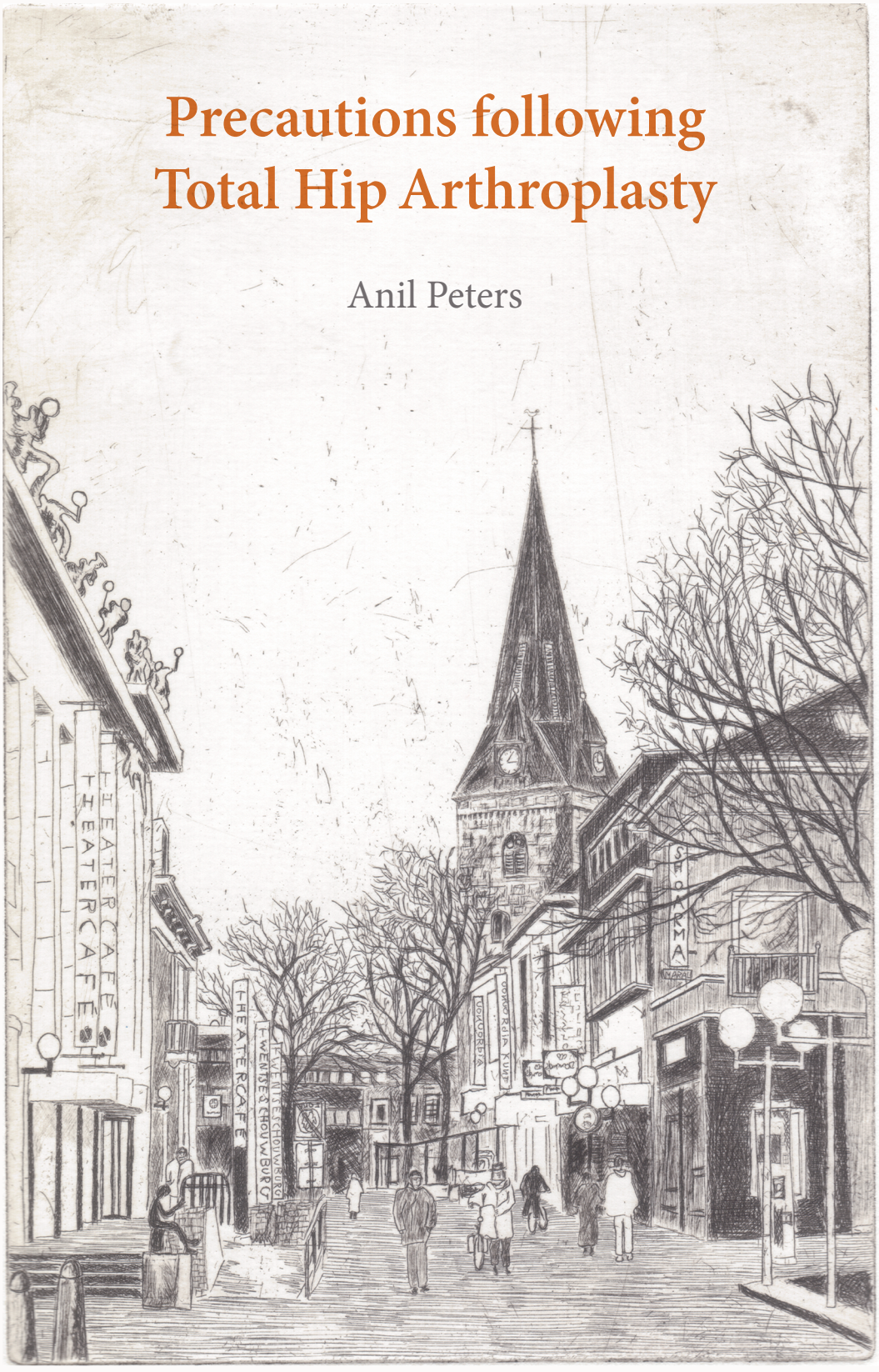
Precautions following Total Hip Arthroplasty

Anil Peters



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PRECAUTIONS FOLLOWING TOTAL HIP ARTHROPLASTY

DISSERTATION

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Voor Minu, mijn lieve dochter, de “stille” kracht achter dit proefschrift…….

Chapter 1

General Introduction

INTRODUCTION

Total hip arthroplasty (THA) is one of the most successful and frequently undertaken elective surgeries [1]. The era of modern THA began in the 1970s, after widespread use of the Charnley prosthesis [2]. In the Netherlands, 33,253 primary THA implants were performed in 2019 [3]. These numbers are predicted to increase due to the high and increasing prevalence of osteoarthritis, the growing demand for increased mobility and quality of life, and the success of joint replacement surgery [4,5]. This rising number of patients will lead to a higher demand for healthcare with increasing costs or waiting lists in healthcare systems with ceiling reimbursement agreements and staff shortages. The largest healthcare costs for osteoarthritis care (52.2%) are incurred in hospitals [6]. Treating more patients without increasing resources can be achieved by reducing the length of stay (LOS) in hospitals following surgery.

Evidence-based practices have demonstrated that surgical recovery can be accelerated by a multimodal approach, referred to as "fast-track surgery" [7]. With this approach, patients are operated on with shorter-acting anesthetics; less invasive, tissue-sparing techniques are implemented; and patients are mobilized early after surgery [8]. In 2009, Husted et al. showed that using fast-track protocols could reduce the LOS from a median of 10–11 days to 4 days [9]. In selected cases, THA is even performed as an outpatient procedure [10].

Another factor that impacts the costs and quality of care is the occurrence of complications following THA. Dislocation is one of the most important complications, affecting up to 11% of patients following primary THA [11]. Over 50% of patients who sustain a dislocation require surgical revision [22]. The influence of the surgical approach on the risk of postoperative THA dislocation has attracted extensive debate. The posterolateral approach, the most frequently used surgical approach to implant a THA in the Netherlands and worldwide, is thought to have a higher risk of dislocation than other approaches [3,12]. When a posterior soft tissue repair is performed, this "increased" dislocation rate through the posterior approach is significantly reduced [13]. Despite this soft tissue repair, a recent large-scale registry study showed that the posterolateral approach is associated with a higher risk of revision due to dislocation than other approaches [14–16]. The advantage of the posterolateral approach is its low overall revision rate and higher patient-reported outcome compared to the other two classical approaches (straight lateral and anterolateral) [17,18].

Postoperative precautions following THA are traditionally prescribed to ensure appropriate healing and prevent early postoperative dislocation of the THA [30].

The set of precautions (Fig. 1) commonly prescribed to patients requires them not to sit cross-legged, bend forward, or flex their hip joints beyond 90° (movement restrictions); to

use walking aids for several weeks (assistive devices); and to sleep in a supine position with an abduction pillow in place (functional restriction). A more comprehensive overview of commonly prescribed restrictions and assistive devices is shown in Table 1.

The set of prescribed precautions is based on long-standing protocols, and there is increased interest in knowledge about using fewer postoperative precautions following THA without increasing the risk of dislocation [19].

Remarkably, most of the available knowledge about reduced postoperative precautions and their effect on dislocation following THA does not concern the posterolateral approach [22–26]. Several systematic reviews conclude that minimizing precautions might also benefit the posterolateral approach; however, more research is needed [20–23].

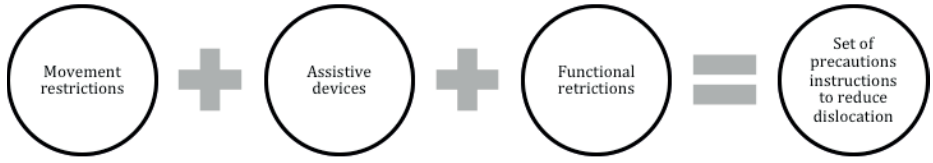

Fig. 1

Precautions	
Functional restrictions	• Sleeping in a supine position • Restrictions regarding driving a car • Restricted sexual activity • Restricted cycling • Not crossing legs while seated • Sitting on a low chair or stool • Avoiding extreme overloading • Turn step-by-step
Movement restrictions	• No trunk flexion > 90° • No hip flexion > 90° • Hip adduction • Hip endo/exorotation
Assistive devices	• Walking devices (e.g. crutches, walker) • Abduction pillow • ADL devices (e.g. toilet seat elevator, helping hand)

Table 1

The preliminary conclusion that can be drawn from the available studies, is the suggestion that using a less restrictive protocol after posterolateral THA does not lead to a worse dislocation rate [24–26] However, these studies were hampered by their low methodological quality [20,24,25,27,28]. These methodological issues concerned the small number of participants, the design of the studies (e.g., poor blinding of assessors to group allocation), the heterogeneity in implants used, and minimized precautions [20].

For example, evidence strongly suggests that larger femoral heads reduce dislocation by increasing the jump distance [15,29]. Since various femoral head sizes were used in the study populations investigating precautions, it is difficult to relate dislocation rates to the effectiveness of postoperative protocols (with or without precautions) or the use of different femoral head sizes. Additionally, studies differ in the degree to which they abandon certain types of restrictions.

Besides the effectiveness of precautions based on dislocation rates, one should also consider the patient perspective. It has been shown that patients appear to hold mixed opinions about precautions. With no precautions, patients appear less hindered in resuming their preoperative daily activities, which argues for omitting these precautions in clinical practice. However, patients treated with precautions felt that these provided guidance and clarity in managing their postoperative recovery process in their daily life [30].

This explains why up to 28% of patients adhere to the set of precautions even when they are not prescribed [31]. However, if a set of precautions is prescribed, it is not known which restrictions patients are likely to comply with. Likewise, it is unknown which restrictions in a set of precautions cause a burden and whether this burden is reduced by removing a specific restriction. More evidence regarding specific restrictions from the set of precautions and using compliance and burden as outcomes could benefit patients in their rehabilitation. For example, in our practice, we noticed that many patients complained about the burden of being restricted to sleep in a supine position following THA. However, this restriction has not been studied extensively in the available literature. Removing this restriction without negatively affecting the dislocation rate potentially reduces the burden.

Exploring patients' perceptions toward precautions and developing strategies for a more individualized approach can optimize rehabilitation following THA.

Generally, tailoring the set of precautions to the needs of individual patients achieves a positive shift toward patient engagement. A more personalized postoperative approach improves the ability to perform physiotherapy exercises and activities of daily self-care, leading to better health outcomes [32,33].

AIMS AND OVERVIEW OF THIS THESIS

The aim of this thesis is to contribute to the optimization of the set of postoperative precautions following the posterolateral THA by generating knowledge regarding its current practice, compliance, and burden, as well as effectiveness.

Chapter 2 presents the results of a prospective nationwide survey on the use of precautions following THA in the Netherlands. The aim of this survey was to describe current practices regarding patient restrictions following THA.

Chapter 3 presents the protocol for a randomised controlled trial (RCT) using fewer postoperative restrictions following THA in the posterolateral approach. Since previous randomised trials used (antero)lateral surgical approaches, we decided to design the first RCT with a posterolateral approach. Furthermore, all patients received the same femoral head size to eliminate potential bias for dislocation.

Chapter 4 presents and discusses the results of the RCT. The aim of this study was to evaluate the rate of early dislocations when patients were restricted to supine sleeping or unrestricted sleeping in the first eight weeks after THA using a posterolateral approach.

Chapter 5 evaluates and discusses compliance with precautions from the RCT. We believe that compliance indicates how relevant patients perceive a restriction to be and that information can be helpful when implementing changes to the precautions policy. The aim of this study was to analyse compliance with the precaution to sleep in a supine position, the impact of this precaution on patients, and whether removing this precaution influenced compliance with the remaining precautions.

Chapter 6 explored the design needs of a hip dislocation alert system i.e. a prototype technical device to help patients in their individual rehabilitation and to monitor and assist with postoperative precautions. We used focus groups to evaluate the design needs, anticipate the device's clinical relevance and assess its usability.

Finally, Chapter 7 summarises the studies described in this thesis with a general discussion and final conclusions

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Chapter 2

Patient restrictions following total hip arthroplasty: A national survey

***Anil Peters**, Anne J.H. Veldhuijzen, Miranda Tijink, Rudolf W. Poolman, Rianne M.H.A. Huis in 't Veld.*

Acta Orthop Belg. 2017 Mar;83(1):45-52.

ABSTRACT

In this prospective nationwide web based survey we describe the current practice regarding patient restrictions following total hip arthroplasty.

A web-based survey involving 20 items was developed and tested prior to administration. The questionnaire included general information, type of restrictions, specification and duration of restrictions. The target population consisted of all orthopaedic surgeons registered with the Dutch Orthopaedic Association working at one of the 94 orthopaedic departments in the Netherlands.

The response rate of the orthopaedic departments was 78% (n=74). The majority of orthopaedic departments use patient restrictions following THA. Restrictions were used with different rates per type of surgical approach: anterior (69%), anterolateral (100%), straight lateral (94%) and posterolateral (93%). The duration of these restrictions is generally six weeks.

Patient restrictions following THA are current practice, regardless of the surgical approach.

INTRODUCTION

Patient restrictions following total hip arthroplasty (THA) are traditionally advised to prevent early hip dislocation *(1)*. More recently, the need of these historically based restrictions has become the subject of debate *(14)*.

Several observational studies show that so called "non-restriction" or "reduced restriction" protocols do not increase the dislocation rate *(2,4,7,11)*. Two randomized trials have shown no increase in early dislocation rate with a reduced restriction protocol for the anterolateral approach *(5,12)*. Furthermore, liberal restriction protocols tend to lead to earlier and better resumption of activities, higher patient satisfaction and earlier return to work without higher dislocation rates *(4,5,14)*.

Guidelines of national orthopaedic associations do not give any advice on the type or duration of patient restrictions following THA *(10)*. Therefore, it is not known which restrictions are used and for how long in clinical practice today. Without knowledge on restrictions commonly applied in routine care it is difficult to determine the clinical relevance of studies comparing groups of non-restriction or reduced restriction protocols.

The aim of this prospective nation-wide survey study in the Netherlands was to describe the current practice regarding patient restrictions following THA. We hypothesized that restrictions are commonly used and that the type of surgical approach has an influence on the restrictions applied.

METHODS

We designed a web-based survey (www.Surveymonkey.com) specifically for the purpose of this study that consisted of three parts (general information, type of restrictions, and the specification and duration of restrictions), with 20 questions in total (appendix 1). During the process of designing the survey we applied the 12 principles for conducting an orthopaedic survey as stated by Spraque et al. 2009 *(9)*. We pretested the survey, in a large non-academic orthopaedic centre with 14 orthopaedic surgeons in the eastern part of the Netherlands, in order to ensure that the participants understood it. Following the results of the pretest, we revised the survey, reorganized and rephrased some of the questions and shortened the length of the survey (figure 1). We administered a cross-sectional national survey study to a sample 692 orthopaedic surgeons from 94 orthopaedic surgical departments who were officially registered as members of the Dutch Orthopaedic Association.

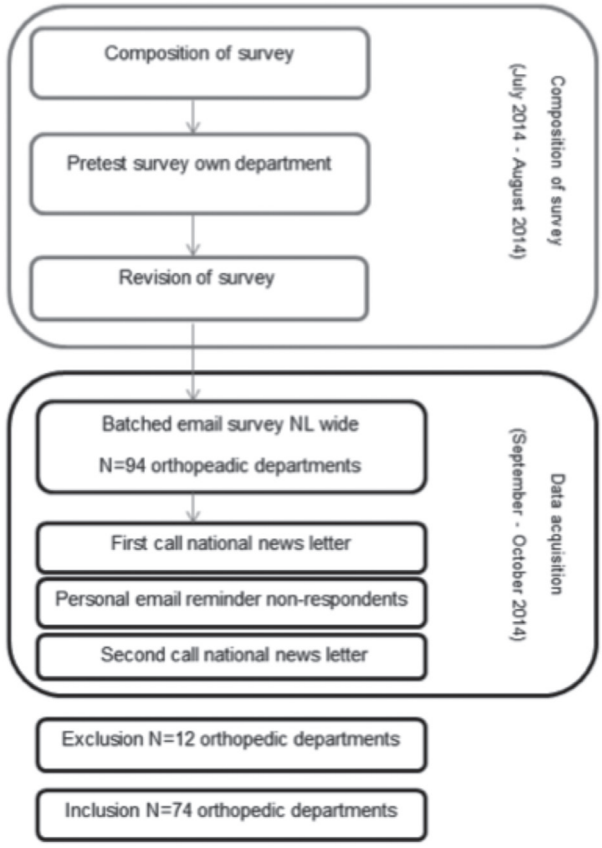

Figure 1 - Flowchart describing method

The first part of the survey assessed the surgical experience of the orthopaedic surgeon as well as his/her orthopaedic department with THA (volume and type of surgical approach). The type of surgical approach was divided into anterior, anterolateral, straight lateral and posterolateral. We excluded the orthopaedic surgeons who did not perform any THA from any further analysis.

The second part of the questionnaire assessed the type of restrictions that are applied. We divided the type of restrictions applied on patients into three categories:

1) The use of *movement* restrictions (no flexion over 90 degrees, no adduction, no rotation more than 45 degrees or no combined flexion, adduction and rotation)
2) The use of *assistive devices* such as mobilization aids (i.e. crutches), sleeping aids (i.e. abduction pillow) and ADL aids (i.e. toilet seat)
3) The use of *daily life functional restrictions* including sleeping position, driving a car and sexual activities.

The third part of the questionnaire elaborated on the specifications of the three types of restrictions and their duration. Furthermore, we asked if there were special circumstances such as ASA classification, age, reason for THA (neck of femur fracture, developmental dysplasia of the hip, rheumatic disorders) or intra-operative findings (greater trochanter fracture or rupture of the gluteus medius tendon) that could influence the restriction protocol routinely used.

We approached the respondents by personal email requesting them to fill out the survey questionnaire as well as by non-personal invitation via a call in the newsletter of the Dutch Orthopaedic Association. A second call in the newsletter of the Dutch Orthopaedic Association served as a reminder to all responders. Finally, we sent personal email reminders to the non-responders. We informed the respondents about the scientific relevance of the study and assured that the data used would be coded and anonymous. In return we received a total of 178 surveys. Of these, we excluded 11 surveys filled out by orthopaedic surgeons who no longer perform any THAs and 31 incomplete surveys with a large number of missing answers, which made them unsuitable for further analysis.

Statistical analysis

We applied descriptive statistics regarding the amount of THA's performed on a yearly basis. In order to assure a representative view of the use of restrictions after THA in clinical practice, data of individual respondents was regrouped into response per orthopaedic department for each of the surgical approaches enlisted above. By doing so, we were able to correct for the dominance of large group of respondents belonging the same orthopaedic department (c.q. the size of the different orthopaedic departments) thereby reducing the risk of distorting the widespread national use of THA restrictions in the Netherlands. In case of inconsistency in answers of respondents within the same orthopaedic department (only applicable for the orthopaedic departments containing two or more respondents for the same surgical approach), this department was included in the analysis when at least one of the respondents answered the question positively.

We analyzed for each of the surgical approaches the use of the three types of restrictions (movement, assistive devices, functional). The duration of restrictions was analyzed on respondent level. We allowed no missing data in the questionnaire so only complete data sets were analyzed. All analyses were conducted in Excel.

RESULTS

We received a response from 74 out of the 94 (78%) orthopaedic departments. The response rate per clinic varied between one and six.

The majority of departments use some sort of restriction after THA (Table I). For the anterior approach the use of restrictions is the lowest (69%).

Table I. — Percentage of orthopaedic departments using restrictions for the various surgical approaches.

		Postero-lateral	Straight-lateral	Antero-lateral	Anterior
		(N=45)	(N=25)	(N=9)	(N=13)
Restrictions		93	94	100	69
Movement restrictions		98	76	100	62
Assistive Devices	*Walking devices*	93	93	100	54
	Abduction pillow	51	22	33	15
	ADL devices	95	61	78	38
Functional restrictions	Sleeping position	82	94	100	38
	Car driving	98	94	100	67
	Sexual activity	36	50	22	31

Movement restrictions

Movement restrictions are less often used (62%) for the anterior approach compared to the other surgical approaches. In contrast, movement restrictions are commonly applied for the anterolateral (100%) and the posterolateral approach (93%). In general, the majority of the respondents (80%) prescribed movement restrictions for a period of 6 weeks (figure 2).

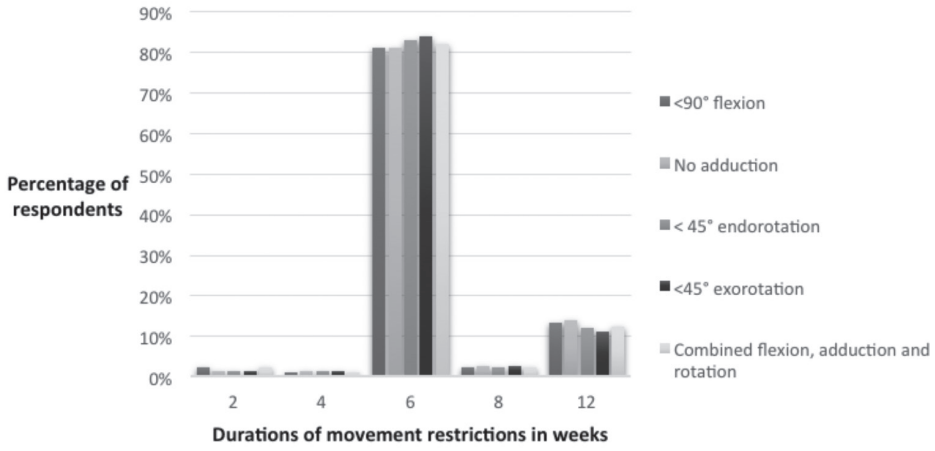

Figure 2 Duration (weeks) of prescribed movement restrictions among the respondents

Assistive devices

The use of assistive devices, in particular walking aids and abduction pillow, is lower for the anterior approach (54%) (Table 3) compared to the other surgical approaches. The use of an abduction pillow is highest for the posterolateral approach. Most of the respondents (75%)

prescribe the use of mobilization aids (i.e. crutches, walker, tripod) for a period of 6 weeks postoperatively (figure 3). The vast majority of respondents advise ADL devices after THA, not only during their hospital stay, but also at home (figure 4).

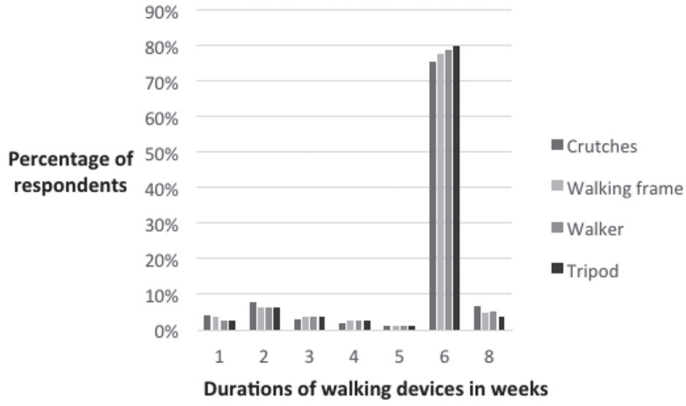

Figure 3 Duration (weeks) of prescribed walking devices among the respondents

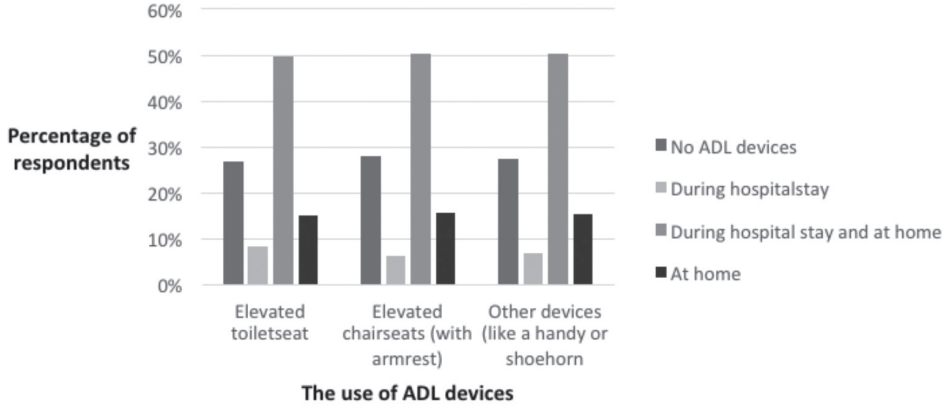

Figure 4 Location and prescribed use per type of ADL devices (elevated toiletseat, chairseat and other devices) among the respondents

Functional restrictions

Table 1 shows that the orthopaedic departments using the anterior approach prescribe sleeping restrictions the least (38%). In addition, the percentage of clinics prescribing sleeping restrictions is highest for the anterolateral and straight lateral approach (100% and 94% respectively), followed by the posterolateral approach (82%). A similar pattern of results emerged for car driving restrictions, being most frequently prescribed by clinics using the anterolateral, posterolateral and straight lateral approach. Restrictions concerning sexual activities are less

common (<50%). The majority of respondents reports not to provide any restrictions on sexual activities after THA. In general functional restrictions are prescribed for six weeks.

Circumstantial patient restrictions

A vast minority of the respondents changes the postoperative restrictions in patients with higher ASA-classification (4%), high age (9%), with cognitive disorders (25%), with the diagnosis neck of fracture (13%) or with the diagnosis rheumatoid arthritis (3%). The majority of respondents (78%) change the postoperative restrictions when there is a fracture of the greater trochanter or a rupture of the gluteus medius tendon

DISCUSSION

The results of this survey demonstrate that the majority of orthopedic departments use patient restrictions following THA (69-100%). The use of restrictions is lowest for the anterior approach. Generally, the duration of prescribing these restrictions is six weeks.

Despite results of previously published studies, which have shown no increase in dislocation rate when using a so called "non-restriction" or "reduced restriction" protocol, the majority of clinics use postoperative restrictions *(2,4,5,7,11,12)*. Likewise most respondents in our survey prescribe restrictions for six weeks while there are indications that the duration of restrictions can safely be shortened from six to four weeks *(8)*. An explanation could be that that restrictions tend to be based on tradition rather than evidence *(3)*. This is supported by the finding that the use of restrictions is higher in the more conventional surgical approaches (e.g. anterolateral, straight lateral and posterior approach) compared to the anterior approach which has gained popularity recently. Another explanation could be that studies investigating non-restriction or reduced restriction protocols eliminate different concrete restrictions *(4,5,7,12)* and thereby making it difficult to compare them and implement new protocols into daily care.

In our survey we discerned three types of restrictions namely 1) movement restrictions 2) the use of assistive devices and 3) functional restrictions such as sleeping position, how long to refrain from driving and restrictions regarding sexual activity. Generally, the so-called 'non-restriction protocols' tend to be related to the use of movement restrictions and assistive devices *(4)*. Only few studies mention whether functional restrictions are abandoned, while these probably have the highest impact on patients' daily life. For example, Peak et al. showed that nearly 70% of the THA patients who were restricted to sleep in a supine position reported it to be highly uncomfortable and that this restriction can safely be abandoned for the anterolateral approach *(5)*. All our respondents using the anterolateral approach prescribed sleeping position restrictions. Wall et al. pointed out that patients find it beneficial to be provided with information

regarding sexual activity following THA *(13)*. Less than 50 % of our respondents provided their patients with information regarding sexual activity. In previous studies the main outcome was dislocation rate. We believe patient reported outcome, perceived burden in terms of psychological distress (anxiety, mental preoccupation) and functional limitations of postoperative restrictions during their rehabilitation are at least equally important outcome measures *(6)*.

A limitation of this study is that the outcome of this survey might only be applicable for the Dutch situation. However, it is reasonable to assume that these results correspond with the rest of Western Europe since the Dutch guideline THA is internationally accepted and peer reviewed *(10)*. Other limitations are related to the study design such as non-responder bias and responder fatigue. The strengths of our study are that it is unique and has a high response rate of 78%.

Liberal restriction protocols tend to lead to earlier and better resumption of activities, higher patient satisfaction and earlier return to work without higher dislocation rates *(4,5,14)*. However, we believe future research directed towards this topic will benefit from a more systematically and detailed description of the type and duration of the restrictions that are eliminated. This will facilitate comparison between studies and hopefully lead to more evidence-based rather than tradition based daily practice.

In conclusion, patient restrictions following THA are current practice, regardless of the surgical approach.

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APPENDIX 1 SURVEY OUTLINE

Part 1 General information

Q1. What is the name of the orthopedic department you are currently working?

Q2. As a orthopaedic surgeon, do you perform primary total hip arthroplasty?

- Yes, please proceed to Q3
- No, end of questionnaire

Q3. On a yearly basis, how often do you perform a primary total hip arthroplasty?

Q4. On a yearly basis, what is the total number of primary total hip arthroplasties performed at your orthopedic department?

Q5. Which surgical approach(es) for primary total hip arthroplasty do you apply? (more answers possible)

- Anterolateral approach
- Posterolateral approach (with and/or without capsular repair)
- Straight lateral approach
- Anterior approach
- Other approach, namely……

Q6. At your orthopedic department do you prescribe postoperative restrictions for patients following total hip arthroplasty?

- Yes
- No

Q7. What is the luxation percentage for primairy total hip arthroplasty at your orthopedic department? (these data will be handled strictly confidential and anonymous)

Part 2 Type of restrictions applied

Q8. Are postoperative movement restrictions applied for your patients following total hip arthroplasty in order to avoid an early dislocation?

- Yes
- No

Q9. Is an abduction pillow applied for patients following total hip arthroplasty?

- Yes
- No

Q10. Are walking devices applied (e.g. crutches, canes) for patients following total hip arthroplasty?

- Yes
- No

Q11. Are ADL devices applied (e.g. wheelchair, rollator) for patients following total hip arthroplasty?

- Yes
- No

Q12. Are postoperative restrictions applied with respect to sleeping position of your patients following total hip arthroplasty in order to avoid an early dislocation?

- Yes
- No

Q13. Are postoperative restrictions applied with respect to car driving following total hip arthroplasty?

- Yes
- No

Q14. Do patients receive information regarding sexual activities following total hip arthroplasty?

- Yes
- No
- Unknown

Part 3 Specification and duration of restrictions

Q15. Which of the following movement restrictions are prescribed to patients following total hip arthroplasty and if so, for how long?

	Not applicable	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks	Unknown
< 90 degrees of hip flexion								
No adduction								
< 45 degrees endorotation								
< 45 degrees of exorotation								
Combined deep flexion, adduction and rotation								

Q16. Which of the following mobilization aids are prescribed to patients following total hip arthroplasty and please indicate the duration of use?

	Not applicable	1 week	2 weeks	3 weeks	4 weeks	5 weeks	6 weeks	7 weeks	8 weeks	Unknown
Crutches										
Walking frame										
Walker / rollator										
Tripod										

Q17. Which of the following ADL aids are prescribed to patients following total hip arthroplasty and please indicate the location of use?

	No ADL aids prescribed	During hospital stay only	At home	During hospital stay and at home
Elevated toilet seats				
Elevated chair seats (with armrest)				
Other devices like a Handy of shoehorn)				

Q18. Which of the following restrictions with respect to sleeping position of your patients following total hip arthroplasty are applicable and for how long?

	Not applicable	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks	Unknown
supine position								
supine position or unoperated side								
supine position patient while using abduction pillow								
Supine or nonoperated side with abduction pillow								

Q19. Car driving restrictions for how long following total hip arthroplasty?

- 2 weeks
- 4 weeks
- 6 weeks
- 8 weeks
- 10 weeks

- 12 weeks
- Unknown

Q20. For which patient-related (co-)morbidities do you selectively indicate restrictions? (Multiple answers allowed)

- High ASA classification
- High age
- Collom fracture
- Development dysplasia
- Rheumatic disorders

Chapter 3

Reduced patient restrictions following total hip arthroplasty: study protocol for a randomized controlled trial

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Trials. 2015 Aug 18;16(1):360

ABSTRACT

Background: Total hip arthroplasty (THA) is a very common procedure in orthopedic surgery. In the Netherlands, 25,642 primary THAs were performed in 2013. Postoperative hip dislocation is one of the major complications and has been reported in 0.5 to 10.6 % of patients after primary THA.

Several reports regarding the use of an anterolateral surgical approach have shown that a non-restriction or reduced restriction protocol does not increase the dislocation rate. For the posterolateral surgical approach it has been suggested that patient restrictions might be unnecessary but the amount of available literature is scarce. As such, randomized controlled trials aimed at investigating restrictions following THA using a posterior approach are strongly recommended.

The aim of this prospective randomized controlled trial is to investigate the non-inferiority hypothesis concerning the early dislocation rate after THA in patients with and without the use of a reduced restriction protocol.

Methods/Design: After providing informed consent a group of 456 patients with symptomatic coxarthrosis will be randomized to receive a THA either with care as usual, i.e. receiving postoperative restrictions including the advice to sleep in a supine position for the first 8 weeks postoperatively, or reduced restrictions with no recommendations regarding the position during sleeping. Primary outcome measure will be the percentage of early dislocations within the first 8 weeks after THA. Secondary outcome measures will be patient satisfaction, time to functional recovery, quality of sleep and patient's self-reported compliance with postoperative instructions.

Discussion: To our knowledge this will be the first randomized controlled trial that compares a reduced restriction protocol with a restricted protocol following THA using a posterolateral surgical approach. Our hypothesis is that a reduced restriction protocol following THA with use of a posterolateral surgical approach has no influence on the early dislocation rate compared to a restricted protocol. Instead, embracing a reduced restriction protocol might even contribute to a higher quality of sleep, thereby facilitating a faster uptake and return to daily functions in patients after THA.

Trial registration: ClinicalTrials.gov NCT02107248, registration date 3 April 2014.

Keywords: Arthroplasty, Replacement, Hip, Posterolateral surgery, Precautions

BACKGROUND

Total hip arthoplasty (THA) is a very common procedure in orthopedic surgery [1]. In the Netherlands, 25,642 primary THA implants were performed in 2013 [2]. Postoperative hip dislocation is one of the major complications and has been reported in 0.5 to 10.6 % of patient after primary THA [3, 4]. Surgical technique and ap- proach as well as implant selection, implant positioning, patient education and patient-related factors have an im- pact on the incidence of dislocations [5–7]. Traditionally, patient restrictions following THA are prescribed in order to prevent early dislocation by limiting the flexion of the hip (<90 degrees) as well as adduction and in- ternal rotation [8]. In modern orthopedic surgery, less invasive, tissue-sparing techniques have been introduced and patients are operated upon using shorter acting anesthetics. Nowadays, surgery duration is shorter and pa- tients are being mobilized early after surgery. These factors possibly contribute to less loss of muscle strength after surgery, resulting in a more stable hip joint immediately postoperative. Postoperative joint stability is further enhanced by the use of larger diameter femoral head components. Patients are also better educated and managed with clinical pathways which include detailed protocols, thereby reducing the risk of an early disloca- tion [6, 9]. However, the aspect of evidence-based application of restrictions after THA has attracted less attention, with long-standing protocols continuing to be routinely used in most hospitals. Several studies have shown that no or reduced restriction protocols do not result in increased dislocation rates [10–12].

Moreover, Talbot et al. have documented that patients had difficulties sleeping and felt discouraged during the time of restricted postoperative hip precautions [12]. Likewise, faster return to normal activities, higher patient satisfaction and earlier return to work are the bene- fits that have been shown when using no or reduced restrictions following THA, making it a cost-effective and patient-friendly alternative to the restricted protocol [10, 13]. Nowadays, most of the available knowledge on the effects of reduced postoperative precautions and restrictions after THA has been obtained utilizing an anterior surgical approach [10–12, 14]. This might be explained by the fact that THA utilizing a posterior ap- proach without repair of the posterior capsule and exter- nal rotators is associated with an increased risk for dislocation when compared to patients undergoing an anterior or anterolateral approach [15]. However, when conducting a posterior soft tissue repair this “increased” dislocation rate through the posterior approach is re- duced [16]. As such, further research on applying a re- duced restriction protocol in this group of patients is warranted [17].

To our knowledge this will be the first randomized controlled trial (RCT) that investigates use of a reduced restriction protocol following THA with use of a posterolateral surgical approach. Our hypothesis is that a reduced restriction protocol following THA with use of a

posterolateral surgical approach has no influence on the early dislocation rate compared to a restricted protocol.

METHODS/DESIGN

Study design

The study design is a single-center, parallel-group, stratified, randomized trial with a planned duration of 3 years in which 456 primary THA patients will be allocated to either a care-as-usual group receiving postoperative restrictions including the advice to sleep in a supine position for the first 8 weeks postoperatively or an ex- perimental group, receiving postoperative instructions without restrictions on sleeping position after THA surgery. The experimental group does not use a pillow be- tween the legs in any sleeping position and the care-as- usual group, that is only allowed to sleep in a supine position, is advised to use a pillow between the legs while doing so.

A non-inferiority design was chosen as a standard ap- proach to assess similarity of results of the experimental as opposed to the care-as-usual treatment. In order to avoid an imbalance in treatment assignments and to reduce the opportunity for bias and confounders, a strati- fied blocked randomization technique will be applied with random sequences of varying block sizes (varying from $n = 2$, $n = 4$ or $n = 6$). Among the stratification factors are operating surgeon and the preferred self- reported sleeping position (supine, prone, on the side, combination/no clear preference) of the patient. Mea- surements will be taken at baseline (preoperatively), 8 weeks (at regular polyclinic visit) 6, 12 and 24 months after surgery (postoperatively).

Setting

Written informed consent, from patients who meet the inclusion criteria for participation in the trial, having verified that the candidate fully understands what is in- volved, will be obtained by the research nurse.

Patients will be recruited by the Center for Orthopedic Surgery OCON, Hengelo, The Netherlands. All THAs will be performed by one of OCON's four orthopedic surgeons specialized in hip surgery and with at least 5 years' experience in THA. Time, duration and type of anesthesia will be recorded in our patient database. The surgical approach is standard posterolateral with use of a capsular repair. The soft-tissue tension is optimized through neck-length adjustments until an axial force with the leg in extension produces 1 to 2 mm of soft-tissue laxity for male patients and 2 to 3 mm of soft- tissue laxity for female patients.

During trial reduction, stability of the hip is tested in full flexion; 90 degrees of flexion and 45 degrees of in- ternal rotation; full extension; 0 degrees of extension and 45 degrees of external rotation; and with and without knee flexion (up to 90 degrees). Such stability testing is routine in our practice and was not modified for the present study. The implants that will be used are: Exceed ABT Ringloc-XShell, Biomet Orthopedics, E-Poly Hi-Wall Liner Biomet Orthopedics, Modular Taperloc complete femoral stem Biomet Orthopedics, Biolox Delta Modular Ceramic Head 32 mm (Dordrecht, The Netherlands). The postoperative protocol is full weight bearing to tolerance from day 1.

The first radiologic assessment, to control prosthetic positioning occurs on the day of the operation, with an anteroposterior (AP) and lateral view of the hip. The second radiographic assessment is at 8 weeks postoperative with an AP pelvic view and a lateral view of the hip. Implant position including cup inclination angle, acetabular component anteversion, hip offset, and leg length will be measured on the 8 weeks postoperative AP pelvic view. The target zones for anteversion and inclination are defined as 10–30 degrees and 30–50 degrees, respectively.

The local Medical Ethical Committee approves the study design, procedures, protocols and informed consent. The trial is registered at ClinicalTrials.gov NCT02107248.

STUDY POPULATION

Patients with symptomatic osteoarthritis of the hip who are planned for THA are included if they meet the following criteria: ASA-classification I or II (American Society of Anesthesiologists); written informed consent provided by the patient.

Exclusion criteria are: blindness, scheduled second THA within 6 months, mental incapacity, or inability to fill in the questionnaires in Dutch, infection in- volvement, wheelchair-dependency, alcohol abuse, and neurological disorders such as Parkinson's disease, or stroke and hypermobility syndromes such as Ehlers- Danlos syndrome.

Interventions

After randomization, patients will receive either care- as-usual; postoperative instructions with the advice to sleep in a supine position for the first 8 weeks postopera- tively or reduced restrictions; postoperative instructions without any restriction on sleeping position. All patients are instructed by the physiotherapist by oral and written guidelines which include the following:

- Not to cross the legs
- Not to squat
- Not to internally rotate the hip more than 45 degrees

- Not to flex the hip more than 90 degrees and
- Not to make a combination of these two movements
- When sitting not to use a very low chair that makes the hip flex more than 90 degrees
- When sleeping only to sleep in the supine position and to use a pillow between their legs during sleep
- When bending move the operated leg backward so the operated hip will not flex more than 90 degrees

Care-as-usual/restricted group

In the restricted group patients have to sleep in a supine position during the first 8 weeks. Hip flexion over 90 de- grees and internal or external hip rotation more than 45 is not allowed for the first 8 weeks. Patient will be mobilized by the physiotherapist at the day of the operation or the first postoperative day with full weight bearing to tolerance.

Experimental/reduced restricted group

In the reduced restricted group patients are allowed to sleep in any position they find comfortable. Hip flexion over 90 degrees and internal or external hip rotation more than 45 degrees is not allowed for the first 8 weeks. Patient will be mobilized by the physiotherapist on the day of the operation or the first postoperative day. Patient will be mobilized by the physiotherapist at the day of the operation or the first postoperative day with full weight bearing to tolerance.

Patients are instructed by the physiotherapist how to lie in bed and how to prevent more than 90 degrees of hip flexion and 45 degrees of rotation. Next to the general instructions as stated earlier, patients in this experi- mental group receive additional instructions on how to lie and turn in bed by preventing more than 90 degrees of hip flexion and 45 degrees of rotation.

Main study parameters/endpoints

Primary outcome measure is the difference in disloca- tion rate, expressed as a percentage, within the first 8 weeks between the group that receives postoperative instructions with the advice to sleep in a supine position for the first 8 weeks postoperatively and the group that receives postoperative instructions without any restric- tion on sleeping position. The diagnosis of a dislocated hip will be confirmed by clinical examination and X-ray findings.

Secondary study parameters/endpoints

Secondary outcome measures are patient's compliance with postoperative instructions, the influence of sleeping position restrictions on quality of sleep [18], the influence

of sleeping position restrictions on patient satisfaction (an- chor questions rating the degree of perceived quality of sleep and burden of the restrictions prescribed, the Client Satisfaction

Questionnaire) and the effects of the advice to sleep in a supine position for the first 8 weeks on func- tional recovery.

Other study parameters

These parameters include:

1. Resumption of specific activities following THA such as driving a car.
2. The use of assistive devices (e.g. pillow between the legs during sleep, crutches).
3. The self-reported compliance of patients with the restrictions prescribed.
4. Satisfaction with received quality of care (Client Satisfaction Questionnaire).

STUDY PROCEDURES

After inclusion and prior to surgery, subject patients will complete the baseline questionnaire at the outpatient clinic during the intake by the nurse practitioner. The physiotherapist will mobilize patients on the day of the operation or the first postoperative day. During this mobilization patients are instructed how turn in bed and how to prevent more than 90 degrees of hip flexion and 45 degrees of rotation. The only difference in instruction between the two study arms is the sleeping position. When discharged to home or nursing home, patients receive a booklet describing the instructions relevant to the study arm they are assigned to. This booklet serves as an enchiridion for partners, physiotherapists, and other persons involved in the care of the patient. In addition, patients are handed a standardized diary book- let in which they are asked to document their sleeping position, exercise activities, experience of pain and any further comments they may want to convey. Patient will visit the outpatient clinic preoperatively and then at 8 postoperative weeks. Routine physical examination will be performed by the orthopedic surgeon. All scores and measurements will be recorded by the nurse practitioner who will also collect the diary booklet from the patients. Preoperative functional assessment will be done by pain severity (Visual Analogue Scale: range 0–10), hip function (Hip Disability and Osteoarthritis Outcome Score) and quality of life (EQ-5D). At 8 weeks follow-up the same functional assessment will be recorded by the nurse practitioner. This visit is combined with the regu- lar postoperative control by the orthopedic surgeon. At 6, 12 and 24 months there will be follow-up questionnaires by Email, paper or telephone depending upon the availability of the patients' Email addresses. The primary outcome: dislocations within the first 8 weeks, will be recorded in the patient's file when visiting the emergency department.

Sample size calculation

The maximum allowable difference in proportion in which there is still equality in the effect is not known in the literature. Previous studies suggested "a three- fold difference in dislocation

rate" to be a clinically relevant difference [4]. Since the literature is suggest- ing an average dislocation rate of 2.03 % [8] in the posterolateral surgical approach, a dislocation percent- age between 2.03 and 6.09 % is considered to be "equal." Hence, the planned sample size is n = 456 THA patients. (One-sided, $\alpha = 0.025$, $\beta = 0.80$, missing data 20 %).

Statistics

Populations

Primary analyses will be performed for both the intention-to-treat (ITT) and per-protocol (PP) populations. The PP population of patients will comprise those who completed all measurements and did not have any reasons for exclusion from this population, including no baseline data, no data at 8 weeks and/or 6 months or major protocol violations (e.g. position compliance < 80 %).

Additional analysis will be based on an ITT (All Patients Treated) population that consists of all randomized patients who had both a baseline and at least one post- baseline measurement.

Primary analysis

Descriptive statistics were calculated for all variables. Depending on the type of data were compared between the groups using either a *t* test (continuous) or chi- square (categorical).

The intervention group that receives postoperative in- structions without any restriction on sleeping position will be declared non-inferior to the group that receives postoperative instructions with the advice to sleep in a supine position for the first 8 weeks postoperatively in case it can be demonstrated that the difference between these 2 groups does not exceed "a 3-fold difference in dislocation rate" in favor of the supine sleeping position group. This margin corresponds to the definition of clin- ically relevant difference in dislocation rate by Peak et al.

The secondary analysis

A repeated measure analysis of (co)variance (ANOVA; group and time) will be applied in order to investigate differences between the groups satisfaction, functional recovery (HOOS) and quality of life (EQ-5D) at 8 weeks, 6 months, 1 and 2 years postoperatively. In addition, correlation coefficients will be calculated between quality of sleep and functional recovery and quality of life. ANCOVA will be conducted dependent upon the ana- lysis of differences in baseline characteristics between groups (e.g. preoperative values, age, radiographic analysis). Subgroup analysis will be directed towards identi- fying differences in functional recovery between patients with and without compliance and patients who were and were not satisfied.

Missing data

Missing values (<30 %) in the APT analysis will be handled by multiple imputation techniques. It will be assumed that any missing data will occur at random and missing values will be imputed for the ITT population using multiple imputation by chained equations. The imputation models will be specified to include the individual scores observed at 8 weeks, 6 months, 1 and 2 years and any available variable that has a statistical association with the outcome to be imputed or with "missingness," as identified in a logistic regression analysis with "missingness" as the dependent variable. Corresponding to the percentage of missing values (with a minimum of 25) datasets with imputed plausible values will be obtained, with 50–100 iterations between datasets. Predictive mean matching will be employed to obtain pooled parameter estimates and their associated standard errors for all analyses.

The results of the analysis of the primary study hy- pothesis using the pooled results will be compared to the results obtained on the observed (PP) data alone.

Ethical considerations

This study is approved by the medical research ethics committee. The Medical Ethics Committee Twente acts as central ethics committee for this trial (Number P13-

.31, NL4670604414). An insurance which is in accord- ance with the legal requirements in the Netherlands (Article 7 WMO and the Measure regarding Compul- sory Insurance for Clinical Research in Humans of 23 June 2003) has been obtained. This insurance provides cover for damage to research subjects through injury or death caused by the study. Once a year, information will be provided to the medical research ethics committee on the numbers of subjects included and numbers of sub- jects that have completed the trial, serious adverse events/serious adverse reactions, and other problems.

DISCUSSION

Various postoperative restrictions have been proposed for patients undergoing THA to prevent early hip dislocation by emphasizing the importance of avoiding extremes of motion as well as to protect the soft tissue repair [8]. However, the scientific rationale for the effectiveness of these postoperative restrictions in the

prevention of early dislocations is limited. Moreover, there are indications that applying a reduced restriction protocol has several benefits. In a prospective, randomized study, with use of an anterolateral surgical approach, Peak et al. reported that patients were much more satisfied when they were given fewer restrictions [10]. Furthermore, these patients achieved a faster

return to daily functions and were able to return to work faster [9]. In addition, sleep was positively affected by the reduced precautions [10]. Ververeli et al. demonstrated that reduced hip precautions can facilitate recovery and are more cost-effective [14].

Today the available knowledge is mainly directed at analyzing the anterior or anterolateral surgical approach. However, there are two cohort studies that have investigated the effectiveness of a reduced restriction protocol in primary THA following a posterolateral instead of an anterolateral approach but these studies lack a randomization procedure. For example, Mikkelson et al. found no difference in dislocation rate comparing two cohorts with and without restrictive motion [13]. The study did not show any beneficial effect of rehabilitation without movement restrictions on patient evaluated function. Schmidt-Braekling et al. showed, in a retrospective analysis, that shortening standard posterior hip precautions from 6 to 4 weeks after primary THA utilizing a posterior approach does not increase the risk for postoperative dislocation within the first year after surgery [7].

In the present study we will compare two postoperative protocols that differ in the restriction of sleeping position following THA via the posterolateral surgical approach. Based on the study of Talbot et al., who found that patients had difficulties sleeping following a re- stricted protocol, our intervention group will not be re- stricted to sleep in a supine position [12]. In previous studies only the duration of the restrictions was shorted or the reduced restriction protocol was di- rected towards movement restrictions and use of as- sistive devices [7, 13].

Another interestingly aspect of the current study compared to the existing literature is that fact that it incorporates an analysis of the patient self-reported compliance to postoperative restrictions. Our study plans to assess patient compliance to the sleeping pos- ition instructions in relation to their preferred sleeping position.

In summary, the aim of this RCT is to show that a re- duced restriction protocol following THA with use of a posterolateral surgical approach has no influence on the early dislocation rate. By omitting the postoperative sleeping restriction patients might have a better quality of sleep, higher patient satisfaction and a faster func- tional recovery. To our knowledge this will be the first RCT that investigates use of a reduced restriction protocol following THA with use of a posterolateral surgical approach.

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Chapter 4

Less Postoperative Restrictions Following Total Hip Arthroplasty with Use of a Posterolateral Approach: A Prospective, Randomized, Noninferiority Trial

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ABSTRACT

Background

Patient restrictions are prescribed after total hip arthroplasty (THA) to ensure proper healing and prevent early dislocation. It has been suggested that less or nonrestrictive protocols following THA do not lead to higher dislocation rates. Nonetheless, restrictions are still widely used. The aim of this study is to evaluate the rate of early dislocations when patients were restricted to supine sleeping or unrestricted sleeping in the first 8 weeks after THA using a posterolateral approach.

Methods

The study design was a single-center, parallel-group, stratified, randomized, noninferiority trial in which primary THA patients were allocated to either a restricted group or a nonrestricted group. The primary outcome was early (<8 weeks) dislocation rate. Secondary outcomes include pain (visual analog scale [VAS]), function in activities of daily living (Hip Disability and Osteoarthritis Outcome Score [HOOS]), and quality of life (EuroQoL 5 Dimension [EQ-5D]).

Results

A total of 408 patients were randomized into 2 groups: those who were restricted in their sleeping position (n = 203) and those who received no restrictions in sleeping position (n = 205). Three patients (1.48%) from the restricted group and 3 patients (1.46%) from the unrestricted group had a dislocation. The noninferiority of the restricted group compared to the nonrestricted group was established for early dislocation. In addition, no statistically significant differences were found for VAS, HOOS, and QoL-5D between both groups. Both groups showed a significant improvement in VAS, HOOS, and QoL-5D.

Conclusion

Early dislocation rates in patients who were advised to comply to an unrestricted sleeping position following THA were not inferior to the dislocation rates in patients who were advised to sleep in a supine position following THA. The results of the present study strengthen the discussion regarding the relevance of providing patients with restrictions following THA.

Keywords: arthroplasty; replacement; hip; posterolateral surgery; precautions; dislocations

Total hip arthroplasty (THA) is a common and successful procedure in orthopedic surgery. However, dislocation is a frequent and costly complication of THA that is a substantial source of patient morbidity [1]. Patient restrictions following THA are prescribed to ensure proper healing and to prevent early dislocation [2]. It has been suggested that less or nonrestrictive

protocols following THA do not lead to worse dislocation rates [3]. Nonetheless, national surveys have demonstrated that patient restrictions are still widely used [4–6]. The reasons for this may be that studies on the subject have significant heterogeneity in terms of surgical approach, femoral head size, and postoperative protocol, which makes it difficult to compare and implement the results to daily practice [3,7]. Patients claim that restrictions interfere with their sleep and clinicians would like to change their practice regarding restrictions [4,8,9]. Therefore, evidence regarding the necessity of postoperative advice to sleep in a supine position in the weeks following THA would be beneficial to patients and clinicians. In the present study, a prospective, randomized, and controlled trial was conducted on patients who were operated on with the posterolateral approach using a 32-mm femoral head implant. It was hypothesized that the early dislocation rate in patients who were not restricted to any sleeping position following THA would not be worse than the early dislocation rate in patients who were restricted to supine sleeping following THA.

MATERIALS AND METHODS

The study was designed as a single-center, parallel-group, stratified, and randomized trial in which primary THA patients were allocated to a restricted group or a nonrestricted group (see Table 1). All patients were educated to avoid activities that could cause the hip joint to be in a position of flexion over 90°, or adduction or rotation past the midline. The only difference being that the unrestricted group did not receive any restrictions on sleeping position. None of the patients had to use a pillow between the legs, and assistive devices were not routinely prescribed. Full details of the protocol have been described previously, and a summary of the methodology follows below [10].

Table 1 inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
THA for osteoarthritis of the hip	THA for femoral neck fracture
Posterolateral approach	Contralateral THA scheduled within 6 moa
Written informed consent provided by the patient	Mental incapacity, or inability to fill in the questionnaires in Dutch
ASA classification I or II	Wheelchair dependency
	Infection involvement
	Blindness
	Alcohol abuse
	Neurologic and hypermobility disorders
ASA, American Society of Anesthesiologists; THA, total hip arthroplasty.	
The first hip was eligible for the study, and the second is an exclusion criterion.	

surgeons who specialized in hip surgery performed the THA operations. The operating surgeons were blinded from randomization to avoid bias. The surgical approach was a standard posterolateral approach with use of a capsular repair in which a 10- to 15-cm curved incision over the posterior edge of the greater trochanter was made. The fascia lata was incised and the fibers of the gluteus maximus were split. After detachment of the internal rotator muscles (piriformis, gemmelli, and obturatorius internus), the capsule was incised. At the end of the procedure, the capsule and the piriformis muscle were reattached to the greater trochanter using drill holes'.

The implants used Patients were recruited from Orthopedisch Centrum Oost Nederland (Hengelo, the Netherlands) between 2014 and 2017. Inclusion and exclusion criteria are illustrated in Table 1. After the patients were randomized, the patients received either care-as-usual or a reduced restriction protocol.

Eleven orthopedic were as follows: Exceed ABT Ringloc-XShell (Biomet Orthopedics), E-Poly Hi-Wall Liner (Biomet Orthopedics), Modular Taperloc complete femoral stem (Biomet Orthopedics), and Biolox Delta Modular Ceramic Head 32 mm. The postoperative protocol involved full weight-bearing to tolerance from day 1.

A stratified and blocked randomization technique was applied with random sequences of varying block sizes (varying from $n = 2$, $n = 4$, or $n = 6$). The stratification factors included the operating surgeon and the patient's preferred sleeping position (supine, prone, on the side, combination/no clear preference). The preferred sleeping position was determined before randomization by means of a single question to the patients: "What is your preferred sleeping position?"

The answer options included the following: supine, prone, on the side, combination/no clear preference. Measurements were taken at baseline before the surgery and 8 weeks after the surgery during the regular outpatient follow-up visit. Additional Q questionnaires were obtained digitally during the follow-up visit at the outpatient clinic (PromsOnline, Interactive Studios, the Netherlands). Patients who did not own a computer were handed hard copies of the questionnaires.

Before the baseline measurement, all subjects provided their informed consent to participate by handwritten signature. The study was approved by an accredited medical research ethics committee (NL4670604413; P13-31 METC Twente) and a local institutional review board. The study was registered in clinical trials (NCT02107248).

Main Study Parameters

The primary outcome was the difference in early dislocation rate between the group that received postoperative instructions to sleep in a supine position for the first 8 weeks and the group that received postoperative instructions without any restrictions on sleeping position. This rate was expressed as a percentage. A dislocation is defined as "early" if it took place within the first 8 weeks postoperatively and was confirmed by X-ray.

The secondary outcome measure was functional recovery. Function in activities of daily living was measured with the Hip Disability and Osteoarthritis Outcome Score (HOOS) [11], and quality of life was measured using the EuroQoL 5 Dimension (EQ-5D) questionnaire [12]. Pain severity was measured by a visual analog scale (VAS) from a range of 0-100 [13].

Sample Size Calculation

The maximum allowable difference in proportion that still preserves equality of effect is unknown in the literature. Previous studies suggested "a 3-fold difference in dislocation rate" to

be a clinically relevant difference [14]. Because the literature suggests an average dislocation rate of 2.03% in the posterolateral surgical approach, a dislocation percentage between 2.03% and 6.09% is considered to be "equal" [15]. Hence, the planned sample size is n = 456 (where n is the number of THA patients) based on a noninferiority hypothesis (1-sided, α = 0.025, β = 0.80, lost to follow-up, 20%). The sample size was calculated by using the program PASS 16 (NCSS Statistical Software).

Statistics

Descriptive analyses on the demographic variables and baseline measures were conducted for both groups. Data were checked for normality with visual inspection of histograms. Differences between study groups in categorical variables were compared using chi-square tests.

For the noninferiority test, the dislocation rate was calculated per group by expressing the number of dislocations within each study group as a percentage of the total amount of patients. The confidence interval of the proportion was then calculated for both treatment groups. A confidence interval of 95% with a Z-value of 1.96 was chosen. The intervention group that received postoperative instructions without any restriction on sleeping position was declared to be noninferior to the group that received postoperative instructions with the advice to sleep in a supine position for the first 8 weeks. This declaration was done in case it could be demonstrated that the upper boundary

of the confidence interval difference between these 2 groups did not exceed "a 3-fold difference in dislocation rate" in favor of the supine sleeping position group. This margin corresponds to Peak et al's [14] definition of clinically relevant difference in dislocation rate.

Paired t-tests were used to compare baseline and 8 weeks to test significant differences in scores between baseline and 8 weeks after follow-up within each treatment group for HOOS and VAS.

To investigate between-group differences in treatment effect (HOOS, VAS, EQ-5D), delta scores (Δ) were calculated by subtracting the mean of the 8-week score from the mean baseline score. Negative delta scores indicate an improvement. Independent t-tests were applied to test for differences in treatment effect between the unrestricted and the restricted group for VAS and HOOS.

For the EQ-5D, which appeared to contain a non-normal distribution, the Wilcoxon signed-rank test was used to conduct a within-group analysis by comparing the baseline and 8-week scores. The Mann-Whitney U test compared the results of the delta EQ-5D score between both treatment groups.

The statistical analysis was performed with the computer program IBM SPSS statistics 24.0.

The alpha (α) was set at 0.05, meaning that a calculated *P* value was considered to be significant if smaller than .05.

RESULTS

Of the 848 patients who were assessed for eligibility, 408 were included for randomization (Fig. 1). None of the patients had missing baseline measurements. One patient refused to return for a follow-up visit but did inform the researchers that there had not been any dislocation. For the functional outcome, this patient was considered to be lost to follow-up.

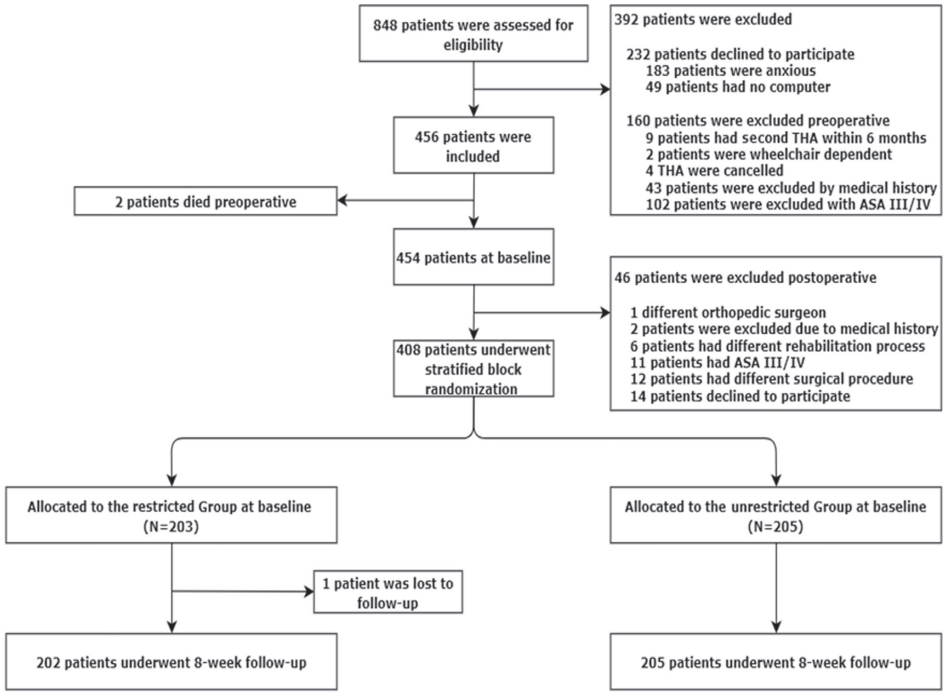

Fig. 1 A Consolidated Standards of Reporting Trials (CONSORT) flow diagram demonstrating the enrollment, randomization, assigned interventions, and follow-up of the study participants. THA, total hip arthroplasty; ASA, American Society of Anesthesiologists.

Patient demographics and baseline outcomes of the questionnaires are presented in Table 2. None of the patient demographics and the baseline outcomes of the questionnaires indicated any statistical difference between the restricted group and the unrestricted group ($P > .14$).

Based on their sleeping position preference, subjects were equally divided over the 2 study arms ($P > .496$).

Table 2 Patient Demographics. Mean Baseline Measurements of Both Treatment Groups.

Demographic characteristics	Unrestricted Group ($N = 205$)	Restricted Group ($N = 203$)
Female sex[a]	124 (61%)	109 (54%)
Left THA[a]	98 (48%)	93 (46%)
Age[b]	64.41 ± 10.22	64.34 ± 10.32
Preferred sleeping position		
Side	160 (78.8%)	159 (77.6%)
Supine	14 (6.9%)	13 (6.3%)
HOOS total score[b]	32.55 ± 13.28	34.47 ± 13.15
VSH total score[b]	90.93 ± 18.98	91.65 ± 21.26
VAS average[b]	49.30 ± 22.53	46.86 ± 22.17
VAS worst moments[b]	67.45 ± 23.12	63.71 ± 25.46
EQ-5D total score[b]	0.49 ± 0.29	0.48 ± 0.29

EQ-5D, EuroQoL 5 Dimension; HOOS, Hip Disability and Osteoarthritis Outcome Score; THA, total hip arthroplasty; VSA, visual analog scale.

[a] The values are presented as the number with accompanying percentage.

[b] The values are presented as mean and standard deviation.

Dislocation and Complications

In both the restricted and the unrestricted groups, 3 patients had early dislocation, which was 1.48% and 1.46%, respectively (Table 3). None of the dislocations occurred during sleep or in bed.

Table 3 Results of All the SAEs Reported Between Baseline and 8-Week Follow-Up.

Kind of SAE	Restricted Group	Unrestricted Group	P Value
Early dislocation	3 (1.48%)	3 (1.46%)	.981
Deep infection of THA	2 (0.99%)	0 (0.00%)	.152
Lung embolism	1 (0.49%)	1 (0.49%)	.989
Deep venous thrombosis	1 (0.49%)	0 (0.00%)	.312

The values are given as the number with accompanying percentage.

THA, total hip arthroplasty; SAEs, serious adverse events.

In the restricted group, the first patient dislocated the hip at 3 weeks postoperatively while walking with crutches.

The second patient dislocated the hip at the second day postoperatively during exercises with the physiotherapist in the hospital. According to the physiotherapist, the patient's foot slipped away on the ground while the patient was getting up from the bed. The third patient dislocated the hip at 1 week postoperatively while reading and sitting on an elevated bench. All patients

had a closed reduction under general anesthesia and were prescribed an antidislocation brace until the routine 8-week follow-up.

In the unrestricted group, the first patient dislocated the hip at 3 weeks postoperatively during exercises with the physiotherapist while stepping off the home trainer. The second patient dislocated the hip at 2 weeks postoperatively while picking up clothes from the sink. The patient had already experienced an odd feeling around the hip that morning. The third patient dislocated the hip at 5 days postoperatively while sitting in a chair. All patients had a closed reduction under general anesthesia, and the second patient received an anti-dislocation brace until the routine 8-week follow-up. The other patients were treated functionally. The use of an anti-dislocation brace is based on the individual surgeon's preference.

As demonstrated by Figure 2, the upper limit of the 1-sided 95% confidence interval of the dislocation rate and the confidence interval of proportion in the unrestricted and the restricted groups lies within the 2.03%-6.09% noninferiority margin.

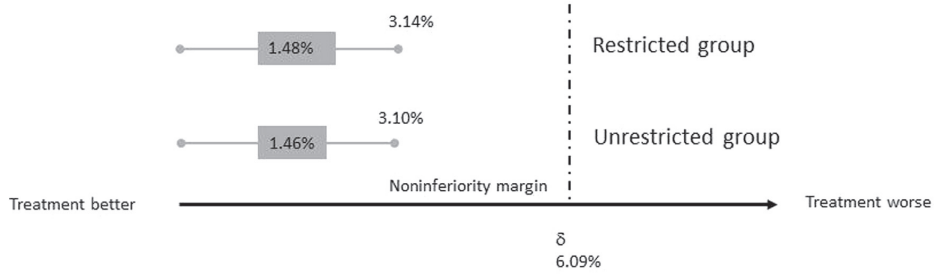

Fig. 2 Dislocation rates of the 2 groups and confidence interval of proportion.

All serious adverse events (SAEs) that occurred within the first 8 weeks are demonstrated in Table 3. None of the SAE demonstrated a significant difference between the unrestricted and the restricted group in early dislocation ($P = .981$) and other SAEs ($P > .152$).

Functional Recovery

Patients in both groups reported a significant improvement in function on the HOOS and the EQ-5D scores at 8 weeks postoperatively compared to baseline ($P < .001$). Patients in the unrestricted group tended to show a better recovery in HOOS scores ($P = .09$; Table 4). No statistically significant nor clinically relevant differences in improvement in HOOS, VAS, and EQ-5D were found ($P > .152$).

Table 4 Differences in Functional Outcomes.

Outcome Measurement	Restricted Group	Unrestricted Group	P Value
HOOS total score	−40.08a (18.62)	−43.66a (14.96)	.09b
VAS average	37.64a (21.37)	40.07a (23.96)	.33b
VAS worst moments	49.80a (29.43)	52.06a (28.24)	.48b
EQ-5D total score	−0.32a (0.30)	−0.34a (0.32)	.40c

The values are presented as mean and standard deviation.
EQ-5D, EuroQoL 5 Dimension; HOOS, Hip Disability and Osteoarthritis Outcome Score; VSA, visual analog scale.
a A delta score is calculated by "mean baseline score" minus "mean 8-week score."
b P value calculated with independent t-test due to normal distribution of data.
c P value calculated with Mann-Whitney U due to not normal distribution of data.

DISCUSSION

To our knowledge, this is the first randomized trial regarding patient restrictions following THA with use of a posterolateral approach. This study demonstrated that the early dislocation rate in patients who were prescribed an unrestricted sleeping position was noninferior to the early dislocation rate of patients who were prescribed a restricted sleeping position.

Previous literature reviews have failed to draw firm conclusions regarding restrictions following THA with use of the posterolateral approach [3,7,16]. In 2 of the 3 systematic reviews regarding restrictions following THA, the conclusions are solely based on the anterolateral approach [7,16]. The third systematic review by van der Weegen et al [3] only included 1 study using the posterolateral approach in both groups. The results of that study were consistent with the finding in the present study that the removal of restrictions had no effect on the functional outcome but no conclusions were drawn regarding the dislocation rate between 2 groups [17].

Furthermore, our results are in line with previous cohort studies, examining the effect of restrictions with use of a posterolateral approach, that did not indicate any effect of restrictions on dislocation rates [18,19]. However, in contrary to our trial, those studies used different femoral head sizes, which introduced a confounder for dislocation [20].

The large heterogeneity in surgical approach, femoral head size, and postoperative protocols in all previous studies may explain why restrictions continue to be used, as has been demonstrated in recent national surveys [4–6]. The present study used 1 surgical approach, 1 femoral head size, and only 1 restriction was removed. The results of the present study can strengthen the discussion about the relevance of providing patients with restrictions following THA.

Of the 232 patients who did not want to participate, 183 (79%) were too anxious. Preoperative anxiety has been demonstrated in previous studies regarding restrictions following THA

[14,17]. However, it appears that simply abandoning restrictions does not necessarily decrease the degree of anxiety [17]. Future research should study how THA patients can be advised to reduce this preoperative anxiety.

The strength of this study is in its design. Although many previous studies have emphasized the need for well-designed trials on the subject, this study is the first randomized, controlled trial that compares a nonrestricted protocol with a restricted protocol following THA using a posterolateral surgical approach [3,7,21].

One limitation of this study is that patients in the restricted group had to sleep in a supine position. Whether they were compliant to this restriction is not known. In other words, the results of this study are based on an intention-to-treat analysis that was conducted. Nevertheless, the present analysis reflects the current clinical practice which involves surgeons and therapists advising patients to follow restrictions. This was demonstrated in 2 surveys. The first survey was under physiotherapists and occupational therapists in the United Kingdom; it indicated that 44% of the patient are advised not to sleep on the operated side and 52% of the patients are advised not to sleep on the nonoperated side [4]. The second survey under Dutch orthopedic departments showed that 82% of the departments using a posterolateral approach restricted patients in their sleeping position till 6 weeks postoperation [5]. Another limitation of the present study could be selection bias. Of the 392 people who chose not to enroll, about 79% cited to be anxious. Assuming a selection bias was caused by anxiety among patients to partly abandon the postoperative

restrictions, one could hypothesize that less anxious patients were included. In literature, increased levels of preoperative anxiety seem to be associated to worse functional recovery in terms of patient-related outcomes postoperatively [22,23]. To the authors' knowledge, no literature is available about the association between (worse) functional recovery and (increased) dislocation rates. As such, it is unknown whether selecting a less anxious patient group could have increased the likelihood of finding a "noninferiority" result. Our results would therefore only be potentially generalizable to fairly healthy patients (American Society of Anesthesiologists classification 1/2) with less preoperative anxiety levels.

Another possible limitation is the choice of the noninferiority margin around the dislocation rate of 2%, which was a prestudy assumption [15]. Defining the noninferiority margin is crucial, although it is one of the most challenging aspects in the design of noninferiority trials [24]. Although this study's margin was based on previous considerations with use of an anterolateral approach to examine differences in dislocation rates between groups

following THA restrictions, our results could have declared noninferiority due to underpowering [14]. However, the statistical difference in the number of dislocations between the 2 study groups contained a *P* value (*P* = .9701) far from significance, thereby making it highly unlikely that noninferiority was declared unjustified.

In conclusion, this study demonstrated that the early dislocation rate in patients who are advised to use an unrestricted sleeping position following THA is not inferior to the early dislocation rate in patients who are advised to sleep in a supine position following THA with use of a posterolateral approach.

Table 2. Patient demographics. Mean baseline measurements of both treatment groups.

	Unrestricted group (*n* = 205)	**Restricted Group (*n* = 203)**
Female sex*	124 (61%)	109 (54%)
Left THA*	98 (48%)	93 (46%)
Age†	64.41 ± 10.22	64.34 ± 10.32
Preferred sleeping position		
Side	160 (78.8%)	159 (77.6%)
Supine	14 (6.9 %)	13 (6.3%)
HOOS total score†	32.55 ± 13.28	34.47 ± 13.15
VSH total score†	90.93 ± 18.98	91.65 ± 21.26
VAS average†	49.30 ± 22.53	46.86 ± 22.17
VAS worst moments†	67.45 ± 23.12	63.71 ± 25.46
EQ5D total score†	0.49 ± 0.29	0.48 ± 0.29

The values are presented as the number with accompanying percentage
The values are presented as mean and standard deviation

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Chapter 5

Patient compliance with postoperative precautions in an unrestricted and a supine sleeping position following posterolateral total hip arthroplasty: a randomized controlled trial

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Disabil Rehabil. 2021 Dec 21:1-8.

ABSTRACT

Purpose

To evaluate compliance with the precaution to sleep in a supine position following total hip arthroplasty (THA) and its impact on the other precautions.

Materials and methods

Single-center, parallel-group, stratified, randomized trial. Patients were allocated to a Restricted Group or an Unrestricted Group. This study focuses on compliance with the precaution to sleep in a supine position, compliance with the remaining set of precautions and the burden of restricted sleeping. Measurements were made using a self-administered diary and questionnaires. Trial registration number: NCT02107248

Results

During the first 2 weeks, 81% of the patients in the restricted group were compliant with sleeping in a supine position.

Patients in the Unrestricted Group significantly kept sleeping fewer days per week in a supine position than patients in the Restricted Group ($p = 0.000$). No significant differences between the two groups were found regarding compliance with the remaining set of precautions. The burden of the sleeping restriction is significantly lowered in the Unrestricted Group ($p = 0.000$)

Conclusions

Compliance with restricting patients to sleep in a supine position is high. Removing this precaution has a significant decrease in burden for patients without affecting compliance with the remaining set of precautions.

IMPLICATIONS FOR REHABILITATION

Sleeping precautions cause a high rate of burden to patients, whereas movement precautions do not.

By removing sleeping precautions, the burden is significantly reduced without affecting the remaining set of precautions. Compliance with movement precautions is high compared to other more functional precautions.

Keywords: Precautions; total hip arthroplasty; compliance; restrictions; supine sleeping

INTRODUCTION

Hip precautions are traditionally prescribed to ensure proper healing and prevent dislocation after total hip arthroplasty (THA) [1]. Several surveys in the United Kingdom, the United States, and the Netherlands have shown the widespread use of precautions following THA, especially in the posterolateral approach [2– 4]. Despite the routine use of precautions following THA none of the existing literature has shown a positive effect of precautions in reducing the dislocation rate [5–12]. A recent survey in the Nordic countries concerning precautions following THA revealed a strong trend towards fewer precautions [13]. This trend in minimizing precautions following THA with a posterolateral approach is likely to follow in the rest of the world.

When changing the precaution policy, it must be decided which precautions can be removed and which should remain. One can advocate abandoning all precautions since studies using a no-precaution protocol tend to show the dislocation rate is not affected. However, so far, this evidence is still inconclusive due to underpowering and may therefore not be sufficient for therapists and surgeons to justify changing practice in a system where surgeons carry the burden of responsibility for patient safety [14].

However, it should not be forgotten that patients hold mixed opinions towards precautions. On the one hand, with no precautions, they appear less hampered in returning to and resuming their pre-operative daily activities [15]. On the other hand, patients treated with precautions feel that these precautions provide guidance. There seems to be a perceived relevance experienced by patients regarding some precautions, and this can explain why up to 28% of the patients keep adhering to precautions even when they are not prescribed [9].

Compliance with precautions can be seen as an expression of this perceived relevance by patients. However, compliance with postoperative precautions following THA has not been studied much, whereas it can be helpful when changing longstanding postoperative protocols to decide which precautions to continue and which to stop. Since the effectiveness of precautions, in general, is debated, it seems obvious to stop precautions with low compliance rather than precautions with high compliance.

Moreover, compliance is influenced by motivation. Removing one precaution can alter this motivation [16]. When one precaution is removed, the influence on compliance with the remaining minimal set of precautions is not known. This study is trying to help professionals involved in the rehabilitation following THA to change longstanding precaution protocols with additional parameters such as compliance.

Our objective was to analyze compliance with the precaution to sleep in a supine position, its impact on patients, and if this precaution is removed then the influence on compliance with the remaining precautions. In this study, the compliance of a group of patients with a less restricted postoperative precaution protocol was compared to a group of patients with a restricted postoperative precaution protocol. The primary outcome of this trial, early dislocation with less postoperative restrictions following THA has been previously published and showed no statistical difference between both groups (Table 2).

Table 1. Inclusion and exclusion criteria.

Study parameter		**Restricted Group (*n* = 203)**	**Unrestricted Group (*n* = 205)**
Preferred sleeping position	Supine	13 (6.3%)	14 (6.9%)
	Side	159 (77.6%)	169 (78.8%)
Female sex[a]		109 (54%)	124 (61%)
Left THA		93 (46%)	98 (48%)
Age		64.34 ± 10.32	64.41 ± 10.22
HOOS		34.47 ± 13.15	32.55 ± 13.28
VAS average[b]		46.86 ± 22.17	49.30 ± 22.53
VAS worst moments[b]		63.71 ± 25.46	67.45 ± 23.12
EQ-5D total score		0.48 ± 0.29	0.49 ± 0.29
Early dislocation THA (<8 wks. after surgery)	$p = 0.981$	3 (1.48%)	3 (1.46%)

EQ5D: EuroQolL 5 Dimension; HOOS: Hip Disability and Osteoarthritis Outcome Score; THA: Total Hip Arthroplasty; VAS: Visual Analoge Scale.

[a]Values are presented as number and percentage; [b]Values are presented as mean and standard deviation.

MATERIALS AND METHODS

Study Design

Operating surgeons were blinded from randomization to minimize the risk of bias. The postoperative protocol involved full weight-bearing to tolerance from Day 1. A stratified and blocked randomization technique was applied with random sequences of varying block sizes (varying from $n = 2$, $n = 4$, or $n = 6$). The stratification factors included the operating surgeon and the patient's preferred sleeping position (supine, prone, on the side, combination/no clear preference). The preferred sleeping position was considered a relevant stratification parameter since we wanted to have an equal distribution of preferred sleeping positions between the groups. By including "preferred sleeping position" as a stratification parameter, the risk of having, for instance, a lot of preferred supine sleepers in the Restricted Group was avoided and vice versa. The preferred sleeping position was determined before randomization through a single question to the patients: "What is your preferred sleeping position?" The answer options included

the following: supine, prone, on the side, combination/no clear preference. Randomization occurred after the baseline assessment.

Nurses and physiotherapists experienced in working with total joint replacement patients cared for all patients. Patients in both study groups were separated in different rooms postoperatively. Also, the physiotherapist to whom patients were transferred after hospitalization was informed about the study protocol. The rationale behind these two measures was that the patients in the Unrestricted Group would not be unduly restricted and would not be made to deviate from their study protocol. Detailed written postoperative instructions were reviewed with each patient by nurses and the physiotherapist before discharge to ensure that each patient fully understood his or her assigned study protocol.

Ethics

Before the baseline measurement, all subjects provided their informed consent to participate by handwritten signature. The study was approved by an accredited medical research ethics committee (NL4670604413; P13-31 METC Twente) and a local institutional review board. The study was registered in ClinicalTrials.gov (NCT02107248).

Participants and recruitment

Patients were recruited from OCON Centre for Orthopedic Surgery and Sports Medicine (Hengelo, the Netherlands) between 2014 and 2017. Inclusion and exclusion criteria are illustrated in Table 1. The cohort was selected from a previously published randomized controlled trial (RCT) in which primary THA patients were allocated to a group that had to sleep supine and a group that was allowed to sleep in any position [10]. This RCT was designed as a single-center, parallel-group, stratified, and randomized trial in which primary THA patients were allocated to a Restricted Group or an Unrestricted Group.

Table 2. Patient demographics.

Inclusion criteria	Exclusion criteria
THA for osteoarthritis of the hip	THA for femoral neck fracture
Posterolateral approach	Contralateral THA scheduled within 6 monthsa
Written informed consent provided by the patient	Mental incapacity, or inability to fill in the questionnaires in Dutch
ASA-classification I or II	Wheelchair dependency
	Infection involvement
	Blindness
	Alcohol abuse
	Neurological and hypermobility disorders

[a]The first hip was eligible for the study, and the second is an exclusion criterion.

Procedure

Eleven orthopedic surgeons specialized in hip surgery performed the THA operations. The surgical approach was a standard posterolateral approach with the use of a capsular repair. The implants used were as follows: Exceed ABT Ringloc-XShell (Biomet Orthopedics), E-Poly Hi-Wall Liner (Biomet Orthopedics), Modular Taperloc complete femoral stem (Biomet Orthopedics), and Biolox Delta Modular Ceramic Head 32 mm.

All patients were educated to avoid activities in which the hip joint is moved into a position of flexion over 90°, adduction, or rotation past the midline. The only difference between the two groups was that the Restricted Group was instructed to sleep in the supine position for the first 8–10 weeks following THA surgery, whereas the Unrestricted Group did not receive any precautions on sleeping position. None of the patients had to use a pillow between the legs during sleep, and additional equipment was not routinely prescribed (i.e. crutches, toilet seats). All patients received a standard set of range-of-motion precautions aimed at avoiding extreme flexion, abduction, and/or rotation of the hip joint. For both groups, the postoperative protocol involved full weight-bearing to tolerance from Day 1. Information regarding these precautions is part of the information brochure patients received from the orthopedic surgeon when obtaining their consent for surgery at the outpatient department. Immediately after surgery on the ward, patients were handed out a leaflet by a physiotherapist specifically explaining all precautions. A physiotherapist supervised exercise with individual patients during hospitalization and provided any clarification needed about the precautions. Before leaving the hospital, patients received a standardized discharge letter, including instructions on exercise and precautions. Patients were instructed to hand over this letter to the outpatient physiotherapist, which they could choose themselves.

At the time of discharge from the hospital, patients were given a follow-up paper-and-pencil survey to be used as a self-administered diary to track compliance and burden with movement and sleeping precautions. Compliance with movement precautions was recorded by a set of questions previously used by Peak et al. in their follow-up questionnaire and named as leg position precautions. Similar statistics, that is, mean compliance, were calculated so that we could compare our results with those of Peak et al. The burden of movement and sleeping precautions were recorded on a 0- to 10-point scale. The median score and the interquartile range were calculated.

A score of the third quartile or more was considered burdensome. These completed diaries were returned to the nurse practitioner at the first postoperative visit, 8–10 weeks after surgery.

Furthermore, a digital survey was completed at the first postoperative visit. Patients who did not own a computer or were reluctant to use one were handed hard copies of the questionnaire.

This survey was designed to evaluate patients' compliance with the set of precautions provided by our clinic in the patient information brochure. Patients were considered compliant when they followed a precaution often or always. Patients who were not able to return for follow-up or who did not complete their surveys were contacted by telephone and/or mail as a reminder.

Data Analysis

Statistical analyses were mainly presented descriptively (frequency tables) and differences between study groups were tested using Fisher's exact test. The level of significance was set at $p = 0.05$. A Bonferroni correction was applied to correct for multiple testing biases.

The statistical analysis was performed with the computer program IBM SPSS Statistics 24.0. Before the start of the study, a power analysis was performed. The maximum allowable difference in proportion that still preserves equality of effect is unknown in the literature. Previous studies suggested "a threefold difference in dislocation rate" to be a clinically relevant difference. Since the literature suggests an average dislocation rate of 2.03% in the posterolateral surgical approach, a dislocation percentage between 2.03% and 6.09% is considered to be "equal." Hence, the planned sample size is $n = 456$ (where n is the number of THA patients) based on a non-inferiority hypothesis (One-sided, $\alpha = 0.025$, $\beta = 0.80$, lost to follow up 20%). The sample size was calculated by using the program PASS 16 (NCSS Statistical Software

RESULTS

Of the 848 patients who were assessed for eligibility, 408 were included for randomization. At 8 weeks follow-up, $n = 343$ patients (84%) returned the paper-and-pencil diaries and $n = 346$ patients filled out the online survey (85%). Missing data were not included in the analysis of that specific question (Figure 1).

Patient demographics and baseline outcomes of the questionnaires are presented in Table 2. None of the patient demographics and the baseline PROMs (patient-reported outcome measurements) indicated any statistical difference between the Restricted Group and the Unrestricted Group ($p > 0.14$). No significant difference was found between the self-reported preferred sleeping position between the groups, implying that the randomization was successful ($p = 0.695$).

A Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing the enrollment, randomization, assigned interventions, and follow-up of the study.

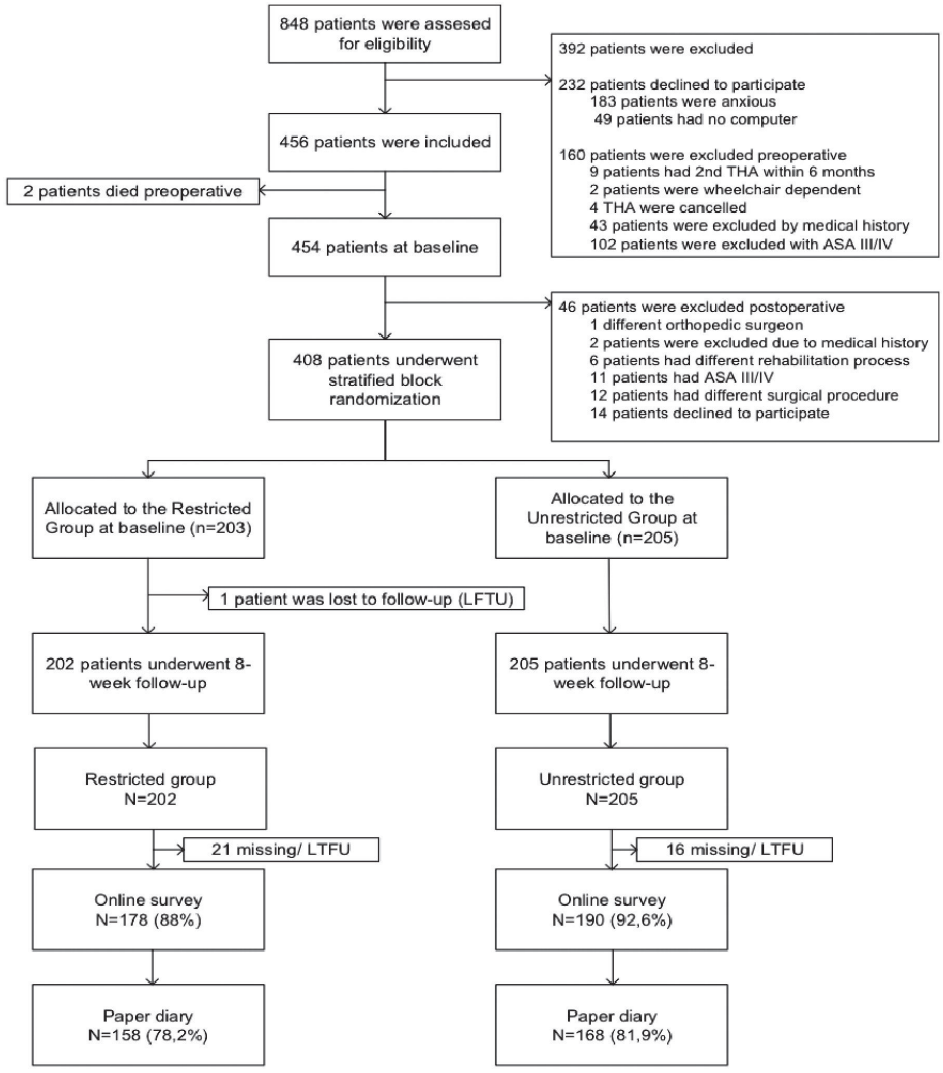

Figure 1. CONSORT flowchart.

During the first 8 weeks postoperative, patients in the Unrestricted Group significantly kept sleeping fewer days per week in a supine position compared to patients in the Restricted Group (p = 0.000). During the first 2 weeks postoperative, 29% in the Unrestricted Group slept every day in supine, whereas in the Restricted Group this was 81% (Figures 2 and 3). At 8 weeks postoperative, this was 2% in the Unrestricted Group and 37% in the Restricted Group (Figures 4 and 5).

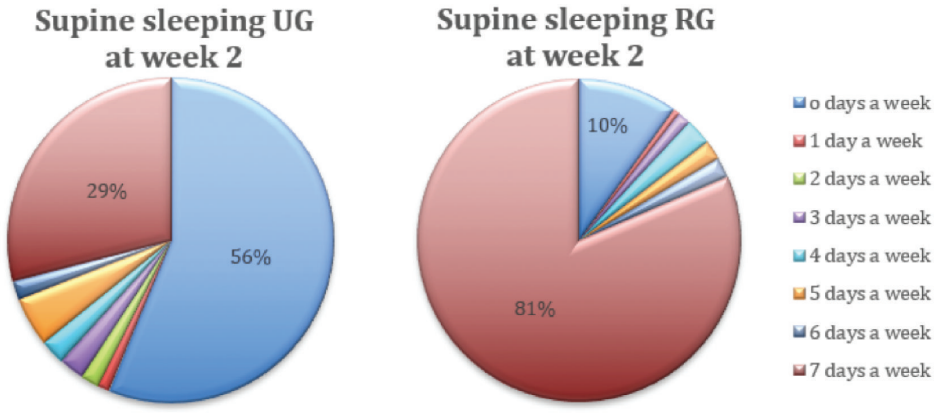

Figure 2. Percentage of patients in the Unrestricted and Restricted Group sleeping supine at 2 weeks postoperative. A pie chart showing in color the percentage of patients sleeping supine two weeks after surgery, the number of days in the week.

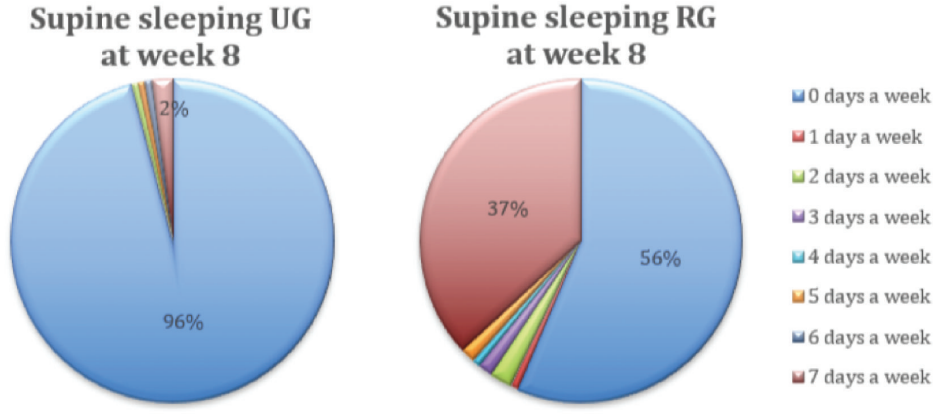

Figure 3. Percentage of patients in the Unrestricted Group and Restricted Group sleeping supine at 8 weeks postoperative. A pie chart showing in color the percentage of patients sleeping supine eight weeks after surgery, the number of days in the week.

No significant differences between the two groups were found in the percentage of time they avoided the movement precautions prescribed by their orthopedic surgeon ($p > 0.05$). Compliance with movement precautions was high in both groups (>90%) (Table 3). Significant differences between the two groups for complying with our clinic-specific precautions were found for placing the operated leg forward when sitting down and sleeping with a pillow between the legs. However, the Unrestricted Group was instructed that there was no need to comply with sleeping with a pillow between the legs (Table 4).

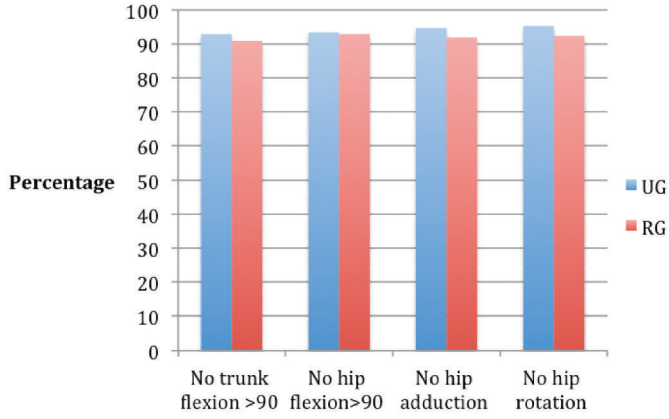

Figure 4. Compliance with movement restrictions. A bar chart showing in color the difference in compliance with movement restrictions for the unrestricted and the restricted group.

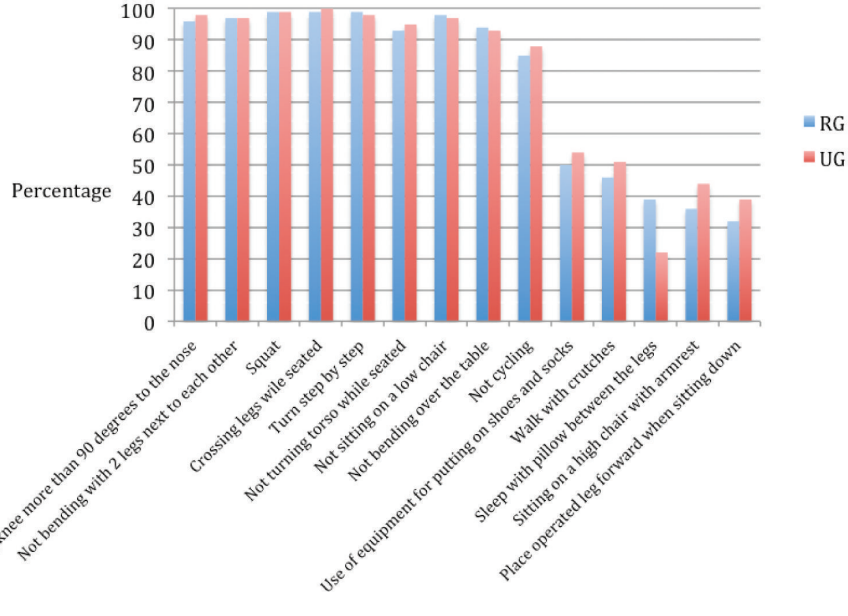

Figure 5. Compliance with functional restrictions. A bar chart showing in color the difference in compliance with functional restrictions for the unrestricted and the restricted group.

In general, compliance with our clinic-specific precautions shows a less distinct picture. Compliance with movement-directed precautions is high, such as bending the knee more than 90°, squatting, crossing the legs while seated, and bending forward with the legs next to each other. Compliance decreases with precautions towards functional restrictions, such as cycling or sitting on a high chair, and compliance decreases further for the use of additional equipment, such as crutches and the use of aids to put on shoes and socks (Table 4).

Table 3. Rates of compliance with range of motion restrictions between Restricted Group (RG) and Unrestricted Group (UG) according to self-administered diary [17].

		Percentage of time avoided						*p*	Mean percentage (%)[a]
		0%	25%	50%	75%	90%	100%		
Trunk flexion >90°	UG	4	4	4	15	22	119		91
	RG	6	4	4	12	20	107	0.981	90
Hip flexion >90°	UG	4	6	1	2	12	142		94
	RG	4	5	2	3	12	129	0.994	93
Hip adduction (crossing legs)	UG	7	0	2	3	7	149		94
	RG	9	2	2	6	14	125	0.226	91
Hip endo/exorot	UG	4	2	2	11	12	137		94
	ation RG	6	4	2	7	16	120	0.681	91

[a]Added to be able to compare our results with Peak et al.

We analyzed the burden that patients experience for movement precautions and for the precautions to sleep in a supine position using a 10-point scale. The median score (3.0) and the interquartile range (1.0–6.0) were calculated. A score of the third quartile (6.0) or more was considered burdensome, and we calculated the percentage of burdensomeness (Figures 6 and 7). Generally, the burden of sleeping precautions (63%) seems higher than the burden of movement precautions (29%). In the Unrestricted Group, the sleeping precaution was removed, and this significantly lowered the burden of this precaution (p = 0.000) without influencing the burden of the movement precaution (p = 0.15) (Table 5).

DISCUSSION

The routine use of precautions following THA using a posterolateral approach is subject to a trend in minimizing these precautions. One of the remaining challenges is determining which precautions are useful to continue and which should be stopped. Compliance with precautions can help in this decision. However, little is known regarding compliance with precautions, and even less is known about compliance with the remaining set of precautions when one precaution is removed from the postoperative precaution protocol.

In our study, the precaution to sleep in a supine position was removed in the Unrestricted Group and continued in the Restricted Group. The Restricted Group significantly slept more days in a supine position than the Unrestricted Group without affecting compliance with the remaining precautions. Patients also graded this supine sleeping position as more burdensome than the unrestricted sleeping position. Therefore removing sleeping precautions from the postoperative protocol in THA seems to be beneficial.

Table 4. Rates of compliance with movement daily life restrictions (online survey).

		Never	Seldom	Regularly	Often	Always	*p*
Bending the knee more than 90 degrees towards the nosea	RG	107	41	22	7	1	0.732
	UG	117	46	21	4	0	
Bending over from position with two legs next to each otherb	RG	119	45	8	4	1	0.683
	UG	124	45	15	3	2	
Squatb	RG	154	16	8	1	0	0.658
	UG	156	24	8	2	0	
Crossing legs while seatedb	RG	154	20	4	1	0	0.390
	UG	166	22	1	0	0	
Avoid extreme overloadingc	RG	4	6	13	38	114	
	UG	10	7	21	33	118	0.360
Turning the torso while seatedd	RG	62	69	34	7	5	0.590
	UG	77	73	30	8	2	
Turn step-by- stepe	RG	115	48	14	1	0	0.722
	UG	125	44	17	3	0	
Place the operated leg forward when	RG	0	11	45	37	83	0.011
	UG	7	6	60	26	87	
Walk with crutchesg	RG	25	15	38	36	54	0.157
	UG	36	18	41	30	60	
Additional equipment in putting on stockings and shoesh	RG	38	22	30	19	70	0.942
	UG	43	28	32	19	68	
Sleep with pillow between the legsi	RG	58	17	35	15	54	0.000
	UG	84	36	26	13	29	
Bending over the tablej	RG	60	75	32	9	2	0.627
	UG	77	67	32	11	3	
Sitting on a low chair or stoolj	RG	101	57	16	3	1	0.318
	UG	106	69	9	2	4	
Cyclingk	RG	80	21	49	20	6	0.469
	UG	91	33	44	16	6	
Sitting on a high chair with armrestl	RG	12	28	23	45	69	0.211
	UG	22	35	26	32	73	

[a]analysis based on *n* = 188 UG and *n* = 178 RG patients, [b]analysis based on *n* = 189 UG and *n* = 177 patients, [c]analysis based on *n* = 189 UG and *n* = 175 RG patients, [d]analysis based on *n* = 190 UG and *n* = 177 RG patients, [e]analysis based on *n* = 189 UG and *n* = 178 RG patients, [f]analysis based on *n* = 186 UG and *n* = 176 RG patients, [g]analysis based on *n* = 185 UG and *n* = 168 RG patients, [h]analysis based on *n* = 190 UG and *n* = 179 RG patients, [i]analysis based on *n* = 188 UG and *n* = 179 RG patients, [j]analysis based on *n* = 190 UG and *n* = 178 RG patients, [k]analysis based on *n* = 190 UG and *n* = 176 RG patients, [l]analysis based on *n* = 188 UG and *n* = 177 RG patients.

Table 5. Rates of burdensomeness of movement and sleeping restrictions (online survey).

		0 Not burdensome	1	2	3	4	5	6	7	8	9	10 Highly burdensome	*p*
Moveme restrictio	nRt G	24	22	19	25	10	18	11	15	10	4	8	0.150
	nsa UG	49	28	16	14	7	16	10	11	8	5	6	
Sleeping position restrictio	RG	13	15	8	9	5	12	9	16	32	21	27	**0.000**
	$_{n}U_{b}$ G	73	23	14	12	4	12	2	7	14	9	4	

[a]Analysis based on *n* = 170 UG and *n* = 166 RG patients, [b]analysis based on *n* = 174 UG and *n* = 167 RG patients.

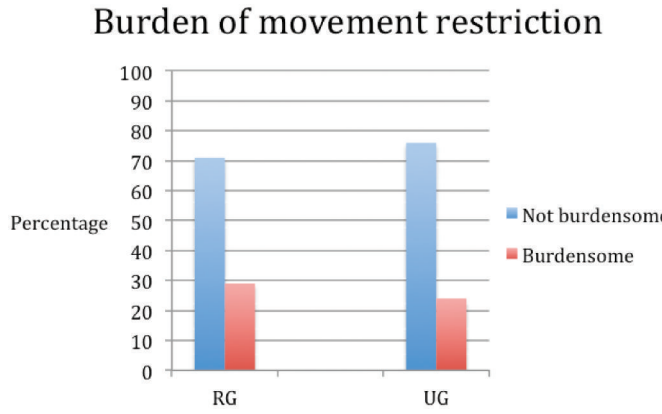

Figure 6. Burden of movement restrictions. A bar chart showing in color the difference in the burden of movement restrictions for the unrestricted and the restricted group.

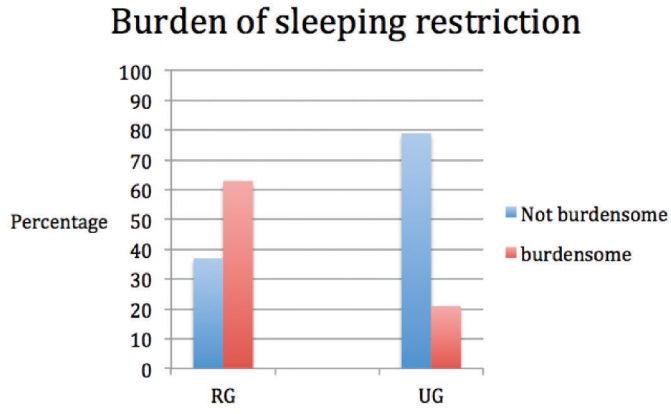

Figure 7. Burden of sleeping restrictions. A bar chart showing in color the difference in the burden of sleeping restrictions for the unrestricted and the restricted group.

In our study, compliance with movement precautions was high. Other clinic-specific precautions following THA showed a less distinct picture regarding compliance. For example, precautions related to the movement of the hip joint, such as squatting and crossing legs, showed higher compliance than compliance with the use of equipment to put on shoes and socks or the use of crutches. But also sitting on a high chair and putting the operated leg forward when sitting down showed compliance of less than 50%. Whether this is explained by the amount of emphasis put on these precautions by surgeons and physiotherapists or the perceived relevance regarding these precautions by patients was not analyzed in this study. The explanation is probably more complex since compliance is influenced by psychosocial factors, education, understanding, motivation, support system, cultural beliefs, and underlying psychiatric disease [16]. Literature regarding compliance with precautions following THA is scarce, not measured uniformly, and therefore difficult to compare. The study by Peak et al. resembled our protocol in which both interventions groups received the same movement precautions since these were not part of minimized set of precautions following THA [17]. Peak et al. found mean compliance regarding movement precautions of 90–96%. These mean percentages are comparable to the mean percentages in our study 91–94% regarding movement precautions. However, Peak et al. found a significant decrease in compliance with movement precautions in the less restricted group, whereas, in our study, a change in compliance with movement precautions in both groups was not observed [17]. This can be attributed to the anterolateral surgical approach used in the study by Peak et al., in which dislocation due to deep flexion is less likely to occur compared to the posterolateral approach used in our study.

Two previous randomized trials have described compliance with precautions following THA with a posterolateral approach. Details of the self-designed questionnaires are only mentioned in one of these studies. Both studies only looked at movement precautions. The first was a study by Dietz et al. in which compliance was 95% in the first 2 weeks and 90% after 6 weeks [9]. In our study, 81% of the restricted patients were fully compliant (sleeping 7 days a week supine) the first 2 weeks. At 8 weeks, this was 37%. This suggests that patients are less compliant regarding sleeping precautions compared to movement precautions as time goes by. The second was a study by Tetreault et al. [11]. In this study, 25.4% admitted failure to observe some or all of the prescribed hip precautions at 6 weeks, suggesting that 74.6% was compliant towards movement restrictions at 6 weeks. This is lower than in our study. Whether the less compliant patients were amongst patients in whom a dual mobility construct or large femoral head (40 mm) was used is not known. These large-diameter femoral heads, used in the study by Tetreault et al., are less likely to dislocate and the precautions might therefore have seemed less relevant to patients and therapists [11,18]. In our study, all patients received a 32 mm femoral head.

A self-designed survey study by Lee et al., using various surgical approaches, looked specifically at functional precautions and ADL activities [19]. In that study, 77% of patients were unable to comply with all precautions.

Besides differences in compliance between specific precautions, we found differences in burden between specific precautions. Our study showed that 63% of patients experienced the sleeping precautions as burdensome. The negative effect on sleeping with precautions and better sleep leading to less musculoskeletal pain has been shown in previous studies [15,17,20].

Only 29% of patients in our study graded movement precautions as burdensome.

Although no previous study analyzed the burden of movement precautions, in the studies by Dietz and Tetrault a fair number of patients 28% and 22.1%, respectively in the Unrestricted Group complied with movement precautions, although this was not mandatory [9,11]. This behavior is not likely if patients consider movement precautions as highly burdensome, and it can be an expression of perceived relevance regarding movement precautions.

Lightfoot et al. studied these patient perceptions regarding precautions [15]. In their study, they found that patients hold mixed opinions towards precautions. On the one hand, precautions provided guidance, but on the other hand, precautions caused anxiety because of uncertainty about how to perform certain movement patterns of everyday activities, such as picking something up off the floor. This lack of clarity regarding precautions can be tackled by a so-called pose avoiding protocol as suggested by Allen et al. or the use of an ambulant dislocation alert system that uses sensors to alert patients during daily activities when they move the hip joint into an unsafe position [21,22].

Future research should focus on implementing such technology to assist patients by providing guidance and individualized care. Data from such technology can then also be used to objectively analyze which factors (patient, surgical, implant) influence the achievement of certain postoperative goals.

Our study has several limitations. Firstly, we looked at self-reported compliance. It has been shown when this is compared with objective data obtained using cameras or sensors, that patients overestimate their level of compliance [14,17,20]. However, if cameras or sensors are used to monitor true compliance, patients will probably behave differently when wearing this equipment, and that this will not be a true reflection of their daily routine. Second, comparing the compliance found in our study with that in the existing literature is complex since there is no uniform scoring system to measure compliance regarding precautions. Therefore, to make such a comparison possible, we decided to use the self-administered diary previously used by

Peak et al. [17]. Thirdly, previous THA can cause bias by the experience of the first rehabilitation. To minimize this bias previous THA within 6 months was an exclusion criterion (Table 1).

The strength of our study is its design. It is the first randomized and stratified study to analyze compliance with precautions following THA and the effect on the remaining set of precautions when one specific precaution is removed. Furthermore, all patients underwent the same surgical approach and were implanted with a 32 mm femoral head.

In conclusion, our results show that removing the precaution for patients to sleep in a supine position following THA effectively lowers the burden of this precaution without affecting compliance with the remaining set of precautions. Compliance with movement precautions is high compared to other precautions. Therefore, our results can help to change longstanding protocols in posterolateral THA. This change will improve postoperative sleep and thereby improve rehabilitation following THA

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Chapter 6

Patient needs for an ambulant dislocation alert system following total hip arthroplasty

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ABSTRACT

Introduction

One of the major complications in total hip arthroplasty (THA) is dislocation of the prosthesis. To prevent early dislocation, patients are instructed with movement restrictions. The first goal of this study is to obtain insight in the movement restrictions that are reported to have low levels of self-efficacy during activities of daily life. The second goal of this study is to reveal the design needs for an ambulant hip dislocation alert system (HipDas).

Methods

Patient-centered experiences with THA were explored by the use of a questionnaire and semi-structured focus group. The questionnaire was administered among n=32 THA patients at 1 week pre-operative and at 3- and 6 weeks post-operative. The questions addressed self-efficacy, performance and effort expectancy and perceived usefulness and social influence. The focus group consisted of patient-journeys and scenario composition.

Results

Flexion of the hip >90°, bending over while sitting in a chair and sleeping in a supine position are the restrictions that have the lowest self-efficacy. The majority of patients (>86.6%) believe that a future HipDas is useful in preventing dislocation following THA and considerer themselves moderately capable in dealing with technology. The daily time preparing the system should not exceed 14 minutes. Focus group outcomes suggest there is a gradual decrease in the threshold for feedback. The system is preferably used in the first 6 weeks after surgery.

Discussion

Patients feel insecure on how to comply with movement restrictions during their daily activities. Interesting THA specific patient needs and system requirements are identified.

INTRODUCTION

In Total Hip Arthoplasty (THA) the hip joint is replaced by a prosthetic implant. It is a high-volume surgical procedure that reduces pain and improves function and quality of life(1). Dislocation is a frequent and costly complication of hip arthroplasty(2) and is a substantial source of patient morbidity. The majority of dislocations occur in the first three months following surgery and the incidence of dislocation varies from 0.2% to 7% after primary THA and 10% to 25% after revision THA. (3). In order to minimize the risk of these early dislocations, patients are instructed to avoid hazardous movements(4). These movements contain deep flexion and internal rotation of the hip, crossing legs, deep crouching and raising the knee more than 90° towards the chest. One of the prognostic factors for dislocation is the efficacy of patients to comply with postoperative movement restrictions(5). Many patients feel anxious and insecure during their daily activities without supervision because they are aware of the risk of dislocation when incorrectly applying the movement restrictions. Consequently, patients tend to avoid or postpone these activities in the unsupervised situation of their daily lives.

An ambulant dislocation alert system (HipDas) following THA can automatically warn people when approaching critical hip angles. This will provide confidence to patients and may prevent dislocations. Moreover, one could hypothesize that by means of such technological support patients will resume their daily activities earlier, thereby increasing the effectiveness of their functional recovery after THA.

In this study, we explored patient-centered experiences with THA restrictions and prototypes of relevant technologies in defining the user and task requirements to design the actual HipDas. The first goal in this development is to obtain insight in the movement restrictions that are reported to have low levels of self-efficacy during activities of daily life (ADL). The second goal is to reveal the design needs of HipDas.

METHODS

Patient-centered experiences with THA were explored through a questionnaire (phase 1) and semi-structured focus group (phase 2) (Fig1).

All participants were recruited from the outpatient department of OCON, Centre for Orthopeadic Surgery Hengelo in the Netherlands. The researchers had access to this population. Patients received an information letter by mail at least 10 days prior to their consultation with the surgeon. The study was officially exempt from medical ethical assessment by the Medical Ethical Committee of the Slotervaart hospital (registered under number P1549).

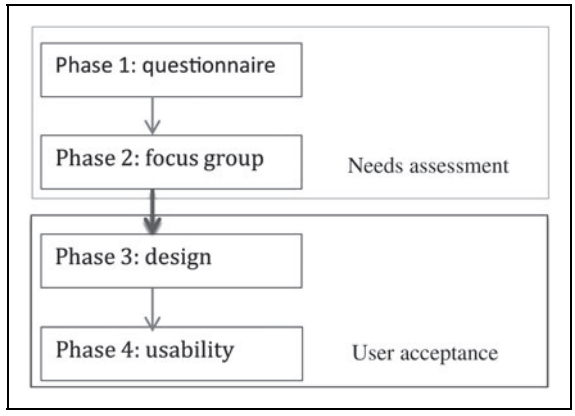

Figure 1 *Flowchart study*
The questionnaire study included 23 patients (12 female, average age: 68 ± 6.9 years) who were approached prior to their total hip arthroplasty. In order to obtain a representative sample, subjects were matched by age (age ≤ 70 years; age > 70 years) and gender.

For the focus group, we invited three THA patients and three of their informal caregivers (n=6 participants). We aimed for an optimal group size of 4 to 8 participants so they could speak freely about their treatment and care providers. Both the questionnaire study and the focus group were used to develop a general "participants journey" regarding their self-efficacy in complying with the movement restrictions.

Phase 1 Questionnaire setup

The questionnaire was administered at 1-week pre-operative and at 3- and 6 weeks post-operative, n=32 THA patients were asked to fill out a questionnaire (**Fig 2**).

The questions concerned their compliance with the movement restrictions and self-efficacy expectations of applying movement restrictions for various ADL with and without the use of HipDas. The questionnaire is designed semi-methodically with a combination of the Attitude Social influence Self-Efficacy (ASE) model and the Unified Theory of Acceptance and Use of Technology (UTAUT) model(6).

The first part of the questionnaire covers the understanding of the user and task requirements for which patients had to report their perceived level of self-efficacy in complying with each of the 13 movement restrictions prescribed by their surgeon and physiotherapist. The second part covers the attitude towards technological acceptance of a future HipDas, for which four key constructs were defined: 1) performance expectancy, 2) effort expectancy, 3) social influence, and 4) facilitating conditions.

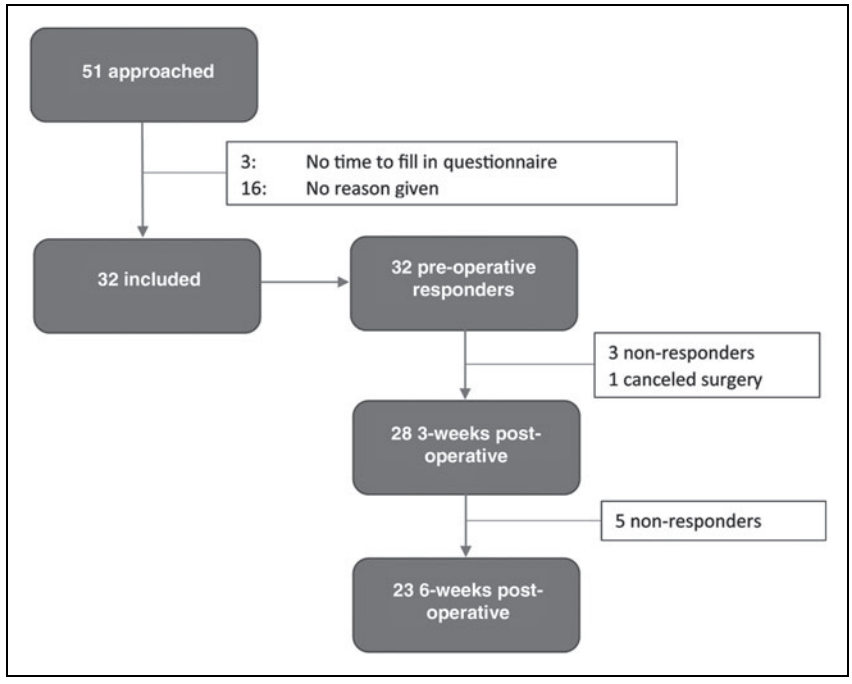

Figure 2 *Response chart questionnaire study*

Figure 3 *Illustrative screenshot to visualize the concept of ambulant anti-dislocation alarming system following total hip arthroplasty*

Phase 2 Focus group setup

All participants provided an informed consent and agreed to audio and video recording. The participants were assured that they would remain anonymous and that their decision to participate would not affect their treatment or professional position in any way. The structure of the focus group is presented in Table 1 below.

Table 1. Focus Group Elements, Methods, and Aims

Focus group element	Method	Aim
Introduction	The focus group started with a presentation of the results obtained from the questionnaire round. We anticipated that it would be difficult for participants to verbalize their thoughts on a HipDas concept in order to increase their self-efficacy. To help them, we provided a screenshot illustrating the concept (figure 3). The screenshot shows the wirelessly connected sensors (i.e magnetic sensors, stretch sensor integrated in a garment and the smartphone to which the measured data is real-time visualized for the patient. We used the results from the questionnaires and the screenshot as a discussion starter.	To evoke end-users' thoughts on the value of technology as part of their pre- and postoperative treatment.
Patient journeys, current and future	Individually, patients constructed their patient journey, which served as an outline of the process that an individual patient follows and indicates where lack of self-efficacy played an important role(7). We used visual material to support this session, i.e a large sheet of paper on which the participants could draw the stakeholders surrounding their postoperative rehabilitation trajectory and write down their thoughts on the use of an ambulant dislocation alert system in the different contexts of use (i.e. living room, kitchen, bed room, outside). Participants marked down where they thought ambulant sensing and feedback of critical hip joint angles plays an important role.	To gain insight in the stakeholders, difficulties patients encounter before, during and after their surgery
Composition of a scenario	Based on the information collected during the workshop participants were instructed to write a scenario about their ideas on future use of HipDas. In the process of writing the scenario they were assisted by the workshop leaders. Crucial elements to be included in the scenario were the People, Activities, Context and Technology (PACS) that were part of their storyline describing the future use of HipDas(8).	To specify the concrete use of HipDas
System buildings blocks and preferences	Different sensing modalities w ere shown to the participants in order to start a discussion on usability in real life.	To define placement of sensors, calibration of sensors, comfort of the sensor garment, feedback interface, authorization of sharing sensor and feedback information, preferred feedback modality, the content of the feedback as well as the feedback frequency.

HipDas, hip dislocation alert system.

Data Analysis

Bar graphs will present the percentage of respondents that perceived a low self-efficacy score (</= 3 on the 7-point answering scale) for the different type of restrictions at different moments in time (baseline, 3 and 6 weeks post THA surgery). Descriptive statistics (mean, SD) were collected to investigate the attitude, performance expectancy, effort expectancy, social influence, facilitating conditions, and self-efficacy of HipDas to be developed. In order to correct for social desirable answers, the percentage of patients who scored in the upper extreme of the answering scale (>5 on a 7 point scale; >7 on a 10 point scale; indicating a positive opinion/ confidence) was presented.

During the focus group, all participants made their own visualization of a patient journey and models of sensing and feedback. Two analysts (RH and AP) grouped similar responses to identify which factors were named most often regarding issues about lack of self-efficacy and the possibilities of wireless sensor technology. Any disputes were resolved by discussion(9). The audio recordings were analyzed on a per-question basis, using inductive thematic analysis(10). For each predefined question that was posed, similar answers were grouped. We determined whether there was no agreement, some agreement, partial agreement, or full agreement among the participants. Final analyses focused on making an inventory of the building blocks and functional requirements obtained from both the questionnaire and the focus group data. Based on the information collected, participants and their informal caregiver were instructed to write a scenario about their ideas on the future use of HipDas. In the process of writing the scenario they were assisted by two workshop leaders. Crucial elements to be included in the scenario were the People, Activities, Context and Technology (PACS) which were part of their storyline describing the future use of HipDas(8). A schematic architecture of a future HipDas was composed.

RESULTS

Phase 1 Questionnaire study

Self-efficacy life style restrictions

Results show that 6 weeks after surgery flexion of the hip >90°, bending over while sitting in a chair and sleeping in a supine position are the restrictions that have the lowest self-efficacy for the respondents. Amongst the movement restrictions that are reported to be low in self-efficacy are deep squatting, crossing legs and sitting down with the operated leg in front (Figure 4).

Performance expectancy

Prior to THA surgery, the majority of patients (>87%) expected HipDas to be a highly useful device in their post operative rehabilitation (mean 6.2 SD 1.2) (Table 2).

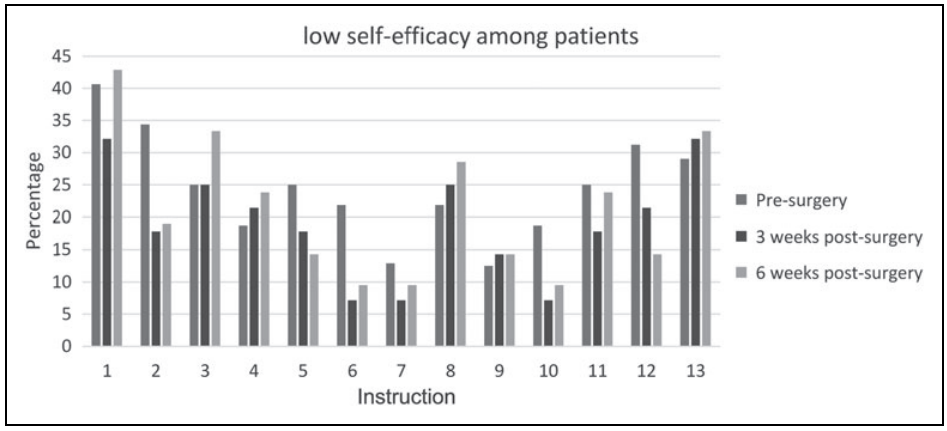

Figure 4 *Percentage respondents reporting low self-efficacy per restriction rule: pre-surgery, 3 and 6 weeks post surgery. Question 1 = Don't bend the hip more than 90°. 2 = don't bend over to put on socks and shoes. 3 = Don't bend over while sitting. 4 = Don't reach over a table. 5 = Don't bend over from an upright position with parallel legs. 6 = Don't squat. 7 = Don't cross the legs. 8 = Don't initiate a turning movement on one leg. 9 = Don't sit on a low chair. 10 = Put one leg in front when getting seated. 11 = Don't rotate the upperbody whilst seated. 12 = Turn step by step, on the uninjured leg. 13 = Sleep on your back. (n=32)*

Patients are on average positive about the performance of HipDas in terms of compliance with movement restrictions, prevention of dislocation and the accessibility of the registered hip angles by their physiotherapist (Table 2). Interestingly, the expected performance of HipDas about its potential to support their compliance with movement restrictions is declining at 3 and 6 weeks post surgery (76%). Nevertheless, it is still considered relevant by the majority of patients.

Effort expectancy

A small majority of patients considered themselves 'moderately' (average score 6,4 SD 2.2 on 10 point rating scale) capable of dealing with technology in general. In addition, the perceived effort to work with HipDas in particular is rated rather similar to technology in general (6.0 SD 2.1) (Table 2). The time willing to spend daily setting up the system should be limited to 13-14 minutes.

Attitude

The majority of patients (>90%) believed using HipDas is a good idea (mean <6.1, SD 1.0). The lowest score (mean 4.8, SD 1,8; 71%) on attitude was found for the item stating whether the use of HipDas makes it more attractive to comply with movement restrictions. Scores decline in the course of the 6 weeks, suggesting the need for HipDas is most salient in the acute periode after THA surgery. The majority of patients were convinced about the fun of using HipDas (mean 4.9 SD 1,5, 83% extremely convinced). (Table 2)

Table 2 Perceived score of HipDas system on UTAUT components according to patients (n= 32).

	Baseline			3 weeks			6 weeks		
	Mean	(SD)	% +	Mean	(SD)	% +	Mean	(SD)	% +
Performance Expectancy (7 pt)									
Do you think this device is useful in the first weeks post-surgery?	6,2	(1,2)	87	6,3	(0,8)	96	6,4	(0,9)	95
Would this device make it easier for you to follow the restrictions?	5,8	(1,4)	87	5,0	(1,7)	77	5,1	(1,9)	76
Do you think less hips would dislocate after surgery when this device is used?	6,3	(0,9)	97	5,9	(1,2)	92	5,9	(1,4)	90
Would you like the physiotherapist to be able to follow-up on the rehabilition through this device?	5,9	(1,1)	93	5,0	(1,6)	80	5,6	(1,3)	95
Effort Expectancy (10 pt)									
What grade would you give yourself in terms of skill in technology?	6,4	(2,2)	67	6,2	(2,2)	60	6,2	(1,9)	43
How hard do you expect it is to use this device	6,0	(2,1)	68	6,1	(1,8)	64	6,3	(1,9)	57
Attitude (7 pt)									
Do you think using this system in the first few weeks after hip surgery is a good idea?	6,1	(1,0)	90	6,3	(1,0)	92	6,1	(1,0)	95
Does the device make adherence to the restrictions more interesting for you?	5,4	(1,3)	86	4,8	(1,8)	72	4,8	(1,8)	71
Would the device make it more fun for you to recover after hip surgery?	4,9	(1,5)	83	4,9	(1,7)	83	5,5	(1,4)	90
Would you like using the device to recover after hip surgery?	5,6	(1,6)	80	5,8	(1,3)	96	5,9	(1,0)	100
Social Influence (7 pt)									
How important is the opinion of the docter/physiotherapist in using this device?	6,3	(0,8)	90	5,4	(1,2)	76	5,6	(1,2)	81
How important is the opinion of the people close to you in using this device?	5,3	(1,9)	63	4,7	(1,3)	48	4,6	(1,7)	67
How important is the helpfulness of the surgeon/physiotherapist helpful in using this device?	6,4	(0,9)	90	5,6	(1,3)	72	6,0	(0,8)	86
How important is the opinion of OCON to you in using this device?	6,4	(0,9)	87	5,9	(1,1)	80	6,1	(0,6)	95
Facilitating Conditions (7 pt)									
Is there someone who can help you with this device?	5,3	(1,9)	71	4,5	(2,2)	52	4,0	(2,1)	43
Is there anything in your life that makes it impossible to use this device?	6,6	(0,7)	7	6,0	(1,2)	14	5,9	(1,6)	14
Self-efficacy (7 pt)									
Do you want to have the possibility to contact someone for help?	7,0	(0,1)	100	6,1	(0,9)	87	5,8	(1,0)	86
Do you want a built-in help function?	6,3	(1,1)	90	6,4	(0,8)	91	6,3	(0,6)	100

%+ = percentage of respondents scoring on the upper extremity (indicating positive about HipDas) of the answering scale.

Social influence

The majority of patients uttered the importance of positive support from their surgeon (80-95%), their physiotherapist (76-90%) and to a lesser extent their informal caregivers (48-67%) in using HipDas (Table 2).

Facilitating Conditions and self-efficacy

A minority of patients (43%) reported to have no available assistance to support in the proper use of HipDas . The majority of patients (86%) believed that the use of the system in daily life could be hampered by co-moribidities, such as visual or hearing impairment. Likewise, the majority of respondents believed their self-efficacy levels for using HipDas could be improved by a helpdesk or an assistance button (Table 2).

Phase 2 Focus group results

Stakeholders involved in the THA trajectory are presented (Figure 5). These stakeholders are likely involved when using HipDas. A typical usage scenario is presented (appendix 1).

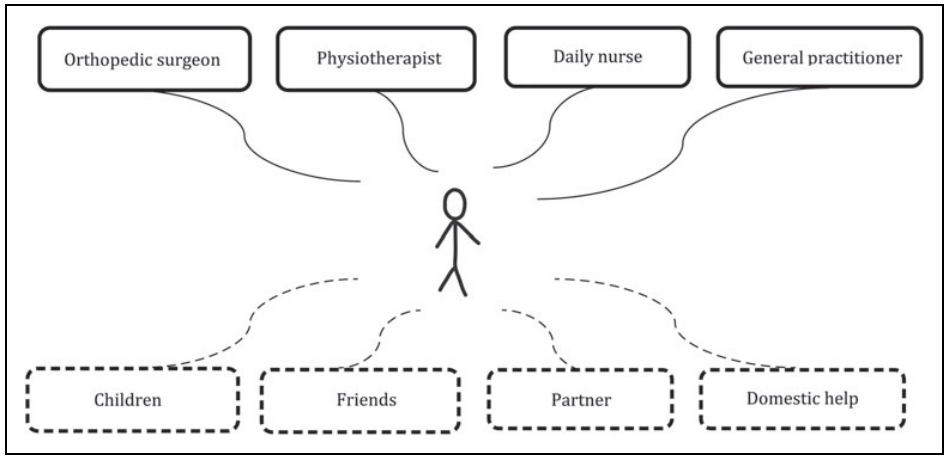

Figure 5 *Stakeholders typically involved in THA trajectory of patients (red = informal caregivers; blue = formal caregivers)*
A schematic overview of the issues addressed during the focus group is presented in Figure 6.

In general, all participants emphasize the difficulty of translating the rather generic restrictions (i.e 'avoid deep flexion') to their personal ADL situation ('will sitting on my garden bench be allowed?'). All participants, except for one, endorsed the idea of wearing a system that will actively and automatically warn in the event of an increased risk for dislocation. The participant who did not endorse this idea criticized the system for making a patient too reliant on this type of feedback (i.e 'what if the system is removed after a couple of weeks? How do you know what is and what is not a safe movement?'). Consequently, a discussion started on how to decrease a patient's dependency on the system. It was suggested to gradually decrease the threshold for

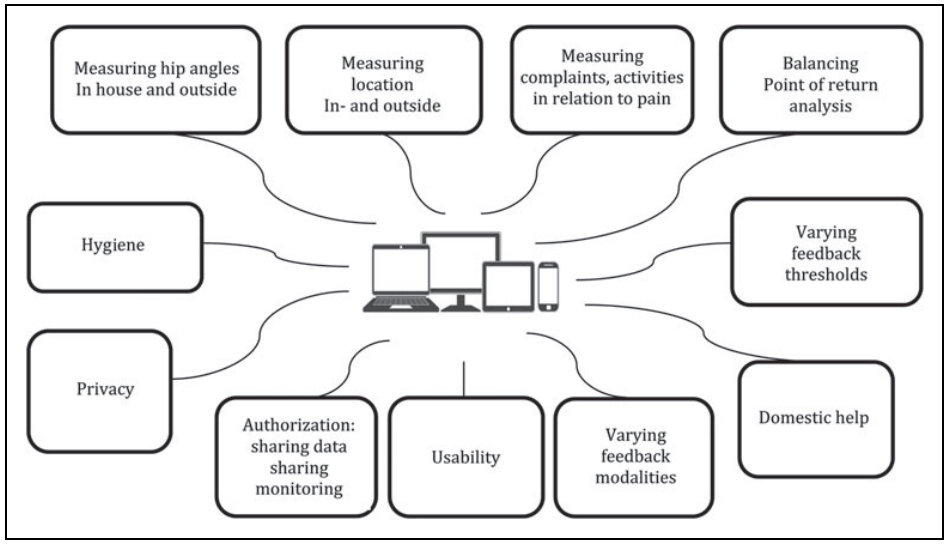

Figure 6 Topics discussed in the focus group

feedback on critical hip angles in the course of the rehabilitation trajectory, e.g. implementing different feedback algorithms ranging from 'extremely safe' to 'safe'. In particular, all attendees reported low levels of self-efficacy in complying with the following restrictions: putting on socks, sleeping in a supine position ('In order to minimize the risk of dislocation during sleep, I slept with a pillow between my legs'), rising from the chair, hip-bending (hip flexion), sitting in a chair or on the toilet ('I have bought an elevated toilet seat in order to make sure I was not sitting too low'). The self-efficacy issues encountered by patients while going outside mostly consisted of finding a balance between under and overloading ('Before I knew it, I had walked a couple of kilometers with my dog but on the way back I perceived pain in my hip and still had to walk quite a distance'). One suggestion was to add GPS to the system in order to track the route, speed and distance completed and 'map' these to a subjective rating of discomfort or pain. ('So that I can learn from my mistakes of overloading, i.e. being too

enthusiastic', 'preferably the system is capable of identifying my optimal point of return while walking my dog'). Interestingly, informal caregivers confirmed the self-efficacy issues of patients ('I'm continuously checking my wife's movements in order to make sure she's is moving safely', 'I noticed the difficulties and anxiety my father encountered in executing the proper movements').

Focus group participants prefer to share the measured data with their informal caregivers and physiotherapist for therapeutic purposes. The majority of informal caregivers preferred to have access to this information about activities that provoked critical hip angles to be able to assist the patient in 'monitoring' their own safety.

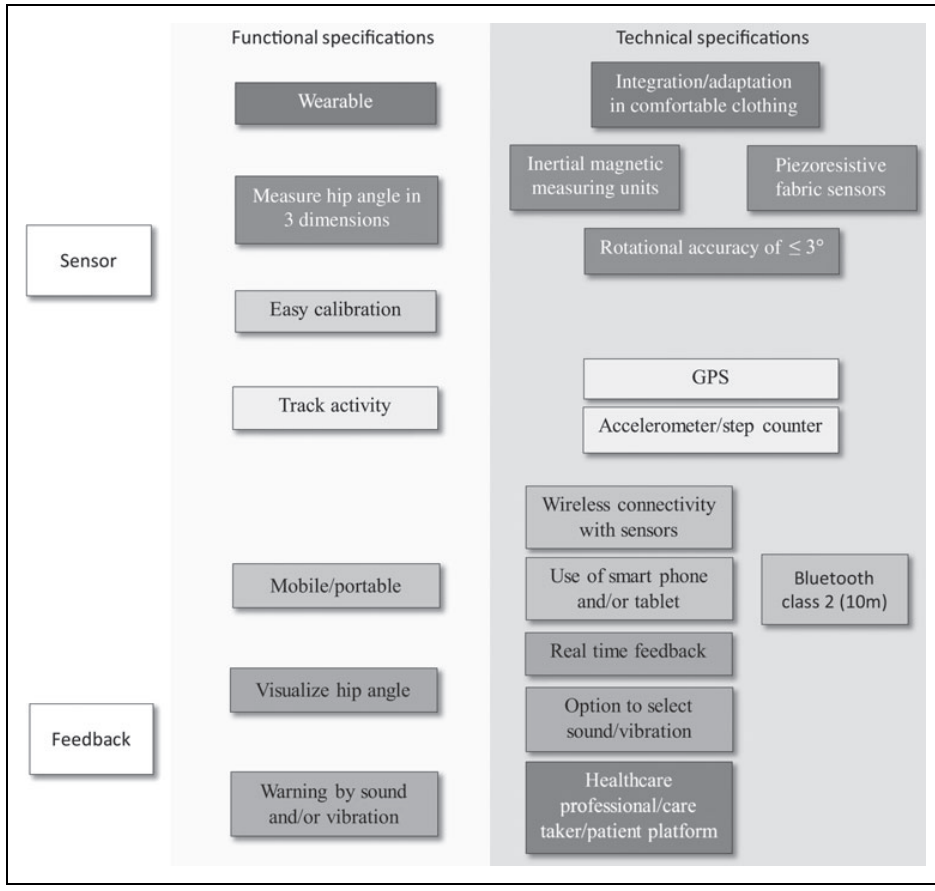

Figure 7 HipDas building blocks

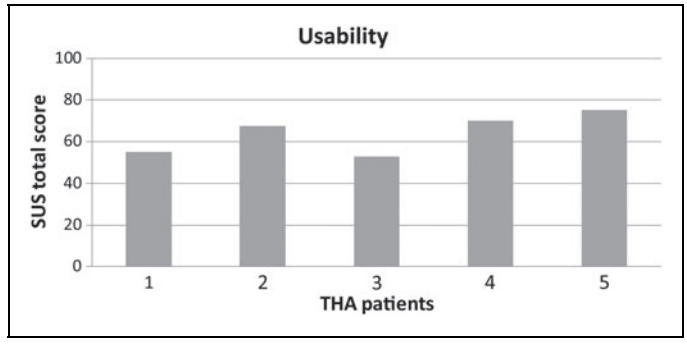

Figure 8. Usability of prototype version of the HipDas telemedicine system.

Patients preferred to use the system in the first 6 weeks after the surgery. They indicated that in the first weeks after surgery movements are naturally restricted due to postoperative pain. However, approximately 3 weeks after surgery, this pain disappears and patients become more active. During this phase, the pain-induced movement restrictions disappear and HipDas is considered valuable. 'The first weeks following surgery I spent most of the time near my house, but after some weeks I started to visit friends again and I had to think about the suitability of the chairs in their house'. Consistency existed among the focus group members regarding the feedback modalities. Given the impairments THA patients generally experience (i.e visual problems, auditive problems) different feedback modalities should be available in order to meet the individual patients needs.

All participants emphasized that privacy of the measured data must be guaranteed. Data must be anonymously stored and transferred. All subjects expected technical support, preferably in-person, in the event of technological difficulties. Although the issues that the patients experienced during their care are unique, there are several similarities regarding situations in which they experienced low levels of self-efficacy in preventing a hip dislocation.

Phase 3 Design

Figure 7 provides an overview of the HipDas architecture, including its buildings blocks (sensor, feedback) and associated functional and technical specifications. Motion sensors (i.e inertial sensors or stretch sensors) register the hip angles and are wireless connected to an android device on which the measured data is analyzed and presented to the patient on the visual interface. Optional interface features should be available during initial set up to personalize the level of visualization for the patient. Automated feedback will be provided to patients when approaching or entering critical joint angles of the hip. Additionally, GPS tracking features and activity-tracking sensors acquire data, which is sent to the android device. A secure central server should be available to store all registered data and should be remotely accessible through personalized login credentials for the patient and their professionals.

DISCUSSION

Movement restrictions following THA are current best-practices instead of evidence-based(11). The main rationale of these guidelines is to prevent dislocation of the newly placed hip prosthesis(4). One of the prognostic factors for dislocation is the efficacy of patients to comply with postoperative movement restrictions(5).

The current study shows that patients tend to have a low level of self-efficacy regarding movement restrictions following THA. Van den Akker- Scheek et. al. 2007 showed that a better

short-term postoperative self-efficacy resulted in a higher long-term postoperative generic outcome measure such as walking speed (12). As such, interventions aimed at enhancing post-operative self-efficacy are strongly recommended. HipDas is an example of a self-efficacy enhancing intervention. In this study the majority of the patients (>76%) believed that a future HipDas is highly useful in preventing dislocation following THA.

Another interesting finding of the current study is the positive attitude of our patients and their informal caregivers towards the relevance and usage of HipDas. Although literature confirms that most older people have a positive attitude towards technology, the adoption rates of technologies like mobile phones generally tend be lower than younger adults (14). However, a positive attitude has also shown to account for about 50% its actual use, suggesting it's importance(6). Possibly, the influence of informal caregivers, most often relatives and family, might be a key strategy to adoption of new technologies for the THA population, such as HipDas. Older adults invest more in emotional ties with family members and established friends but are less interested in forming ties with new acquaintances(6). Grandchildren and children tend to be highly influential in the decisions that older adults make about adopting and using a new technological device, since they can help in the usage of the device(15). In our study, THA patients were rather confident about the support from their relatives in using HipDas. This might explain why the issue of authorization in sharing sensor information with their informal caregiver was high during the focus group. Additionally, it might be the explanation for the absence of a discussion about authorization with other THA patients ('strangers') during our focus group meeting.

THA patients are willing to spend a maximum of 10-15 minutes per day calibrating and preparing the technology for use. They prefer to have the possibility to set individually tailored feedback modalities (sound, vision) and they value appropriate hygiene protocols (i.e. for the sensor pants).

Importantly, the current study shows that THA patients consider themselves 'moderately' capable of dealing with technology like HipDas emphasizing the need for proper support modalities. This might be due to the fact that our THA population, like the THA population in general, on average is typically an older population. Ageing comes with physical, cognitive and sensory impairments. This needs to be considered in terms of an older person's needs and capabilities to use when using technology or technical devices. Self-rated physical condition and cognitive ability play a major role in the use of different technologies(16). Older adults with physical difficulties in vision, hearing and motion use fewer technologies than people with good health. Our future HipDas system is recommended to deal with the impairments that come along with aging, by providing individually tailored feedback modalities (sound,

vibration, vision) by providing personalization options (i.e. to set their preferred feedback modality).

The results also show that feedback thresholds should be tighter in the early phase of recovery than in the later phase in order to prevent dependency to the system. More research is needed on the exact thresholds and optimal timing of changing these.

CONCLUSION

In conclusion, the current study shows that patients self-efficacy level towards restrictions prescribed by orthopeadic surgeons tend to be low. In particular, the guideline to avoid severe bending of the hip is rather generic and difficult to translate to the own specific home situation. THA patients show receptivity towards an assistive ambulant technology in improving their self-efficacy levels and consider themselves 'moderately' capable of dealing with it. As such, HipDAS is considered to be an interesting concept possibly leading to which could prevent dislocation following THA and thereby reducing health care costs.

APPENDIX 1

Scenario:

Mrs. Koumeijer is 72 years old and has just been discharged from the hospital after a total hip arthroplasty. She wanted to rehabilitate more under the supervision of a local rehabilitation clinic, but they were completely full. Mrs. Koumeijer was sent home, but was very afraid of the possible hip luxation the doctor warned her about. So afraid in fact, that she just wanted to lie in bed all day to make sure she wouldn't make any of the restricted movements. Her own physiotherapist noticed this and pointed out to Mrs. Koumeijer that lying in bed all day would only hamper her functional recovery. The physiotherapist then advised her to try the HIP-DAS system to aid her in her functional rehabilitation. The HIP-DAS system is a sensor system that measures (critical) hip angles and informs the user about them. The system consists of a pair of tights with 5 imbedded inertial magnet sensors to measure the joint angles. The sensors are connected to a smart phone that visualizes the current hip angles for Mrs. Koumeijer and warns her when she approaches the critical angles.

At first, Mrs. Koumeijer and her husband were hesitant, since neither of them owns a smartphone and aren't very fond of technology in general. Her physiotherapist, who has treated Mrs. Koumeijer for several years and is very trusted by her and her family, promised to help them in the use of the device and explained how easily the smartphone with the HIP-DAS system can be used. He helped her with the initial set up and sent her home. This instantly showed Mrs. Koumeijer the device's usefulness, as it started beeping when she wanted to get into the car. The physiotherapist showed her how to enter the car properly and she was able to imitate these movements and safely get into the car without a warning from the HIP-DAS system.

Every morning Mrs. Koumeijer puts on the HIP-DAS system with help from her husband and together they calibrate the system as he presses the 'calibrate' button on the smartphone while she stands as straight as possible. With the HIP-DAS system, Mrs. Koumeijer is much more confident during her daily activities and has started walking outside with her dog again. Her husband told her not to go too far, as he feared she would overload her hip and hamper the rehabilitation process. But when the physiotherapist saw the distance she walked, as the (GPS) data from the HIP-DAS system is also sent to him with Mrs. Koumeijer's permission, he assured her husband that she wasn't walking too far and showed him the distance she could safely walk on the smartphone. Mr. Koumeijer noticed that the distance increased every week and on a sunny day in the third week, he encouraged his wife to take the longer route with him through the park, feeling confident that she wasn't overloading her operated hip. During their meetings every other day, the physiotherapist and Mrs. Koumeijer look through the data and analyze the situations that cause the HIP-DAS system to send a warning. This has helped Mrs.

Koumeijer to gain more insight into risky movements and situations, and to learn strategies to avoid them.

After 8 weeks, Mrs. Koumeijer was supposed to return the HIP-DAS system, but she asked if she could keep it a little longer, as it made her feel really happy and

After 8 weeks, Mrs. Koumeijer was supposed to return the HIP-DAS system, but she asked if she could keep it a little longer, as it made her feel really happy and confident, and she wanted to use it relearn how to cycle first. This was no problem of course and Mrs. Koumeijer returned the HIP-DAS system by bike after 3 months.

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Chapter 7

General discussion

DISCUSSION

The overall aim of this thesis was to contribute to the optimization of the set of postoperative precautions following the posterolateral THA by generating knowledge regarding its current practice, compliance, and burden, as well as effectiveness. This chapter discusses the main findings of our study and their significance for clinical practice and future perspectives. The first part discusses the available evidence on precautions as well as the evidence generated regarding the use of a minimized set of precautions. The second part reflects on patients' perspectives regarding precautions and shifts from generalized precautions to individualized guidance following THA. The third part discusses precautions and their relationship with new surgical approaches and value-based care.

Building evidence on precautions and postoperative dislocation

There is increased interest in knowledge about using fewer postoperative precautions following posterolateral THA without increasing the risk of dislocation [1]. Several studies have investigated the use of a protocol with fewer or even no precautions [2–7]. However, the set of precautions prescribed in one study differed from that in another, making it difficult to compare these with existing new protocols, let alone implement them into daily care based on sufficient scientific evidence. The heterogeneity in precautions found in the literature is confirmed by the results of our national survey (Chapter 2), which showed that most orthopedic departments prescribe varying sets of precautions. Generally, these can be categorized into three types: 1) movement restrictions, 2) the use of assistive devices, and 3) functional restrictions.

The so-called "no-precautions protocols" now tend to be related to abandoning or minimizing movement restrictions and assistive devices (4). Only a few studies indicate that functional restrictions were abandoned, while these probably have the highest impact on a patient's daily life since two-thirds of patients claim that these precautions limit them from performing their desired activities after their THA [8].

For instance, in our national study, more than 80% of orthopedic departments prescribed the functional restriction of sleeping in a supine position, whereas Peak et al. showed that sleeping supine is perceived as uncomfortable by most patients [3]. The current thesis confirms (Chapter 5) that sleeping in a supine position causes a high rate of burden, whereas, surprisingly, movement restrictions appear to cause much less burden.

The literature contains preliminary indications that it is safe to use no or minimized precautions [4,5,9], creating the opportunity to effectively remove restrictions that are burdensome for patients. However, these studies are hampered by their low methodological quality [2,3,5,9,10]. To address these methodological shortcomings, we designed a randomized controlled trial

(RCT; Chapter 3) to generate a higher quality of evidence concerning precautions following THA using a posterolateral approach.

The results of our RCT, the first randomized controlled design to investigate the effectiveness of a minimized set of precautions for a posterolateral surgical approach, demonstrated that the early dislocation rate in patients who were prescribed an unrestricted sleeping position was non-inferior to that in patients prescribed a restricted sleeping position (Chapter 4). In our trial, the set of precautions was minimized by only removing the restriction to sleep in a supine position for the intervention group. The results of our trial allowed us to adapt the postoperative THA protocol, meaning that in current practice all patients are now allowed to sleep in any desired position following THA.

However, conducting such a large trial to evaluate a single restriction is highly time-consuming and relatively expensive. This is complicated by relatively low rates of dislocation in modern primary THA [11]. To circumvent the methodological problems resulting from the low dislocation rates in primary THA would be to study precautions in a population with a higher dislocation rate, such as revision THA. However, due to the heterogeneity of this population, more efficient ways of collecting evidence deemed necessary to further optimize the set of precautions prescribed after THA are needed. One option may be to use real-life cohorts, such as the joint registries. Total joint registries provide scalability of targeted research populations because they collect high-volume-data on patients receiving joint arthroplasty in their natural environment. Because registries lack data on postoperative protocols and non-surgically treated dislocation it is recommended to extend the data with the dislocation data that are already available in hospital and insurance registration systems. Preferably data that are now digitally offered by smartphone applications about postoperative protocols, including the prescribed set of precautions should be added, [12].These integrated data-sets provide the opportunity to conduct big data research toward optimizing postoperative care protocols. These results can generate more insight in daily care, including the precautions prescribed, the adherence obtained and which postoperative protocols are effective in preventing dislocation.

From precautions to guidance

Despite the literature trend to reduce or remove precautions, patients appear to hold mixed opinions about these precautions [13]. With no precautions, patients appear less hindered in resuming their preoperative daily activities, which supports omitting these precautions in clinical practice. However, patients treated with precautions feel that these provide guidance and clarity in managing their postoperative recovery process in their daily life [13].

Chapter 5 illustrates the mixed opinions concerning the different prescribed restrictions based on the different rates of patient compliance with precautions. Our study confirmed (Chapter 5)

that patients' compliance with movement restrictions is very high (>90%) [3,7]. The literature shows that even when patients are prescribed no movement restrictions, up to 28% voluntarily comply with them [6,7]. This differs from the instruction to sleep supine, where compliance decreased from 81% at 2 weeks to 37% at 8 weeks. Chapter 5 describes not only how patients have mixed opinions regarding the use of precautions but also how burdensome they consider different types of restrictions from the set of precautions. It was shown (Chapter 5) that the burden of sleeping restrictions is higher than that of movement restrictions. Thus, one can conclude that there appears to be a difference in burden and perceived relevance for patients' prescribed restrictions.

In order to reduce the burden patients have expressed their needs for advice and guidance regarding other functional activities, for which no advice is commonly prescribed [14]. An example of such a functional activity where patients have indicated their need for more guidance is sexual activity following THA [14]. The minimal attention surgeons show to sexual function-related issues in THA patients is not consistent with patients' needs [15]. Our survey confirmed that orthopedic departments in the Netherlands only sporadically advise on sexual activity following THA (Chapter 2).

Traditionally, studies examining precautions following THA use patient-reported outcome measurements (PROMs) to measure functional outcomes [6,7,9]. None of those trials have shown an increase in functional outcomes using PROMs when comparing patients prescribed with no or fewer restrictions. In our RCT (Chapter 4), PROMs for patients prescribed with more and less restrictions were compared. The Hip Disability and Osteoarthritis Outcome Score (HOOS) and EuroQol 5D (EQ5D) were used for this, and we were unable to detect a statistically significant difference between the groups. The current debate in the literature about measuring the patient acceptable symptom state (PASS) rather than a change in PROMs is relevant here. PASS is defined as the highest level of symptom beyond which a patient considers them self well [16,17]. This allows monitoring of individual responses to therapy over time and treatment adaptation at the individual level [18]. In our study (Chapter 5), we took a step in this direction by measuring burden, and we considered a restriction burdensome above a certain threshold. Although not validated, this is an example of a simple question to assess a patient's experience with healthcare [19,20]. Improving this patient's experience (Chapter 6) and thereby influencing satisfaction with treatment is an important outcome when striving for modern value-based healthcare [21].

Precautions in perspective

There are several surgical approaches to implanting a THA. The posterolateral approach a traditional approach, remains the most commonly performed approach in the Netherlands and worldwide [22,23]. The newer direct anterior approach (DAA) has gained interest due to its

perceived advantages of earlier functional gains, less risk of dislocation, and thereby a reduced need for precautions [24–27]. In the posterolateral approach, the hip is accessed posteriorly through the division of the gluteus maximus and the short external rotator muscles [28]. In the DAA, an internervous intermuscular plane between the sartorius and tensor fascia latae is used to access the hip joint anteriorly [28]. Precautions in the posterolateral approach are directed to prevent posterior dislocation by limiting flexion and internal rotation. Conversely, anterior dislocation, more likely to occur with the DAA, is prevented by limited extension and external rotation.

The results of our survey study (Chapter 2) showed that departments using the relatively new DAA prescribe fewer precautions compared to the posterolateral approach. These results are consistent with other surveys on precautions [27,29]. However, there is still conflicting evidence on which approach to use in THA [24], and it remains unknown why fewer precautions are prescribed with the DAA. Patients are attracted by the introduction of new approaches such as the DAA, which claim less risk of dislocation and less need for precautions. However, new approaches have a learning curve and potential risks, whereas the posterolateral approach is an established approach, which has evolved toward fewer dislocations, and now knowledge has increased regarding the minimized use of precautions [11,30,31]. Thus, overall the aim is to identify the criteria that are most important for a patient to be able to make a choice in the available approaches. Therefore, sharing the total package of knowledge with patients is important as this will empower them to choose the treatment that best fits their personal values.

Another aspect requiring attention is the "one size fits all" postoperative precautions. It is strongly recommended to direct optimization of postoperative precaution protocols toward a more individualized level rather than basing it on the surgical approach.

Chapter 6 assesses the individual needs and expectations of patients regarding precautions, as suggested in patient-centered care [32]. Patient-centered care necessitates respecting patients' values, preferences, and expressed needs. Our study showed that some patients struggled to apply the generic movement restrictions to their specific home/work/social situations. Future research should focus more on assessing preoperative patient perspectives on treatment and individual postoperative goals to administer an individualized set of evidence-based precautions tailored to the patient's specific situation, which will guide the patient in the postoperative phase. To achieve these goals, patients should be administered the necessary assistive devices and resume certain functional activities, such as driving a car, on a more individual timeframe in their rehabilitations process. One could compare this with the return to sport criteria in ACL surgery [19].

Additionally, some patients tend to have low self-efficacy regarding the prescribed movement restrictions. Self-efficacy is someone's belief about their ability to execute behavior needed to achieve a desired personal goal; it is linked to patient well-being and empowerment [33] [34]. Technology is hypothesized to be potentially useful in this respect [35]. An example is the prototype sensor-based guidance system described in Chapter 6. A wearable that alerts patients when the hip is extended to a critical angle, risking a dislocation, can have the same function as a car parking sensor, which effectively prevents a crash [18]. Such a system will ideally lead to a faster return to recreational and work activities.

Besides patients' preferences and values, costs have become increasingly important in modern healthcare. People are living longer and making increasing demands on available care and resources. Additionally, COVID-19 has demonstrated that care is being crowded out [36]. Value-based healthcare is introduced to control rising healthcare costs. Value is defined as the health outcomes achieved per dollar spent [33]. The relationship between healthcare costs and precautions is revealed in direct costs, such as the use of equipment, walking aids, and toilet elevators. These costs have been estimated to reach $655 per patient and can be reduced by a more individualized approach rather than by standard application [3,37][2,3]. However, there are also indirect costs when using precautions, which are related to the disease burden of osteoarthritis through reduced employment and productivity [34].

If optimizing the set of precautions accelerates the return to daily activities and participation in work and society, these indirect costs will decrease. Many patients with osteoarthritis are of working age [38]. In our RCT (Chapter 4), the mean age was 64.5 years, and the official retirement age is 67 years in the Netherlands. Although there is much variation regarding when patients return to work following THA [35], precautions such as when to drive, cycle, or sit on a normal chair will influence when a patient returns to work. Returning to work and work participation are particularly relevant due to the expected shortage of staff in all fields [36].

The overall aim of this thesis was to contribute to optimizing the set of postoperative precautions following posterolateral THA by generating knowledge regarding its current practice, compliance, and burden, as well as effectiveness.

Precautions are part of current practice following posterolateral THA. This thesis indicated that there is considerable heterogeneity in the prescribed precautions. Compliance with movement restrictions is higher than with functional restrictions. The burden of sleeping restrictions is high, and these restrictions can be effectively removed without increasing the risk of dislocation. Optimizing the set of postoperative precautions following posterolateral THA will create opportunities for more personalized care.

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SUMMARY

Total hip arthroplasty (THA) is one of the most successful and frequently undertaken elective surgeries. The posterolateral approach, the most frequently used surgical approach to a THA in the Netherlands and worldwide, is thought to have a higher risk of dislocation than other approaches. Postoperative precautions following THA are traditionally prescribed to ensure appropriate healing and prevent early postoperative dislocation. Precautions can be divided into movement restrictions, using assistive devices, and functional restrictions. The prescribed precautions are based on long-standing protocols, and besides the burden they cause, they can hinder the resumption of activities after THA. There is increased interest in knowledge about using fewer postoperative precautions following THA without increasing the risk of dislocation.

This thesis aims to contribute to optimizing the set of postoperative precautions following posterolateral THA by generating knowledge regarding current practice, compliance, and burden, as well as effectiveness.

Chapter 2 presents the results of a prospective nationwide survey on the use of precautions following THA in the Netherlands. The survey was sent to all orthopedic surgeons registered with the Dutch Orthopedic Association and working in one of the orthopedic departments in the Netherlands. The results show that most orthopedic departments use patient restrictions following THA. Restrictions are used at different rates based on the type of surgical approach: anterior (69%), anterolateral (100%), straight lateral (94%), and posterolateral (93%). The duration of these restrictions is generally 6 weeks. The percentage of clinics using the precaution to restrict patients to a supine sleeping position is highest for the anterolateral, straight lateral, and posterolateral approaches (e.g., 100%, 94%, and 82%), followed by the direct anterior approach (38%). In daily practice, it was noticed that many patients complained of the restriction to sleep in a supine position following THA, resulting in the design of a randomized controlled trial (RCT), which is presented in **Chapter 3.** The unique features of the design are that all patients received the same implant with a 32 mm femoral head; all surgeries were performed through a posterolateral approach; and only one specific restriction, the instruction to sleep supine, was removed. The control group received standard care with supine sleeping among the precautions, whereas the experimental group received standard care with sleeping in any position. The results of this trial are presented in Chapters 4 and 5. **Chapter 4** evaluates early dislocations when patients were restricted to supine sleeping or unrestricted sleeping in the first 8 weeks after THA using a posterolateral approach. The functional outcomes of these two groups were measured by patient-reported outcome measures (PROMS) A total of 456 patients were enrolled. The study demonstrated that the early dislocation rate in patients advised to use an unrestricted sleeping position following posterolateral THA was not inferior to the early dis-

location rate in patients advised to sleep in a supine position. Patients in both groups reported a significant improvement in function on the PROMS at 8 weeks postoperatively compared to the baseline ($p < .001$). For the measurements the Hip Disability and Osteoarthritis Outcome Score (HOOS) and the EuroQoL 5-Dimension (EQ-5D) questionnaires were used. No statistically significant nor clinically relevant differences in improvement in the HOOS and EQ-5D scores were found between the two groups. **Chapter 5** presents the results of our RCT regarding burden and compliance with precautions. Compliance with movement restrictions was high. Conversely, other clinic-specific restrictions show a less distinct picture regarding compliance. Generally, the burden of sleeping precautions (63%) appears higher than that of movement precautions (29%). The sleeping restriction was removed for the unrestricted group, which significantly lowered the burden. **Chapter 6** explores the design needs for a technical device to help patients in their individual rehabilitation and to monitor and assist with postoperative precautions. The future technical device was named the hip dislocation alert system (HipDas). A questionnaire was administered to patients scheduled for THA surgery, and a focus group was used to assess the design needs. The usability of the developed prototype was tested and evaluated by a hands-on session with patients following THA surgery. The results show that 6 weeks after surgery, flexion of the hip > 90 degrees, bending over while sitting in a chair, and sleeping in a supine position were the restrictions with the lowest self-efficacy for the respondents.

THA patients showed receptivity toward HipDas for improving their self-efficacy levels and considered themselves "moderately" capable of using it. The developed prototype HipDas is considered highly clinically relevant and usable. **Chapter 7** presents a general discussion, including the main findings of our study and their significance for clinical practice and future perspectives. The first part discusses the available evidence on precautions as well as the evidence generated regarding the use of a minimized set of precautions. The second part reflects on patients' perspectives regarding precautions and shifts from generalized precautions to individualized guidance following THA. The third part discusses precautions and their relationship with new surgical approaches and value-based care.

In conclusion, precautions are part of current practice following posterolateral THA. This thesis indicates considerable heterogeneity in the prescribed precautions. Compliance with movement restrictions is higher than with functional restrictions. The burden of sleeping restrictions is high, and these restrictions can be effectively removed without increasing the risk of dislocation. Optimizing the set of postoperative precautions following posterolateral THA will create opportunities for more personalized care.

SAMENVATTING

Het operatief vervangen van het heupgewricht door een totale heupprothese (THP) is een van de succesvolste en vaakst uitgevoerde electieve operaties. De posterolaterale benadering, is hiervoor de meest gebruikte chirurgische benadering zowel in Nederland als wereldwijd. Bij deze benadering is de veronderstelling dat er een groter risico op luxatie van de prothese is dan bij andere benaderingen. Leefregels na een THP worden van oudsher voorgeschreven voor een goede genezing van de weke delen en om een vroege luxatie (het uit de kom schieten) van de prothese te voorkomen. Leefregels kunnen worden onderverdeeld in bewegingsbeperkingen, het gebruik van hulpmiddelen en functionele beperkingen. De gehanteerde leefregels zijn gebaseerd op lang bestaande protocollen en kunnen belastend zijn voor de patiënt en het hervatten van activiteiten na een THP belemmeren. Er is steeds meer interesse in kennis over het gebruik van minder leefregels na een THP zonder dat het het risico op luxatie vergroot. Dit proefschrift heeft als doel bij te dragen de set postoperatieve leefregels na een posterolaterale THP te optimaliseren, door kennis te genereren over het huidige gebruik, de compliance (in hoeverre wordt het nageleefd), de ervaren belasting, en de effectiviteit. In **Hoofdstuk 2** worden de resultaten gepresenteerd van een prospectief landelijk onderzoek naar het gebruik van leefregels na een THP in Nederland. De enquête is verstuurd naar alle orthopedisch chirurgen die lid zijn van de Nederlandse Orthopedische Vereniging (NOV) en werkzaam zijn op een van de orthopedische afdelingen in Nederland. De resultaten laten zien dat de meeste orthopedische afdelingen leefregels hanteren na een THP. Leefregels worden in verschillende mate gebruikt afhankelijk van de chirurgische benadering: anterieur (69%), anterolateraal (100%), straight-lateral (94%) en posterolateraal (93%). De duur dat deze leefregels worden voorgeschreven is over het algemeen 6 weken. Het percentage klinieken dat de leefregels voorschrijft de patiënten verplicht om op de rug te slapen is hoog voor de anterolaterale, straight-lateral en posterolaterale benaderingen (100%, 94% en 82%), en in minder bij de directe anterieure benadering (38%). De observatie dat patiënten in de dagelijkse praktijk klagen over de beperking die voorschrijft om op de rug te slapen na een THP, heeft geleid tot de opzet van een gerandomiseerde gecontroleerde studie (RCT), die wordt gepresenteerd in **Hoofdstuk 3**. Het unieke aan het ontwerp is dat alle patiënten hetzelfde implantaat hebben gekregen met een kopje van 32 mm; alle operaties werden uitgevoerd via een posterolaterale benadering; en slechts één specifieke leefregel, de instructie om op de rug te slapen, werd verwijderd. De controlegroep kreeg de standaardzorg met het de instructie op op de rug te slapen als een van de leefregels, terwijl de experimentele groep de standaardzorg kreeg waarbij de slaaphouding volledig vrij werd gelaten. De resultaten van deze studie worden gepresenteerd in Hoofdstukken 4 en 5. **Hoofdstuk 4** evalueert het aantal vroege luxaties van patiënten die al dan niet op hun rug moesten slapen in de eerste 8 weken na een THP via een posterolaterale benadering. De functionele uitkomsten van deze twee groepen werden gemeten met behulp van patient-reported outcome measures (PROMS). In totaal werden 456 patiënten geïncludeerd.

De studie toonde aan dat het percentage vroege luxaties bij patiënten met een onbeperkte slaaphouding na een posterolaterale THP niet-inferieur (non-inferior) was aan het percentage vroege luxaties bij patiënten die geadviseerd worden om op de rug te slapen. Patiënten in beide groepen lieten na 8 weken postoperatief een significante verbetering in de PROMS zien ten opzichte van voor de operatie ($p < .001$). Voor de metingen werden de Hip Disability and Osteoarthritis Outcome Score (HOOS) en de EuroQoL 5-Dimension (EQ-5D) vragenlijsten gebruikt. Er werden geen statistisch significante of klinisch relevante verschillen in verbetering van de HOOS- en EQ-5D-scores gevonden tussen de twee groepen. In **Hoofdstuk 5** worden de resultaten gepresenteerd van onze RCT met betrekking tot belasting en compliance van leefregels. De compliance bij bewegingsbeperkingen is hoog. Daarentegen laten andere meer kliniek-specifieke beperkingen een minder duidelijk beeld zien met betrekking tot compliance. Over het algemeen lijkt de belasting van het beperken tot een bepaalde slaaphouding (63%) hoger dan die van bewegingsbeperkingen (29%). Bij de onbeperkte groep met een vrije slaaphouding, was de belasting van een verplichte slaaphouding significant minder (P= 0,000). In **Hoofdstuk 6** worden de ontwerp behoeften voor een technisch hulpmiddel om patiënten te helpen bij hun individuele revalidatie en om postoperatieve leefregels op te volgen en te ondersteunen onderzocht. Het toekomstige technische apparaat werd het heupluxatie waarschuwingssysteem (HipDas) genoemd. Er werd een vragenlijst afgenomen bij patiënten die waren gepland voor een THP, een focusgroep werd gebruikt om de ontwerp behoeften te beoordelen. De bruikbaarheid van het ontwikkelde prototype werd getest en geëvalueerd door een hands-on sessie met patiënten na een THP-operatie. De resultaten laten zien dat 6 weken na de operatie, flexie van de heup > 90 graden, voorover buigen in een stoel en slapen op de rug de leefregels zijn met de laagste self-efficacy (het geloof in het eigen kunnen) voor de respondenten. THP-patiënten toonden zich ontvankelijk voor HipDas voor het verbeteren van hun self-efficacy niveau en beschouwden zichzelf als “matig” in staat om het te gebruiken. Het ontwikkelde prototype HipDas wordt als klinisch zeer relevant en bruikbaar beschouwd. In **Hoofdstuk 7** worden de belangrijkste bevindingen van onze studies en hun betekenis voor de klinische praktijk en toekomstperspectieven bediscusieerd. In het eerste deel wordt het beschikbare bewijs over leefregels besproken, en het bewijs dat is gegenereerd met betrekking tot het gebruik van een verminderde set aan leefregels. Het tweede deel reflecteert op de patiënt perspectieven met betrekking tot leefregels en een verschuiving van meer algemene leefregels naar een meer individuele begeleiding na een THP. Het derde deel bespreekt leefregels en hun relatie met nieuwe chirurgische benaderingen en op waardegedreven zorg. Concluderend maken leefregels deel uit van de huidige praktijk na een posterolaterale THP. Dit proefschrift laat zien dat er een grote verscheidenheid is aan voorgeschreven leefregels. De compliance met bewegingsbeperkingen groter is dan de compliance met functionele beperkingen. Dat de belasting van de leefregel die het verplicht om op de rug te slapen hoog is en dat deze leefregel effectief kan worden verwijderd zonder dat het het risico op luxatie vergroot. Het optimaliseren

van de set postoperatieve leefregels na een posterolaterale THP creëert de mogelijkheid voor een meer gepersonaliseerde zorg.

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CURRICULUM VITAE

Anil Peters-Veluthamaningal was born on 26-04-1972 in Osnabruck (Germany). His parents are Indian immigrants from the state of Kerala in India; both came to study medicine and further specialize in Germany. In 1977, they moved with their three children to Hengelo in the Netherlands. After graduating from high school (Bataafse Kamp, Hengelo), Anil moved to Amsterdam to study medicine at the University of Amsterdam (UvA). He spent his first junior internship (verpleeghulpstage) at the Mission Hospital in Trichur (Kerala, India). During his studies, he joined the department of anatomy and embryology to teach anatomy to junior medical students. For his voluntary internships in 1998, he worked at St. John's Hospital, Bangalore (India). After returning, he obtained his M.D. degree from the UvA and thereafter gained experience as a resident in orthopedic surgery (ANIOS) at Slotervaart Hospital in Amsterdam. In 2000, he was admitted to the orthopedic training program at the Academic Medical Centre (AMC) and Slotervaart Hospital. He undertook his general surgical training at the Jeroen Bosch Hospital, Den Bosch. For his orthopedic training, he returned to Amsterdam to the Slotervaart Hospital and the AMC. During his residency training, he worked at the Queen's Medical Centre (Nottingham, the United Kingdom) as a fellow (trauma and foot and ankle surgery) for 6 months. After finishing his residency training, he started in 2006 as a consultant orthopedic surgeon in Ziekenhuis Groep Twente (ZGT), Hengelo.

Together with his seven colleagues at that time, he founded OCON (Centre for Orthopedic Surgery), an independent orthopedic clinic within ZGT, in 2010. The clinic has evolved into one of the largest orthopedic surgery and sports medicine clinics in the Netherlands and is now owned by its 15 orthopedic surgeons and five anesthesiologists. When Anil started as a consultant, he practiced as a general orthopedic surgeon. He now specializes in total hip arthroplasty and pathologies of the foot and ankle. He is married to Bernadette Kim, a general practitioner, and together, they have three children, Minu, Max, and Tim.