\textit{Process of data collection}

The informal interviews took place in connection with informal meetings with participants. The first interview was when participants were recruited for the study (Days 1-3 after amputation). The second was after observations (Days 3-5 after amputation), and the third was on the day before discharge when participants were approached to arrange an interview appointment for two weeks later. These informal interviews focused on what the patient had on his mind at that time and observations were made regarding behavior. At the first meeting, the project was presented with the sentence: ‘I’m investigating what people’s concerns are when they have had a leg amputated.’ All participants then had a narrative to tell describing what was on their minds. At the second meeting, participants were encouraged to further assess and explore observed opinions and feelings that arose from meetings with their healthcare providers. At the third meeting, some hardly remembered being part of a research project while others picked up the conversation from the last meeting. Narratives were told and notes of observation were written immediately after these meetings and stored on a computer.

Social process and interaction between patients and their healthcare providers were observed through non-participant observations\textsuperscript{73} in order to capture behavior as well as verbal and non-verbal communication that would further saturate the emerging concepts and categories. Observations were performed during the bedside meeting three to five days post-amputation where, according to the clinical pathway, the physician, nurse and physiotherapist were to evaluate whether the patient was suitable for prosthesis fitting as well as make plans for discharge of the patient. I sat at the back of the room to avoid interfering with the ongoing interactions. My co-supervisor (CBB) was present at the first observation to support my learning of what to focus on when performing non-participant observations. Field notes were taken during the observations and immediately reviewed, elaborated and stored on a computer. Each observation lasted 20-45 minutes.

In-depth interviews were performed at the patients’ homes two weeks post-discharge. An interview guide with open-ended questions based on the concepts and categories of interest that emerged from the other observations was developed and introduced to the participants with the statement: ‘I am interested in your experiences and concerns while you were hospitalized to have your leg amputated.’ The interview started with the question: ‘Would you please start telling me what led to the amputation?’ This was followed by questions about experiences and concerns during the hospital stay. Incidents and concepts from the in-hospital observations were brought forward to explore the opinions and feelings associated with them. Probing questions could be: 'What did you think about that?’ or 'Please say
something more about that.’ Additionally, all participants talked about coming home and their present concerns. Three of the participants wanted their spouses present to support their memory. The interview guide was customized from interview to interview as analysis developed and was, thus, congruent to theoretical sampling. Interviews lasted between 58 and 65 minutes and were digitally recorded and transcribed verbatim by URM.

Data for this study consists of field notes from 30 informal meetings, ten non-participant observations and transcripts of nine in-depth interviews. Analyses were performed by URM and supervised by last author (CBB) who read all coded data.

**Analysis**

Transcriptions from observations, interviews and memos were initially coded line-by-line after each session and URM looked for behavior related to the research question: “What is the main concern of patients shortly after having a leg amputated and how do they resolve it?” Initial codes were compared while looking for patterns in data and constructing early concepts. Further data were collected, coded line-by-line and compared until seven categories could be constructed as seen in Table 2. At this point, the patients’ main concern was adopted from an early in-vivo code and formulated as “How do I manage my life after having lost a leg?”. Further data collection was based on the seven categories that emerged from the theoretical sampling and focused coding was conducted hereafter to delimit data collection only to relevant categories. Theoretical sampling ceased when these categories were saturated and further data collection did not contribute new knowledge to the emergent theory. Through continually and systematically comparing categories with concepts while writing memos, analysis was brought to a higher level of abstraction which revealed the properties and range of emergent categories. Finally, the ‘puzzle’ was put together by explaining the behavior of the patients as reactions in a three-phased process where they realize they are experiencing a life-changing event. Eventually, the core category of Pendulating emerged to describe the general pattern of behavior throughout the process.
<table>
<thead>
<tr>
<th>Code</th>
<th>Category</th>
<th>Phase</th>
</tr>
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<tbody>
<tr>
<td>Having extensive thoughts</td>
<td>Being overwhelmed</td>
<td>Loosing control</td>
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<tr>
<td>Having fragmented memory</td>
<td></td>
<td></td>
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<tr>
<td>Letting things happen</td>
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<td>Defending and protecting oneself</td>
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<td>Surrendering</td>
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<td>Escaping</td>
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<tr>
<td>Limiting the consequences</td>
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<tr>
<td>Hoping to get a prosthesis</td>
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<td></td>
<td>Facing dependency</td>
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<tr>
<td>Seeking confirmation</td>
<td>Swallowing the life-changing event</td>
<td>Digesting the shock</td>
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<tr>
<td>Torturing oneself with mental pictures</td>
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<tr>
<td>Facing lethal consequences</td>
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<td>Relating to surgeon</td>
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<td></td>
<td>Detecting the amputated body</td>
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<tr>
<td>Telling about body experiences</td>
<td></td>
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<tr>
<td>Awareness of physical appearance</td>
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<tr>
<td>Having a limiting picture of ability as an amputee</td>
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<tr>
<td>Feeling relieved and yet frustrated</td>
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<td>Being torn between desire and reality</td>
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<td>Loosing courage</td>
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<td>Struggling dualism</td>
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<tr>
<td>Not knowing what to expect</td>
<td>Managing consequences</td>
<td>Regaining control</td>
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<tr>
<td>Downscaling expectations and compromising to solve practicalities</td>
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<tr>
<td>Knowing adapting takes time</td>
<td>Building up hope and self-motivation</td>
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<td></td>
</tr>
<tr>
<td>Counting positive signs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparing with other (worst case)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sorting bad memories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prioritizing functioning over feelings</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Study II

A systematic review was performed according to the steps of the Cochrane Handbook for Systematic Reviews of Interventions\textsuperscript{74} to assess the effect of early mobilisation of patients after dysvascular LLA and to compare the effectiveness of different mobilisation regimens (Paper II).

This review has been reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement\textsuperscript{75}.

Sampling

According to the Cochrane Handbook for Systematic Reviews of Interventions\textsuperscript{74}, the first step when performing a systematic review is to investigate whether any studies covering the topic of interest already exists. Thus, preliminary searches for existing systematic reviews were conducted on Cochrane, PubMed, PROSPERO, and Cinahl databases in January 2016. These searches did not reveal any studies of this nature.

Search strategy

Systematic searches were performed on PubMed (including MEDLINE), CINAHL and EMBASE in January 2016. An intentionally broad search strategy was used and aimed at identifying as many studies as possible. The strategy contained four blocks and included terms for ‘amputations’ OR ‘amputees’ AND terms for ‘leg’ AND terms for ‘dysvascular’ OR ‘non-traumatic’ AND terms for ‘mobilisation’ OR ‘ambulation’ respectively (full search strategy available in Appendix A). In addition to the electronic search, reference lists of the included articles were used as a source to identify relevant studies.
Inclusion criteria

Articles were included if they reported a trial evaluating early mobilisation of patients after amputation surgery as described in the PICO\textsuperscript{76} question in Figure 4:

- **P** What is the effect in patients having a lower limb amputated (transtibial, knee disarticulation, transfemoral) caused by vascular disease,
- **I** of early mobilization (all ‘out-of-bed’ activity starting within the first postoperative week),
- **C** when early mobilization vs usual care is compared, in a hospital setting,
- **O** measured as complication rates, survival rates, time to recovery, functional level & time to prosthesis fitting.

**Figure 4. PICO question\textsuperscript{76} describing the scope of the literature review**

Design of studies included comprised (Cluster-) randomized controlled trials, (un-) controlled before-and-after studies, interrupted times series (ITS) studies and pilot studies comprising of the above-mentioned study designs. Case studies with historic control designs, and thus with a high risk of bias, were included as they might contribute insight into components important to designing interventions customized to the heterogenic population of patients who have leg amputations in the post-surgery setting.
Inclusion process

The process of identification and selection of studies for inclusion is visualized in a flow diagram (Figure 5). A total of 1836 records were identified from the electronic search. After titles and abstracts were screened, 13 articles were assessed for eligibility by two independent reviewers along with four records which were found from reference lists. Each article was checked twice and doubts were resolved by discussion. These 17 resources had their full-texts screened by the first (URM) and last author (CB). Twelve articles were excluded of which six had a wrong design (case story or cohort study), four studies had the wrong setting (rehabilitation facility describing mobilisation after day 10) and two did not report outcome of mobilisation. In the end, five articles were included.

Figure 5. Process of identification and selection of studies for Study II
Quality assessment

To assess the risk of bias, the Cochrane Effective Practice and Organization of Care Review Group (EPOC) ‘risk of bias assessment tool’ was used. This tool is a domain-based evaluation to assess selection, performance, attrition, detection and reporting biases. For non-randomized studies, Cochrane recommends the addition of additional domains. Thus, 2 domains were added to the tool: (1) randomization (yes/no) and (2) control group (yes/no). The quality assessment was performed by URM and thoroughly reviewed by and discussed with CB.

Data collection

Data were extracted by URM and thoroughly reviewed by and discussed with CB. For data extraction, the EPOC data collection checklist was used. The general characteristics of each study (design, setting and sample size) were extracted from the included studies. Characteristics of participants consisted of inclusion and exclusion criteria, number of participants screened and included average age, comorbidities, gender and level of amputation. Descriptions of modalities and duration of the interventions were considered as well as healthcare professional involvement in interventions (nurses, physiotherapists, physicians, prosthetists). Details of how and when relevant outcome measures were collected were likewise examined. As part of this process, all sections of the included studies were carefully read to find additional information of interest.

Analysis

Due to the heterogeneity of the studies, it was not possible to perform a meta-analysis. Instead, the studies were analyzed and a qualitative synthesis including aggregating and summarizing the results was conducted. These observations are presented in summary tables and in narrative form.

The study protocol was registered at PROSPERO database (2016) (reg. CRD42016033344) to avoid unplanned review duplication and to facilitate comparison of review conduct with what was planned in the protocol.
Studies III and IV

A prospective cohort study design was used to investigate functional status on Day 21 after dysvascular major lower limb amputation compared with functional level one-month pre-amputation and to evaluate factors potentially influencing short-term functional outcome as well as to report characteristics of a consecutive sample of patients having amputations and compare participants with non-participants (Study III). Additionally, effect of time and age on HRQOL, general self-efficacy and functional level twelve months following dysvascular major lower limb amputation was evaluated (Study IV).

Sampling

Participants for Studies III and IV were consecutively recruited among patients having primary major LLA (amputation at tibia (TTA), knee (TKA) or femoral (TFA) level) from April 2015 to April 2016 at the two study sites. Patients with bilateral amputations (previously having a major LLA at the contralateral leg, or bilateral procedure) were included. Patients with a diagnosis of documented dementia and severely deteriorated health lasting > Day 21 as well as non-Danish speaking patients were excluded as it was assessed they were not eligible for the interviews needed for data collection.

Nurses on the wards identified patients daily, and referred new patients to the first author (URM). If the patient fulfilled the inclusion criteria, the nurse asked the patient whether he/she would allow URM to contact them about the study and gave them a written information leaflet. URM then approached the patient to provide verbal information about the study and to obtain written consent for participation.
Patients and participants

Process of inclusion and attrition is shown in Figure 6. In all, 60 patients participated at baseline in Study III. Two had LLA based on trauma or cancer and were therefore not eligible for inclusion in Study IV. Of the 45 patients not participating, 27 were excluded because of dementia, deteriorated health or confusion, nine were deceased before inclusion, three were identified too late to be included and six declined. In all, 51 patients completed Study III, and a total of 38 patients completed all follow-up in Study IV. A total of 7 participants dropped out and twelve deceased before 12-month follow-up. Characteristics of patients eligible for inclusion, those not participating at baseline and those completing Studies III and IV, respectively, are presented in Table 3.
Table 3. Characteristics eligible patients for inclusion, and non-participants vs participants completing study III & IV.

<table>
<thead>
<tr>
<th>Patients (n)</th>
<th>Eligible</th>
<th>Non-participants</th>
<th>Study III</th>
<th>P valuea</th>
<th>Study IV</th>
<th>P valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean (SD)</td>
<td>105</td>
<td>45</td>
<td>51</td>
<td>&lt;.001b</td>
<td>38</td>
<td>.001*</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>17 (16)</td>
<td>2 (4)</td>
<td>12 (24)</td>
<td></td>
<td>11 (29)</td>
<td></td>
</tr>
<tr>
<td>65-75</td>
<td>46 (44)</td>
<td>18 (40)</td>
<td>26 (51)</td>
<td></td>
<td>18 (47)</td>
<td></td>
</tr>
<tr>
<td>75+</td>
<td>42 (40)</td>
<td>25 (56)</td>
<td>13 (26)</td>
<td>.008*</td>
<td>9 (24)</td>
<td>.006*</td>
</tr>
<tr>
<td>Sex: male</td>
<td>69 (66)</td>
<td>24 (53)</td>
<td>39 (77)</td>
<td>.024*</td>
<td>26 (74)</td>
<td>.037*</td>
</tr>
<tr>
<td>Indication:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>40 (38)</td>
<td>16 (36)</td>
<td>21 (41)</td>
<td>.643</td>
<td>16 (42)</td>
<td>.684</td>
</tr>
<tr>
<td>Trauma/cancer</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td></td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>ASA b 1-2</td>
<td>8 (8)</td>
<td>1 (2)</td>
<td>5 (10)</td>
<td>.134</td>
<td>4 (11)</td>
<td>.128</td>
</tr>
<tr>
<td>3</td>
<td>76 (72)</td>
<td>34 (76)</td>
<td>37 (74)</td>
<td>.719</td>
<td>27 (73)</td>
<td>.823</td>
</tr>
<tr>
<td>4</td>
<td>18 (17)</td>
<td>9 (20)</td>
<td>8 (16)</td>
<td>.552</td>
<td>6 (16)</td>
<td>.823</td>
</tr>
<tr>
<td>5</td>
<td>1 (1)</td>
<td>1 (2)</td>
<td>0</td>
<td></td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Two or more co-morbd</td>
<td>74 (71)</td>
<td>33 (73)</td>
<td>35 (69)</td>
<td>.578</td>
<td>24 (63)</td>
<td>.828</td>
</tr>
<tr>
<td>Confuse d</td>
<td>48 (46)</td>
<td>33 (73)</td>
<td>10 (20)</td>
<td>&lt;.001*</td>
<td>5 (13)</td>
<td>&lt;.001*</td>
</tr>
<tr>
<td>30 day mors</td>
<td>19 (18)</td>
<td>16 (36)</td>
<td>1 (2)</td>
<td>&lt;.001*</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Amputation level:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TTA</td>
<td>40 (38)</td>
<td>9 (20)</td>
<td>27 (53)</td>
<td>.001*</td>
<td>22 (58)</td>
<td></td>
</tr>
<tr>
<td>TKA</td>
<td>12 (11)</td>
<td>9 (20)</td>
<td>2 (4)</td>
<td>.017*</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>TFA</td>
<td>53 (51)</td>
<td>27 (60)</td>
<td>22 (43)</td>
<td>.091</td>
<td>15 (39)</td>
<td>.009*</td>
</tr>
<tr>
<td>Re-amputation</td>
<td>22 (21)</td>
<td>10 (22)</td>
<td>11 (22)</td>
<td>.782</td>
<td>7 (18)</td>
<td>.531</td>
</tr>
<tr>
<td>Final level TTA e</td>
<td>27 (26)</td>
<td>3 (7)</td>
<td>20 (39)</td>
<td>&lt;.001*</td>
<td>17 (45)</td>
<td>&lt;.001*</td>
</tr>
<tr>
<td>Bilateral amp</td>
<td>15 (14)</td>
<td>6 (13)</td>
<td>6 (12)</td>
<td>.809</td>
<td>7 (18)</td>
<td>.809</td>
</tr>
</tbody>
</table>

*a statistical significant values p< .05, a Chi-square test of homogeneity for categorical variables, Fisher's exact test in cells <5, and Mann-Whitney U test for continuous variables (completed study vs non-participants). b missing n=2. Diagnosis besides diabetes & dementia. c Described as 'some' or 'much' confused in records. d Number of patients with final amputation level at TTA. e Contralateral leg amputated earlier n=12, bilat amputation n=3.
Data collection

Data were collected via in-person interviews using structured instruments covering different time spans as illustrated in Figure 2. In Study III, data were collected twice: at baseline and at follow-up on Day 21. In Study IV, data were collected four times: at baseline and at follow-up after three, six and twelve months, respectively (Figure 2). For both Studies III&IV, the battery of instruments used at baseline were repeated at follow-up. An overview of instruments used is shown in Table 4 and explained in detail in the ‘Structured instruments and measures’ section.

Table 4. Instruments used in Study II and IV

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Measuring</th>
<th>Scoring range</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barthel index 100</td>
<td>Independence in ADL activities</td>
<td>Overall score 0-100, individual items score 0-5, 0-10, 0-15 respectively, highest score= independent</td>
<td>III &amp; IV</td>
</tr>
<tr>
<td>Locomotor Capabilities Index (LCI-5)</td>
<td>Basic and demanding gait skills</td>
<td>0-56, ↑ score= better skills</td>
<td>III</td>
</tr>
<tr>
<td>Short form 36 (SF36)</td>
<td>HRQOL</td>
<td>0-100, ↑ score =better HRQOL</td>
<td>IV</td>
</tr>
<tr>
<td>The general self-efficacy scale (GSE)</td>
<td>General self-efficacy</td>
<td>10-40, ↑score = better GSE</td>
<td>IV</td>
</tr>
<tr>
<td>Mini-Mental-State Examination (MMSE)</td>
<td>Cognitive impairment</td>
<td>0-30, ↑score = better cognitive function</td>
<td>III</td>
</tr>
<tr>
<td>Complementing self reported items*</td>
<td>Prosthesis provisiona, Painb, social networkc, aidsd, homecared, accommodatione, rehabilitation serviceb and complicationsb</td>
<td>Individual</td>
<td>III &amp; IV</td>
</tr>
<tr>
<td>Medical record review</td>
<td>Level of amputationa, co-morbiditya, complicationsa, rehabilitation serviceb</td>
<td>Individual</td>
<td>III</td>
</tr>
</tbody>
</table>

* referring to concepts in the ICF model, figure 7. a Used in study IV, b used in study III.
Baseline assessments were performed in-hospital. Considerable consideration was taken not to overburden the already vulnerable patients who were admitted to a busy ward; thus, the baseline assessments were performed whenever possible after the written consent was filled in and at the latest on Day 21. At baseline, participants were asked about one month pre-amputation, and all questions were preceded by the sentence: “In the following questions, I am asking you about the month BEFORE your amputation.” As part of the daily and routine in-hospital care, a physiotherapist evaluated pre-amputation walking ability, function of the remaining leg and documented daily physiotherapy provided (Study III).

Follow-up on Day 21 was performed in the outpatient clinic when participating patients had their stitches removed. Follow-up at three, six and twelve months was performed at participants’ homes.

Day 21 interviews were performed by three specially trained nurses, and URM performed all other interviews. Patients were encouraged to bring a relative to all occasions if desired. Medical records were reviewed for clinical and demographic data on all patients having LLA during the study period by a specially trained physiotherapist and URM. All data were documented directly into a trial software (http://www.easytrial.net).
Structured instruments and measures

Study III investigates functional status on Day 21 compared with functional level one-month pre-amputation and evaluates factors potentially influencing short-term functional outcome. Study IV investigates effect of time and age on HRQOL, general self-efficacy and functional level twelve months following LLA. Data were collected at baseline, Day 21 and three, six and twelve months post-amputation. The presentation of the instruments used in the data collection was structured from the ICF model\textsuperscript{35} as shown in Figure 7.

![Figure 7](image)

**Figure 7.** Overview of data collected in Study III and IV framed by the ICF model\textsuperscript{35}. Colors indicates which study the construct is analysed in. Letter a-f refers to which instruments are used to collect data on the construct, shown in Table 4. \textsuperscript{g} Data were collected from medical records.

With reference to the overview of the structured instruments used (shown in Table 4), Figure 7 shows which instruments were used to measure which construct in the ICF model. All instruments are described in detail in the following text. As illustrated in Figure 7, the data collection in Studies III and IV measure all constructs in the model. The instruments used in this thesis are validated for use among the population of patients having LLA when available.
a. Barthel index 100

The Barthel index 100 was originally developed to measure independence in ADL activities after stroke. This instrument measures the level of assistance an individual needs to perform 10 ADL activities (personal hygiene, bathing self, eating, toilet, dressing, bowel control, bladder control, ambulation or wheelchair (if no ambulation), chair/bed transfers and stair climbing.) Overall scores range from 0-100. Each item is scored on a five-point likert scale (0-5, 0-10, 0-15 respectively) where the highest score represents independence in the activity. Barthel index 100 has shown good reliability and adequate validity for the amputee population.

Assessments are performed based on participants’ description of how they performed individual activities. Barthel index 100 is analyzed as functional outcome in Studies III and IV.

To evaluate short-term functional outcome in Study III, the Barthel index 100 item bed-chair transfer was analyzed as a dependent variable. Independence in bed-chair transfer is a basic activity needed to become independent in a number of ADLs and an activity realistic to regaining independence within 21 days after LLA. Maximum scores were dichotomized into ‘independent’ (representing participants performing bed-chair transfers without any assistance necessary) and ‘dependent’ (representing participants in need of at least one person’s assistance in bed-chair transfers).

b. Locomotor Capabilities Index (LCI-5)

LCI-5 was developed to measure walking ability after LLA with prosthesis. It measures walking ability by 14 items in a five-point likert scale and covers basic and demanding gait skills as perceived by the informant. The LCI-5 has shown good reliability in terms of Cronbach alpha value of .95. It has been translated and validated in a Swedish context and includes the use of the instrument to measure pre-amputation gait skills. The Danish version used in this study is translated from Swedish in collaboration with the above-mentioned authors and is used in this thesis with their permission. LCI-5 (pre-amputation gait skills) is analyzed in Study III as a possible influencing factor on short-term functional outcome (independent variable).

c. Short form 36 (SF36)

SF36 was originally developed for use in clinical practice as well as for research, and is widely used and validated in various settings with Cronbach alpha value of .88-.94 (ibid). SF36 is a multipurpose short-form health survey which addresses eight domains that contribute to HRQOL: physical function, role limitation physical, pain, general health, vitality, social function, role limitation emotional and mental health. Each domain scale ranges from 0-100 with higher values representing better HRQOL. As recommended, norm-based scores are used which means that
a score of 50 corresponds to the population norm. Group scores < 47 correspond to values below population norms. SF36 is one of the HRQOL instruments mostly used in the literature concerning patients having LLA\textsuperscript{36,84}. In Study IV, changes in the eight subgroups of SF36 is analyzed both over time and among age groups.

d. The general self-efficacy scale (GSE)
Self-efficacy originates from cognitive theory and refers to the extent to which an individual believes that he/she is capable of performing in specific situations\textsuperscript{66}. GSE measures general self-efficacy for 10 items and each of these items is rated on a four-point likert scale\textsuperscript{85}. Each item is formulated as positive statements such as: "Thanks to my resourcefulness, I can handle unforeseen situations." Possible responses include 1) not at all true, 2) hardly true, 3) moderately true and 4) exactly true. Scores range from 10-40 and a higher score = better self-efficacy. The GSE instrument has shown to have good reliability in terms of Cronbach’s alpha (.86-.94)\textsuperscript{86} and has recently been positively correlated to the number of hours a day prostheses were used among a sample of non-vascular amputees\textsuperscript{87}. In Study IV, changes in GSE over time and among age groups is analyzed.

e. Mini-Mental-State Examination (MMSE)
MMSE measures cognitive impairment\textsuperscript{88,89}. Seven cognitive dimensions are covered by the instrument: orientation to time, orientation to space, short-term memory, attention and calculating recall of three words, short task testing language and visual construction. Maximum score is 30 which indicates full cognitive capacity. The instrument has shown good reliability in terms of Cronbach alpha .92, and test-retest reliability $\alpha$.89\textsuperscript{88}. The MMSE test was used in Study III as a possible influencing factor on short-term functional outcome (independent variable).

f. Complementing self-reported items
Participants were asked a number of questions about factors potentially influencing their functional outcome which were not covered by the aforementioned instruments as illustrated in Figure 7. These questions were intended to cover prosthesis provision (Studies III+IV), pain, social network, aids, homecare, accommodation and rehabilitation service (Study III) and were created for this purpose. In Study III, these items were analyzed as independent variables.

Prosthesis provision were covered with two items. On Day 21, follow-up participants were asked, ‘Do you intend to have a prosthesis?’ and response options were ‘yes’/’no’/’haven’t decided’ (Study III). At three, six and twelve months follow-up participants were asked if they had been given a prosthesis and, if they had been, the date they first brought it home was recorded (Study IV). Patients were also asked if they had had any fall incidents (Study III).
Pain was divided into the categories of stump and phantom pain and was covered by two questions: ‘Have you had any pain in the stump during the past week?’ and ‘Have you had any phantom pain during the past week?’ Response options were ‘no’/‘a little’/‘some’/‘much’ (Study III).

Social network was covered by two questions; ‘Do you live alone or are you cohabiting?’ and ‘Do you have assistance from any relative or friend to manage daily living?’ If yes, number of incidents of help were noted (daily, weekly, less) (Study III).

Aids were covered by one question: ‘Do you lack any assistive devices to manage your everyday life at home?’ (yes vs no) (Study III).

Homecare was covered with one question: ‘Do you have any assistance from homecare?’. If yes, number of incidents (visits) of help were noted (daily, weekly, less) (Study III).

Accommodation was divided into the categories of independent living, wheelchair accessible/ independent living, not wheelchair accessible/ nursing home/ temporary care facility (Study III).

Rehabilitation service was documented as whether the participant had initiated physiotherapy sessions by Day 21 (yes/no), amount of time to first physiotherapy session after discharge and frequency of physiotherapy sessions (Study III).

g. Medical record review

The medical records were reviewed for data covering amputation specific details, co-morbidity, complications and rehabilitation service and analyzed as independent variables in Study III.

Amputation specific details were recorded as level of initial amputation, final amputation level, condition of the other leg (amputated, full or partial weight bearing)

Co-morbidity was recorded as number of diagnoses besides diabetes and dementia and with the American Society of Anesthesiologist score 1-5 (ASA).

Two main complications were documented for use in Study III: postoperative confusion and re-amputation. Neither of the wards collect data on confusion systematically, and thus all records (nurse and physician notes) were reviewed for descriptions of episodes of confusion during in-hospital stay. Degree of confusion was rated as ‘not at all’, ‘a little’, ‘some’ or ‘much’. ‘A little’ was used to evaluate notes containing the wording ‘a little’ (or a synonym) and was found on a few occasions. ‘Some’ and ‘much’ were used if notes contained the words ‘some’ or ‘much’ confusion on several or more than several occasions. Any re-amputation within 30 days was documented (Study III).
Rehabilitation services were covered in two ways: recorded number of days without physiotherapy in hospital and whether the patient was assessed suitable for prosthesis before discharge. Number of days without physiotherapy in-hospital was recorded by all physiotherapists daily and noted on a special form. Only data from Days 1-7 post-amputation were used to secure complete data on all participants (Study III). Prosthesis suitability assessment was routinely performed by orthopaedic physicians before discharge and documented in the medical record.

Clinical and demographic data

The second aim of Study III was to report characteristics of a consecutive sample of patients having amputations and compare participants with non-participants. Medical records were, therefore, reviewed to find clinical and demographic data comprising of data on age, sex, primary etiology of amputation (diabetes, peripheral artery disease or trauma/cancer), ASA score, co-morbidity, level of amputation (TTA, TKA, TFA), any re-amputation within 30 days, postoperative confusion, plan of rehabilitation provided, pre-amputation walking ability (indoor walking aid, none, crutches/walking frame, not walking), prosthesis suitability assessment as documented in the record, discharge destination, length of stay from day of surgery (LOS) and mortality.

Analysis

To compare ‘participants with non-participants’ (Studies III+IV), and ‘those who completed study vs those who dropped out or deceased’ (Study IV), proportions of characteristics were calculated. Differences were tested with the Chi square test of homogeneity or Fisher's exact test. Continuous variables were tested with Students T test (Study III) or Mann-Whitney U test (Study IV).

In Study III, participants’ functional levels on Day 21 were investigated by calculating mean values of Barthel index 100 (both overall and individually for each activity item) at baseline and on Day 21. A paired-sampled t-test was used to test mean difference in overall functional level. A Wilcoxon signed rank test was run to test individual items.

To evaluate potential relationships between the hypothesized influencing factors and independence in transfer on Day 21 (Study III), associations were tested in univariate analyses. Factors found statistically significant in these analyses were entered into a backwards elimination logistic regression procedure, and a model was developed for explaining factors influencing the likelihood that participants were independent in transfer on Day 21.
Study IV investigated changes in HRQOL, GSE and functional level over time by calculating mean values from each of the eight SF36 domains, the GSE and the Barthel index 100 overall score as well as for each activity item individually: at baseline (one-month pre-amputation) and at three, six and twelve months follow-up. A Wilcoxon signed rank test was used to test mean difference between scores at each follow-up with baseline scores.

Study IV further investigated whether HRQOL, GSE and Barthel changed in different patterns related to age. To do this, the sample was divided into three age groups: younger (<65 years), older (65-74 years) and oldest (75+ years). A Kruskal-Wallis H test was run to determine if there were differences in the SF36 median subscale scores, the GSE and the Barthel (overall and individual activities), respectively, from baseline and through follow-up between the three age groups. For statistically significant relationships, pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. Finally, differences between age groups regarding decline in functional level at twelve months were tested by comparing differences in Barthel score (overall and individual activities) at twelve months compared with baseline using a Kruskal-Wallis H test.

IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA), was used for the statistical analysis described. Level of significance was set as a p-value of <0.05 for all analyses. Descriptive data were reported as number and percentage and mean ± standard deviation as appropriate.

Optum Smart Measurement System Scoring Solution was used to score SF36. As recommended, SF36 norm based scores were used [30].
Ethical considerations

The study design and research program for this thesis were approved by the Danish Data Protecting Agency (Region Sjaellands j.nr. 12-000179) and has been presented to the Regional Ethics Committee whose secretariat did not find the project notifiable under Danish law (Region Sjaelland j.nr. 12-000660). According to Danish law, formal ethical approvals are not required for studies not involving biomedical issues. Not having to apply for ethical approval does not make the responsibility of acting in an ethically responsible manner less important. In the studies presented here, ethical considerations have been guided by the principles of autonomy, beneficence, non-maleficence and justice. The studies have been conducted in accordance with the basic principles for research given in the Helsinki Declaration and the ethical guidelines for nursing research in the Nordic countries. All data have been treated as confidential, and it has been ensured that no patient can be identified during the presentation of this study.

Autonomy refers to the individual’s right to make his or her own choices. To ensure autonomy, all patients were given written and verbal information before study entrance. All patients were informed that their participation was voluntary and that they could withdraw from the study at any time without any explanation or effect on their care. Before entering the study, all patients signed a written consent form. When a relative was present, both the patient and the relative signed a consent form that stated it was with both of their approval that the patient participated. The Head of Department was given written approval of the research being performed on the wards, and healthcare professionals participating in the meetings where observations were performed (Study I) were informed that the subject of observation was the patient and not them.

Beneficence refers to the value and benefits of the study and non-maleficence refers to the risk of doing harm to those participating. In this thesis, people in exposed situations have been included. Some of the participants were cognitively impaired and/or emotionally distressed. These patients have been included as we have a moral obligation to produce insight that can improve quality of care and enhance the dignity of these very vulnerable patients.

The ethical challenges of including patients with cognitive impairment may be unpredictable because of the capacity to make decisions and understand the situation varies from individual to individual. In addition to traditional ethical considerations, this fact requires special moral sensitivity throughout the whole research process. However, as researchers, we have an ethical responsibility to uncover the needs of patient groups who cannot, under normal circumstances, draw attention to themselves. Furthermore, it is known that participating in research...
projects can be experienced positively, given the opportunity to tell one’s story and help others\textsuperscript{93}.

It required concerted consideration not to exceed the limits of these vulnerable people. Thus, all participants were given the opportunity to have a relative or another person present at all interviews. All interviews were planned and performed at the participants’ premises which meant that time and place was arranged according to the participant’s wishes. Breaks were taken if desired by the participants, and participants were allowed to talk about related topics if they wished.

In cases where interviews revealed unmet needs, we had a special responsibility to make sure participating patients received help. In such cases, it was assured (in agreement with the patient) that relevant health staff were informed (general practitioner, homecare, municipality nurse).

Participation in the project involved several interviews with each participant over time and very few chose to drop out which I interpreted as having maintained participants' confidence and met their needs for ethical considerations.

Justice refers to fairness and equity among individuals\textsuperscript{90}. These principles were particularly considered in the choice of study population and in the design of the studies where efforts were made to include the most vulnerable patients who are generally not represented in research. An example of this is that the data collection for Studies III and IV were carried out as interviews instead of surveys.
Main results

Our overall results show that having a leg amputated can result in better HRQOL in all domains but physical function. However, results from the different studies provide unique insight into the dysvascularly-amputated patients lives for a year after an amputation and reveal that, although it is a heterogeneous group with widely different functional levels and psychosocial needs, dysvascularly-amputated patients as a whole are vulnerable. Healthcare is not always adapted to the care needs of dysvascularly-amputated patients and quality improvements are required in several areas to optimize quality of life.

The overall aim of this thesis was to investigate health-related quality of life, functional level and needs of care the first year after a dysvascular major LLA. The main results will be presented under the headings:

- **Psychosocial needs**—comprising of:
  - Pendulating—A grounded theory
  - Postoperative confusion
  - Changes in HRQOL and General self-efficacy

- **Functional needs**—comprising of:
  - Effect of early mobilisation
  - Effect of time and age on functional outcome
  - Factors influencing short-term functional outcome

**Psychosocial needs**

Results reported under this heading derive from Studies I, III and IV. First, the grounded theory (Study I) explains the main concern of patients shortly after having leg amputation and how patients resolve these issues. Second, prevalence of postoperative confusion is analyzed (Study III). Third, the longitudinal data on psychosocial well-being (HRQOL and General self-efficacy) (Study IV) is explored.
Pendulating—A grounded theory

The grounded theory of ‘Pendulating’ (Study I) was constructed to explain patients’ behavior shortly after having a leg amputated due to vascular disease. As mentioned earlier, the patients’ main concern was identified as: ‘How do I manage my life after having lost a leg?’ The substantive theory of ‘Pendulating’ (illustrated in Figure 8) explains patients' behavior while resolving their main concern. It was found that patients went through a three-phased process as they realized they were experiencing a life-changing event. The first phase was ‘Losing control’ and comprised of the sub-categories of ‘Being overwhelmed’ and ‘Facing dependency’. The second phase was ‘Digesting the shock’ and comprised of the sub-categories ‘Swallowing the life-changing decision’, ‘Detecting the amputated body’ and ‘Struggling dualism’. The third phase was ‘Regaining control’ and comprised of the sub-categories ‘Managing consequences’ and ‘Building-up hope and self-motivation’. ‘Pendulating’ was identified as the core category describing the general pattern of behavior throughout the process and illustrated how patients were swinging both cognitively and emotionally. The theory is briefly presented in the following text and elaborated in Paper I.

![Figure 8](image-url)
Losing Control

The first phase of the process was ‘Losing Control’ and describes the immediate reactions to having lost control in more aspects of life.

The phase started with patients being overwhelmed. Patients often experienced an unpleasant period of fragmented memory or confusion which resulted in fear that they would not regain clarity of mind. This period was described as ‘having a thousand thoughts but not being able to hold on to any one of them.’ The patients at this stage took a passive role when interacting with healthcare professionals and behavior was affected by their state of feeling overwhelmed. Protective behavior was common and demonstrated in acts such as choosing who they trusted and wanted to relate to. This behavior also resulted in only communicating what was absolutely necessary with everyone else. The period of being overwhelmed could last a few days or continue for weeks and came in different intensities.

Patients’ actions while Facing dependency was based on reactions to the need for assistance and personal aids necessitated by the amputation. Actions were characterized by ignorance and uncertainty about the future. The patients repeatedly spoke of specific issues without really knowing what to expect. Heavy thoughts such their own stigmatized view of worth and ability of disabled people were often not expressed aloud. Some believed they had to give up all independent mobilization while others compared themselves with amputated elite soldiers who run on two prostheses.

The only obvious and desirable solution for these patients regarding getting mobility back was to get a prosthesis. Some patients established a sense of control by mentally escaping the situation and by thinking of the situation as temporary until they could get a prosthesis and walk again regardless of whether this was a realistic option or not. These patients accepted support and aids unwillingly and believed going home would solve many problems.

Others maintained a sense of control by surrendering to their destiny. They accepted the inevitability of the situation and downscaled expectations by accepting a lower level of functionality and uncritically accepting the support offered while holding onto modest hopes of regaining mobility.

At this point in the process Pendulatiing described how patients were cognitively and emotionally affected as they lost control in more aspects of their lives. They clung to the pendulum which was in constant motion and swung them in and out of heavy thoughts and from one worry to the next as well as through diverse feelings of injustice, relief, panic and gratefulness.
Digesting the shock

Having a leg amputated was perceived as a life-changing event and the second phase of the process ‘Digesting the shock’ describes how the patients processed the shock of deciding to have a leg amputation after surgery.

Swallowing the life-changing decision. Having to decide to have a leg amputated triggered a shock in patients that needed to be processed. Some patients experienced the physician as compassionate and empathetic and even though accepting the amputation was hard, they found this comforting. Others described how the physician came and confronted them with the necessity of the amputation and had detailed pictorial descriptions of the situation following them. Stories of having a leg rescued in the past made it harder for patients to be convinced of the inevitability of their situation. In the days following the amputation, it was important to get confirmation from clinicians they trusted as well as from relatives that amputation had been the right decision so that they could ‘swallow’ the shock.

Detecting the amputated body described reactions to the changing body. Some avoided looking at the stump for as long as possible as they summoned the courage to be visually confronted with the missing leg. Others had already prepared themselves. Talking with the professionals about experiences of phantom-sensations or phantom-pain was comforting when they feared losing sanity. Social awareness made them hide the amputated leg.

Struggling dualism explains how opposing emotional reactions caused both frustration and alleviation. Positive emotions such as relief sometimes overshadowed the difficulties experienced. This was especially true among those who had had unbearable pain or stressful wound trajectories preceding the amputation. Even so, patients struggled with the consequences the amputation caused. Others struggled with diverse feelings of extreme frustrations caused by the limitations the missing leg put on their lives and confusion as they knew the amputation had been life-saving.

At this point the pendulum was rapidly swinging from one side to the other. Some patients had a degree of control over the swing as they could divert themselves from heavy thoughts by deliberately thinking positively and thereby swinging the pendulum away from their worries. Others tried to stop the pendulum for a moment (e.g. by refusing to participate in training or insisting on staying in bed). Hence, they processed the shock while they were, emotionally and cognitively, Pendulating.

Regaining control

Ignorance and uncertainty still marked patients’ actions in the third phase of ‘Regaining control’. There was awareness that adaption would take time and would require even more willpower and strength than patients believed they had.
When able to hang onto their thoughts long enough to plan and decide how to handle everyday tasks, patients began to regain control by *Managing consequences*. They struggled with their desire for independence and had to downscale expectations as well as compromise to adjust to the situation. The patients who received help from homecare were grateful for the help but described the situation as living in Central Station. Having help from family instead of homecare raised other questions of being a burden to those assisting.

Patients regained emotional control by *Building hope and self-motivation*. All had been confronted by their mortality and focused on their responsibility for creating a good life despite the missing leg and new dependency. Deliberately thinking positively about the future, downscaling difficulties and problems as well as selectively distorting memories in ways that promoted emotional well-being, made the situation easier to accept.

There was an awareness of existential losses—such as loss of independency, change of social roles, plans for the future and identity as a walking person among other things—having a leg amputation causes. Relating to these existential thoughts was postponed until the shock had been digested and some control was regained.

*Pendulating* at this point of the process described emotional control of the situation. The pendulum was now swinging more slowly and was mostly controlled by the patients who pushed themselves away from uncomfortable and undesirable thoughts by deliberately thinking of something positive and occupying their minds with practicalities.

**Postoperative confusion**

Experiencing a period of fragmented memory or confusion was common among the patients participating in Study I and is described in the subcategory of ’Being overwhelmed’. In Study III data were collected on the prevalence of postoperative confusion by reviewing medical records. It was found that 48 of the total consecutive sample of patients having dysvascular major LLA (n=103, 47%) were described as being some or much confused in the days following the amputation. In another ten medical records, patients were described as being a little confused (10%).

**Changes in HRQOL and General self-efficacy**

Changes over time and among age groups in the psychosocial well-being of patients after LLA was investigated in the longitudinal Study IV with data reported from the psychosocial subscales of the SF36 and the GSE and measured at baseline, three,
six and twelve months, respectively. The SF36 subscales reported here covers pain, general health, vitality, social functioning, role, emotional and mental health although the domains of pain, general health and vitality do not purely affect the psychosocial well-being.

**Main results**

The psychosocial well-being of patients surviving twelve months after the amputation was affected one month preceding the amputation with reported levels of all SF36 subscales being below population norms (<47). After three months, the problems with pain, general health and vitality seemed resolved and did not appear at six and twelve months as illustrated in Figure 9.

![Figure 9. Changes in SF36 subscale: Pain, General Health and Vitality from baseline to twelve months.](image)

In contrast, the psychosocial well-being measured as SF36 social functioning, role emotional, mental health and GSE fluctuated over the first twelve months after amputation. Social function increased from baseline to three and six months and then dropped at twelve months though the difference from six to twelve months was not statistically significant. The role-emotional and mental health subscale scores increased at three months, dropped at six months and then increased again at twelve months (Figure 10+11). From three to six months, the mean difference was -1.4 (SD 10.7, p=.257) for role-emotional and -2.1 (SD 7.9, p=.240) for mental health. From six to twelve months, the difference was 1.9 (SD14.1, p=.460) for role-emotional and 1.6 (SD 9.2, p=.155) for mental health. Thus, the observed changes were not
statistically significant which could be explained by the relatively small sample tested. These findings indicate that psychosocial care needs persisted.

Figure 10. Changes in SF36 subscale: Social function, Emotional role and Mental Health from baseline to twelve months.

Figure 11. Changes in General Self-efficacy (GSE) from baseline to twelve months.
Big differences were evident between those reporting the best and the worse psychosocial well-being. During interviews, some stated that they had got their life back and should have had the amputation years ago instead of being immobilised by wounds. Others struggled to have a dignified life and several patients had severe depressive symptoms.

Another important finding in these longitudinal data was that there was no detectable difference between age groups in terms of psychosocial well-being. The sample was divided into three age groups: younger (<65 years), older (65-74 years) and oldest (75+ years). A Kruskal-Wallis H was run on all age groups and no differences were found in any of the above six mentioned SF36 subscales or GSE at any timepoint.

Functional needs

Results reported under this heading derive from Study II, III and IV all of which reveal needs related to the functional level achieveable for patients. Firstly, the main results from the systematic review (Study II) assess the effect of early mobilisation of patients after dysvascular lower limb amputation and compare the effectiveness of different mobilisation regimens presented. Secondly, the main results from the longitudinal data on functional outcomes reported in Study III and IV are presented. Finally, factors influencing short-term functional outcome are presented (Study III).

Effect of early mobilisation

Five articles were included in the systematic review (Study II) which was aimed at assessing the effect of early mobilisation of patients after dysvascular lower limb amputation and compared the effectiveness of different mobilisation regimens.

Risk of bias

Four out of the five included studies were assessed as being at high risk of bias\textsuperscript{94-97} mostly due to uncontrolled before-and-after designs that used retrospectively collected data. All results should therefore be read with caution. These studies were included in our research as they deepened our understanding of important details which could be used when designing interventions customized for post-surgery in a heterogenic population of patients who have had dysvascular major LLA.
Main results
The main finding from this systematic review is that there is a lack of evidence to determine whether early mobilisation is beneficial to patients having dysvascular major LLA though no risk of harm was identified. That being said, early mobilisation with temporary prosthesis is possible from the first postoperative day among consecutive samples of patients having dysvascular major LLA but only in settings where an interdisciplinary team is dedicated to the task. A brief presentation of study characteristics and interventions performed are presented below and examined in Paper II.

Study characteristics
All but one study used a retrospective design\textsuperscript{94-97}, and the latter study used a randomized controlled design\textsuperscript{98}. Four studies investigated early mobilisation promoted through a type of immediate postoperative prosthesis with partial weight-bearing on the amputated leg\textsuperscript{94,96-98}. One study investigated whether functional outcome among patients after lower limb amputation would improve by reorganizing care and thereby increase mobilisation\textsuperscript{95}. The interventions varied as did the population included in the studies and outcome measures used made comparisons of the results difficult.

Samples
Two studies included consecutive samples of both patients having TTA and TFA\textsuperscript{95,98}. The other three included either a consecutive sample of patients having TTA\textsuperscript{94} or selected samples of patients who had TTA and were assessed for their potential to become prosthetic walkers after amputation\textsuperscript{96,97}.

Control group
All but one study compared the intervention with standard care. None of these studies described the amount of mobilisation provided patients in the control group (standard care). The latter\textsuperscript{98} compared the intervention with two weeks of bed rest.

Outcome measures
The measured outcomes included systemic complications\textsuperscript{97,98}, wound complications and revisions or re-amputation\textsuperscript{94,97,98}, falls\textsuperscript{94,96,97}, time to prosthesis\textsuperscript{94,96-98} and Functional Independence Score (FIM)\textsuperscript{95}.

Interdisciplinary team
Two studies reported implementing a detailed interdisciplinary protocol in pre- and post-operative care along with the ambulation intervention which stresses the importance of dedicated and specially trained surgeons, nurses, physiotherapists and prosthetists\textsuperscript{94,97}. These studies achieved ambulation of included patients on Day One
or Two after amputation. Another study managed to ambulate a consecutive sample of both patients with TTA and TFA but did not report the professionals need or setup necessary to perform the intervention. One study failed to carry out the early ambulation in 11 out of 30 included patients and did not report if an interdisciplinary rehabilitation protocol had been implemented. Marzen-Groller et al. described how mobilising patients became a priority among nurses and physiotherapists while implementing the interdisciplinary mobilisation protocol.

*Time to prosthesis*

Time to prosthesis was reported as shorter in all four studies of immediate prosthesis interventions. Whether early ambulation within the first postoperative days contributed to the effect or if it would be the same if a temporary prosthesis was provided 2-3 weeks post-amputation cannot be concluded within the scope of this review. Moreover, several authors stressed the psychological benefits of immediate prosthesis. These potential benefits, nevertheless, need to be investigated with appropriate methods.

*Short-term functional level*

Only a single study was found that measured the effect of increased mobilisation on a short-term functional level measured on the Functional Independence Score (FIM). The indicated effect on FIM scores needs to be replicated in larger populations to be convincing.

*Effect of time and age on functional outcome*

Changes over time and among age groups in functional outcome was investigated in longitudinal Study IV, and short-term functional outcome was reported in Study III. Results from both Studies III&IV will be presented in this section.

In Study IV, three different perspectives of functional outcome were measured: independence in ADL measured with Barthel index 100 and two SF36 subscales—physical function and role physical (to which degree the patient experienced physical function as limiting their daily life).

Independence in ADL (Barthel index 100) was measured on Day 21 (Study III), and at three, six and twelve months (Study IV). SF36 was administered at three, six and twelve months (Study IV). All mean scores were compared with functional level one month pre-amputation (baseline). Subsequently, the sample was divided into three age groups: younger (<65 years), older (65-74 years) and oldest (75+ years) and a Kruskal-Wallis H test was run to determine if there were differences between age groups in any of the functional scores at any timepoint (Study IV). Changes in Barthel index 100 individual activities are presented in Table 5. Here data from
Study III (Day 21) and Study IV (three, six and twelve months) are combined and presented together (shown only in this thesis).

**Changes over time**

Patients reported their physical function and physical limitations (SF36) were affected to a level below population norms one month before the amputation (baseline) (Study IV). Physical function then decreased from baseline to three months, increased to baseline level at six months and then further increased at twelve months ending at a level not statistically significantly higher than baseline and still lower than population norm scores as illustrated in Figure 12. Patients reported fewer limitations caused by physical health (role-physical) already three months post-amputation even though physical function had the lowest scores at that point (Figure 12).

![Physical Function and Role Physical](image)

**Figure 12. Changes in SF36 subscale Physical function and Role-physical from baseline to twelve months**

Patients were found to be more dependent on help after amputation than before amputation in all ADL activities on Day 21 (Study III), in four activities at the three time points measured (Study IV) and had significantly lower function in toilet, self-bathing, ambulation and bed-chair transfer still present at twelve months.

The biggest decline at twelve months was found in ambulation (Table 5). Being independent in ambulation after LLA naturally depends on whether the patient has a prosthesis. In our study, 28 patients (74%) were provided a prosthesis and had the first prosthesis home with them within a mean of 161 days with a wide range of 34
to 312 days (Study IV). Having a prosthesis is not the same as walking successfully; yet being provided with a prosthesis is a prerequisite to ambulate, and time spent waiting for the prosthesis explains part of the loss of ambulation skills at three and six months. The most common explanation for the late prosthetic supply was waiting for a referral or delays in grants.

Significant individual differences were detected. The majority of patients were independent in all ADL activities at twelve months. A fraction needed assistance in bathing in a secure manner (mostly due to the layout of the bathroom). In contrast, some patients were dependent on a lift in transfer from bed to chair and were therefore dependent on assistance in other ADL activities as well.

In Study III, it was demonstrated that mean functional level score in transfer from bed to chair decreased from 14.53 (SD 1.13) pre-amputation to 11.49 (SD 5.23) on Day 21, \( p < .001 \). In other words, 41% of the participants (n=21) were dependent on assistance from at least one person when moving from chair to bed on Day 21 compared with 6% (3) pre-amputation.

**Effect of age**

Loss of physical function, whether it was measured with SF36 (physical function subscale) or Barthel index 100, was unevenly distributed among age groups. All age groups had equal scores at baseline in both measures. The lowest scores in Barthel index 100 were reported on Day 21 (Table 5). Hereafter, the oldest group (age 75+) reported smaller gains in functional level and were carrying the biggest loss of physical function at twelve months. This contrasted with the other two age groups who regained their level of physical function from one month pre-amputation or even improved (Study IV).

No statistically significant difference was found between the three age groups regarding bed-chair transfer at three, six and twelve months (Study IV), but there was a significant difference on Day 21 (\( \chi^2(2) = 11.746, \ p = .003 \)) (Figure 13). A post hoc analysis revealed a statistically significant difference in mean bed-chair transfer between the younger, (14.3) the older (13.0) and the oldest (6.6)(\( p < .003 \)) (results shown only in this thesis).
Figure 13. Changes in bed-chair transfer skills (Barthel index 100) from baseline to twelve months
Table 5. Barthel index 100 scores Day 21, and three, six and twelve months post amputation compared with baseline only showed in this thesis

<table>
<thead>
<tr>
<th>n = 38</th>
<th>Baseline Mean (SD)</th>
<th>Day 21 Mean (SD)</th>
<th>p value</th>
<th>3 Months Mean (SD)</th>
<th>p value</th>
<th>6 Months Mean (SD)</th>
<th>p value</th>
<th>12 Months Mean (SD)</th>
<th>p value</th>
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<tr>
<td>Personal hygiene(^1)</td>
<td>4.6 (.9)</td>
<td>4.3 (1.3)</td>
<td>.021</td>
<td>4.7 (.7)</td>
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<td>4.8 (.5)</td>
<td>.233</td>
<td>4.9</td>
<td>.145</td>
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<td>Bathing(^1)</td>
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<td>3.3 (1.6)</td>
<td>&lt;.001</td>
<td>4.0 (1.1)</td>
<td>.188</td>
<td>4.1 (1.0)</td>
<td>.314</td>
<td>3.9 (1.3)</td>
<td>.052</td>
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<td>Eating(^1)</td>
<td>4.9 (.4)</td>
<td>4.6 (.8)</td>
<td>.028</td>
<td>5.0 (.2)</td>
<td>.257</td>
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<td>.004</td>
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<td>Bed-chair transfer(^3)</td>
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<td>3.2 (4.3)</td>
<td>.003</td>
<td>4.7 (4.5)</td>
<td>.127</td>
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</table>

\(^1\) Wilcoxon signed-rank test compared with baseline (one month pre amputation). \(^2\) Score 0-10; 0=not actively contributing in activity, 10=performing the activity independently. \(^3\) Score 0-15; 0=not actively contributing in activity, 15=performing the activity independently.
**Effect of age**

At baseline, no differences were revealed in functional level between the three age groups by any measure. However, differences were detected between the three age groups over time in the SF36 subscale physical function and in Barthel scores but not in the SF36 subscale role-physical (Study IV).

Median scores were found to be statistically significantly different between age groups in the subscale ’physical function’ at twelve months, \( \chi^2(2) = 8.478, p = .014 \). Subsequently, pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. The adjusted p-value is presented. This post hoc analysis revealed a statistically significant difference in median physical function between the younger (<65 years) (36.49), older (65-74 years) and the oldest (75+ years) (23.09) (p=.001) groups but not between the older (31.71) and any other group combination.

When functional level among the three age groups at twelve months was compared with functional level at baseline, the oldest group had the biggest decline of all three age groups in Barthel overall score with a mean difference for the younger, older and oldest of -0.5 (SD 9.7), -3.7 (SD 14.5), -24 (SD 19.4), \( \chi^2 (2)= 9.676, p=.008 \), respectively. Thus, final decline was almost solely found among the oldest (75+ years).

**Factors influencing short term functional outcome**

In Study III, factors potentially influencing short-term functional outcome (independence in bed-chair transfer) were investigated. Associations were tested in univariate analyses between four health conditions, ten body function factors, nine environmental factors and independence in transfer on Day 21. Factors found statistically significant in these analyses were entered into a logistic regression procedure, and a model was developed for explaining factors that influenced the likelihood that participants were independent in transfer on Day 21.

**Main results**

Testing a comprehensive list of factors potentially influencing the chance of being independent in transfer on Day 21 after a major LLA, four factors were found to be statistically significant: age, ASA score, being assessed suitability for prosthesis before discharge and whether patients had started physiotherapy after discharge and before Day 21. Patients above 65-years-old had significantly higher risk of being dependent in transfer on Day 21 (51% vs. 8%). It was also observed that the higher the ASA score, the higher the risk of being dependent in transfer on Day 21. Being assessed suitable for prosthesis at discharge as well as whether patients had started
physiotherapy after discharge and before Day 21 was associated with achieving independence in transfer or not (Study III).

Only two factors remained independent predicting variables in the logistic regression model: age and if physiotherapy was initiated before Day 21. This model was statistically significant ($\chi^2(2) = 36.009, p < .0005$). The model explained 75.9% (Nagelkerke R2) of the variance in being dependent or independent in transfer on Day 21 and correctly classified 88.6% of the cases. Sensitivity was 92.6%, specificity was 82.4%, positive predictive value was 89.3% and negative predictive value was 12.5%. Older age was associated with decreased likelihood of independence in transfer on Day 21; those who had physiotherapy initiated before Day 21 had a 19.98 times higher chance of being independent in transfer on Day 21.
Discussion

Methodological considerations

In all research, the methods used to obtain findings need to be questioned before the utility of findings can be assessed and conclusions proposed. In this mixed method project, four studies with three different study designs are included, and criteria for evaluating quality for each design differs. The quality of a constructivist grounded theory study is evaluated using criteria specific to the grounded theory approach while quantitative studies (including systematic review of quantitative trials) are evaluated with regard to validity and reliability.

Evaluating grounded theory

Though qualitative researchers agree on the importance of doing high-quality research, there is no common vocabulary for quality criteria in qualitative research. In this thesis, the quality of the grounded theory study (Study I) is evaluated according to the following criteria set up by Charmaz: credibility, originality, resonance and usefulness.

Credibility

In general, the criteria of credibility in qualitative studies refers to confidence in the true value of the data and interpretations of them. One way of increasing credibility in a grounded theory study is for the researcher to obtain familiarity with the study setting by collecting rich data through different data collection methods and a range of participants with experience with the topic under study. Data collection was therefore performed among a heterogenic sample of patients who had dysvascular amputation. As the main investigator, I achieved intimate familiarity with the topic through a combination of observations and interviews.

Analysis in a qualitative study is built upon a subjective process where the researcher is an important actor and preconceived ideas may comprise credibility in data collection and analysis. Grounded theorists are enjoined to avoid forcing their data into preconcieved codes and categories and to engage in reflexivity about preconceptions. Thus, during all data collections and analyses, I aimed to stay...
neutral and open-minded and to keep the initial codes short, simple, spontaneous and analytical as recomended by Charmaz. In line with this, I was able to reflect on and explore my preconcieved ideas and beliefs in my logbook as I became aware of them.

Investigator triangulation was used to further reduce the risk of researcher bias. Investigator triangulation reduces the possibility of one-sided interpretations of data by seeking to demonstrate that the study’s findings were not imagined but firmly linked to data (ibid). Thus, my co-supervisor read all coded data and assisted in analyses, and the emergent theory was discussed in the research group.

Data and categories were systematically compared by using the constant comparative method. The categories cover a wide range of empirical observations thereby fulfilling two other aspects of achieving credibility in constructivist grounded theory studies.

**Originality**
The criteria of originality refers to the social and theoretical significance of the study: 'Does the study offer new insights and/or a new conceptual rendering of the data?' and 'How does the study challenge, extend or refine current ideas, concepts or ideas?'

Originality is achieved by constructing the theory on the basis of the theoretical analysis of data where coding and memo writing constantly focus on actions in the data as recommended. Existing literature was searched and compared only after the theory was written. This study offers unique insight into a vulnerable group of patients’ experiences not previously reported. Part of the theory has similarities with the well-known phases of shock and reaction. That being said, this study adds important detailed insight into the process of adjustment specific to patients who have had a leg amputated and illustrates that losing a leg is somewhat different from other achieved disabilities. The present study expands a category constructed by Charmaz which will be explored in more details later.

**Resonance and usefulness**
The criteria of resonance refers to whether the theory makes sense to the participants and/or people with whom they share their circumstances. Usefulness refers to whether people can use the knowledge from the theory in their everyday worlds. One way of evaluating this criteria is by member-checking. Member-checking refers to taking ideas back to participants for confirmation. We found that for our purposes, it was inappropriate to go back to the already exposed patients; therefore, another approach was used. While writing the manuscript for Study I, I started inclusion for Studies II+IV. Here I met more than 60 patients who had experienced leg amputation during the previous two weeks. These patients connected to the
concepts of ‘Losing control’ and ‘Digesting the shock’ and used these concepts to talk about their own experiences. I took this as an indicator of resonance and usefulness among patients although further research is needed to confirm this. The theory has been presented to nurses, physiotherapist and physicians in several clinical settings who have found it relevant and useful in their clinical practice.

Validity

Validity is a quality criteria which refers to the degree to which inferences made in a quantitative study are accurate and well-founded as well as the degree to which an instrument measures what it is intended to measure. Four aspects of validity are used to evaluate the quality of Studies II - IV: Internal, external, statistical conclusion and construct validity.

Study design

The systematic review (Study II) was conducted in accordance with the steps of the Cochrane Handbook for systematic reviews of interventions which provides a reputable systematic guide for the process.

A prospective cohort study design was used in Studies III and IV. This design was chosen as it described the strongest design for prognostic and etiology questions when randomization is not an option.

Internal validity

Internal validity refers to the extent that conclusions drawn are depending on what the researcher says it depends on and nothing else. This, therefore, refers to the confidence that design, conduct and analysis has minimized or avoided bias. In this thesis, the following potential threats to internal validity in Studies III-IV could be addressed.

Patients having dysvascular major LLA are vulnerable for many reasons which affect selection and attrition negatively. We sought to include a consecutive sample of patients, but high prevalence of dementia, acute confusion and severely deterioriated health prevented a large group from being included in the study at baseline. Mortality was the main reason for drop-out. As a result of the observational design, this is mainly a problem for external validity as results are only partly generalizable to the entire population of patients having dysvascular major LLA.

Performing research in a vulnerable population such as this adds more challenges such as high risk of missing values if the questionnaires are administered as surveys. Data were therefore collected via interviews and supported by software making it feasible to put answers directly into an electronic database during interviews. This
approach minimized the amount of missing values to nearly zero and made it possible to include patients that would have otherwise been excluded if surveys had been chosen.

In Study III, the data collection was performed by several researchers which could lead to risk of difference in assessment. To minimize this risk, URM observed the first two interviews performed by each of the three nurses taking part in data collection and received regular feedback from them. Moreover, the instrument used (Barthel index 100) is known to have high interrater reliability79. One physiotherapist was taught to review medical records for data in Studies III+IV. URM reviewed a number of records and compared the assessments without finding any discrepancies. All data were put into the electronic database.

One researcher (URM) performed all interviews in Study IV. This may lead to an issue regarding researcher bias with regard to the risk of inputting systematic bias. That being said, one researcher performing all interviews minimized the risk of difference in assessments and gave the opportunity to gain the participants’ trust and obtain additional information that added to the understanding of the questions on the questionnaires.

Letting patients bring relatives to the interviews could affect their answers. This approach was chosen based on experiences from Study I where several patients expressed that they preferred having a relative present for support and help with memory. However, even if the presence of a relative influenced patients’ answers, responses could still be close to the patients’ own answers. When relatives act as a proxy and grade the experiences of the patient, the difference in scoring between patients and proxy tends to be small with a tendency for relatives to score slightly lower in functions and higher in symptoms102.

By measuring pre-amputation function after amputation, there is a risk of recall bias. We considered recruiting patients pre-amputation but found it was not feasible in the acute setting. Nevertheless, a previous study showed high compliance in recording this kind of data up to six weeks post-amputation103.

When administering the same instrument a number of times, there is a potential risk that participants reflect on what they believe they are expected to answer. I tried to avoid this by starting each interview by stressing that I was interested in how they were performing now and by pointing out the timeframe each questionnaire covered. I used language such as: ‘In the next questions I am asking you about xxx the past month—namely from date x to date y.’

Another potential problem with administering the same instrument over time is the risk of response shift99 (a shift in the person’s self-evaluation of the construct rather than a change in the construct itself). Expectations and importance of different aspects (e.g. HRQOL) might not be the same after experiencing a life-changing
event such as a LLA. Such a response shift has previously been reported in LLA populations\textsuperscript{43,104}. It is also known that people with extreme values seek to equalize their answers in later assessments which is known as regression to the mean\textsuperscript{99}.

Finally, the possibility that other factors may have influenced outcome cannot be ruled out. This is especially in Study III where we lack data on how much and how early patients were mobilised during in-hospital stay, data on nutrition or potential psychological factors that may have influenced patients.

There are some aspects to consider concerning the instruments used. It could be discussed whether Barthel index 100 is the most appropriate measure of functional level in the context of lower limb amputation as it was originally developed for functional level after stroke and therefore includes items not relevant to the majority of patients having LLA. Another aspect is that many patients became independent in all ADL activities rather quickly and therefore ‘grew out’ of the scale (ceiling effect). Depending on the aim of the study, Kristensen \textit{et al.}\textsuperscript{106} suggest the measurement of ‘basic amputee mobility score’ (BAMS) as a post-operative functional level measure. BAMS is a recently developed instrument measuring independence in four mobilising actions among patients after amputation: moving from lying to sitting bed-side, sitting to standing, transferring from bed to chair and wheelchair mobility. These functions are vital for new amputees to remain independent in basic functions in the post-surgical setting. Even so, measuring independence in ADL functions as a long-term functional outcome (Study IV) was shown to be important to the frailest patients in the sample and highlighted their specific need for increased rehabilitation.

Measuring HRQOL with SF36 not only has obvious benefits but also some limitations. The SF36 is a generic HRQOL questionnaire and results can therefore be compared across different populations. Use of generic measures, however, does not identify issues that are of specific importance to the LLA population, and questions formulated for a walking population could distort answers from patients without walking ability. The amputation-specific measures available are developed for individuals with prostheses\textsuperscript{78} and are thus not relevant to a significant proportion of patients having LLA due to vascular disease. Development and use of patient recorded outcome measures (PROMs)\textsuperscript{107} could be a solution for future studies.

The internal validity of Study II was ensured by conducting the review in concordance with the Cochrane Effective Practice and Organization of Care group and by ensuring transparent reporting according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). All items used were up-to-date and in complete concordance with these tools. Due to a high heterogeneity of designs, methods, interventions and populations in the studies, it was not possible to perform any meta-analysis. Including studies with a high risk of bias is a limitation because the reported outcome effect cannot be trusted and must be read
with reservation. Even so, including these studies makes it possible to identify details important to mobilising lower limb-amputated patients.

**External validity**

External validity addresses to what extent findings can be generalized to a wider population. Previously, problems with the selection and attrition that limit the generalization of the findings were described. The fact that the study was conducted in two hospitals, and patients were living in twelve municipalities strengthens external validity. Nonetheless, local and cultural differences cannot be excluded, and further studies are needed to replicate the results in other settings. By detailed reporting on attrition and characteristics of non-participants, we hope to improve the comparability of our results. With the broad range of data available on non-participants, we were able to generalize, to some degree, our findings about the population having dysvascular LLA in Study III. In Study IV, we found that it would only be meaningful to generalize the findings for patients surviving twelve months.

**Statistical conclusion validity**

Statistical conclusion validity concerns threats to data evaluation and the number of patients in our study could be discussed. When the study was designed, no specific hypothesis was to be tested and an explorative observational design of the study was chosen which is why no power calculation was performed. Sample size was decided based on practical considerations of how many patients were available within a reasonable amount of time, and we estimated that a minimum of 35 patients completing the study would lead to clinically interesting findings. We managed to recruit 57% of a consecutive sample of which 34% of those eligible for were too ill to participate. Of those recruited, 85% (n=51) completed Study III and 63% (n=38) completed the Study IV. These numbers correspond with other studies on the dysvascular LLA population. That being said, the relatively small sample represents a limitation especially when considering the heterogeneous population.

**Contruct validity.**

Contruct validity refers to the interpretation of the causal relationship presented in the study. In the design of the cohort study (Studies III+IV) the intention was to collect data based on factors influencing HRQOL and functional level over time. According to the ICF model, a range of factors potentially influence the functional level achieved after a LLA, and we decided to collect data representing all constructs in the model (Figure 7). When available, instruments validated in the population were used, and we believe that this strengthened the construct validity of the study.
Reliability

Reliability refers to the degree to which a measurement is free from measurement errors. Most instruments used to measure HRQOL and functional level among the LLA population would benefit from further investigation to better define their optimal use. However, the instruments used in these studies have all been psychometrically tested and have shown good or moderate results for validity and reliability within the LLA population. One exception is the GSE which instead has shown good reliability in terms of Cronbach’s alpha (.86-.94) in varied groups and cultures including elderly and fragile patients. Moreover, the fact that the measures used are commonly used within this context allows for result comparisons with other studies.

General discussion of results

A mixed method approach was used to investigate health related quality of life (HRQOL), functional level and needs of care the first year after a dysvascular major lower limb amputation.

Results from the different studies provides unique insight into dysvascularly-amputated patients lives the first twelve months after amputation and shows that having leg amputation can result in better HRQOL in all areas except physical function. The variety of data collected also illustrate that dysvascularly-amputated patients as a group are vulnerable in more aspects and that healthcare is not always adapted to the complex care needs of these patients. With that said, dysvascularly-amputated patients constitute a heterogeneous group with widely different functional levels and psychosocial needs and quality improvements are required in several areas to optimize quality of life for these patients.

The main results will be discussed under two main headings—Psychosocial needs and Functional needs—and will attempt to integrate data from all four studies in the overall data interpretation.
Psychosocial needs

Study I provides a unique insight into patients’ concerns and reasons for acting as they do shortly after leg amputation. This study shows that, independent of age and condition, leg amputation is a life-changing event. Our findings in Study I illustrates how cognitively and emotionally vulnerable patients are shortly after having a leg amputated which underpins the moral and ethical obligation to plan and execute care to meet the complex physical, practical and psychosocial needs of these patients.

Based on prospectively longitudinal data results collected from Study IV, it was shown that patients having dysvascular LLA and who survive twelve months report absence of pain at three months and also had improved general health and vitality. It was found that independent of age, psychosocial well-being seemed to fluctuate throughout the first twelve months which indicated psychosocial need of care persisting throughout the first twelve months after the amputation among all age groups.

Pendulating-A grounded theory

Some degree of losing control was an experience most patients seemed to live through after having a leg amputated, and patients’ struggle while losing control received surprisingly little acknowledgement from hospital healthcare providers (Study I). Consequently, the patients protected and defended themselves when interacting with professionals and many of the patients’ worries were never communicated. These results provide vital information to nurses and other healthcare providers about patients’ experiences and can be used when organizing, and providing care that is perceived as directed at more than practical problems and physical needs. Moreover, these results underscores the importance of nurses and other professionals being particularly attentive to patients’ concerns.

The same applies to the phase ‘Digesting the shock’ where deciding to have leg amputation triggered a shock that patients had to process after the operation in spite of intellectually accepting the amputation as being for their good. ‘Swallowing the life-changing decision’ seemed easier for those who experienced empathy when amputation was decided. The process was also eased for those who had the opportunity to discuss their thoughts with a physician whom they trusted after surgery. Nevertheless, many patients reported not being met with empathy or having had the opportunity to discuss what led to the amputation. This finding underscores the necessity for continued work in hospitals to disseminate knowledge and skills
on how to communicate bad news and how to perform follow-up conversations as recommended in the literature\textsuperscript{108,109}.

Having a leg amputated can be experienced by the chronically ill person as a crisis that potentially threatens his or her identity. In studies of the lives of chronically ill people, Charmaz\textsuperscript{110} showed that many ill people hold values of independence and individual responsibility; as a result, these patients question their own self-worth and view developing limitations as losses. This adds an interesting and contradictory perspective to the understanding of the scope of suffering patients’ experience when ‘Facing dependency’. For nurses, it is a daily routine to assess a patient’s need for assistance and arrange for this assistance after discharge. That being said, this can be a situation which arouses strong emotions for patients who have experienced leg amputation and it is important for nurses to understand and recognize this.

In the present study, the category ‘Facing dependency’ explained reactions to the need for assistance and personal aids. As mentioned previously, the behavior of mentally escaping expands the category of ‘Facing dependency’ constructed by Charmaz\textsuperscript{101}. This category explains how many chronically ill people cannot accept dependency, even when foisted upon them, as dependency remains a greater specter than death. Patients may reject anything they view as symbols of failing specter or a testimony to dependency. Our category adds that some patients surrender as another behavior. By accepting the inevitability of the situation, they downscale expectations and uncritically accept the support offered. In the clinical setting, there is a risk that these patients will be met with more restrictions than necessary as it does not occur to them to ask for additional aids or support.

The fact that patients believe they will have the possibility of getting a prosthesis whether a realistic option or not, separates the experience of having a leg amputated from other achieved handicaps. Imagining how the missing leg could be replaced with a prosthesis symbolises regaining independence and is related to hope. In contrast, symbols of disability such as a wheelchair are related to despair as it symbolises giving up independence. The idea is neglected or rejected in the first few days after amputation by some patients as part of coping with the situation.

Patients’ reactions to ‘Facing dependency’ underpins the importance of acknowledging and supporting the patient’s wish of returning to as normal and independent a life as possible regardless of age or condition. This finding prompted us to investigate what factors potentially affect the short-term functional outcome in Study III and to perform a systematic review to investigate potential effect of early mobilisation interventions (Study II).
Postoperative confusion

Experiencing a period of fragmented memory or confusion was common among patients participating in Study I. Data from Study III showed that almost half of the total consecutive sample of patients having dysvascular major LLA were described as being some or much confused in the days following amputation. In another ten percent of the medical records, patients were described as being a little confused.

Not only was amputation an experience that resulted in the patients fearing they would not regain clarity of mind (Study I), acute confusion was also associated with mortality and impaired physical function 30 days or more after discharge\(^\text{111}\). Acute confusion is partially preventable and caring for those with acute confusion places great demands on clinical expertise, interdisciplinary collaboration and care environment (e.g. quiet surroundings) (ibid). This finding indicates a high prevalence of acute confusion among the dysvascular LLA population though an unvalidated measure of acute confusion was used. This study led to the discovery of a gap in current care practice that needs to be addressed.

Psychosocial wellbeing over time and among age groups

Changes over time and among age groups in the psychosocial well-being of patients after LLA was investigated in Study IV. Longitudinal data were reported from the psychosocial subscales of the SF36 and the GSE and measured at baseline, three, six and twelve months, respectively. Patients reported their quality of life in the social function, role-emotional and mental health-scales at below population norms at baseline which reflects the vulnerability of patients having major dysvascular amputations at time of surgery. This is important to be aware of when caring for these patients both pre- and post-amputation and supports the findings of Study I.

These findings are in partial in contrast to previous findings. In a longitudinal study of HRQOL after dysvascular LLA, Fortington et al.\(^\text{58}\) included patients up to five days post-amputation. In this particular study, 35 patients filled in a HRQOL questionnaire at three times points. In line with our findings, that study reported HRQOL scores below population norms at time of amputation though not in the general health and mental health subscales, and the study did not report data on limitations caused by emotional challenges (role-emotional). This might be explained by differences in study design. In our study, patients were recruited from a consecutive sample of patients having dysvascular amputations until Day 21 post-amputation and administered the HRQOL measures as interviews; thus, we were able to include more vulnerable patients who would have been excluded in the Fortington study.
Patients reported fewer problems with pain and had improved general health and vitality comparable to a stable level above population norms already after three months. In the Fortington et al. study, this positive change was found at six months post amputation; however, HRQOL was not measured from baseline until six months, and it is unknown whether the improvement was already present at three months. That significant improvements in these aspects of HRQOL can be achieved already after three months is vital knowledge to communicate when counselling patients before amputation.

Patients reported that their psychosocial well-being fluctuated throughout the first twelve months post-amputation. That these changes were not statistically significant could be a result of the relatively small and heterogeneous sample which contained large differences in scores between individuals. Furthermore, expectations and importance of different aspects of HRQOL might not be the same after experiencing a life-changing event such as a LLA and could result in a shift in patients’ self-evaluation of the construct rather than a change in the construct itself. Such a response shift has previously been reported in LLA populations.

The changing patterns might also reflect the process of psychosocial adaption to disability that patients go through after LLA and indicate a need for psychosocial support at this stage of rehabilitation as suggested by Price et al. Symptoms of depression, distress, sleeplessness and anxiety are the most common emotional and mental problems presented in the months following LLA, and six month post-amputation is suggested as an appropriate time for counselling. Not all patients need counselling as some experience few if any psychological problems. Some patients even report having psychological gains when amputation results in less pain, less restrictions in mobility and better general health and vitality which was also found among the patients participating in our study. With limited resources available, it becomes crucial to identify those patients in most need for psychosocial interventions. This should be further explored.

Whether older people adapt differently to leg loss than younger people has been debated and which age group is more or less psychosocial affected has also been discussed. Based on longitudinal data, this study found no difference among younger, older or oldest patients regarding how they reported level of any of the psychosocial sub-scales of SF36 or the general self-efficacy scale. This contrasts with a study which suggests that activity restrictions causes older people less distress because of lower expectations about functional capacity. It is also in contrast with a large study of HRQOL among patients having upper and lower-limb amputations which found better HRQOL, including emotional responses, are independently associated with younger age. Our findings are in line with other studies which report depression and adjustment to amputation are independent of age. Our findings in Study I, where younger and older patients' immediate reactions did not
differ, support this finding. The aforementioned reported differences could be attributed to the cross sectional design and study limitations excluding the oldest people. It is important to note though that reporting problems with psychosocial aspects of quality of life is not the same as wanting healthcare interventions and future appropriate designed studies should investigate whether the need for psychosocial interventions differ between age groups.

Functional needs

Study II aimed to assess the effect of early mobilisation on patients after lower limb amputation and to compare the effectiveness of different mobilisation regimens. Despite a comprehensive and structured search procedure, only five studies were identified that covered the aim of the study, and none of these were high quality. The review reveals a gap in research. Though positive effects of early mobilisation is expected, based on the existing literature, it cannot be concluded that early mobilisation is beneficial to patients having dysvascular LLA. It should also be noted that no harm was detected. The most interesting finding of this review is that ambulation on a temporary prosthesis from first postoperative day is possible among the heterogeneous population of dysvascular lower-limb amputated patients if the necessary interdisciplinary team is dedicated to the task.

Functional level was investigated in Studies III&IV. Based on prospectively longitudinal collected data, results from Study IV show that dysvascular lower limb amputated patients who survive have better HRQOL twelve months after amputation in all subscales but physical function when compared with one month prior to amputation and are significantly more dependent on assistance in ADL functions. The patients’ functional level decreased significantly by Day 21 compared to one month prior to amputation in all ADL activities (Study III). Loss of physical function after twelve months was almost exclusively evident among the oldest patients (Study IV).

In Study III, it was shown that 40 % of participating patients were dependent on assistance in bed-chair transfer on Day 21. Independence in transfer on Day 21 was associated with whether the patients had started physiotherapy after discharge or not, and the findings indicate that short-term functional outcome is modifiable by care provided and thus highlights the need of increased focus on postoperative care to maintain ADL functions as well as to establish and provide everyday rehabilitation in the general population of patients having dysvascular LLA with a special focus on older patients.
Effect of early mobilisation

The systematic review conducted in Study II revealed that the quality of the present evidence is too low to conclude whether early mobilisation interventions are beneficial to patients having dysvascular LLA though the included studies indicate that early mobilisation interventions might reduce some complications in this vulnerable population. The most significant result was that it is possible to ambulate patients after dysvascular amputation as early as the first postoperative day on a temporary prosthesis. This includes older, multi-comorbid and cognitively impaired patients and is not affected by the level of amputation. Early mobilisation interventions that included dedicated interdisciplinary teams working together toward common goals and teams that had a specified care protocol to follow were the most successful in terms of getting patients mobilised. These studies did not reveal any risk of harm to the patients from early mobilisation.

Timing and intensity of early mobilisation

One study showed a decrease in systemic complications by mobilisation within 48-72 hours post-operation on a pneumatic prosthesis compared with bed rest\(^98\). Another study, without detailing the amount of mobilisation received in standard care, found no difference in systemic complications compared with standard care\(^97\). In the future, well-designed studies are required to determine the timing of first mobilisation and the intensity-level of activities needed in a mobilisation regime to achieve the desired decrease in systemic complications. Only one study was identified as measuring the effect of increased mobilisation on a short-term functional level\(^95\). In this study, the indicated effect on FIM scores needs to be replicated in larger populations to be convincing. The mobilisation regime evaluated\(^95\) was not as ambitious as other interventions (i.e., performing the first out-of-bed mobilisation on Day Two) and was performed for a restricted time while all other interventions were performed during the first ambulation on Day One with no time restriction described. It is interesting to note that it was possible to ambulate a consecutive sample of both patients with TTA and TFA in the Pollack and Kerstein\(^98\) study. Unfortunately, the authors did not report the setup necessary to perform the intervention.

Interdisciplinary teamwork

Two studies reported implementing a detailed interdisciplinary protocol in pre- and postoperative care along with the ambulation intervention, and stressed the importance of dedicated and specially trained surgeons, nurses, physiotherapists and prosthetists\(^94,97\). These studies achieved ambulation of included patients on Day One or Two after amputation. These findings contrast with the Schon et al.\(^96\) study which, despite including only the most well-functioning patients, failed to carry out the early ambulation in 11 out of 30 included patients. It could be speculated whether
more patients would have completed the trial if an interdisciplinary rehabilitation protocol had been implemented. Marzen-Groller et al.\textsuperscript{95} described how mobilising patients became a priority among nurses and physiotherapists while implementing the interdisciplinary mobilisation protocol.

\textit{Time to prosthesis fitting}

As found in other studies on providing patients with temporary prosthesis until they are fitted for definitive prosthesis\textsuperscript{118}, shorter time to prosthesis was reported in all four studies of immediate prosthesis interventions. Whether early ambulation within the first postoperative days contribute to the effect or it would be the same if a temporary prosthesis was provided later cannot be concluded within the scope of this review. However, taking into consideration that the prolonged time to prosthesis fitting found in Study IV was mainly explained by organizational waiting time, it could be speculated that the more aggressive attention patients received in the described interventions resulted in reduced organizational waiting time, and thus the ‘active ingredient’ in the interventions is the increased attention these patients received.

Several authors stressed the psychological benefits of immediate prosthesis; these potential benefits, however, need to be investigated with appropriate methods. Nevertheless, experiences from Study IV shows that waiting for an unnecessarily long time to get a prosthesis can negatively impact both the physical and psychosocial aspects of HRQOL and interventions to reduce waiting time is warranted.

\textit{Mobilising patients—a fundamental care task}

Even though mobilising patients in-hospital is the overall responsibility of nurses\textsuperscript{55}, only one nurse-initiated mobilisation intervention was identified in Study II. Taking into consideration the potential effect structured and intense early mobilisation intervention could have—preventing complications and restoring basic functions in an especially vulnerable patient population—this fundamental care task deserves more attention from clinical practice and research. Feo and Kitson\textsuperscript{119} recently discussed fundamental care being overlooked in sophisticated, highly technological acute care settings. They argue that this shortcoming is a consequence of the invisibility and subsequent devaluing of fundamental care brought about by the continued dominance of the bio-medical model and managerial approaches adhered to by most healthcare systems as well as the devaluing of fundamental care by nurses themselves and the environment in which they work.

According to Feo and Kitson\textsuperscript{119}, fundamental care is seen as less valuable than other aspects of clinical care and is not, as a result, researched or taught systematically or implemented at a consistently high standard. Moreover, there is minimal understanding of how and at what point fundamental care work of nurses intersects
with that of other health professionals. It is therefore imperative to emphasize that effective early mobilization will not be successful without interdisciplinary teams working together towards the common goals for the patient. Management must prioritize and focus on mobilising patients as a vital care procedure which they expect performed as well as support necessary initiatives. What’s more, research is highly warranted in early post-amputation mobilising interventions that use appropriate methods to produce high-quality evidence with patient-relevant outcomes.

**Effect of time and age on functional outcome**

Study IV shows that patients who survive have better HRQOL twelve months after amputation in all subscales but physical function when compared with one month pre-amputation and are significantly more dependent on assistance in ADL functions measured at group level. When looking at individuals, significant differences exist in functional level achieved.

An interesting and positive finding is that patients participating in our study reported less limitations caused by their physical health (role-physical) already three months post-amputation even though their physical function had the lowest scores to that point. That less limitations were reported could reflect the fact that physical function is not the only impact on physical limitations experience. The high level of pain, low general health and vitality of patients reported at baseline could be experienced as limitations that are no longer present after three months. The previously mentioned risk of response shift could also play a role.

While patients in Study IV reported physical function (SF36) at a level below population norms at twelve months, this was unchanged compared with baseline. Nonetheless, a clinically significant decrease in functional level when measured with Barthel index 100 was found. Almost all patients were more dependent on help after amputation than before amputation in one or more ADL activities on Day 21 (Study III). As expected, the biggest declines were found in ‘ambulation’ and ‘stairclimbing’—two functions most patients were not expected to regain without prosthesis. More surprising was the decrease in all of eight other functions including basic functions such as bowel and bladder control and eating which indicates a range of potential care needs among patients after discharge. At three, six and twelve months, the patients were more dependent in four activities and had significantly lower function in toilet, self-bathing, ambulation and bed-chair transfer still present at twelve months (Study IV). This loss of physical function, whether it was measured with SF36 (physical function subscale) or Barthel index 100, was unevenly distributed among age groups and there were big differences between individuals.
All age groups had equal scores at baseline (Study IV) with the lowest scores evident on Day 21 (Table 5). The oldest group (age 75+) reported only small gains in functional level and were carrying the biggest loss of physical function at twelve months whether measured with SF36 or Barthel index 100. On the other hand, younger and older patients regained their level of physical function from one month pre-amputation or even improved. Although it is well-documented that age influences physical function after LLA\textsuperscript{29,36,39}, comparisons of these results are difficult because of diversity in outcome measures\textsuperscript{120}, populations studied\textsuperscript{36,84} and the fact that the majority of studies in HRQOL are performed more than twelve months post-amputation\textsuperscript{36}. More studies are required to find out whether the oldest patient group’s physical potential is exhausted or other factors, such as rehabilitation, account for some of these differences in long-term functional outcome achieved. The biggest decline was found in ambulation. Being independent in ambulation after LLA naturally depends on whether the patient has a prosthesis. In our study, 28 patients (74%) were provided a prosthesis and had the first prosthesis home with them within the mean of 161 days with a wide range of 34 to 312 days. Depending on the population studied and criteria for assessment, the proportion reported having had a prosthesis difference of between 5-100\%\textsuperscript{46} within a time range of 19-76 days\textsuperscript{121}. Having a prosthesis is not the same as walking successfully; yet being provided with a prosthesis is a prerequisite to ambulate, and the time spent waiting for the prosthesis explains part of the loss of ambulation skills at three and six months in our study.

The second biggest decline was found in bed-chair transfer. Again, the oldest were most affected with severe decline evident on Day 21. These patients showed an increase in bed-chair transfer at three months but had no signs of improving from that point. Though it was showed in Study II that early mobilisation is possible even among the heterogeneous population of vascular amputated, it is known that hospitalized older people lose basic functions due to immobilisation during their in-hospital stay\textsuperscript{47}. A short, early pre-prosthetic rehabilitation intervention could result in independence in bed-chair transfer for 80\% of a sample comparable to ours\textsuperscript{81}. More studies are required to find out whether interventions such as early mobilisation and/or early rehabilitation initiatives could prevent the oldest from loss of basic functions.

**Factors influencing functional outcome**

Data showed that 40 \% of the patients participating in Study III were dependent on assistance in bed-chair transfer on Day 21. Independence in transfer on Day 21 was associated with whether the patients had started physiotherapy after discharge or
not. Consistent with studies on long-term functioning\textsuperscript{29}, older patients were found to be at higher risk of short-term functional decline; and the risk was even bigger when multi-comorbidity was present.

Of interest were the factors not associated with being independent in transfer on Day 21. Pre-amputation walking ability, having full weight-bearing on the remaining leg, level of amputation, cognitive function, having had re-amputation, being bilaterally amputated and level of pain are all factors known to predict long-term functional outcome\textsuperscript{29}. These findings could indicate that short-term functional outcome is modifiable by care provided and is supported by a recent study by De-Rosende Celeiro \textit{et al.}\textsuperscript{81} In this pre-post intervention study which included a sample comparable to ours, it was shown that a short rehabilitation intervention after post-operative care increased ADL function. Intervention started at a median of 16 days post-amputation and lasted nine days. The total score in the Barthel index increased from 60 at the start to 80 after intervention and 61.5 - 98.1\% of patients regained independence in bathing, toileting, transfer and dressing.

In Study IV, an additional range of data characterizing a consecutive sample of patients having major LLA was reported, and participants were compared with non-participants which showed that non-participants were significantly older and had a higher prevalence of dementia, acute confusion and severely deterioriated health and were therefore expected to have worse outcomes than participating patients.

\textit{Rehabilitation practices}

Patients participating in Study III were discharged from hospital approximately twelve days post-surgery and were dependent on help from homecare and relatives. Rehabilitation interventions initiated immediately after discharge could lead to higher independence in ADL and thereby less dependence on personal assistance.

Internationally, there are major local and regional differences in how perioperative and rehabilitation programmes are organized\textsuperscript{2}. While some studies suggest that amputees rehabilitated in specialist units achieve higher levels of function more quickly and experience less emotional strain\textsuperscript{29,40,122,123}, there is a trend in Denmark towards increasingly shorter hospital stays and rehabilitation care is provided by municipalities. There is a constant requirement to streamline workflow in hospitals, and concerted effort is made to discharge patients early. This means, among other things, that the municipality has to pay if homecare cannot take care of a patient the hospital considered ready for discharge. This tendency requires high professionalism and collaboration across sectors, and there is a risk of patients not receiving appropriate care as indicated by the findings in Study III. Overall, patients participating in Study III were younger and less frail than non-participants; therefore, it was assumed that non-participants manage even worse which highlights the need of increased focus on post-operative care to maintain ADL function as well
as to establish and provide everyday rehabilitation in the general population of patients having dysvascular LLA.

**Suitable for prosthesis fitting**

Patients who were found suitable for prosthesis before discharge were more often independent in transfer on Day 21 (Study III) which makes sense as a relationship between having a certain level of physical strength and being deemed fit for prosthesis was expected. It was actually anticipated that all patients assessed suitable for prosthesis would be independent in transfer on Day 21 which was not the case. The fact that this effect disappeared in the multiple regression model could be explained by the immediately initiated physiotherapy patients received. That being said, questions could be raised about whether some patients’ potential for prosthesis use is missed in the assessment process. It was found that when asked, most patients 78% (n=40) planned to have a prosthesis on Day 21. This was in contrast to the 39% (n=20) who were assessed suitable before discharge. In all, 74% (n=28) were provided a prosthesis within the first twelve months. In view of these findings and taking into consideration the description in Study I of the ignorance that characterizes patients' actions during hospitalization as well as the symbolic meaning of hope that prostheses give shortly after leg amputation, it could be questioned whether assessing patients suitability for prosthetic fitting at this early stage is the best practice. Clinicians’ perspectives on decision-making when assessing patients potential for prosthesis in LLA rehabilitation has been investigated by Sansam et al.\textsuperscript{124}. This study found that clinicians made decisions based on a range of factors including estimation of the patient’s potential to learn to use the prosthesis and level of mobility likely to be achieved. Great importance was placed on patient motivation, determination and coping ability. It is therefore debatable whether the patients were assessed equally in light of how much functionality is lost during hospitalization, high incidence of confusion and lack of guidelines to support clinicians in the decision-making process.
Conclusions and clinical implications

This mixed method project provides unique insight into the dysvascularly-amputated patients’ lives the first twelve months after an amputation and shows that dysvascularly-amputated patients as a group are vulnerable in more aspects even though having a leg amputated can result in better HRQOL in all domains but physical function. Dysvascularly-amputated patients constitute a heterogeneous group with widely different functional levels and psychosocial needs and have a range of complex care needs not always met by the healthcare provided especially since quality improvements are required in several areas to optimize quality of life.

The substantive theory of ‘Pendulating’ constructed in Study I explains patients’ behavior shortly after having a leg amputated as a result of vascular disease and provides unique insight into patients’ concerns and reasons for acting as they do shortly after having had a leg amputated. The patients main concern was identified as: ‘How do I manage my life after having lost a leg?’ The substantive theory of ‘Pendulating’ shows that patients, independent of age and condition, go through a three-phased process as they realize they are experiencing a life-changing event which illustrates how cognitively and emotionally vulnerable patients are shortly after having leg amputation. These findings underpins the moral and ethical obligation to plan and give care to meet the complex physical, practical and psychosocial needs of these patients. Not least should the experience of confusion be addressed. This study was designed to address the question ‘How do we support them psychologically during their in-hospital stay?’ which was put forward by the clinicians at the beginning of the project. The theory provides important information to nurses and other healthcare providers who plan and perform care and offers a tool to understand and acknowledge patients’ behavior and underlying concerns after having had a leg amputated. Concepts from this theory could be used to support patients who are coping by offering terms to express and recognize their reactions.

Early mobilisation interventions have the potential of preventing patients from loss of basic functions and other complications. Nevertheless, the systematic review conducted in Study II highlighted a lack of research evidence to determine whether early mobilisation interventions are beneficial to this vulnerable patient group. It did, however, show that ambulation from first postoperative day with temporary prosthesis is possible among the heterogeneous population of dysvascular lower limb-amputated patients if the necessary interdisciplinary team is dedicated the task. Nursing scholars, practitioners and healthcare managers are urged to take responsibility for this fundamental care task and to engage the necessary collaboration of an interdisciplinary team to develop, implement and evaluate ambitious early mobilisation interventions to fill this identified gap in knowledge.
Functional status on Day 21 after dysvascular major lower limb amputation compared with functional level one month pre-amputation was investigated in Study III where factors potentially influencing short-term functional outcome were also evaluated. A second aim of this study was to report characteristics of a consecutive sample of patients having amputations and compare participants with non-participants. This study was designed to address the third question put forward by the clinicians: ‘How do they manage after discharge?’ The functional level had decreased significantly by Day 21 compared with one month pre-amputation. Short-term functional level (independence in bed-chair transfer) was positively associated with lower age and physiotherapy initiated after discharge and indicates that the outcome is modifiable by care provided. Non-participants were significantly older than participants and had a high prevalence of dementia, acute confusion and severely deterioriated health and were therefore expected to have worse outcomes than the patients participating. Thus, Study III highlights the need of increased focus on post-operative care to maintain ADL functions as well as to establish and provide everyday rehabilitation in the general population of patients having dysvascular LLA with a special focus on older patients. The findings, however, need to be tested in experimental research. Additionally, current practice in assessing patients’ need for prosthesis should be improved to ensure equal conditions.

Unique prospective longitudinal data on patients after dysvascular LLA who survive twelve months were reported in Study IV which investigated effect of time and age on HRQOL, functional level and general self-efficacy. This study was designed to address the question ‘What kind of a life do we give them?’ and documents that significant improvement in more aspects of HRQOL can be achieved as soon as three months postamputation. Psychosocial problems persist and fluctuate throughout the first twelve months in all age groups indicating a need for counselling as part of the rehabilitation services provided. This knowledge is important when planning rehabilitation services. It is crucial to identify those patients in most need of such psychosocial interventions, and future appropriate designed studies should investigate whether all age groups demand the same modes of psychosocial interventions. Evidence from Study IV indicates that waiting for an unnecessarily long period of time for a prosthesis can negatively impact both the physical and psychosocial aspects of HRQOL and interventions to reduce waiting time are warranted. Big differences were identified between age groups in physical function over time with loss of physical function almost solely evident among the oldest patients after twelve months. Experienced limitations in physical function became less although the physical function never became better than the poor level at baseline. There is a need for more studies to determine whether the oldest patients’ physical potential is exhausted or if they could benefit from further rehabilitation to regain basic physical functions and thereby gain higher quality of life.
Future research

Taking the insights from this thesis into consideration, more research is warranted to test modes of both pre- and postoperative as well as rehabilitative care. This includes interventions directed for psychosocial needs as well as physical needs to retain or regain basic physical functions.

In particular, future well-designed studies are required to determine the timing of first mobilisation and the intensity-level of activities in a mobilisation regime needed to achieve the desired decrease in systemic complications.

It would be desirable to be able to monitor the complex needs of this relatively small, heterogeneous group of patients over time. This could be done, for example, by establishing a national clinical database.

A large number of patients having dysvascular LLA were too fragile to participate in the studies included in this thesis and mortality was high among this population. This indicates that we still know far too little about the needs of care among the most vulnerable patients including their needs for palliation. That could be an interesting topic to investigate.
Acknowledgements

This thesis was made possible through employment at the Orthopaedic Surgery Department at Slagelse and Holbaek Hospital, Region Zealand, Denmark, and was supported by grants from Region Zealand and Naestved, Ringsted, Slagelse hospitals Scientific Fund. I would like to express my most sincere gratitude to everybody who helped and supported me through the process of my doctoral work and studies. In no particular order, I would especially like to acknowledge:

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Appendix A


**PUB MED**

Search (((((((((((amputation) OR amputees) OR amputee) OR amputations) OR "amputation stumps") OR "amputation stump") OR ((("Amputation"[Majr]) OR "Amputation Stumps"[Majr]) OR "Amputees"[Majr])))) AND ((("Walking"[Majr]) OR "Early Ambulation"[Majr])) OR (((mobilisation) OR ambulation) OR "early ambulation") OR "early mobilization") OR "early mobilisation") OR mobilization))) AND (((((diabetes) OR dysvascular) OR vascular) OR "non traumatic")) OR ((("non traumatic") OR ("Peripheral Vascular Diseases"[Majr]) OR "Vascular Diseases"[Majr])) OR ("Diabetes Complications"[Majr]) OR "Diabetes Mellitus, Type 2" [Majr]) OR "Diabetes Mellitus/complications"[Majr)]) AND (((("lower extremities") OR "lower limbs") OR legs) OR leg) OR "lower limb") OR "lower extremity") OR "Leg"[Mesh])

Results: 733

**Embase**

exp amputation/ or exp leg amputation/ or exp amputation stump/ exp disabled person/rh [Rehabilitation] 1 or 2 exp mobilization/ exp physical mobility/ exp rehabilitation/ 4 or 5 or 6 exp diabetes mellitus/ exp peripheral vascular disease/ or exp vascular disease/ 8 or 9 exp leg/ or exp leg amputation/ 3 and 7 10 and 12

Results: 626

**Cinahl:**

(MM "BelowKnee Amputation") OR (MM "AboveKnee Amputation") OR (MM "Amputation Stumps") OR (MM "Amputation Care (Iowa NIC)") OR (MM"Amputation+") OR "amputation" OR (MM "Amputees") AND MM "Ambulation Therapy (Saba CCC)") OR (MM "Early Ambulation") OR (MM "Ambulation: Walking (Iowa NOC)") OR (MM "Walking+") OR "ambulation" OR MM "Rehabilitation+") OR (MM "Physical Therapy+")

Results: 804
Original paper I-IV
Pendulating—A grounded theory explaining patients’ behavior shortly after having a leg amputated due to vascular disease

ULLA RIIS MADSEN, RN, MPH, PhD student1, AMI HOMMEL, RN, PhD, Associated Professor2, CARINA BAÅTH, RN, PhD, Assistant Professor3, & CONNIE BÖTTCHER BERTHELESEN, RN, MScN, PhD, Assistant Professor4

1Department of Orthopedic Surgery, Slagelse & Holbæk Hospital, Region Sjaelland, Denmark, 2Faculty of Health, Department of Health Sciences, Lund University, Lund, Sweden, 3Faculty of Health, Department of Health Sciences, Karlstad University, Karlstad, Sweden, and 4Institute of Health, Section of Nursing, Aarhus University, Aarhus, Denmark

Abstract

Introduction: Although the group of vascular leg amputated patients constitutes some of the most vulnerable and frail on the orthopedic wards, previous research of amputated patients has focused on patients attending gait training in rehabilitation facilities leaving the patient experience shortly after surgery unexplored. Understanding patients’ behavior shortly after amputation could inform health professionals in regard to how these vulnerable patients’ needs at hospital can be met as well as how to plan for care post-discharge.

Aim: To construct a grounded theory (GT) explaining patients’ behavior shortly after having a leg amputated as a result of vascular disease.

Method: In line with constructivist GT methodology, data from ethnographic observations and interviews were simultaneously collected and analyzed using the constant comparative method covering the patients’ experiences during the first 4 weeks post-surgery. Data collection was guided by theoretical sampling and comprised 11 patients. A GT was constructed.

Results: Patients went through a three-phased process as they realized they were experiencing a life-changing event. The first phase was “Losing control” and comprised the sub-categories “Being overwhelmed” and “Facing dependency.” The second phase was “Digesting the shock” and comprised the sub-categories “Swallowing the life-changing decision,” “Detecting the amputated body” and “Struggling dualism.” The third phase was “Regaining control” and comprised the sub-categories “Managing consequences” and “Building-up hope and self-motivation.” “Pendulating” was identified as the core category describing the general pattern of behavior and illustrated how patients were swinging both cognitively and emotionally throughout the process.

Conclusion: The theory of “Pendulating” offers a tool to understand the amputated patients’ behavior and underlying concerns and to recognize where they are in the process. Concepts from the theory could be used by health professionals who support patients coping with the situation by offering terms to express and recognize patients’ reactions.

Key words: Adaption, coping, dysvascular amputees, grounded theory, life situation, orthopedic nursing, pendulating, post-operative care, psycho-social needs, quality of life

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Losing a leg presents an array of physical, emotional, and social challenges for patients (Horgan & MacLachlan, 2004). Several studies have documented that patients struggle with higher levels of anxiety, depression, restricted mobility, and social isolation (Briggs, 2007; Horgan & MacLachlan, 2004). Furthermore, themes of low self-esteem, changes in self, and a struggle to accept a new identity as disabled (Senra, Oliveira, Leal, & Vieira, 2012) are described as dominant among amputees in the months following amputation. Patients also deal with a sense of grief, loss, and shock (Hanley et al., 2004). Previous studies are mostly cross-sectional and include selected populations of patients attending gait-training at rehabilitation facilities (Briggs, 2007; Fleury et al., 2013). Consequently, the psychosocial challenges among patients not attending gait-training as well as the immediate reactions to amputation have yet to be investigated (Horgan & MacLachlan, 2004). Liu et al. (2010) investigated the lived experience after amputation among 22 Taiwanese amputees attending gait-training 2 months post-discharge and found participants reported suffering in the physical and psychosocial realms and felt strongly that their lives had completely changed. Although they appreciated the amputation intellectually, they simultaneously struggled to accept the decision emotionally and found professional help primarily directed on physical and practical aspects of the amputation even though their focus was on coping with fear and anxiety. In a Danish study performed 1–5 months post-discharge, Norlyk et al. (2013) found losing a leg to be a radical and existential upheaval which restricts patients’ lifestyles and changes their lifeworld dramatically. Restrictions to lifeworld were related to a sense of great loss as well as hope of regaining lost territory and personal independence. It is interesting to note that participants were not always supported by health professionals during this process.

Previous research indicates a gap in current care regarding support of leg amputation patients’ transition towards life as physically impaired and leaves the patient experience shortly after surgery unexplored. Understanding patients’ behavior shortly after amputation could inform health professionals in regard to how these vulnerable patients’ needs at hospital can be met as well as how to plan for care post-discharge which includes emotional and existential dimensions.

The study

Aim

To construct a grounded theory (GT) explaining patients’ behavior shortly after having a leg amputated because of vascular disease.

Research question: What is the main concern of patients shortly after having a leg amputated and how do they resolve it?

Design

A constructivist GT approach was used (Charmaz, 2014) which brought subjectivity into view and assumes that people, including researchers, are constructing the realities in which they participate. Constructivist grounded theorists aim for abstract understanding of studied life and view their analysis as located in time, place, and the situation of inquiry (Charmaz, 2014).

Setting

The study was performed from April 2013 to January 2014 in orthopedic wards of two regional hospitals in rural Denmark. These hospitals perform 100 leg amputations annually. The care is organized in clinical pathways and mean length-of-stay in hospital after amputation is 11 days.

Participants

Initial recruitment of participants was based on the researchers wish to investigate concerns and behavior among the heterogeneous population of patients who experienced leg amputation due to vascular disease for the first time. This meant that the researchers did not limit themselves to patients who could participate in prosthesis training. Thus, the first two patients who were Danish-speaking and did not have a diagnosis of dementia were included based on accessibility. Further recruitment was guided by the principles of theoretical sampling (Charmaz, 2014) and choices were made about where to look for data that could expand the emerging categories and concepts. As the researchers’ focus was the patients’ immediate reactions, and it was found early in the study that observing the patients in hospital gave insight not available when the participants had rationalized their experiences after discharge, it was decided to continue recruiting patients experiencing their first leg amputation based on accessibility. It was also decided that the same data collection process would be used for all participants.
In all, eight men and three women were recruited within 3 days of unilateral leg amputation due to vascular disease. Age range of participants was 45–84. Two patients only participated in-hospital: one withdrew his consent and one was re-amputated before the after-discharge interview. Six participants had undergone below-knee amputation, one was amputated through the knee and four above the knee. All had at least one comorbidity. Six participants lived with their spouse and the rest lived alone. All participants were retired. All but one was discharged to their former independent living situation with the latter being released to a temporary nursing home.

Data collection

Data collection, analysis, and coding were performed simultaneously. By constant comparison of concepts and incidents, data emerged while memos were written (Charmaz, 2014). The study was designed to gain insight into the participants’ views, feelings, intentions, and actions shortly after amputation. Attempting not to interfere with the process under study and recognizing the vulnerability of these patients, ethnographic observations were performed during hospital stay and in-depth interviews given 2 weeks post-discharge. This was performed to compare the behavior observed with the narratives told by the participants at interviews and, thereby, expand understanding as recommended by Charmaz (2014).

All data were collected by the first author who met each participant on four occasions during the time he or she was admitted to hospital as well as at their homes 2 weeks post-discharge. The first occasion was when consent was obtained between days 1 and 3. When the project was presented with the phrase “I’m investigating what people’s concerns are when they have had a leg amputated,” all participants had a narrative that told what was on their mind. Immediately after, notes of observations were written and stored on a computer.

On the second occasion, non-participant observations (Spradley, 2008) were performed during the bedside meeting 3–5 days after amputation where, according to the clinical pathway, the physician, nurse and physiotherapist were to evaluate whether the patient was suitable for prosthesis fitting as well as make plans to discharge the patient. The observer sat in the back of the room to avoid interfering with ongoing interaction. Field notes were taken during the observations with full observation notes being written immediately after. Each observation lasted 20–45 min.

The third occasion occurred later the same day when participants were encouraged to further assess and explore opinions and feelings that arose from meeting with their healthcare providers. On the fourth occasion, the participants were approached the day before discharge to arrange an interview appointment 2 weeks later. This informal interview started where the participant was at that point. Some hardly remembered being part of a research project while others picked up the conversation from the last meeting. Again, notes of observation were written immediately after the interviews and stored on a computer.

In-depth interviews (Charmaz, 2014) were performed at the patients’ homes 2 weeks post-discharge. Three of the participants wanted their spouses present to support their memory. An interview guide with open-ended questions was developed to help the researcher cover the concepts of interest and was introduced with the statement, “I am interested in your experiences and concerns while you were hospitalized to have your leg amputated.” The interview was started with the question, “Would you please start telling me what led to the amputation?” followed by questions about experiences and concerns during hospital stay. Incidents and concepts from the in-hospital observations were brought forward to explore the opinions and feelings associated with them. Additionally, all participants talked about getting home and their present concerns.

The interview guide was customized from interview to interview as analysis developed and was, thus, congruent to theoretical sampling (Charmaz, 2014). Interviews lasted between 58 and 65 min and were digitally recorded and transcribed verbatim by the first author. Data consist of field notes from 30 informal meetings, 10 non-participant observations and transcripts of nine in-depth interviews. All of this combined information is treated as a single lot of data in analysis. Analysis was performed by the first author and supervised by the last author who read all coded data.

Data analysis

Transcriptions from observations, interviews and memos were initially coded line-by-line looking for behavior related to the research question, “What is the main concern of patients shortly after having a leg amputated and how do they resolve it?” Initial codes were compared while looking for patterns in data and constructing early concepts. Further data were collected, coded line-by-line and compared until seven categories could be constructed (Table I) along with the patients’ main concern: “How do I manage my life after having lost a leg?” Further data
collection was based on the seven categories according to theoretical sampling and focused coding was conducted (Charmaz, 2014) to delimit data collection only to the relevant categories. Theoretical sampling ceased when these categories were saturated and further data collection did not contribute new knowledge to the emergent theory. Through continually and systematically comparing categories with concepts while writing memos, analysis was brought to a higher level of abstraction which revealed properties and a range of the emergent categories. Finally the “puzzle” was put together by explaining the behavior of the patients as reactions in a three-phased process where they realize they are experiencing a life-changing event. Eventually, the core category of Pendulating emerged to describe the general pattern of behavior throughout the process. The presented findings are, in line with constructivist GT (Charmaz, 2014), the product of this analytic process and do not distinguish between the various types of data the analysis is based on.

Ethical considerations

The study was approved by the Danish Data Protection Agency (Region Sjaellands j.nr. 12-000179) and has been presented to the Regional Ethics Committee whose secretariat did not find the project notifiable under Danish law (Region Sjaelland j.nr. 12-000660). In accordance with the basic principles for research given in the Helsinki Declaration and the Northern Nurses’ Federation (2003), the patients received written and verbal information about the purpose of the study, were informed of their right to withdraw and were advised about the confidentiality of the data given before giving their written consent.

Findings

The GT of “Pendulating” (visualized in Figure 1) was constructed to explain the patients’ behavior shortly after having a leg amputated due to vascular disease. We found that the patients went through a three-phased process as they realized they were experiencing a life-changing event. “Pendulating” was identified as the core category describing the general pattern of behavior and illustrates how the patients swung both cognitively and emotionally throughout the process. The patients’ main concern was “How do I manage my life after having lost a leg?” The three phases of the process are labeled “Losing control,” “Digesting the shock,” and “Regaining control.”

Table I. The process of analysis and coding.

<table>
<thead>
<tr>
<th>Code</th>
<th>Category</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Having extensive thoughts</td>
<td>Being overwhelmed</td>
<td>Losing control</td>
</tr>
<tr>
<td>Having fragmented memory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letting things happen</td>
<td></td>
<td></td>
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<tr>
<td>Defending and protecting oneself</td>
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<td></td>
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<tr>
<td>Surrendering</td>
<td>Facing dependency</td>
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<tr>
<td>Escaping</td>
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<tr>
<td>Limiting the consequences</td>
<td></td>
<td></td>
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<tr>
<td>Hoping to get a prosthesis</td>
<td></td>
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Losing control indicated the first phase of the process and comprised the sub-categories “Being overwhelmed” and “Facing dependency.” One put it this way:

I think that even though you don’t want to admit it, you have got a fright. There is something inside you which you have never experienced before, and you think thousands of thoughts—what will happen and how will I manage and things like that. But you do not hold onto any of those thoughts because you are simply just not able to. (Male 84 years, interview)

Being overwhelmed explained how patients reacted as they were put out of action by medication, experienced deteriorated health and dealt with emotional shock. Experiencing a period of fragmented memory or confusion was common. This experience was unpleasant and resulted in fear that the patient would not regain clarity of mind. The patients were aware that they needed help to make plans and see the bigger picture and sought this help from relatives.

When interacting with health professionals, the patients took a passive role, answered questions politely and calmly received advice and information. In spite of this, they were not met with appropriate patience from professionals as the patients, in their overwhelmed state, tried to find words to communicate. Some protected themselves by choosing who they trusted and wanted to relate to which resulted in them communicating only the absolute necessities to the rest of the professionals.

This period of “Being overwhelmed” lasted a few days or continued for weeks.

Facing dependency explained how patients reacted to the need for assistance and personal aids necessitated by the amputation. Their actions were characterized by ignorance and uncertainty about the future. How they thought of themselves was influenced by their own stigmatized view of worth and ability of disabled people. As one said:

Well now I am handicapped. Now I am done. (Woman 82, interview)

These thoughts were often not spoken aloud but were part of the “thousand thoughts” described
previously. The patients repeatedly spoke of specific issues, often related to participation in future social life, without really knowing what to expect realistically. Some thought they had to give up all independent mobilization. Others compared themselves with amputated elite soldiers who run on two prostheses.

Getting a prosthesis was, at this early stage, the only obvious and desirable solution for getting mobility back, and the process of prosthesis fitting was envisioned as a passive process comparable to fitting a pair of boots. In contrast, the wheelchair became the visual symbol of the undesirable dependency; therefore, the wheelchair was tolerated but not accepted.

Patients who accepted the inevitability of the situation maintained a sense of control by surrendering to their destiny. As one stressed:

I cannot run away if I wanted to. I have no leg to run with. (Male 75, observation)

Surrendering meant downscaling expectations by accepting a lower level of functionality and uncritically accepting the support offered while holding onto modest hopes of regaining mobility, if possible with a prosthesis, but most of all aiming to manage everyday life at home.

Others mentally escaped by thinking of the situation as temporary until they could get a prosthesis and walk again regardless of whether this was a realistic option or not. These patients accepted support and aids unwillingly and wanted to go home as soon as possible as they believed going home would solve many problems and ease recovery.

Pendulating at this point of the process described how patients were cognitively and emotionally affected as they lost control in more aspects of their lives. They clung to the pendulum which was in constant motion and swung them in and out of heavy thoughts and from one worry to the next as well as through diverse feelings of injustice, relief, panic and gratefulness.

Digesting the shock

“Digesting the shock” indicated the second phase of the process and comprised the sub-categories “Swallowing the life-changing decision,” “Detecting the amputated body” and “Struggling dualism.” Having a leg amputated was perceived as a life-changing event to which participants had to adjust.

My life has changed dramatically with this operation. (Woman 78, interview)

Swallowing the life-changing decision explains how the patients after surgery processed the shock of deciding to have leg amputation. By accepting the amputation, each patient was aware of his or her responsibility although there was no real choice as the pain or the threat of lethal consequences was unendurable.

I had to accept. Otherwise I could risk dying. (Male 83, interview)

Detailed pictorial descriptions of the situation when the decision was made followed them. Some had experienced the physician as compassionate and empathetic and even though the patients had a hard time accepting the amputation, they found this comforting. Others described how the physician had come in and confronted them with the necessity of the amputation or as one described:

He was downright drooling to take my leg off. (Woman 79, interview)

Despite the recommendation for amputation, stories of having a leg rescued in the past made it harder for participants to be convinced of the inevitability of the present situation. It was important to get confirmation from experts and relatives that the amputation had been the right decision post-surgery in order for the patient to “swallow” the decision. Trust in the relationship with the surgeon was described as crucial.

Detecting the amputated body described reactions to the changing body. How patients perceived their body was closely related to function:

Asked how he assesses his health today on a 1–10 scale, he evaluates how his arms, legs and body work. About the legs he says, “I can move at least one leg.” I ask if he cannot move the other leg. “Well yes, but I cannot walk! And I live on the second floor!” (Male 84, observation)

At an individual pace, patients began looking at the stump. Some avoided this for as long as possible as they summoned the courage to be visually confronted with the missing leg. Others had prepared themselves. Experiencing phantom-sensations or phantom-pain made patients fear loss of sanity and talking with the professionals about it was comforting. Social awareness made them hide the amputated leg as they imagined other people looked down on them as handicapped.

Struggling dualism explained how opposing emotional reactions caused both frustration and alleviation.

A feeling of relief was common among those who had had unbearable pain or stressful wound trajectories preceding the amputation. This positive emotion sometimes overshadowed the difficulties they
were facing; yet at the same time, patients struggled with the consequences. As one said:

Before I had two problems (pain and wound), now I have one. (Male 45, interview)

Others were extremely frustrated by the limitations the missing leg put on their lives. These patients struggled with feelings of confusion as they knew the amputation had saved their lives. Some experienced regret about the decision and tortured themselves with mental pictures of the sawn off leg.

Having days where they lost courage and rejected training caused patients to struggle with their conscience and, looking back, they were grateful for professionals who understood and motivated them anyway.

Pendulating, at this point, described how patients processed the shock while they, emotionally and cognitively, were rapidly swinging from one side to the other. Some had a degree of control over the swing when they diverted themselves from heavy thoughts by deliberately thinking positively and thereby swinging the pendulum away from their worries. Others tried to stop the pendulum for a moment (e.g., by refusing to participate in training). At the existential level, themes of justice and guilt were predominant and these themes were difficult to put into words. Somehow, patients digested the shock, a necessary step, before moving forward and regaining control.

Regaining control

“Regaining control” indicated the third phase of the process and comprised the sub-categories “Managing consequences” and “Building up hope and self-motivation.” Ignorance and uncertainty still marked patients’ actions and there was awareness that adaptation would take time and require energy.

It won’t help me to look back. I will have to make the best out of the situation. (Male 76, interview)

Managing consequences explained how the patients began to regain control when they were capable of hanging onto their thoughts long enough to plan and decide how to handle everyday tasks.

The patients who received help from homecare were grateful for the help but described the situation as living in central station. They struggled with their desire for independence and had to downscale expectations as well as compromise to adjust to the situation. An example of this was when patients were trapped inside because of stairs and doorsteps. Having to sleep separated from a spouse was also pointed out as a painful compromises.

Other patients relied on help from family instead of homecare as help from relatives was considered less invasive. These arrangements raised other questions of being a burden to those relatives and sometimes shifted roles between husband and wife.

One described how he forced himself to participate in training in order to be less of a burden to his wife. Another instructed her husband to push her to manage tasks on her own so that she would not end up as a passive invalid sitting in the corner.

Building up hope and self-motivation described how patients regained emotional control by focusing on their responsibility for creating a good life despite the missing leg and new dependency. All had been confronted with their mortality and stressed that having a good life was up to themselves. As one said:

... and lovely grandchildren, right, I want to see them growing up. So, I thought, I can live without a leg (tears in her eyes, emotion in voice) and then it is up to me to get a good life... (Woman 82, interview)

Adapting to the situation required even more willpower and strength than patients believed they had. Deliberately thinking positively about the future, downscaling difficulties and problems as well as selectively distorting memories in ways that promoted emotional well-being, made the situation easier to accept and was used, along with diverting oneself with busyness, to create self-motivation.

To build up hope, different signs were attributed positive meaning and as markers of luck. This translated into how lucky they felt about the level of their amputation. The ones who had leg amputation below the knee felt fortunate to have more leg left. Others assessed themselves as being fortunate to have leg amputation above the knee as the risk of re-operation was minor. All thought prosthesis-fitting would be easier. Relatives calling, visiting and helping without being asked made them feel worthwhile to other people.

Pendulating at this point of the process, described how the patients were emotionally controlling the situation. The pendulum was now swinging more slowly and was mostly controlled by the patients who pushed themselves away from uncomfortable and undesirable thoughts by deliberately thinking of something positive and occupying their minds with practicalities.

Patients were aware of the existential losses having a leg amputation had caused them. These losses included loss of independency, change of social roles, plans for the future and identity as a walking person among other things. In spite of these losses, patients postponed relating to these existential
thoughts until they had digested the shock and regained some control.

Discussion

This study provides a unique insight into patients’ concerns and reasons for acting as they do immediately after having leg amputation. It shows that having a leg amputated is a life-changing event even for frail patients of all ages who were included in this study. This study illustrates how cognitively and emotionally vulnerable patients are shortly after having a leg amputated, which underpins the moral and ethical obligation to plan and perform care to meet the physical, practical, emotional, and existential needs of these patients.

Not surprisingly, the identified phases of “Losing control” and “Digesting the shock” have similarities with the well-known grief phases of shock and reaction (Cullberg, 2007). This study adds detailed insight into the process specific for patients having lost a leg. It was surprising how little the patients’ struggle in the phase “Losing control” was acknowledged when they were cared for in hospital. While experiencing “Being overwhelmed” and “Facing dependency,” the clinical pathway advised that caregivers discuss rehabilitation goals, prosthesis and other practicalities in order to plan discharge. This was performed without always giving patients’ time to express themselves. Consequently, the patients protected and defended themselves when interacting with professionals and many of the patients’ worries were never communicated. Instead they repeatedly addressed specific issues of more a practical nature and chose the professionals whom they trusted and related to. This meant that patients only communicated what was absolutely necessary with the rest of their healthcare providers.

These findings provide important additional insight into the experience of patients and details what other studies have found about patients experiencing professional help as primarily directed towards the physical and practical aspects after amputation (Liu et al., 2010; Norlyk et al., 2013). Losing control in the acute phase after having a leg amputated is something patients remember long after as a period of suffering (Livingstone, Mortel, & Taylor, 2011; Sjødahl, Gard, & Jarnlo, 2008), and the fact that losing control is a phase all patients have to live through after having a leg amputated underscores the importance of nurses and other professionals being particularly attentive to these patients’ concerns. The same applies to the phase “Digesting the shock” where deciding to have leg amputation triggered a shock that patients had to process afterwards in spite of intellectually accepting the amputation as being for their good. “Swallowing the life-changing decision” seemed easier for those who experienced empathy when amputation was decided and for those who after surgery had the opportunity to discuss with an expert whom they trusted what had led to the necessity of leg amputation. In spite of this, many patients reported not being met with empathy which underscores the necessity for continued work in hospitals to disseminate knowledge and skills among physicians and other health professionals who care for these patients. This includes how to communicate bad news and how to perform follow-up conversations as recommended in the literature (Fallowfield & Jenkins, 2004; Schmidt Mast, Kindlimann, & Langewitz, 2005).

The theory of “Pendulating” offers a tool to understanding patients’ behavior and underlying concerns as well as to recognize where they are in the process. Concepts from the theory could be used by health professionals who support patients coping with the situation by offering terms to express and recognize their reactions.

Understanding the leg-amputated patient’s behavior in the acute setting as a chronically ill person experiencing a crisis that potentially threatens his or her identity helps with understanding the scope of suffering when “Facing dependency.” In studies of the lives of chronically ill people, Charmaz (1983) showed that many ill people hold values of independence and individual responsibility; as a result, these patients question their own self-worth and view developing limitations as losses. In this study, the category “Facing dependency” explains how participants reacted to the need for assistance and personal aids. The behavior of the participants’ mentally escaping resembles a category of “Facing dependency” constructed by Charmaz (1991/1997) which explains how many chronically ill people cannot accept dependency, even when foisted upon them, as dependency remains a greater specter than death. Patients may reject anything that they view as a symbol of failing health or a testimony to dependency. This study expands the category by adding that some patients surrender by accepting the inevitability of the situation. They downscale expectations and uncritically accept the support offered. There is a risk that these patients will meet more restrictions than necessary as it does not occur to them to ask for additional aids or support.

The experience of having a leg amputated separates patients from other achieved handicaps as patients believe they will have the possibility of getting a prosthesis whether that is a realistic option or not. Imagining how the missing leg can be replaced with a prosthesis constitutes a symbol of “Regaining independence.” In contrast, symbols of disability, such as
the wheelchair, are neglected or rejected in the first few days after amputation as part of coping with the situation. “Facing dependency” underpins the importance of acknowledging and supporting the patient’s wish of returning to as normal and independent a life as possible whether they are they younger, older, stronger, or weaker.

This study has several limitations. To increase credibility, data collection was performed in a heterogenic sample of participants by one researcher who achieved intimate familiarity with the setting through a combination of observation and interviews. Analysis in a qualitative study is built upon a subjective process where the researcher is an important actor and preconceived ideas may influence data collection as well as analysis. To minimize this risk, the last author, who also assisted the process of analysis, read all coded data. Two important criteria to evaluate a GT are resonance and usefulness (Charmaz, 2014). These criteria determine whether the theory makes sense to the participants and/or people who share their circumstances. It also helps evaluate if people can use the information in their everyday world. While writing this manuscript, concepts from the theory were presented to more than 40 patients who had experienced leg amputation within the prior 2 weeks as part of another research project. These patients immediately connected to the concepts of “Losing control” and “Digesting the shock.” This indicates resonance and usefulness although further research is needed.

Conclusion

The substantive theory of “Pendulating” explains the behavior and underlying concerns of patients shortly after leg amputation and is linked to the process of realizing that they are experiencing a life-changing event which has potential life- and identity-threatening consequences. This study offers unique insight into this vulnerable group of patients’ experiences not previously examined and underpins the moral and ethical obligation to plan and perform care to meet the physical, practical, emotional and existential needs of these patients. The theory of “Pendulating” offers a tool to understand the patients’ behavior and underlying concerns and to recognize where they are in the process. Concepts from the theory could be used by health professionals who support patients coping with the situation by offering terms to express and recognize patients’ reactions. Taking the insights from this study into consideration, more research is warranted to test modes of pre- and post-operative care.

Authors’ contributions

The study was designed by URM, CBB, AH, and CB. Data collection was performed by URM. Analysis and draft of the manuscript was performed by URM, supervised by CBB. Critical revisions for important intellectual content were provided by AH and CB.

Ethical approval

The project has been presented to the regional ethic comity, whose secretariat did not find the project notifiable in relation to Danish law (Region Sjaellands j.nr. 12-000660) and the Danish supervisory authority on data security has approved the project (Region Sjaellands j.nr. 12-000179).

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Conflict of interest and funding

The authors have declared no conflict of interest.

References


Aims and objectives. To assess the effect of early mobilisation of patients after dysvascular lower limb amputation and to compare the effectiveness of different mobilisation regimens.

Background. Patients who have undergone dysvascular major lower limb amputations are at high risk of postoperative complications, which include loss of basic functions, and early mobilisation interventions might prevent these complications.

Design. Systematic review.

Methods. Systematic searches were performed on PubMed (including MEDLINE), CINAHL and EMBASE databases to identify studies investigating the effects of (early) mobilisation interventions in dysvascular lower limb-amputated patients. Data collection and quality assessment were performed using the Cochrane Effective Practice and Organization of Care Review Group data collection checklist and the Cochrane Handbook for Systematic Reviews of Interventions, respectively.

Results. Five studies were included in the review: four pre- to post-case studies and one randomised controlled study. However, none of these studies were of high quality. Four studies investigated early mobilisation promoted by immediate postoperative prosthesis. One study investigated whether reorganizing care increases mobilisation and thereby functional outcome.

Conclusions. This systematic review reveals a lack of evidence to determine whether early mobilisation interventions are beneficial to this vulnerable patient group. Nevertheless, ambulation from the first postoperative day with temporary prosthesis is possible among the heterogeneous population of dysvascular lower limb-amputated patients if the necessary interdisciplinary team is dedicated to the task.

Relevance to clinical practice. Mobilisation is a fundamental care task often missed for several reasons. Moreover, mobilisation of the newly amputated patient is complex, and knowledge of effective strategies to promote postoperative mobilisation in this vulnerable population is desired. Nurses are urged to take responsibility for this fundamental care task and to engage the necessary collaborative interdisciplinary team to develop, implement and evaluate ambitious early mobilisation interventions.

What does this paper contribute to the wider global clinical community?

• This systematic review highlights a research evidence gap that needs to be addressed.
• Mobilisation of the newly amputated patient is complex, but possible, and knowledge of effective strategies to promote postoperative mobilisation in this vulnerable population is desired.
• Although postoperative mobilisation is often a nurse responsibility, it is crucial to have the collaboration of a dedicated interdisciplinary team with common goals for the patients to succeed.
Key words: ambulation, amputation, amputee, basic functions, early mobilisation, fundamental care, interdisciplinary team work, lower limb amputation, mobilisation, postoperative care

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Introduction

Patients who have undergone dysvascular major lower limb amputations are at high risk of postoperative complications, which include loss of basic functions, and early mobilisation interventions might prevent these complications. This systematic review aims to assess the evidence base to support the effects of early mobilisation interventions in this vulnerable patient group.

Background

Patients who have undergone major lower limb amputations based on dysvascular indication constitute some of the most vulnerable and frail patients in orthopaedic and vascular departments. Many of the patients have been restricted in mobility prior to amputation as a result of pain and months of treatments designed to save the leg (Goodridge et al. 2005). When combined with high age (mean age over 70 years) (Global Lower Extremity Amputation Study Group 2000), chronic illness and multimorbidity (Kristensen et al. 2012, Fortington et al. 2013), these patients are at high risk of postoperative complications. Thirty-day mortality rates of 30% have been reported (Dillingham et al. 2005, Kristensen et al. 2012, Fortington et al. 2013), with the main causes of death being cardiovascular and respiratory complications. Wound complications resulting in re-amputation at a higher level were found in 20–23% of patients who had undergone transtibial amputations (TTAs) (Eneroth 1999, Dillingham et al. 2005).

In addition to the risk of medical complications, the surviving patients are at high risk for functional decline (Frykberg et al. 1998). Postoperative care and early rehabilitation should be aimed at regaining independence in basic functions such as transferring from a bed to a chair, going to the toilet and independent mobility, as patients describe dependence in these areas as reducing their quality of life (Ragnarson & Apelqvist 2000). In-hospital immobilisation has been shown to lead to declines in activity of daily living function among older patients (Brown et al. 2004). However, postoperative early mobilisation starting as early as the day of surgery is known to prevent a range of postoperative complications in different settings (Kamel et al. 2003, Lorello et al. 2014, Bakker et al. 2015). Mobilising patients in the acute care setting is a fundamental care task (Kalisch et al. 2013) that is provided when ordered by the physicians. As such, it is the responsibility of the nursing staff (Sheets 2012) to mobilise patients, although this care can be partially provided by allied health professionals such as physiotherapists. Nurses have been identified as the most capable healthcare professionals to promote functional independence in the chain of care providers surrounding older hospitalised patients (Sheets 2012). Despite this finding, nurses often do not ambulate patients (Kalisch et al. 2011), and hospitalised patients spend most of their time in bed or in a chair (Brown et al. 2004). Nurses, physicians and older adults themselves are reluctant to mobilise patients who have symptoms of weakness, pain, fatigue, concerns about falls or medical devices. Lack of staff and devices to assist with out-of-bed activity combined with lack of motivation from patients have been identified as further barriers to mobilising older hospitalised patients (Brown et al. 2007). Doherty-King & Bowers (2011) investigated how registered nurses decide to ambulate hospitalised older adults and found that nurses often labelled patients as either ‘community’ or ‘nursing home residents’, with the latter label being assigned when patients had either come from a nursing home or looked like they should be in a nursing home. Nursing home patients were seen as patients who fell frequently, required considerable assistance with activities of daily living, or were confused. Patients labelled ‘nursing home residents’ were significantly limited to the bed or chair, and ambulation was not considered. Two groups with particular traits characterised the nurses’ behaviour. One group claimed that the ambulation of patients was in their responsibility of practice, and a second group attributed the responsibility to another discipline. Nurses who claimed responsibility for ambulation were more likely to take actions that initiated ambulation, while those who attributed responsibility to another discipline waited to act (Doherty-King & Bowers 2013).

Mobilising patients after major lower limb amputation is challenging for more reasons than those noted above. The fact that the patient has only one leg is an obvious challenge. Additionally, factors such as age,
low muscle strength, uncertain balance, multicomorbidity, cognitive impairments, pain and emotional distress (Higgins & Green 2011) make mobilisation of the newly amputated patient a complex care task, and knowledge of effective strategies to promote postoperative mobilisation of patients after major lower limb amputations is desired.

Aims
The aim of this study was to assess the effect of early mobilisation of patients after dysvascular lower limb amputation and to compare the effectiveness of different mobilisation regimens.

Method
Design
A systematic review of the literature was performed according to the steps of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green 2011). The study protocol was registered at PROSPERO database (2016) (reg. CRD42016033344), comprising full search strategies and inclusion criteria. This review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al. 2015).

Search strategy
Preliminary searches for existing systematic reviews were conducted on Cochrane, PubMed, PROSPERO and CINAHL databases in January 2016 without identifying any studies covering the topic of interest. Systematic searches were performed on PubMed (including MEDLINE), CINAHL and EMBASE in January 2016. Intentionally broad search strategies contained the terms ‘amputations’ OR ‘amputees’ AND terms for ‘leg’ AND terms for ‘dysvascular’ OR ‘non-traumatic’ AND terms for ‘mobilization’ OR ‘ambulation’. In addition to the electronic search, reference lists of the included articles were used as a source to identify relevant studies. Full electronic search strategies are available in Appendix S1. The following criteria were used to include studies in the review.

Types of studies
The included studies comprised (Cluster-)randomised controlled trials, (un-)controlled before-and-after studies, interrupted times series (ITS) studies and pilot studies comprising the above-mentioned study designs; the included studies described all types of interventions aimed at increasing early in-hospital mobilisation after amputation surgery. Early mobilisation was defined as all ‘out-of-bed’ activity starting within the first postoperative week. Case studies with historical control designs, and thus with a high risk of bias, were included as they might contribute insight into components important to designing interventions customised to the heterogenic population of patients who have leg amputations in the postsurgery setting.

Population and setting
Patients who had a major lower limb amputation at trans-tibia (TTA), through-knee (TKA) and trans-femoral (TFA) levels due to dysvascular (inclusive of diabetes) indication in orthopaedic or vascular surgery departments were included. Excluded were studies performed in rehabilitation settings more than two weeks postoperation or studies describing mobilisation starting ≥10 days postsurgery, as these interventions were not defined as early mobilisation.

Outcome measures
Effects of early mobilisation included measures of functional level, time to recovery, pain, complication rates, survival, health-related quality of life, time to prosthesis fitting and patient-rated quality of care. It was anticipated that the operational definitions and time points of the outcomes would vary across studies. As such, studies were included irrespective of how outcomes had been defined or at what point of time they were measured.

Study selection procedure
All articles were screened by title and abstract by two independent reviewers (first and last author). Each article was checked twice, and doubts were resolved by discussion. Articles were included if the title or abstract described early mobilisation of patients after amputation surgery and fulfilled the inclusion criteria. The remaining articles had their full texts screened by the first and last author. Additionally, reference lists of included articles were screened. No conference abstracts, editorials, personal communications or unpublished studies were included.

Quality assessment
To assess the risk of bias, we used the Cochrane Effective Practice and Organization of Care Review Group (EPOC)
‘risk of bias assessment tool’ (Higgins & Green 2011). This tool is a domain-based evaluation to assess selection, performance, attrition, detection and reporting biases. For non-randomised studies, Cochrane recommends the addition of additional domains. Therefore, we added two domains to the tool: (1) randomization (yes/no) and (2) control group (yes/no). The quality assessment was performed by the first author and thoroughly reviewed by and discussed with the last author.

Data extraction
Data were extracted by the first author and thoroughly reviewed by and discussed with the last author. For data extraction, we used the EPOC data collection checklist (Higgins & Green 2011). The general characteristics of the study with respect to design, setting and sample size were extracted from the studies that were read. Characteristics of participants consisted of inclusion and exclusion criteria, number of participants screened and included, average age, comorbidities, gender and level of amputation. Descriptions of modalities and duration of the interventions as well as healthcare professional involvement in interventions (nurses, physiotherapists, physicians, prosthetists) were also considered. Details of how and when relevant outcome measures were collected were likewise examined. As part of this process, we carefully read all sections of the included studies to find additional information of interest.

Data synthesis and presentation
Due to the heterogeneity of the studies, a meta-analysis was not possible. Therefore, we extensively analysed the studies and conducted a qualitative synthesis, aggregating and summarizing the results. The results will be presented in summary tables and in narrative form.

Results
A total of 1836 records were identified from the electronic search. After titles and abstracts were screened, 13 articles were assessed for eligibility along with four records that were found from reference lists. Five articles were included. The selection process can be visualised in the PRISMA (Moher et al. 2015)-inspired flow chart (Fig. 1). No high-quality studies were identified that covered the aim of this review. Four of five included studies were assessed as being at high risk of bias (Tables 1 and 2) (Ivanic et al. 2002, Schon et al. 2002, Marzen-Groller et al. 2008, Ali et al. 2013) due to an uncontrolled before-and-after design that included mostly retrospectively collected data (Table 2). All results should therefore be read with the understanding that false results are possible. These studies were included, as noted above, because they contribute to understanding important details when designing interventions customised for the postsurgery, heterogeneous population of patients who have had major lower limb amputations.

Study characteristics
Characteristics of the included studies are displayed in Table 1. Four studies were performed in the USA and one in Europe. All but one study used retrospective design (Ivanic et al. 2002, Schon et al. 2002, Marzen-Groller et al. 2008, Ali et al. 2013). Two used an uncontrolled before-and-after design (Marzen-Groller et al. 2008, Ali et al. 2013). Two performed case studies using a historical sample as a control (Ivanic et al. 2002, Schon et al. 2002). The latter study used a randomised controlled design (Pollack & Kerstein 1985). Four studies investigated a type of immediate postoperative prosthesis that promoted early mobilisation through ambulating with partial weight-bearing on the amputated leg (Pollack & Kerstein 1985, Ivanic et al. 2002, Ali et al. 2013). One study investigated whether reorganizing care increases mobilisation and thereby improves the functional outcome among patients after lower limb amputation (Marzen-Groller et al. 2008). Two studies included consecutive samples of both patients having TTA and TFA (Pollack & Kerstein 1985, Marzen-Groller et al. 2008). One study included a consecutive sample of TTA (Ivanic et al. 2002). The last two studies included selected samples of patients who had TTA and who were assessed for their potential to become prosthetic walkers after amputation (Schon et al. 2002, Ali et al. 2013). Mean age varied from 53–69 years. All but one study compared the intervention with standard care, as displayed in Table 3. None of the studies described the amount of mobilisation provided patients in the control group except Pollack and Kerstein (1985), who compared the intervention with two weeks of bed rest. Professionals needed for the intervention were physicians, physiotherapists, nurses and prosthetists (Ivanic et al. 2002, Schon et al. 2002, Ali et al. 2013) (one study did not describe prosthetists (Marzen-Groller et al. 2008), and one did not describe the professionals needed to provide the intervention (Pollack & Kerstein 1985)) (Table 3). The outcomes measured included systemic complications (Pollack & Kerstein 1985, Ali et al. 2013), wound complications (Pollack & Kerstein 1985, Ivanic et al. 2002, Ali et al. 2013), revisions or re-amputation (Pollack & Kerstein 1985, Ivanic et al. 2002, Ali et al. 2013).

Immediate postoperative prosthesis interventions

Four studies described interventions that applied temporary prostheses immediately postsurgery – one using a hard cast prosthesis and three using a pneumatic prosthesis. The interventions varied, as did the population included and the outcome measures, making comparisons of the results difficult. Each study is therefore presented separately.

Ali et al. (2013) evaluated complication rates and time to prosthesis among 77 patients who had undergone TTA in a retrospective case-control study (chart review of routinely collected clinical data). Included in the study were 37 patients who received an immediate hard cast prosthesis (IPOP) from 2007–2010. Selection criteria for IPOP were pre-ambulatory patients with no active infection and who were judged to have the necessary motivation and likelihood of healing. Excluded were nonambulatory patients and those with previous contralateral higher than transmetatarsal or with re-amputation to a higher level within the same hospitalisation. A historical control group of 35 possible IPOP candidates who had received standard care was found among patients who had undergone a TTA in the same unit from 2006–2007. The intervention group was younger than the control group (mean 61.5 vs. 69 years, \( p = 0.010 \)). The hard cast was applied in the operating room, and patients were mobilised with partial weight-bearing in standing and transfers from days 1–7. A cast was reapplied on day 7, at which time the wound was inspected and gait training started. In addition to the IPOP, patients in the intervention group received intensive information and aggressive follow-up from specially trained vascular surgeons, physiotherapists, nurses and prosthetists. As shown in Table 4, no significant difference was found in systemic complications (in-hospital), wound complications or falls, although a trend of fewer falls was found among IPOP patients. More skin breakdowns occurred and were explained by the hard cast. Significantly fewer surgical revisions were performed in the IPOP group, which could be attributed to aggressive follow-up, where early wound issues were addressed before deterioration into advanced complications that necessitated revisions. The authors argue for the physiological and psychological benefits of IPOP, as it allows for earlier ambulation and a shorter rehabilitation period, minimising the duration of postoperative immobility.

Ivanic et al. (2002) prospectively evaluated the effects and feasibility of a new rehabilitation concept that includes an immediate postoperative pneumatic prosthesis (air limb) among 25 consecutive patients who had undergone a TTA at an orthopaedic clinic. This group was compared with a historical group of 23 randomly chosen patients who received standard care under the care of the same surgeon. The intervention group was younger (mean 54 vs. 57 years).
Table 1. Characteristics of included studies (n = 5)

<table>
<thead>
<tr>
<th>First author (Year)</th>
<th>Country</th>
<th>Design</th>
<th>Aim</th>
<th>Population</th>
<th>Results</th>
<th>Comments on risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ali et al. (2013), USA</td>
<td>Retrospective before-and-after study</td>
<td>To evaluate complications and time to prosthesis with early ambulation on IPOP compared with standard care</td>
<td>77 patients selected with potential to ambulate after amputation, nontraumatic TTA; Intervention n = 37, (mean age 61.5, male = 31). Control n = 40, (mean age 69, male = 27)</td>
<td>No difference in systemic complications, more skin breakdown among IPOP, fewer revisions, fewer falls and shorter time to prosthesis</td>
<td>HIGH: Retrospective design, inclusion criteria include subjective judgements, no blinding, interventions found in a four-year cohort, control in a two-year cohort</td>
<td></td>
</tr>
<tr>
<td>Ivanic et al. (2002), Austria</td>
<td>Prospective case study with historical control</td>
<td>To test effect and feasibility of a new rehabilitation concept including an immediate postoperative pneumatic prosthesis (air limb) compared with standard care</td>
<td>48 consecutive TTA patients. Intervention n = 25, (4 traumatic, mean age 54, male = 12). Control n = 23 selected from same surgeon (mean age 57, male = 12)</td>
<td>Fewer wound complications, revisions, falls and days to prosthesis fitting among intervention group</td>
<td>HIGH: Historical control, no blinding characteristics of control not detailed, control older than intervention</td>
<td></td>
</tr>
<tr>
<td>Marzen-Groller et al. (2008), USA</td>
<td>Prospective case study with retrospective control</td>
<td>To evaluate the effect of the Amputee Mobility Protocol (AMP) on patient functional independence compared with standard care</td>
<td>19 TTA and 12 TFA patients, all dysvascular, Intervention n = 8, Control n = 23. Age and gender not described</td>
<td>‘Stand to pivot’ and ‘Sit to stand’ increased 1-2 levels after implementing Amputee Mobility Protocol</td>
<td>HIGH: Retrospective control, no blinding, no characteristic of population described, congruence in FIM scoring could be questioned, small sample</td>
<td></td>
</tr>
<tr>
<td>Pollack and Kerstein (1985), USA</td>
<td>RCT</td>
<td>To demonstrate a decrease in frequency of typical postamputation complications in early ambulation by a pneumatic prosthesis compared with bed rest two weeks postoperation</td>
<td>80 consecutive TTA and TFA patients. Intervention n = 40 (28 TTA/12 TFA, mean age 61, male = 40). Control = 40 (26 TTA/14 TFA, mean age 58, male = 34)</td>
<td>Significantly fewer pulmonary and urinary complications. No re-amputations in either group. More complications among TFA</td>
<td>MODERATE: Prospective design. Randomization based on admission nr, no blinding described, characteristics of participants not detailed, time point for outcomes measured not stated</td>
<td></td>
</tr>
<tr>
<td>Schon et al. (2002), USA</td>
<td>Case study with historical control</td>
<td>To test whether an early postoperative pneumatic prosthesis would reduce postoperative complications compared with standard care being soft dressing and no weight-bearing (same prosthesis as tested by Ivanic)</td>
<td>54 selected TTA with potential for ambulation after amputation, 31 intervention (mean age 53, 18 male, 27 dysvascular, 4 traumatic) 23 matched historical controls (mean age 54, 16 male)</td>
<td>Significantly fewer falls and wound complications. Shorter time to prosthesis fitting</td>
<td>HIGH: Historical control, no blinding, interventions found in a two-year cohort, control in a 10-year cohort. Very high dropout rate</td>
<td></td>
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</tbody>
</table>

TTA, transtibial amputation; TF, transfemoral amputation.
and all male (vs. 12 males/11 females in control). Other characteristics were not provided to assess the comparability of the groups, but the report stated that they were matched according to age, health status and underlying diseases. The intervention consisted of an intensive protocol describing the interdisciplinary care path pre-operation and six weeks postoperation with follow-up until custom prosthesis. A pneumatic prosthesis was applied in the operating room with patients ambulating from day 1 or 2 with partial weight-bearing. Patients received daily wound inspections and physiotherapy until day 21. In all, 24 of 25 patients were ambulated within the first five postoperative days with the pneumatic prosthesis and 17 of 25 walked independently at some point during their in-hospital stay; however, 11 patients dropped out before day 21 because of dementia, stroke, depression or social reasons. Only two wound complications were found among the intervention group, compared with 17 in the control group. None of these led to surgical revision, compared with 17 in the control group (Table 4). Six times more falls in the control group were recorded, but the actual numbers were not provided. Time to custom prosthesis was 94 (30–548) days for 13 of 24 patients who had a custom prosthesis, compared with 138 (48–180) days in the control group. The authors concluded that even though the results should be read with caution, it is possible to administer the air limb for immediate postoperative mobilisation among a heterogeneous sample of patients who have undergone TTA.

Pollack and Kerstein (1985) used a randomised controlled design to evaluate whether postoperative complications could be prevented with early ambulation of patients with a pneumatic prosthesis. Included in the study were 80 consecutive patients with TTA or TFA who were randomised based on admission number. The intervention group was older (mean age 61 vs. 58 years) and contained no women vs. six women in the control group. No data were provided regarding the indication for amputation. The authors reported similar incidences of diabetes and cardiopulmonary disease in both groups. The pneumatic prosthesis was applied 24–48 hours postsurgery, and patients started ambulation 48–72 hours postsurgery. Controls were bedridden the first two weeks. The two groups were compared for incidence of pulmonary, cardiac, urinary and wound complications as well as thrombophlebitis. It was not clearly stated at what point these complications were evaluated. There were significantly fewer pulmonary and urinary complications among the early ambulated patients (Table 4). The authors describe the findings as being largely attributable to the comparison of a bedridden group and a more active group, and thus, they expected similar results with other interventions of early mobilisation. Anecdotally, it was found that rehabilitation was hastened and improved by the use of the pneumatic prosthesis as a means of reducing the deterioration of postural reflexes and kinaesthetic senses. Additionally, general and specific muscle work was encouraged, contractures were prevented, and there was a shorter time to prosthesis.

Schön et al. (2002) tested the same pneumatic prosthesis as Ivanic (air limb) in a case study of 31 selected patients who had undergone a TTA from 1998–2000 in an orthopaedic department compared with a historical group receiving standard care. Controls were matched with respect to age, diagnosis and inclusion/exclusion criteria, and controls were treated at the same institution by the same surgeons from 1989–1998. The intervention consisted of pre-operative assessment and information, a pneumatic prosthesis applied in the operating room.
(n = 20) or within five days (n = 10) and ambulation from day 1 with partial weight-bearing. The wound was inspected daily until wound healing (2–3 weeks) and weekly or every other week thereafter. In contrast to the study of Ivanic, no interdisciplinary rehabilitation protocol was implemented. One patient was excluded postoperatively because the residuum was too big to fit the prosthesis. Eleven of the 30 patients dropped out within the first two weeks because of dementia/stroke (4), lack of confidence with ambulating on the residuum (3), advice from subsequent treating physiatrist (2) or noncompliance and inability to take off the device (2). The 19 patients completing the trial had significantly fewer wound complications and falls and a shorter time to custom prosthesis fitting (Table 4). All patients in both groups were eventually fitted with a custom prosthesis.

Reorganizing care to increase postoperative mobilisation

In one of the five included studies, Marzen-Groller et al. (2008) performed a before-and-after study to test the effect on functional outcome in patients who have undergone TTA or TFA in a vascular unit whose care was reorganised by means of implementing a mobilisation protocol. (This study also included patients who had transmetatarsal amputation. Results not shown here.) All patients admitted for amputation were enrolled over a five-month period and compared with routine collected data on all (TTA and TFA) patients admitted one year earlier. Physiotherapists held pre-operative consultations, which included functional assessment of the Functional Independence Score (FIM). Nurses and physiotherapists worked together mobilising patients following the protocol with first ‘out-of-bed’ mobilisation on day 2 and restricted ‘out-of-bed’ time on days 2 and 3. The functional outcome was measured post-operatively and at discharge by the physiotherapist. Before implementation of the mobilisation protocol, pre- and immediate postoperative activities varied from physician to physician, who randomly ordered physiotherapy. Furthermore, there was an inconsistent plan of care because of lack of vascular nursing experience. FIM measures ‘Stand to pivot’ and ‘Sit to stand’ increased by one to two levels both before and after implementing the protocol. Before the intervention, only 44% of the patients who had a TFA had

<table>
<thead>
<tr>
<th>First author (Year)</th>
<th>Country</th>
<th>Intervention</th>
<th>Control</th>
<th>Setting/professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ali et al. (2013), USA</td>
<td>Hard cast applied immediately postsurgery, amputation on stump from day 1, following a protocol with specified stump-check, weight-bearing and cast re-application</td>
<td>Standard care with traditional soft comprehensive dressings, Details of mobilisation not described</td>
<td>Vascular unit in a not-for-profit hospital, Specially trained and dedicated vascular surgeon, nurse, physiotherapist, and prosthetist</td>
<td></td>
</tr>
<tr>
<td>Ivanic et al. (2002), Austria</td>
<td>Pneumatic prosthesis applied immediately postsurgery, amputation at day 1 or 2, intensive pre- and postsurgery rehabilitation protocol</td>
<td>Standard care, details not described</td>
<td>Orthopaedic department in a not-for-profit hospital, Physicians, nurses, physiotherapist, prosthetist</td>
<td></td>
</tr>
<tr>
<td>Marzen-Groller et al. (2008), USA</td>
<td>Amputee mobility protocol implemented describing ambulation day 1 until discharge</td>
<td>Standard care, inconsistently prescribed and performed</td>
<td>Medical-surgical vascular unit in a not-for-profit hospital, Vascular surgeons, physiotherapist, nurses</td>
<td></td>
</tr>
<tr>
<td>Pollack and Kerstein (1985), USA</td>
<td>Ambulation within one week postoperatively (48–72 hours), whenever possible with the pneumatic splint and gradually increasing weight-bearing</td>
<td>Bed rest two weeks postoperation</td>
<td>Department of surgery, for profit hospital, Professionals needed for intervention not stated</td>
<td></td>
</tr>
<tr>
<td>Schon et al. (2002), USA</td>
<td>Pneumatic prosthesis applied immediately postsurgery, controlled weight-bearing from day 1. Daily wound inspections until healing (2–3 weeks)</td>
<td>Standard care with elastic bandages and wound inspection every other day. Amount of mobilisation not described, although no early weight-bearing</td>
<td>Department of orthopaedic surgery, not-for-profit hospital, Special educated physician, nurses, physiotherapist, prosthetist</td>
<td></td>
</tr>
</tbody>
</table>
The most important result found in the included studies is that it is possible to ambulate patients after dysvascular amputation as early as the first postoperative day on a temporary prosthesis. This includes older, multimorbid and cognitively impaired patients and is not affected by the level of amputation. The early mobilisation interventions that included dedicated interdisciplinary teams working together towards common goals and teams that had a specified care protocol to follow were the most successful in terms of getting the included patients mobilised.

**Discussion**

This study aimed to assess the effect of early mobilisation on patients after lower limb amputation and to compare the effectiveness of different mobilisation regimens. Despite using a comprehensive and structured search procedure, very few studies were identified that covered the aim of this study, and none was high quality. These studies did not reveal any risk of harm to the patients from early mobilisation, and collectively, they indicate that early mobilisation interventions might reduce some complications. However, the quality of the present evidence is too low to conclude whether early mobilisation interventions are beneficial to this vulnerable patient group. The most important result found in the included studies is that it is possible to ambulate patients after dysvascular amputation as early as the first postoperative day on a temporary prosthesis. This includes older, multimorbid and cognitively impaired patients and is not affected by the level of amputation. The early mobilisation interventions that included dedicated interdisciplinary teams working together towards common goals and teams that had a specified care protocol to follow were the most successful in terms of getting the included patients mobilised.

**Comparing details of the interventions**

One study showed a decrease in systemic complications by ambulation within 48–72 hours postoperative on a pneumatic prosthesis compared with bed rest (Pollack & Kerstein 1985). Another study found no difference in systemic complications compared with standard care (Ali et al. 2013) but without detailing the amount of mobilisation.

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Table 4 Outcome results and measures

<table>
<thead>
<tr>
<th>First author (year)</th>
<th>Country</th>
<th>Primary outcome</th>
<th>Results: after-and-before intervention, (p-value)</th>
<th>Statistical test performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ali et al. (2013)</td>
<td></td>
<td>1 Systemic complications (in-hospital) (%)</td>
<td>2 29.7–31.4 (0.876)</td>
<td>Student’s t-test and chi-squared test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 Wound infection (%)</td>
<td>3 29.7–25.0 (0.673)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 Wound dehiscence (%)</td>
<td>4 18.9–3.6 (0.062)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>4 Skin breakdown (%)</td>
<td>5 5.4–27.6 (0.013)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>5 Revisions (%)</td>
<td>6 10.8–21.8 (0.240)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>6 Fall (%)</td>
<td></td>
<td></td>
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<tr>
<td>Ivanic et al. (2002)</td>
<td></td>
<td>1 Wound complications (n)</td>
<td>1 2–17</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>2 Revisions (n)</td>
<td>2 0–20</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 Fall (n)</td>
<td>3 6–10</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>4 Time to prosthesis (days)</td>
<td>4 95 (48–185)–38 (30–548)</td>
<td></td>
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<tr>
<td>Pollack and Kerstein (1985)</td>
<td></td>
<td>Complications:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1 Pulmonary (n)</td>
<td>2 2–6 (0.26)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>2 Cardiac (n)</td>
<td>3 2–12 (0.006)</td>
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<td></td>
<td></td>
<td>3 Urinary (n)</td>
<td>4 0–1</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>4 Thrombophlebitis (n)</td>
<td>5 2–7 (0.154)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>5 Wound (n)</td>
<td>6 0–0</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>6 Re-amputations (n)</td>
<td></td>
<td></td>
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<tr>
<td>Schon et al. (2002)</td>
<td></td>
<td>1 Wound complications (patient/month)</td>
<td>1 0.043–0.181 SD ± 0.026–0.420 (Not reported)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>2 Revisions (n)</td>
<td>2 0–10</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 Falls (patient/month)</td>
<td>3 0.183–0.42 SD ± 0.57–219 (0.113)</td>
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<tr>
<td></td>
<td></td>
<td>4 Time to prosthesis (months)</td>
<td>4 3–4.5 1 SD ± 0.3–1.0 (Not reported)</td>
<td></td>
</tr>
<tr>
<td>Marzen-Groller et al. (2008)</td>
<td></td>
<td>FIM</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1 Stand to Pivot</td>
<td>1 4 (up 1 level) – 3 (up 1.1 level)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>2 Sit to Stand</td>
<td>2 4 (up 0.6 level) – 2 (up 0.2 level)</td>
<td></td>
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</tbody>
</table>

Fischer exact test

*Statistically significant.
received in standard care. Future well-designed studies are required to determine the timing of first mobilisation and the intensity level of activities in a mobilisation regime needed to achieve the desired decrease in systemic complications. It is interesting to note that it was possible to ambulate a consecutive sample of both patients with TTA and TFA within the study of Pollack and Kerstein (1985). Unfortunately, the authors did not report the setup necessary to perform the intervention.

Two studies reported implementing a detailed interdisciplinary protocol in pre- and postoperative care along with the ambulation intervention, stressing the importance of dedicated and specially trained surgeons, nurses, physiotherapists and prosthetists (Ivanic et al. 2002, Ali et al. 2013). These studies achieved ambulation of included patients on day 1 or 2 after amputation. This finding is in contrast to the study of Schon et al. (2002), who, despite including only the most well-functioning patients, failed to carry out the early ambulation in 11 of 30 included patients. It could be speculated whether more patients would have completed the trial if an interdisciplinary rehabilitation protocol had been implemented. Marzen-Groller et al. (2008) described how mobilising patients became a priority among nurses and physiotherapists while implementing the interdisciplinary mobilisation protocol. Their mobilisation regime was not as ambitious as other interventions (i.e. performing the first out-of-bed mobilisation on day 2) and was performed for a restricted time, while all others performed the first ambulation on day 1 with no time restriction described.

Three studies found fewer wound complications among the patients ambulated with a pneumatic prosthesis (Pollack & Kerstein 1985, Ivanic et al. 2002, Schon et al. 2002) and reduced need for surgical revision (Pollack & Kerstein 1985, Ivanic et al. 2002, Schon et al. 2002, Ali et al. 2013). However, evidence was not provided to show that this effect is caused by ambulation on an immediate prosthesis, and it was not clear whether fewer wound complications occurred because of the more aggressive attention intervention patients received, which resulted in opportunities for staff to follow up on emerging problems and correct counterproductive behaviour.

The four studies investigating early ambulation on an immediate prosthesis (Pollack & Kerstein 1985, Ivanic et al. 2002, Schon et al. 2002, Ali et al. 2013) measured the number of falls, and all found a decrease in falls, although the decreases were not statistically significant. These results indicate that early ambulation with an immediate prosthesis that maintains a level of walking ability among patients may prevent the patients from falling. With one in five patients experiencing falls (Pauley et al. 2006), this is an important find. However, it is not evident whether the same preventive effect could be achieved with other intensive mobilisation interventions (Dyer et al. 2008). Further studies are required to confirm that immediate prosthesis prevents falls.

As found in other studies of providing patients with temporary prosthesis until definitive prosthesis fitting (van Velzen et al. 2006), time to prosthesis was reported as shorter in all four studies of immediate prosthesis interventions (Pollack & Kerstein 1985, Ivanic et al. 2002, Schon et al. 2002, Ali et al. 2013). Whether the early ambulation within the first postoperative days contribute to the effect or would be the same if a temporary prosthesis was provided 2–3 weeks postamputation cannot be concluded within the scope of this review. Several authors stressed the psychological benefits of immediate prosthesis; these potential benefits, however, need to be investigated with appropriate methods.

Only one study was identified as measuring the effect of increased mobilisation on a short-term functional level (Marzen-Groller et al. 2008), and the indicated effect on FIM scores needs to be replicated in larger populations to be convincing. It could be discussed whether FIM is the most appropriate measure of functional level in the context of lower limb amputation surgery, as it was originally developed for functional level after brain injury and, therefore, includes items not relevant in patients who have lost a leg. Kristensen et al. (2015) suggest the measurement of ‘basic amputee mobility score’ (BAMS) as a patient-relevant outcome measure. BAMS is a recently developed instrument measuring independence in four mobilising actions among patients after amputation: moving from lying to sitting bedside, sitting to standing, transferring from bed to chair and wheelchair mobility. These functions are vital for the new amputee to remain independent in basic functions (Kristensen et al. 2015).

Even though mobilising patients in-hospital is overall the responsibility of nurses (Sheets 2012), this review identified only one nurse-initiated mobilisation intervention. Taking into consideration, the potential effect structured and intense early mobilisation intervention could have – preventing complications and restoring basic functions in an especially vulnerable patient population – this fundamental care task deserves more attention from research and clinical practice. The discussion of fundamental care being overlooked in sophisticated, high technology acute care settings has recently been raised by Feo and Kitson (2016). They argue this shortcoming to be a consequence of the invisibility and subsequent devaluing of fundamental
care brought about by the continued dominance of the bio-medical model and managerial approaches adhered to by most healthcare systems as well as the devaluing of fundamental care by nurses themselves and the environment in which they work. According to Feo and Kitson (2016), fundamental care is seen as less valuable than other aspects of clinical care and is not, as a result, researched or taught systematically or implemented at a consistently high standard. Furthermore, there is minimal understanding of how and at what point the fundamental care work of nurses intersects with that of other health professionals. It is therefore important to stress that effective early mobilisation of the vascular amputated patients will not succeed unless an interdisciplinary team is in place and well organised. Management must prioritise and focus on mobilising patients as a vital care procedure they expect performed. Support for necessary initiatives is also needed. Moreover, research is highly warranted in early postamputation mobilising interventions that use appropriate methods to produce high-quality evidence with patient-relevant outcomes.

Study strengths and limitations

This review was conducted in concordance with Cochrane Effective Practice and Organization of Care and used PRISMA for transparent reporting. All items used are up to date and in complete concordance with these tools. Due to a high heterogeneity of designs, methods, interventions and populations in the studies, it was not possible to perform any meta-analysis. Including studies with a high risk of bias is a limitation because the reported outcome effect could not be trusted and must be read with reservation. Nevertheless, including these studies makes it possible to identify details important to mobilising lower limb-amputated patients. This systematic review highlights a research evidence gap that needs to be addressed.

Conclusion

Although patients who have undergone dysvascular major lower limb amputations are at high risk of complications and loss of basic functions due to postoperative immobilisation, this systematic review has highlighted the lack of research evidence that supports effective mobilisation interventions to this vulnerable patient group. However, this review does show that ambulation from first postoperative day with temporary prosthesis is possible among the heterogeneous population of dysvascular lower limb-amputated patients if the necessary interdisciplinary team is assigned the task, and these interventions might prevent complications.

Relevance to clinical practice

Mobilisation is a fundamental care task often missed for several reasons. Moreover, mobilisation of the heterogenic population of newly amputated patients is complex, yet possible, and further knowledge of effective strategies to promote postoperative mobilisation in this vulnerable population is desired. Nursing scholars, practitioners and healthcare managers are urged to take responsibility for this fundamental care task and to engage the necessary collaboration of an interdisciplinary team to develop, implement and evaluate ambitious early mobilisation interventions to fill the identified gap in evidence.

Contributions

Study design: URM, AH, CBB, CB; review and selection of papers: URM, CB; data collection, analysis and draft of manuscript: URM CB; critical revisions for important intellectual content: AH, CB.

Funding

Region Sjaelland funds this research, and the study data collection, analysis and draft of the manuscript: URM CB; was accomplished, while URM was affiliated with the Swedish National Graduate School for Competitive Science on Ageing and Health (SWEAH), which is funded by the Swedish Research Council.

Conflict of interest

The authors have declared no conflict of interest.

Ethical approval

The project is not notifiable in relation to Danish law.

Supporting information

Additional Supporting information may be found in the online version of this article:

References


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Paper III
A prospective study of short-term functional outcome after dysvascular major lower limb amputation

Ulla Riis Madsen a,*, Carina Bååth b, Connie Böttcher Berthelsen c, Ami Hommel d

a Department of Orthopedic Surgery, Slagelse Hospital, Ingemannsvej 18, 4200 Slagelse, Denmark
b Karlstad University, Sweden
c Aarhus University, Denmark
d Lund University, Sweden

ABSTRACT

This study investigates functional status on Day 21 after dysvascular major lower limb amputation compared with one month pre-amputation and evaluates factors potentially influencing outcome.

Methods: A prospective cohort study design was used. Data were collected via in-person interviews using structured instruments and covered functional level (Barthel index 100) one month pre-amputation and on Day 21. Out of a consecutive sample of patients having major lower limb amputation (tibia, knee or femoral) (n = 105), 51 participated on Day 21 follow-up. Clinical, demographic, body function and environmental data were analysed as factors potentially influencing outcome.

Results: From pre-amputation to Day 21, participants' functional level decreased significantly in all ten activities of daily living activities as measured by the Barthel Index. Almost 60% of participants were independent in bed-chair transfer on Day 21. Being independent in transfer on Day 21 was positively associated with younger age and attending physiotherapy after discharge.

Conclusions: The findings indicate that short-term functional outcome is modifiable by quality of the postoperative care provided and thus highlights the need for increased focus on postoperative care to maintain basic function as well as establish and provide everyday rehabilitation in the general population of patients who have dysvascular lower limb amputations.

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Introduction

Independent of the aetiology of amputation, having a leg amputated constitutes a major life-changing event, and a strong desire to manage and become independent in everyday life is often the patient's main concern. In spite of this, little is known about factors influencing short-term functional level even though this knowledge is crucial when arranging discharge from acute wards and setting up realistic rehabilitation goals with the patient.

Background

Patients having major lower limb amputations are some of the frailest and most vulnerable patients in orthopaedic settings, with dysvascularity (peripheral artery disease, diabetes & infection) being the underlying cause in more than 90% of the cases (Global Lower Extremity Amputation Study Group, 2000). These individuals are characterized by high age, multi co-morbidity (Kristensen et al., 2012; Fortington et al., 2013a) and low survival prognosis (Kristensen et al., 2012; Fortington et al., 2013a). Many of these patients have been restricted in mobility prior to amputation as a result of pain and months of treatments designed to save the leg (Goodridge et al., 2005). In addition to risk of medical complications, these patients are at high risk of functional decline (Frykberg et al., 1996). Madsen et al. (2016) recently investigated patients' behaviour shortly after having lower limb amputation (LLA). This study found that patients lost control when faced with dependency on assistive devices and the need for personal assistance following limb loss. Autonomy in self-care has been described as one of the most important goals for patients admitted to rehabilitation after LLA.

* Corresponding author.
E-mail address: urm@regionsjaelland.dk (U.R. Madsen).

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at admission to rehabilitation after LLA, is significantly associated with higher rates of survival after six months (Stineman et al., 2009), prosthetic use (Bilodeau et al., 2000) and predicts good walking ability (Sansam et al., 2009). Independence in other aspects of daily living, such as instrumental activities of daily living (IADL) (e.g., cooking, shopping, keeping track of finances) (Wiener et al., 1990), has been largely unexplored by research.

Whether the realistic long-term goal is mobility in wheelchair or prosthetic walking, remaining and regaining personal independence should be highly prioritized in postoperative care and early rehabilitation after LLA (Fleury et al., 2013; Taylor et al., 2005; Hakimi, 2009). Previous studies have focused on factors associated with post-rehabilitation recovery of ambulation and prosthetic use (Fortington et al., 2012). Even so, there is little evidence of short-term functional level and factors influencing activities of daily living (ADL) among the heterogeneous population of patients who have dysvascular LLA.

According to the International Classification of Functioning, Disability and Health (ICF) model (WHO, 2010), level of function after being disabled is the result of a range of factors comprising of characteristics of the disorder itself as well as body function, environmental and personal factors. While factors such as age, level of amputation, low muscle strength, uncertain balance, multi-comorbidity, cognitive impairments, emotional distress and pain have been described as influencing early post-operative mobilization crucial to preserve ADL function after LLA (Madsen et al., 2017), no studies were identified that systematically evaluated short-term ADL outcomes compared with pre-amputation functional level and included environmental factors which could potentially influence the outcome.

The aim of this study was to investigate functional status on Day 21 after dysvascular major lower limb amputation compared with functional level one month pre-amputation and to evaluate factors potentially influencing short-term functional outcome. A second aim was to report characteristics of a consecutive sample of patients having amputations and compare participants with non-participants.

**Methods**

A prospective cohort study design was used. Data were collected via in-person interviews using structured instruments covering functional level (Barthel index 100 (BI)) one month pre-amputation (baseline) and at follow-up on Day 21. Clinical, demographic, body function and environmental data were analysed as factors potentially influencing short-term functional outcome. This paper presents the first results of a larger longitudinal study.

**Sample and setting**

Participants were recruited from a consecutive sample of patients having primary major LLA (amputation at tibia (TTA), knee (TKA) or femoral (TFA) level) on orthopaedic wards at two rural hospitals in Denmark from April 2015 to April 2016. Patients with a diagnosis of documented dementia and severely deteriorated health lasting > Day 21 as well as non-Danish speaking patients were excluded as it was assessed they were not eligible for interviews.

**Data collection**

At baseline, participants’ functional level one month prior to amputation was assessed via in-person interviews using structured instruments. Patients were approached for consent on Days 3–6 post-amputation by the first author who also performed baseline assessments. All interviews started with the sentence: ‘In the following questions, I am going to ask you about how you managed one month BEFORE your amputation’. As part of the daily, routine in-hospital care, a physiotherapist evaluated pre-amputation walking ability, function of the remaining leg and documented daily physiotherapy provided. On Day 21 participating patients went to the outpatient clinic to have their stiches removed, and three specially trained nurses assessed status on functional level and influencing factors with the same instruments used at baseline. If desired, patients were encouraged to bring a relative on both occasions.

Finally, as part of the larger study, medical records were reviewed by a specially trained physiotherapist and the first author who looked for clinical and demographic data on all patients having LLA during the study period at both study sites. All data were documented directly into a trial software (http://www.easytrial.net). Instruments used and variables tested are described below.

**Functional outcome measures**

Functional level was measured by the Barthel Index 100 (BI) (Shah et al., 1989). BI measures the level of assistance an individual needed to perform 10 ADL activities (personal hygiene, bathing self, eating, toilet, dressing, bowel control, bladder control, ambulation or wheelchair (if no ambulation), bed-chair transfers and stair climbing (Shah et al., 1989)). Each item is scored on a five-point scale, and the highest score represents independence in function. BI has been shown to have good reliability and provides adequate validity for the amputee population (Deathe et al., 2009).

To evaluate short-term functional outcome, we analysed the BI item bed-chair transfer (hereafter referred to as transfer) as a dependent variable. Independence in transfer is a basic activity needed to become independent in a number of ADLs and an activity realistic to regaining independence within 21 days after LLA (De-Rosende Celeiro et al., 2016). We dichotomized maximum score into ‘independent’ (representing participants performing transfers without any assistance necessary) and ‘dependent’ (representing participants in need of at least one person’s assistance in all transfers).

**Factors potentially influencing functional outcome**

Inspired by the ICF model (WHO, 2010) and based on literature on long-term functional outcome (Deathe et al., 2009; Fleury et al., 2013; Fortington et al., 2012; Sansam et al., 2009), health conditions, body functions and environmental factors were used as independent variables to evaluate potential influence on functional outcome (independence in transfer on Day 21).

**Health conditions**

Four health conditions were analysed as potentially influencing factors together with age and sex, 1) American Society of Anaesthesiologist score 1–5 (ASA), 2) final amputation level (TTA vs TKA), 3) any re-amputation within 30 days (yes vs no) and 4) bilaterial amputation. All data were collected from patient records.

**Body function**

The following ten body function factors were hypothesized as potentially influencing functional outcome: 1) pre-amputation walking ability measured by the Locomotor Capabilities Index (LCI-5) (Franchignoni et al., 2004), 2) transfer ability pre-
amputation measured by BI (independent vs dependent), 3) weight-bearing on remaining leg (full vs restricted), 4) stump pain (no/little vs some/much), 5) phantom pain (no/little vs some/much), 6) fall incidents (no vs yes), 7) cognitive ability measured with Mini-Mental-State Examination (MMSE) (Folstein et al., 1975), 8) episodes of postoperative confusion (no or a little vs some or much), 9) assessed suitability for prosthesis before discharge (no vs yes) and 10) patient plan to have a prosthesis on/by Day 21 (no vs yes).

The LCI-5 (Hypothesis 1) measures self-perceived basic and demanding gait skills in 14 items. Each item is scored on a scale 0–4 where ‘0’ representing informants not able to perform the activity and ‘4’ representing ability to perform activity independently without walking aid. Stump pain (Hypothesis 3) was assessed with one question: ‘Have you had any pain in the stump during the past week?’. Phantom pain (Hypothesis 4) was assessed similarly: ‘Have you had any phantom pain during the past week?’.

Degree of confusion was rated as 'not at all', 'a little', 'some' or 'much'. 'A little' was used to evaluate notes containing the word 'a little' (or a synonym) and was found on a few occasions. 'Some' and 'much' were used if notes contained the words 'some' or 'much' confusion on several or more than several occasions. Prosthesis suitability assessment (Hypothesis 9) was routinely performed by orthopaedic doctors before discharge and documented (Hypothesis 9). Patients assessed suitable started prosthesis fitting immediately: all others had to re-apply if conditions improved. The patient’s plan for having a prosthesis (Hypothesis 11) was assessed by one question: ‘Do you intend to have a prosthesis?’.

Environmental factors

Nine environmental factors were hypothesized as potentially influencing functional outcome: 1) Living alone (yes vs no), 2) accommodation (independent wheelchair accessible or not, nursing home), 3) having daily assistance from homecare (yes vs no), 4) having daily assistance from relatives (yes vs no), 5) self-reported lack of any assistive devices to manage (yes vs no), 6) number of days without physiotherapy in-hospital, 7) physiotherapy initiated after discharge and before Day 21 (yes vs no), 8) time to first physiotherapy session after discharge and 9) frequency of physiotherapy (twice a week vs > 3 times/week).

Data on environmental factors were all collected on items constructed for the purpose. Having daily assistance from either homecare or relatives (Hypothesis 3&4) was defined as one or more occasions of daily assistance. Number of days without physiotherapy in-hospital (Hypothesis 6) was recorded by all physiotherapists daily and noted on a special form. Only data from Days 1–7 post-amputation were used to secure complete data on all participants. Participants were asked whether they were attending physiotherapy (Hypothesis 7), and the date of first planned or initiated physiotherapy session after discharge (Hypothesis 8).

Clinical and demographic data

Data characterizing the consecutive sample (both participants and non-participants) comprised of information on age, sex, primary etiology of amputation (diabetes, peripheral artery disease or trauma/cancer), ASA score, co-morbidity, level of amputation (TIA, TKA, TFA), any re-amputation within 30 days, plan of rehabilitation provided (secured-by-law plan for physiotherapy after discharge), pre-amputation walking ability (indoor walking aid, none, crutches/walking frame, not walking), prosthesis suitability assessment as documented in the record, discharge destination, length of stay from day of surgery (LOS) and mortality. All information was retrieved from the patients’ records.

Statistical analysis

IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA), was used for the statistical analysis described.

To compare participants with non-participants, proportions of characteristics were calculated. Differences were tested with the Chi square test of homogeneity or Fisher’s exact test. Continuous variables (age and LOS) were tested with Students T test.

To investigate the participants’ functional level on Day 21, mean values were calculated for BI (both overall and individually for each activity item) pre-amputation (baseline) and on Day 21. Data were reported as mean ± standard deviation. A paired-sampled t-test was used to test mean difference in overall functional level. A Wilcoxon signed rank test was run to test individual items.

To evaluate potential relationships between the hypothesized influencing factors and independence in transfer on Day 21, associations were tested in univariate analyses. Factors found statistically significant in these analyses were entered into a backwards elimination logistic regression procedure, and a model was developed for explaining factors influencing the likelihood that participants were independent in transfer on Day 21.

Ethical considerations

The study was conducted in accordance with the basic principles for research given in the Helsinki Declaration and the Northern Nurses’ Federation, 2003 (Northern Nurses’ Federation, 2003). It was approved by the Danish Data Protecting Agency (Region Sjaellands j.nr. 12–000179) and was presented to the Regional Ethics Committee whose secretariat did not find the project notifiable under Danish law (non-experimental) (Region Sjaelland j.nr. 12–000660). This approval covers use of data collected from medical records on the entire consecutive sample of patients having LLA during the study period.

Results

A total of 105 patients had LLA during the study period. Of these, 60 participated at baseline (57%) (Fig. 1). In all, 36 were excluded because of dementia, deteriorated health or death before enrolment. Another six declined and three patients were not identified in time to participate. Before Day 21 follow-up, nine patients dropped out—four because of deteriorated health, three because of death and two declined further participation after the first assessment. Thus, 51 patients (49%) participated in Day 21 follow-up.

Clinical and demographic characteristics of participants (baseline & Day 21) and non-participants are presented and compared in Table 1. Baseline participants had more males (75% vs 53%) and were younger (69 vs 77 years) than non-participants; these differences were statistically significant. Participants did not differ from non-participants in terms of underlying causes of the LLA, ASA score and co-morbidity but had higher incidence of TTA as final amputation level and mortality was significantly lower. We found 25% of participants (n = 15) were described in records as having ‘some’ or ‘much’ confusion by physicians and/or nurses. This number was 75% (n = 33) among non-participants.

Significantly more participants than non-participants were provided with a plan for physiotherapy at discharge (87% vs 55%). Individuals not having a physiotherapy plan had either bilateral...
amputation and were assessed not suitable for prosthesis or were nursing home residents. Most patients (n = 25) assessed suitable for prosthesis before discharge participated at baseline (n = 23) and had more instances of walking indoors without assistive aids (57% vs 11%). The nine patients who dropped out before Day 21 were comparable to Day 21 participants in all characteristics apart from being more confused.

**Functional level Day 21**

Almost all participants (48/51) had decreased overall functional level as measured by the Barthel Index (BI) from pre-amputation to Day 21 (Table 2). Mean overall values decreased from 84.5 ± 13.5 before amputation to 59.2 ± 19.2 on Day 21 which is a statistically significant decrease of -25.3 (95% CI, -30.7 to 20.0), t(50) = 9.520, p < 0.001. The decrease in functional level covered all ten activity items which measured functional level in the BI including basic functions such as eating and bowel and bladder control. Mean functional level score in transfer from bed to chair decreased from 14.53 (SD 1.13) pre-amputation to 11.49 (SD 5.23) on Day 21, p < 0.001. In other words, 21 participants (41%) were dependent on assistance from at least one person when moving from chair to bed on Day 21 compared with 3 (6%) pre-amputation.

To evaluate factors potentially influencing independence in ADL, associations between health conditions and body function factors vs independence in transfer on Day 21 were calculated (Table 3). Three factors were statistically significant: age, ASA score and assessed suitability for prosthesis before discharge. Participants above 65-years-old had significantly higher risk of being dependent in transfer on Day 21 (51% vs. 8%). It was also observed that the higher the ASA score, the higher the risk of being dependent in transfer on Day 21. Finally, though not all patients attained independence (n = 4 dependent), being assessed suitable for prosthesis at discharge was associated with being independent in transfer on Day 21 (80% vs 20%). Patients who were independent in transfer were more likely to have TTA as final amputation level, be able to have full weight-bearing on the remaining leg, been independent in transfer pre-amputation and have better walking ability compared to patients who were dependent. These differences were not statistically significant.

The nine environmental factors hypothesized that could potentially be associated with patients being independent in transfer on Day 21 are presented in Table 4. Whether patients had started physiotherapy after discharge and before Day 21 was the only factor statistically significant when associated with achieving independence in transfer or not (n = 16 (80%) vs n = 4 (20%) p = 0.020). Those who achieved independence had fewer days without physiotherapy in hospital (2.67 days (SD 2.30) vs 3.14 days (SD 2.83)), but the difference was not statistically significant. Only five participants reported having more than three physiotherapy sessions a week after discharge (12%); all others had two sessions of one hour a week. Five patients, who were all previously contralaterally amputated, had no physiotherapy planned.

A backwards elimination logistic regression procedure was performed to ascertain the effects of age, ASA score, being assessed suitable for prosthesis before discharge and if physiotherapy was

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initiated before Day 21 in the likelihood that participants were independent in transfer on Day 21 (BI). The final model contained two of the four predicting variables: age and if physiotherapy was initiated before Day 21. This model was statistically significant ($\chi^2(2) = 36.009, p < 0.0005$). The model explained $75.9\%$ (Nagelkerke $R^2$) of the variance in being dependent or independent in transfer on Day 21 and correctly classified $88.6\%$ of the cases.

Sensitivity was $92.6\%$, specificity was $82.4\%$, positive predictive value was $89.3\%$ and negative predictive value was $12.5\%$. Older age was associated with decreased likelihood of independence in transfer on Day 21; those who had physiotherapy initiated before Day 21 had a $19.98$ times higher chance of being independent in transfer on Day 21; those who had physiotherapy initiated before Day 21 in the likelihood that participants were independent in transfer on Day 21 and correctly classified $88.6\%$ of the cases. Sensitivity was $92.6\%$, specificity was $82.4\%$, positive predictive value was $89.3\%$ and negative predictive value was $12.5\%$. Older age was associated with decreased likelihood of independence in transfer on Day 21; those who had physiotherapy initiated before Day 21 had a $19.98$ times higher chance of being independent in transfer on Day 21.

### Discussion

From pre-amputation to Day 21, participants’ functional level decreased significantly in all ten activities of daily living activities (ADL) as measured by BI; thus, almost all participants were dependent on assistance in one or more ADL functions on Day 21. As expected, we found the biggest decline in ‘ambulation’ and ‘stairclimbing’—two functions most patients most often were dependent on in all the eight other functions including basic functions such as bowel and bladder control and eating. Independence in transfer on Day 21 was associated with whether participants had started physiotherapy after discharge or not. Consistent with studies on long-term functioning (Fleury et al., 2013), we found that older patients were at higher risk of functional decline; and the risk was even bigger when multi-comorbidity was present.

Of interest were the factors not associated with being independent in transfer on Day 21. Pre-amputation walking ability, having full weight-bearing on the remaining leg, level of amputation, cognitive function, having had re-amputation, being bilaterally amputated and level of pain are all factors known to predict long-term functional outcome (Fleury et al., 2013). These findings could indicate that short-term functional outcome is modifiable by care provided and is supported by a recent study by De-RosendeCeleiro et al. (2016). This particular study showed that short rehabilitation intervention after post-operative care increased ADL function. Intervention in the study started at a median of 16 days post-amputation and lasted nine days. BI total score increased from
60 at the start to 80 after intervention, and 61.5–98.1% of patients regained independence in bathing, toileting, transfer and dressing. Our participants were discharged from hospital approximately twelve days post-surgery and were dependent on help from homecare and relatives. Rehabilitation interventions initiated immediately after discharge could lead to higher independence in ADL and thereby less dependence on personal assistance. Intervention care provided by municipalities. This tendency requires high professionalism and collaboration across sectors. Overall, our participants were younger and less frail than non-participants; therefore, it was assumed that non-participants manage even worse which highlights the need of increased focus on post-operative care to maintain ADL function as well as to establish and provide everyday rehabilitation in the general population of patients having dysvascular LLA.

Internationally, there are major local and regional differences in how perioperative and rehabilitation programmes are organized (Global Lower Extremity Amputation Study Group, 2000). While some studies suggest that amputees rehabilitated in specialist units achieve higher level of function more quickly and experience less emotional strain (Fleury et al., 2013; Fortington et al., 2013a, b; Johannesson et al., 2010; Pezzin et al., 2013), there is a trend in Denmark towards increasingly shorter hospital stays and rehabilitation care provided by municipalities. This tendency requires high professionalism and collaboration across sectors. Overall, our participants were younger and less frail than non-participants; therefore, it was assumed that non-participants manage even worse which highlights the need of increased focus on post-operative care to maintain ADL function as well as to establish and provide everyday rehabilitation in the general population of patients having dysvascular LLA.

Participants who were found suitable for prosthesis before discharge were more often independent in transfer on Day 21 which makes sense as a relationship between having a certain level

Table 2
Functional level pre-amputation and on Day 21, Barthel index 100.

<table>
<thead>
<tr>
<th>Pre amputation Mean (SD)</th>
<th>Day 21 Mean (SD)</th>
<th>Difference, Mean (SD)</th>
<th>P value*</th>
<th>&quot;Statistical significant&quot;</th>
<th>Negative/positive rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>84.53 (13.46)</td>
<td>59.22 (19.64)</td>
<td>−25.31 (18.99)</td>
<td>&lt;0.001**</td>
<td>48/1</td>
</tr>
<tr>
<td>Personal hygiene</td>
<td>4.61 (0.94)</td>
<td>3.96 (1.23)</td>
<td>−0.65 (1.20)</td>
<td>0.001*</td>
<td>24/4</td>
</tr>
<tr>
<td>Bathing self</td>
<td>4.31 (1.20)</td>
<td>3.18 (1.59)</td>
<td>−1.14 (1.86)</td>
<td>&lt;0.001*</td>
<td>29/4</td>
</tr>
<tr>
<td>Eating</td>
<td>4.82 (1.10)</td>
<td>4.47 (0.65)</td>
<td>−0.35 (0.89)</td>
<td>0.005*</td>
<td>13/1</td>
</tr>
<tr>
<td>Toilet</td>
<td>9.43 (1.92)</td>
<td>6.78 (3.68)</td>
<td>−2.65 (3.60)</td>
<td>&lt;0.001*</td>
<td>48/2</td>
</tr>
<tr>
<td>Dressing</td>
<td>9.22 (1.77)</td>
<td>7.25 (2.86)</td>
<td>−1.96 (2.77)</td>
<td>&lt;0.001*</td>
<td>25/2</td>
</tr>
<tr>
<td>Bowel control</td>
<td>9.37 (1.92)</td>
<td>8.31 (2.84)</td>
<td>−1.06 (2.88)</td>
<td>0.015*</td>
<td>16/4</td>
</tr>
<tr>
<td>Bladder control</td>
<td>9.37 (2.16)</td>
<td>8.20 (3.35)</td>
<td>−1.18 (3.14)</td>
<td>0.011*</td>
<td>11/2</td>
</tr>
<tr>
<td>Ambulation†</td>
<td>12.71 (3.79)</td>
<td>1.37 (3.92)</td>
<td>−11.33 (4.43)</td>
<td>&lt;0.001*</td>
<td>47/0</td>
</tr>
<tr>
<td>Chair/bed transfers</td>
<td>14.75 (1.13)</td>
<td>11.49 (5.23)</td>
<td>−3.25 (4.98)</td>
<td>&lt;0.001*</td>
<td>21/1</td>
</tr>
<tr>
<td>Climbing stairs</td>
<td>5.76 (4.25)</td>
<td>0.51 (1.99)</td>
<td>−5.26 (4.74)</td>
<td>&lt;0.001*</td>
<td>35/1</td>
</tr>
</tbody>
</table>

Table 3
Health condition and Body function vs independent transfer Day 21 (Barthel index 100).

<table>
<thead>
<tr>
<th>Age</th>
<th>Dependent transfer d21</th>
<th>Independent transfer d21</th>
<th>P value * signs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;65</td>
<td>75.52 (7.43)</td>
<td>64.17 (7.90)</td>
<td>p &lt; 0.001*</td>
</tr>
<tr>
<td>65–79</td>
<td>14 (42)</td>
<td>19 (56)</td>
<td></td>
</tr>
<tr>
<td>80+</td>
<td>6 (100)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>15 (39)</td>
<td>24 (41)</td>
</tr>
<tr>
<td>ASA Mean (SD)</td>
<td>3.24 (0.54)</td>
<td>2.83 (0.70)</td>
<td>0.030*</td>
</tr>
<tr>
<td>Confusion in hospital†</td>
<td>5 (50)</td>
<td>5 (50)</td>
<td>0.122</td>
</tr>
<tr>
<td>MMSE day 21</td>
<td>Mean (SD)</td>
<td>25.40 (3.65)</td>
<td>25.83 (3.10)</td>
</tr>
<tr>
<td>TPA final level</td>
<td>5 (25)</td>
<td>15 (75)</td>
<td>0.059</td>
</tr>
<tr>
<td>Re-amputated</td>
<td>6 (55)</td>
<td>5 (45)</td>
<td>0.309</td>
</tr>
<tr>
<td>Bilateral amputated</td>
<td>3 (50)</td>
<td>3 (50)</td>
<td>0.640</td>
</tr>
<tr>
<td>Stump pain day 21</td>
<td>8 (38)</td>
<td>13 (62)</td>
<td>0.001*</td>
</tr>
<tr>
<td>Phantom pain day 21</td>
<td>10 (45)</td>
<td>12 (55)</td>
<td>0.589</td>
</tr>
<tr>
<td>Independent pre-amputation</td>
<td>19 (40)</td>
<td>29 (60)</td>
<td>0.355</td>
</tr>
<tr>
<td>Full weight bearing on second leg†</td>
<td>8 (30)</td>
<td>19 (70)</td>
<td>0.076</td>
</tr>
<tr>
<td>Pre walking ability LCI 5†</td>
<td>32 (17.67)</td>
<td>40.88 (17.96)</td>
<td>0.239</td>
</tr>
<tr>
<td>Fall incident after discharge†</td>
<td>1 (12)</td>
<td>7 (88)</td>
<td>0.164</td>
</tr>
<tr>
<td>Assessed suitable for prosthesis at discharge‡</td>
<td>4 (20)</td>
<td>16 (80)</td>
<td>0.014*</td>
</tr>
<tr>
<td>Plan to have a prosthesis at d21</td>
<td>14 (35)</td>
<td>26 (65)</td>
<td>0.087</td>
</tr>
</tbody>
</table>

Proportion of day 21 participants (n = 51) if not otherwise stated.

*a Statistically significant p values (0.05).

A. Assessed in-hospital.
B. LCI 5 max score (−56) indicates independent walking ability without assistive devices in all 14 items.
C. Proportion of patients discharged day 21.
D. Rest: 'perhaps suitable' n = 2, not suitable n = 17, not assessed n = 6.
E. Rest: do not plan to have prosthesis n = 4, not decided n = 5.
of physical strength and being deemed fit for prosthesis was expected. It was also expected that all patients assessed suitable for prosthesis would be independent in transfer on Day 21 which was not the case. The fact that this effect disappeared in the multiple regression model could be explained by the immediately initiated physiotherapy these patients received. That being said, questions could be raised about whether some patients' potential for prosthesis use is missed in the assessment process. Sansam et al. (2014) investigated clinicians' perspectives on decision-making in LLA rehabilitation and found that clinicians made decisions based on a range of considerations including estimation of the patient's potential to learn to use the prosthesis and level of mobility likely to be achieved. Great importance was placed on patient motivation, determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability. We found that most participants wanted to have a prosthesis, and it is debatable whether the patients were assessed equally in light of how much functionality is wanted to have a prosthesis and level of mobility likely to be achieved. Determination and coping ability.

Another important finding was that almost half of the total cohort was described as having 'some' and/or 'much' confusion during in-hospital stay. Acute confusion is associated with mortality and impaired physical function 30 days or more after discharge (Inouye et al., 2014). It is partially preventable and caring for those with acute confusion places great demands on clinical expertise, interdisciplinary collaboration and care environment (e.g. quiet surroundings) (Inouye et al., 2014). Though we did not use a validated measure of acute confusion, this finding indicates a high prevalence among the LLA population that needs to be addressed.

Though some limitations must be considered, this study provides unique prospectively collected data on factors which potentially influence short-term functional outcome after a dysvascular LLA. We only managed to recruit 57% of a consecutive sample, and 34% of those eligible for the study were too ill to participate. These numbers correspond with other studies on the dysvascular LLA population. Czerniecki et al. (2012) showed high compliance in recording this kind of data up to six-weeks post amputation. We acknowledge that we lack information about other important factors such as how much and how early the patients were mobilized during the in-hospital stay, data on nutrition or potential psychological factors that may have influenced the patients.

Conclusions

The functional level of patients having dysvascular LLA decreased significantly by Day 21 compared to one month before amputation. Short-term functional outcome (independence in ADL) was positively associated with lower age and physiotherapy initiated after discharge. A high prevalence of post-surgery confusion was found. These findings indicate that short-term functional outcome is modifiable by care provided and thus highlights the need of increased focus on post-operative care to maintain ADL functions as well as to establish and provide everyday rehabilitation in the general population of patients having dysvascular LLA with a special focus on older patients. The findings, however, need to be tested in experimental research.

Conflicts of interest

The authors have declared no conflict of interest.

Author contributions

URM collected data, performed analysis and drafted the

Table 4

<table>
<thead>
<tr>
<th>Environmental factors</th>
<th>Independent transfer</th>
<th>Independent transfer</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>d21 n = 21</td>
<td>d30 n = 30</td>
<td></td>
</tr>
<tr>
<td>Relative present at interview</td>
<td>12 (57)</td>
<td>10 (65)</td>
<td>0.091</td>
</tr>
<tr>
<td>Discharged</td>
<td>17 (39)</td>
<td>27 (61)</td>
<td>0.355</td>
</tr>
<tr>
<td>Living alone</td>
<td>10 (44)</td>
<td>13 (56)</td>
<td>0.762</td>
</tr>
<tr>
<td>Accommodation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent living, wheelchair accessible</td>
<td>6 (43)</td>
<td>8 (57)</td>
<td></td>
</tr>
<tr>
<td>Independent living, not wheelchair accessible</td>
<td>3 (19)</td>
<td>13 (81)</td>
<td></td>
</tr>
<tr>
<td>Nursing home</td>
<td>8 (57)</td>
<td>6 (43)</td>
<td>0.091</td>
</tr>
<tr>
<td>Daily assistance:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homecare</td>
<td>17 (45)</td>
<td>21 (55)</td>
<td>0.377</td>
</tr>
<tr>
<td>Relatives</td>
<td>13 (45)</td>
<td>16 (55)</td>
<td>0.543</td>
</tr>
<tr>
<td>Lacking assistive devices</td>
<td>7 (35)</td>
<td>13 (65)</td>
<td>0.651</td>
</tr>
<tr>
<td>Days with no physiotherapy in hospital, day 1–7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiotherapy initiated day 21</td>
<td>Mean (SD)</td>
<td>3.14 (2.83)</td>
<td>2.67 (2.30)</td>
</tr>
<tr>
<td>Time to start physiotherapy in days</td>
<td>Mean (SD)</td>
<td>2.0 (20)</td>
<td>16 (80)</td>
</tr>
<tr>
<td>Frequency of physiotherapy:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 x week</td>
<td>11 (32)</td>
<td>23 (68)</td>
<td></td>
</tr>
<tr>
<td>&gt;3 x week</td>
<td>2 (60)</td>
<td>3 (60)</td>
<td></td>
</tr>
</tbody>
</table>

Proportion of patients discharged at day 21 if not otherwise stated.

1 Relative present at interview:
2 Discharged in hospital on day 21.
3 Living alone: Includes those living alone and with a relative.
4 Accommodation: Includes those living at home, in a nursing home, in independent living or in a wheelchair accessible living arrangement.
5 Lacking assistive devices: Includes those who lacked help with bathing, dressing, toileting or feeding.
6 Frequency of physiotherapy: Includes those who received physiotherapy as needed or ≥3 x week (≥3 sessions per week).

* P value < 0.05.
manuscript. AH, CB, CB contributed to interpretation of the results and preparation of the manuscript.

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