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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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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.

Results: 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.

Trial registration number: ClinicalTrials.gov NCT02107248 – <https://clinicaltrials.gov/ct2/show/NCT02107248?term=anil+peters&draw=2&rank=1>

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KEYWORDS

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

► 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.

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).

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.

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.

Table 1. Inclusion and exclusion criteria.

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

^aThe first hip was eligible for the study, and the second is an exclusion criterion.

Table 2. Patient demographics.

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: EuroQoL 5 Dimension; HOOS: Hip Disability and Osteoarthritis Outcome Score; THA: Total Hip Arthroplasty; VAS: Visual Analogue Scale.

^aValues are presented as number and percentage; ^bValues are presented as mean and standard deviation.

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

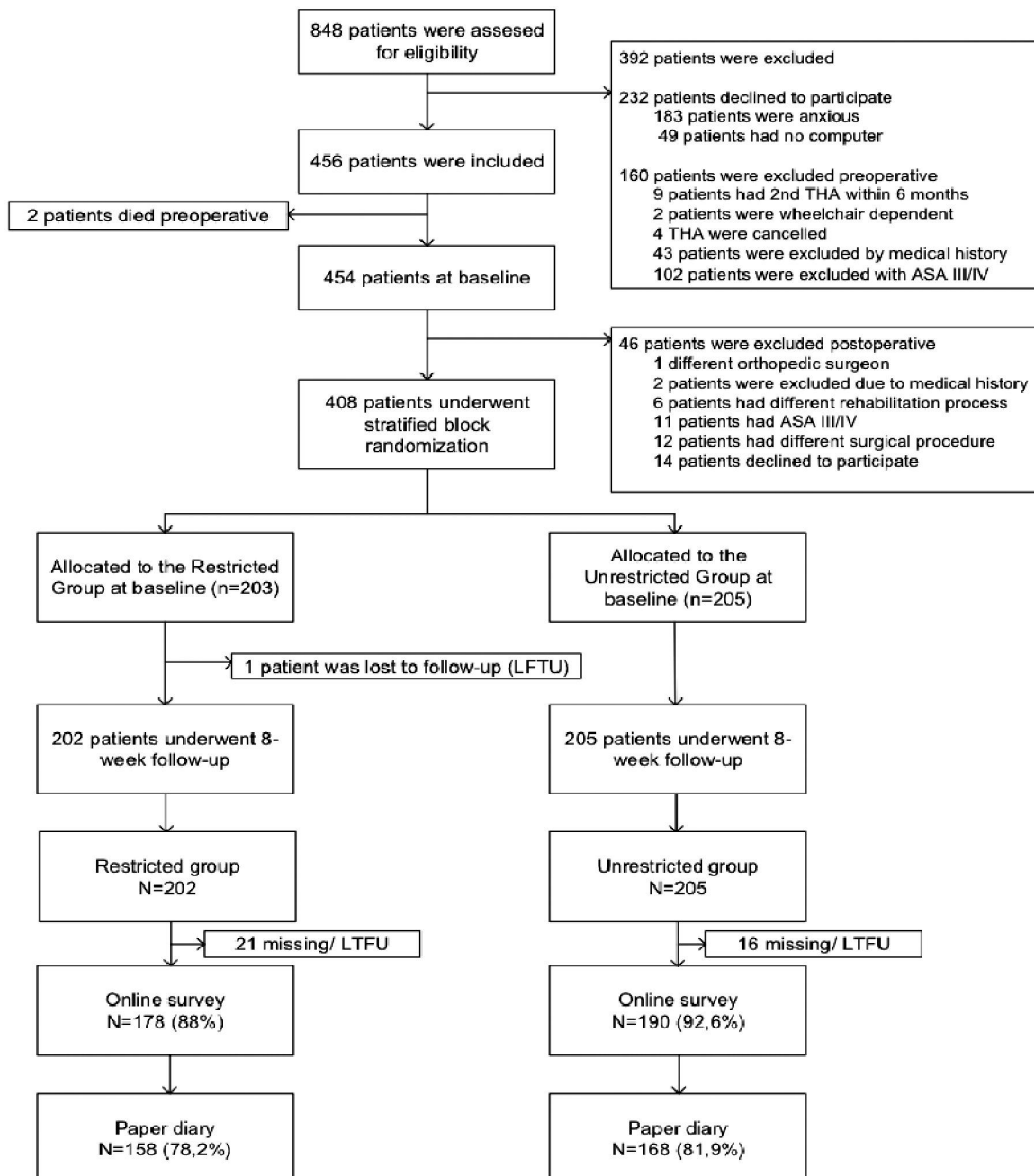


Figure 1. CONSORT flowchart.

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

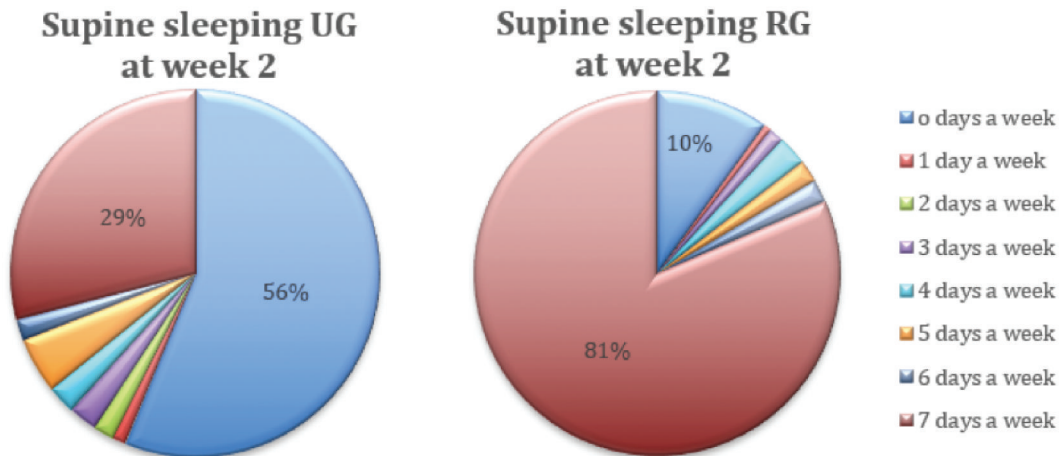


Figure 2. Percentage of patients in the Unrestricted and Restricted Group sleeping supine at 2 weeks postoperative.

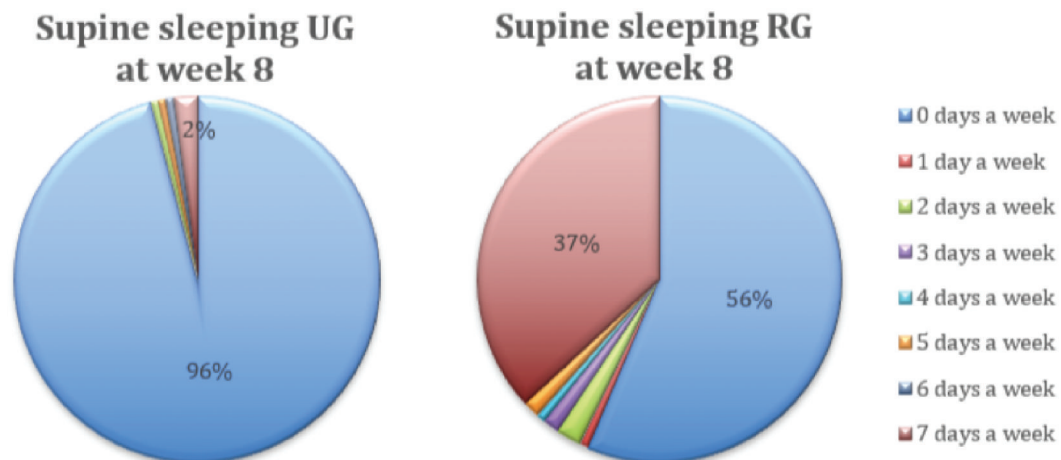


Figure 3. Percentage of patients in the Unrestricted Group and Restricted Group sleeping supine at 8 weeks postoperative.

between the groups, implying that the randomization was successful ($p = 0.695$).

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).

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).

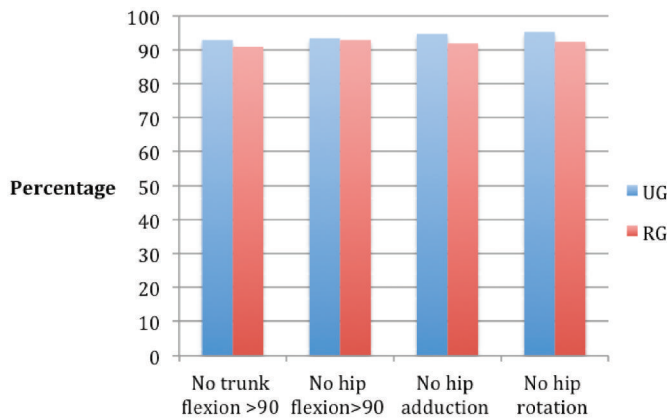


Figure 4. Compliance with movement restrictions.

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).

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

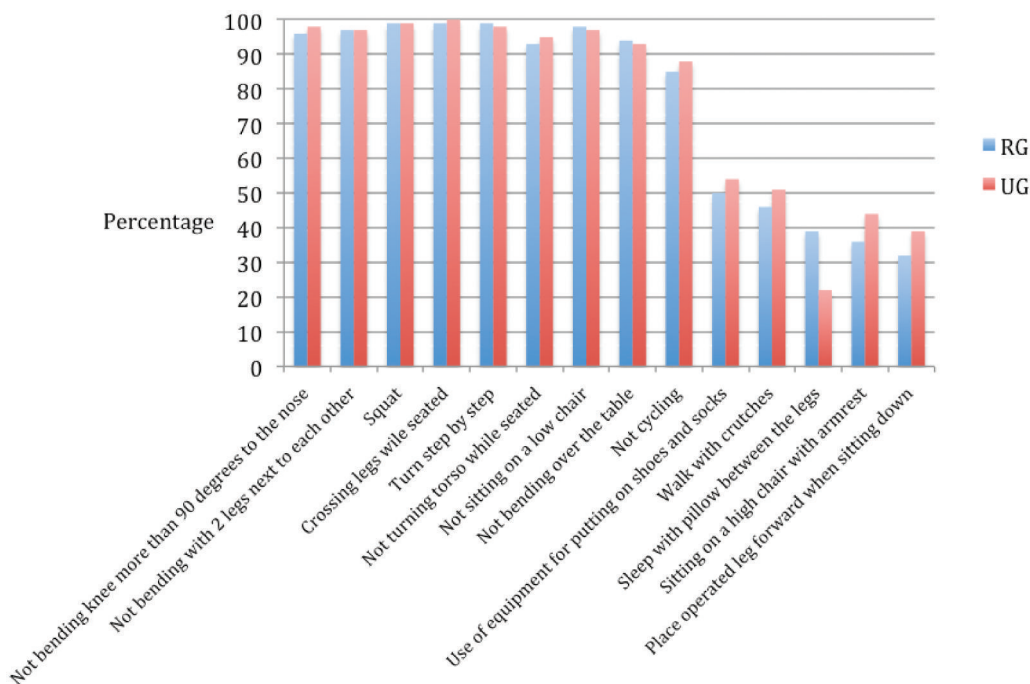


Figure 5. Compliance with functional restrictions.

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					<i>p</i>	Mean percentage (%) ^a
		0%	25%	50%	75%	90%		
Trunk flexion >90°	UG	4	4	4	15	22	0.981	91
	RG	6	4	4	12	20		107
Hip flexion >90°	UG	4	6	1	2	12	0.994	94
	RG	4	5	2	3	12		129
Hip adduction (crossing legs)	UG	7	0	2	3	7	0.226	94
	RG	9	2	2	6	14		125
Hip endo/exorotation	UG	4	2	2	11	12	0.681	94
	RG	6	4	2	7	16		120

^aAdded to be able to compare our results with Peak et al.

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

		Never	Seldom	Regularly	Often	Always	<i>p</i>
Bending the knee more than 90 degrees towards the nose ^a	RG	107	41	22	7	1	0.732
	UG	117	46	21	4	0	
Bending over from position with two legs next to each other ^b	RG	119	45	8	4	1	0.683
	UG	124	45	15	3	2	
Squat ^b	RG	154	16	8	1	0	0.658
	UG	156	24	8	2	0	
Crossing legs while seated ^b	RG	154	20	4	1	0	0.390
	UG	166	22	1	0	0	
Avoid extreme overloading ^c	RG	4	6	13	38	114	0.360
	UG	10	7	21	33	118	
Turning the torso while seated ^d	RG	62	69	34	7	5	0.590
	UG	77	73	30	8	2	
Turn step-by-step ^e	RG	115	48	14	1	0	0.722
	UG	125	44	17	3	0	
Place the operated leg forward when sitting down ^f	RG	0	11	45	37	83	0.011
	UG	7	6	60	26	87	
Walk with crutches ^g	RG	25	15	38	36	54	0.157
	UG	36	18	41	30	60	
Additional equipment in putting on stockings and shoes ^h	RG	38	22	30	19	70	0.942
	UG	43	28	32	19	68	
Sleep with pillow between the legs ⁱ	RG	58	17	35	15	54	0.000
	UG	84	36	26	13	29	
Bending over the table ^j	RG	60	75	32	9	2	0.627
	UG	77	67	32	11	3	
Sitting on a low chair or stool ^j	RG	101	57	16	3	1	0.318
	UG	106	69	9	2	4	
Cycling ^k	RG	80	21	49	20	6	0.469
	UG	91	33	44	16	6	
Sitting on a high chair with armrest ^l	RG	12	28	23	45	69	0.211
	UG	22	35	26	32	73	

^aanalysis based on $n=188$ UG and $n=178$ RG patients, ^banalysis based on $n=189$ UG and $n=177$ patients, ^canalysis based on $n=189$ UG and $n=175$ RG patients, ^danalysis based on $n=190$ UG and $n=177$ RG patients, ^eanalysis based on $n=189$ UG and $n=178$ RG patients, ^fanalysis based on $n=186$ UG and $n=176$ RG patients, ^ganalysis based on $n=185$ UG and $n=168$ RG patients, ^hanalysis based on $n=190$ UG and $n=179$ RG patients, ⁱanalysis based on $n=188$ UG and $n=179$ RG patients, ^janalysis based on $n=190$ UG and $n=178$ RG patients, ^kanalysis based on $n=190$ UG and $n=176$ RG patients, ^lanalysis based on $n=188$ UG and $n=177$ RG patients.

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.

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 (40mm) 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

Burden of movement restriction

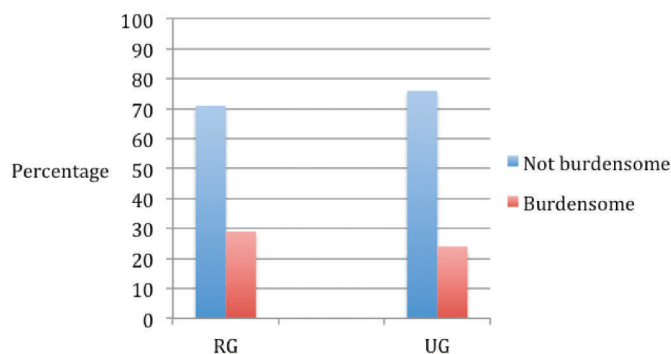


Figure 6. Burden of movement restrictions.

Burden of sleeping restriction

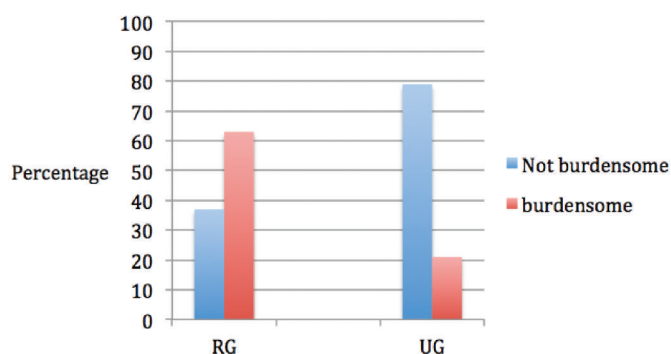


Figure 7. Burden of sleeping restrictions.

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

		0										10	p
		Not burdensome	1	2	3	4	5	6	7	8	9		
Movement restrictions ^a	RG	24	22	19	25	10	18	11	15	10	4	8	0.150
	UG	49	28	16	14	7	16	10	11	8	5	6	
Sleeping position restriction ^b	RG	13	15	8	9	5	12	9	16	32	21	27	0.000
	UG	73	23	14	12	4	12	2	7	14	9	4	

^aAnalysis based on n = 170 UG and n = 166 RG patients, ^banalysis based on n = 174 UG and n = 167 RG patients.

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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