



Immediate versus delayed removal of urinary catheter after laparoscopic hysterectomy: a randomised controlled trial

EM Sandberg,^a ARH Twijnstra,^a CA van Meir,^b HS Kok,^c N van Geloven,^d K Gludovacz,^c W Kolkman,^e HTC Nagel,^f LCF Haans,^f K Kapiteijn,^g FW Jansen^{a,h}

^a Department of Gynaecology, Leids Universitair Medisch Centrum, Leiden, the Netherlands ^b Department of Gynaecology, Groene Hart Ziekenhuis, Gouda, the Netherlands ^c Department of Gynaecology, Alrijne Ziekenhuis, Leiden/Leiderdorp, the Netherlands ^d Department of Biomedical Data Sciences, Section Medical Statistics, Leids Universitair Medisch Centrum, Leiden, the Netherlands ^e Department of Gynaecology, HagaZiekenhuis, The Hague, the Netherlands ^f Department of Gynaecology, Haaglanden Medisch Centrum, The Hague, the Netherlands ^g Department of Gynaecology, Reinier de Graaf Gasthuis, Delft, the Netherlands ^h Department of Biomechanical Engineering, Delft University of Technology, Delft, the Netherlands

Correspondence: EM Sandberg, Department of Gynaecology, Section Minimally Invasive Surgery, Leiden University Medical Centre, PO Box 9600, 2300 RC Leiden, the Netherlands. Email: e.m.sandberg@lumc.nl

Accepted 13 November 2018. Published Online 1 March 2019.

Objective To evaluate if immediate catheter removal (ICR) after laparoscopic hysterectomy is associated with similar retention outcomes compared with delayed removal (DCR).

Study design Non-inferiority randomised controlled trial.

Population Women undergoing laparoscopic hysterectomy in six hospitals in the Netherlands.

Methods Women were randomised to ICR or DCR (between 18 and 24 hours after surgery).

Primary outcome The inability to void within 6 hours after catheter removal.

Results One hundred and fifty-five women were randomised to ICR ($n = 74$) and DCR ($n = 81$). The intention-to-treat and per-protocol analysis could not demonstrate the non-inferiority of ICR: ten women with ICR could not urinate spontaneously within 6 hours compared with none in the delayed group (risk difference 13.5%, 5.6–24.8, $P = 0.88$). However, seven of these women could void spontaneously within 9 hours without additional intervention. Regarding the secondary outcomes, eight women from the delayed group

requested earlier catheter removal because of complaints (9.9%). Three women with ICR (4.1%) had a urinary tract infection postoperatively versus eight with DCR (9.9%, risk difference -5.8% , -15.1 to 3.5 , $P = 0.215$). Women with ICR mobilised significantly earlier (5.7 hours, 0.8–23.3 versus 21.0 hours, 1.4–29.9; $P \leq 0.001$).

Conclusion The non-inferiority of ICR could not be demonstrated in terms of urinary retention 6 hours after procedure. However, 70% of the women with voiding difficulties could void spontaneously within 9 hours after laparoscopic hysterectomy. It is therefore questionable if all observed urinary retention cases were clinically relevant. As a result, the clinical advantages of ICR may still outweigh the risk of bladder retention and it should therefore be considered after uncomplicated laparoscopic hysterectomy.

Keywords Laparoscopic hysterectomy, urinary catheter, urinary retention.

Tweetable abstract The advantages of immediate catheter removal after laparoscopic hysterectomy seem to outweigh the risk of bladder retention.

Please cite this paper as: Sandberg EM, Twijnstra ARH, van Meir CA, Kok HS, van Geloven N, Gludovacz K, Kolkman W, Nagel HTC, Haans LCF, Kapiteijn K, Jansen FW. Immediate versus delayed removal of urinary catheter after laparoscopic hysterectomy: a randomised controlled trial. BJOG 2019;126:804–813.

Trial registration: The trial was registered at www.clinicaltrials.gov (NCT02742636).

Introduction

During laparoscopic hysterectomy (LH), it is standard care to place an indwelling catheter to avoid iatrogenic injuries

of the bladder, monitor urinary output and check for haematuria.¹ However, it remains unclear what the best moment is to remove the catheter after an uncomplicated LH. Most specific guidelines on LH report limited information on this topic.² A recent telephone survey to all 89 hospitals in the Netherlands demonstrated that 78% of the hospitals have the policy of leaving the catheter in place until the next morning after LH.³ Although no robust scientific support exists for this regimen, the few available studies on this topic all favour direct catheter removal after hysterectomy.^{4–6}

The Infectious Diseases Society of America as well as the Cochrane review on this topic recommend not leaving the catheter in place longer than necessary after any type of surgery.^{7,8} A prolonged catheterisation is known to be associated with increased risk of urinary tract infection as well as delayed mobilisation and prolonged hospital stay.^{4–6} Additionally, patients have reported that they find the indwelling catheter inconvenient.^{9,10} On the other hand, immediate removal of the catheter after surgery has been associated with higher rates of urinary retention, which can result in re-catheterisation and other morbidities. Specifically for LH, urinary retention rates of 14%–34% have been reported after immediate removal.^{4,5}

To fully benefit from the advantages of minimally invasive surgery, all postoperative complications and side effects leading to prolonged recovery should be minimised.¹¹ As a result, an adequate catheter management can be valuable for patients and their recovery. With this in mind, the aim of our study was to evaluate if immediate catheter removal (ICR) after LH was associated with similar outcomes compared with delayed catheter removal (DCR). As the advantages associated with a reduced catheterisation time are well-known (early mobilisation and reduced risk of urinary tract infection),⁹ we specifically aim to demonstrate that ICR is non-inferior to DCR in terms of risk of urinary retention.

Material and methods

A multi-centre non-inferiority randomised controlled trial (RCT) was conducted following the CONSORT recommendations.¹² The protocol was approved by the Ethics Committee of Leiden University Medical Centre (LUMC) in Leiden, the Netherlands (P15.382/NL55504.058.15) and the boards of all participating hospitals. The trial was registered in clinicaltrials.gov (NCT02742636). The study was conducted in LUMC, an academic hospital in the Netherlands, and its five affiliated teaching hospitals (Alrijne Ziekenhuis, Groene Hart Ziekenhuis, Haaglanden Medisch Centrum, HagaZiekenhuis and Reinier de Graaf Gasthuis). There was no patient or public involvement in this study and no core set outcomes were used.

All women undergoing LH for benign indication or low-grade cervical or endometrial malignancies were asked to participate if fulfilling study criteria. Women had to be older than 18 years and scheduled for LH. Women with concomitant procedures such as prolapse surgery, extensive endometriosis surgery or advanced oncological dissection including nodal dissection, were excluded, as well as those with stress and urge incontinence, or other systemic diseases potentially influencing their ability to void (e.g. multiple sclerosis). Women were counselled by their gynaecologist during an outpatient visit before surgery and were given written information. If, after consideration, they agreed to participate, written informed consent was obtained and they were enrolled in the study. LH was performed according to standard local protocol and under general anaesthesia.

In the operating room, at the end of the surgery, patients were randomised (1:1 ratio) to either ICR or DCR. Women randomised to ICR had their catheter removed directly in the operating room at the end of the procedure, whereas women with DCR had their catheter removed between 18 and 24 hours after surgery (regular treatment in all participating hospitals). If the gynaecologist judged that for any reason prolonged catheterisation was necessary, the women were considered as dropouts.

The randomisation procedure was performed by the operating gynaecologist through an online and secured program called PROMISE (www.msbi.nl/much). The randomisation sequence was computer-generated with variable blocks of two and four, stratified by centre. The allocation code was disclosed directly on the website after entering patient identification number and confirming inclusion criteria. Neither the women nor the medical staff were blinded for the allocated treatment. At any time, a woman could decide to opt out. The secured program PROMISE was also used for data collection.

Primary, outcome of the study was urinary retention defined as the inability to void completely within 6 hours after catheter removal.⁵ If a woman could not void within the given time a bladder scan was performed to assess the amount of retention, as described in Figure 1. Further actions were undertaken accordingly. Before discharge, women in both groups had a bladder scan after voiding to ensure that no one was sent home with increased post-void residual volume.

Secondary outcomes were (suspicion of) urinary tract infection (based on the results of a standard urine test for nitrite and leucocytes in combination with clinical symptoms); time to mobilisation (defined as the first time out of bed after surgery) and the length of hospital stay (same day discharge coded as 0). Additionally, women were asked to fill in self-developed questionnaires 6 and 24 hours after surgery, and after 6 weeks during the outpatient follow-up visit. There were no valid questionnaires available that

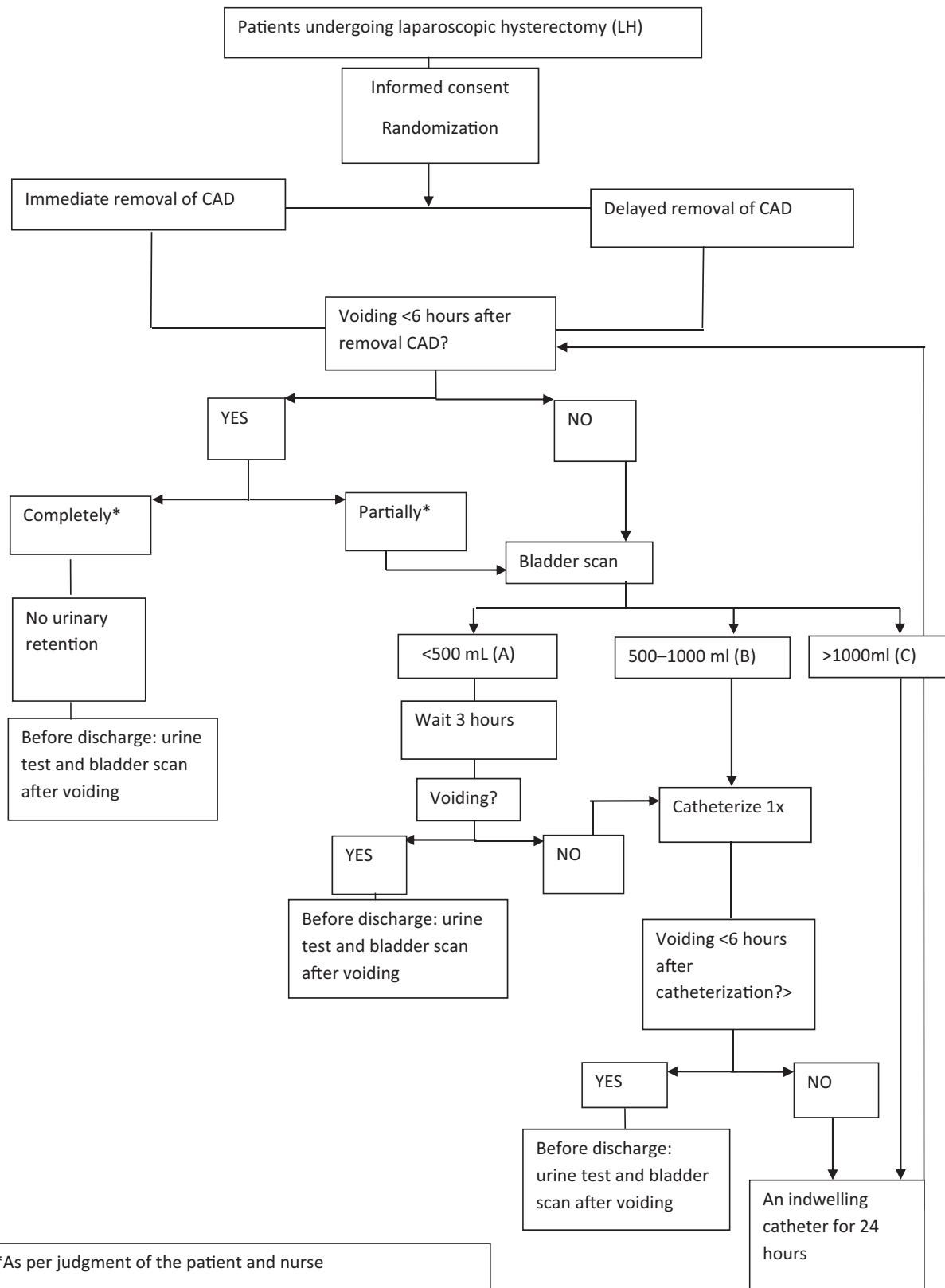


Figure 1. Summary of study flow chart.

covered all the topics, so our own questionnaire was developed. Questions regarding pain and discomfort of the urinary catheter were asked, as well as patient satisfaction. The visual analogue score (VAS) was used (0–10) to evaluate pain and satisfaction. Questionnaires can be found in the Supplementary material (translated from Dutch to English, Appendix S1).

Patient and surgical baseline characteristics were extracted from the medical records. Patient characteristics included age at surgery, body mass index (kg/m^2), American Society of Anesthesiologists classification, history of previous abdominal procedures and indication for hysterectomy. The type of surgery [total, supra-cervical or laparoscopic assisted vaginal hysterectomy (LAVH)] and any concomitant procedures such as adnexal surgery were also recorded. Surgical outcomes included intra-operative blood loss, operative time (skin incision to skin closure), uterine weight and complications (recorded up to 6 weeks after surgery). Complications were defined according to the internationally recognised classification of the Dutch Society of Obstetrics and Gynaecology (NVOG)¹³ and were further divided into major and minor complications.

After completion of the study, source data verification from the medical charts was performed in all hospitals by the principle investigator (EMS) and two research nurses.

Statistics

A non-inferiority study design was chosen. The rationale of this study design was that if the risk of urinary retention after ICR could be proven to be no worse than in the DCR group, we can conclude that direct catheterisation is preferable over DCR based on the known benefits of ICR (risk of urinary tract infection, time to mobilisation and length of hospital stay).

To ascertain the required group size, a power calculation was performed. We hypothesised that DCR was associated with 5% retention based on a small retrospective review of patients treated in LUMC. A non-inferiority margin of 10% was used as we considered a difference of up to 10 percentage points in favour of DCR acceptably small in exchange for the anticipated benefits of ICR (infections, time to mobilisation and hospital stay). Using a one-sided Z-test (α error 0.025, β error 0.20), two groups of 75 women were needed to assess the non-inferiority of ICR. An additional ten women were included to intercept any unanticipated dropouts. As a result, a sample size of 160 women was planned.

Statistical analysis was performed using SPSS software (IBM SPSS Statistics for Windows, version 20.0, Chicago, IL, USA). As a result of the low event numbers observed, we calculated exact confidence intervals with the EXACTCI-DIFF package in R. For the *P*-value of the primary outcome, a non-inferiority test was performed with an exact method

as suggested by Chang.¹⁴ Data were summarised and extreme values were verified to be correct. All statistical analyses were performed by both intention-to-treat and per-protocol approaches, as stated in the CONSORT recommendations for non-inferiority RCTs.¹² In the intention-to-treat analysis we included randomised patients who met our inclusion and exclusion criteria according to the allotted randomisation group. In the per-protocol analysis we included for the group randomised to ICR all those women who had their catheter directly removed in the operating theatre and for the group randomised to DCR we included all women who had their catheter removed between 18 and 24 hours after surgery. To assess the non-inferiority of the ICR policy, the difference between the rates of urinary retention (primary outcome) in the intervention and control groups was compared with the non-inferiority margin of 10 percentage points. Accordingly, non-inferiority was met if the upper limit of the two-sided 95% confidence interval around this difference would not cross the predefined margin of 10 percentage points. In case the non-inferiority test would not be proven, we additionally looked at whether the lower limit of the confidence interval exceeded zero (i.e. superiority test).

For the other variables, we assessed normality and continuous data were presented as mean with standard deviation (SD) or as median (range) and categorical data as frequency (percentage). The secondary outcomes of the two groups were compared using the Student's *t* test or Mann–Whitney *U* test and chi-square test or Fisher's exact test as appropriate. *P*-value and 95% confidence interval were reported. A *P*-value of < 0.05 was considered significant.

Results

Between 31 May 2016 and 22 July 2017, 162 eligible patients were included in the trial (Figure 2). Three women withdrew consent within 24 hours after surgery and four women were randomised despite the fact that the gynaecologist decided immediately at the end of the surgery that prolonged catheterisation was necessary regardless of the randomisation result. These cases were considered dropouts and were not included in any further analyses. As a result, a total of 74 women were analysed in the group with ICR and 81 women in the group with DCR. Of the women randomised to DCR, eight requested earlier catheter removal (between 2 and 12 hours after surgery) because of unbearable complaints (9.9%). Baseline characteristics and surgical outcomes of the included women are listed in Table 1 and were well balanced.

Regarding the primary outcome, ten women in the ICR group could not urinate spontaneously within 6 hours (13.5%) compared with none in the DCR group (Table 2;

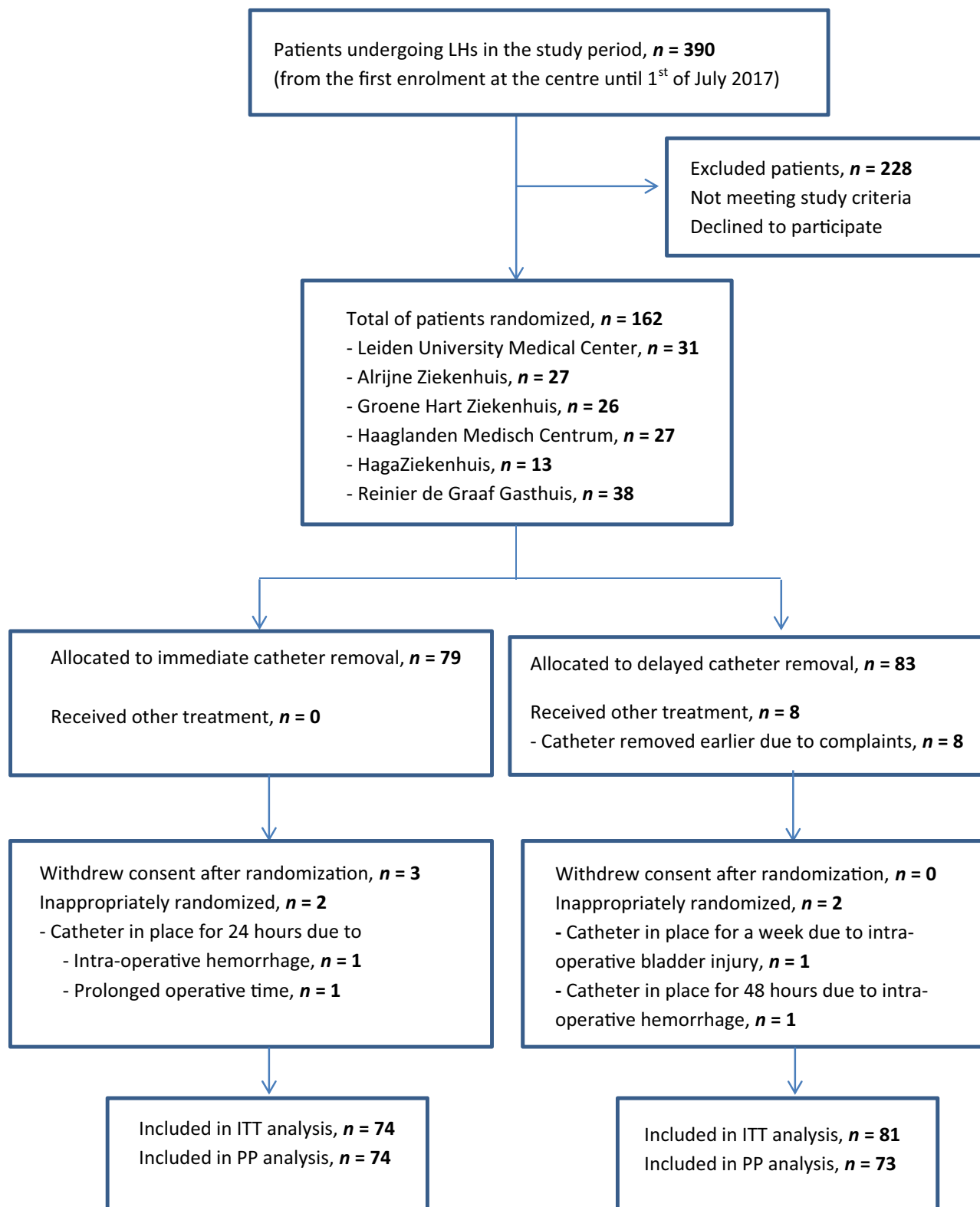


Figure 2. Overview of included patients.

Table 1. Baseline characteristics and surgical outcomes – intention-to-treat analysis

	Immediate catheter removal (n = 74)	Delayed catheter removal (n = 81)
Baseline characteristics		
Age, years, mean (SD)	49.3 (10.5)	51.5 (11.9)
Body mass index, kg/m ² , mean (SD) (n = 154)	26.4 (5.5)	28.5 (5.6)
ASA classification, n (%)		
ASA I	32 (43.2)	37 (45.7)
ASA II	40 (54.1)	43 (53.1)
ASA III	2 (2.7)	1 (1.2)
ASA IV	0	0
Previous procedures, n (%)		
Laparoscopic	13 (17.6)	18 (22.2)
Laparotomic	12 (16.2)	16 (19.8)
Indication(s) for LH, n (%)*		
Heavy or irregular menstrual bleeding	37 (50)	43 (53.1)
Pain	14 (18.9)	16 (19.8)
Fibroids	21 (28.4)	15 (18.5)
Malignancy	25 (33.8)	34 (42.0)
Cervix	11	12
Endometrium	14	22
Other	3 (4.1)	9 (11.1)
Preventive (genetics)	2	5
Adenomyosis/endometriosis	0	4
Bicornuate uterus	1	0
Type of hysterectomy, n (%)		
TLH	73 (98.6)	78 (96.3)
LAVH	1 (1.4)	3 (3.7)
SLH	0	0
BSO, n (%)	35 (47.3)	38 (46.9)
Tubectomy, n (%)	12 (16.2)	12 (14.8)
Uterine weight, grams, mean (SD), (n = 148)	213.8 (170.7)	217.9 (227.9)
Surgical outcomes		
Operative time, minutes, mean (SD)	116.0 (44.0)	105.4 (29.6)
Intra-operative blood loss, ml, mean (SD)	131.8 (136.9)	108.1 (122.3)
Complications, n (%)		
Major complications	1 (1.4)	6 (7.4)
Ureter injury	1	1
Bladder injury	0	0
Postoperative haemorrhage (re-operation)	0	3
Vaginal cuff abscess (drainage)	0	1
Re-operation**	0	1
Minor complications	5 (6.8)	10 (12.3)
Infection (wound)	1	2
Fever eci (>38°C)	0	1

Table 1. (Continued)

	Immediate catheter removal (n = 74)	Delayed catheter removal (n = 81)
Haemorrhage/haematoma/abscess/defect (vaginal cuff)	3	4
Hematoma in abdomen	1	1
Transient kidney failure eci	0	1
Gauze left in vagina	0	1

ASA, American Society of Anesthesiologists; (B)SO, (bilateral) salpingo-oophorectomy; eci, *e causa ignota* (of unknown origin); SLH, supracervical laparoscopic hysterectomy; TLH, total laparoscopic hysterectomy.

Data are presented as mean (standard deviation) or as number (percentage). Baseline characteristics were well balanced.

*Indications: patients could have more than one indication.

**Re-operation due to suspicion of herniation but this was not the case.

risk difference 13.5%, range 5.6–24.8). The intention-to-treat analysis and per-protocol analysis could not demonstrate non-inferiority of ICR over DCR ($P = 0.88$ and $P = 0.88$). As the lower boundary of the confidence interval of the difference exceeded zero, ICR was associated with a significantly higher rate of urinary retention 6 hours after catheter removal.

Of the ten women with voiding dysfunction in the ICR group, seven were able to urinate spontaneously within 9 hours after catheter removal without any additional interventions, as demonstrated in the Supplementary material (Table S1). The other three women required re-catheterisation because they could not void spontaneously despite several attempts. The first patient, who had had her surgery at the end of the morning, was intermittently catheterised after the bladder scan revealed a urinary retention of 908 ml. The second patient, who had had her surgery in the beginning of the afternoon, received immediately an indwelling catheter overnight (urinary retention 550 ml). Both women urinated spontaneously after catheter removal and did not encounter any further problems. The last patient, who had been the first case in the morning, also received an indwelling catheter overnight (residual volume unknown). The next day, this catheter was removed but the patient could still not urinate spontaneously and the decision was made to discharge her with an indwelling catheter. After 7 days, the catheter was removed and she could void spontaneously. Bladder scan showed no urinary retention. Detailed information regarding the ten women with voiding dysfunction is provided in the Supplementary material (Table S1).

Table 2. Primary and secondary outcomes of the trial – intention-to-treat analysis

	Immediate catheter removal (n = 74)	Delayed catheter removal (n = 81)	Difference in percentages (95% CI)	P-value
Primary outcome				
Unable to void within 6 hours, n (%), (n = 155)	10 (13.5)	0	13.5 (5.6; 24.8)	0.88
Additional interventions required	3*	0		
Secondary outcomes				
Urinary tract infection treated with antibiotics, n (%)	3 (4.1)	8 (9.9)	–5.8 (–15.1; 3.5)	0.215
During hospitalisation	0	4		
After discharge	3	4		
Urine test positive for nitrite and/or leucocytes, n (%), (n = 98)	25 (48.1)	24 (52.2)	–4.2 (–10.9; 21.1)	0.840
Mobilisation, hours, median (range), (n = 134)	5.7 (0.8–23.3)	21.0 (1.4–29.9)		<0.001
Length of hospital stay, days, median (range)	1.5 (0–4)	1 (1–4)		0.954
Exploratory outcomes				
Bladder scan at discharge, ml, mean (SD), (n = 116)	46.6 (70.7)	37.5 (64.7)	(–15.8; 34.0)	0.471
Questionnaires 6 hours after surgery (n = 103)				
Overall VAS score, mean (SD)	3.2 (2.0)	3.5 (2.4)	(–1.2; 0.5)	0.426
VAS score for the catheter, mean (SD)	–	2.9 (2.9)		–
Expected discharge time according to patient, n (%)				0.621
Today	2 (4.5)	1 (1.9)		
Tomorrow	14 (31.8)	22 (41.5)		
The day after tomorrow	15 (34.1)	15 (28.3)		
Not any time soon	2 (4.5)	5 (9.4)		
I don't know	11 (25.0)	10 (18.9)		
Questionnaires 24 hours after surgery (n = 101)				
Overall VAS score, mean (SD)	2.9 (2.0)	2.8 (2.3)	(–0.7; 1.0)	0.719
Expected VAS score specific for the catheter for patients without, mean (SD)	4.7 (2.9)	3.0 (2.9)	(0.6; 3.0)	0.004
Questionnaires 6 weeks after surgery (n = 70)				
Satisfaction with treatment, VAS score, mean (SD)	8.9 (0.9)	9.0 (1.7)	(–0.8; 0.5)	0.709
Satisfaction with hospitalisation, VAS score, mean (SD)	8.5 (1.5)	9.1 (1.1)	(–1.2; 0.2)	0.056

UTI, urinary tract infection.

Data are presented as mean (standard deviation), as median (range) or as number (percentage).

*One patient was discharged with an indwelling catheter.

For the secondary outcomes (Table 2), we observed that after ICR and DCR, respectively, three (4.1%) and eight (9.9%) women had a suspicion of urinary tract infection postoperatively requiring antibiotics. No significant difference was observed between the two groups (risk difference –5.8%, range –15.1 to 3.5, $P = 0.215$). In the ICR group, all three women were treated with antibiotics approximately 2 weeks after surgery. In the DCR group, four women were treated with antibiotics after discharge while four women were treated directly 1 or 2 days after surgery. No significant difference was observed between the two groups for the results of the urine test (risk difference –4.2, range –10.9 to 21.3, $P = 0.840$) or the post-voiding residual at discharge [46.6 (SD 70.7) ml versus 37.5 (SD 64.7) ml, $P = 0.471$]. Patients in the ICR group mobilised significantly earlier than the group with DCR [median of

5.7 hours (range 0.8–23.3) versus 21 (range 1.4–29.9), $P \leq 0.001$]. The length of hospital stay did not differ between the two groups [1.5 (range 0–4) versus 2 (range 1–4), $P = 0.954$].

No clinically relevant differences were observed for the overall pain VAS between the two groups 6 and 24 hours after LH (Table 2). The group with an indwelling catheter in place reported 6 hours after surgery a VAS specific for the indwelling catheter of 2.9 (2.9). No significant difference was observed regarding the number of days a woman expected to stay in the hospital when asked 6 hours after surgery ($P = 0.621$). Twenty-four hours after surgery, the women without a catheter were asked to assess the expected pain score for the catheter as if they still had one. Women in the ICR group reported a significantly higher expected VAS than the DCR group with a catheter still in

place [4.7 (SD 2.9) versus 3.0 (SD 2.9), $P = 0.004$, 95% CI 0.6–3.00]. Six weeks after surgery, no clinically relevant differences were seen with respect to satisfaction of the procedure and satisfaction of the hospitalisation ($P = 0.709$; $P = 0.056$).

The results of the per-protocol analysis are available in the Supplementary material (Table S2 and Table S3). The eight women who had been randomised to DCR but requested earlier catheter removal were excluded. No relevant differences were observed compared with the intention-to-treat analysis.

Discussion

Main finding

In the present RCT, comparing 74 women with ICR after LH with 81 women with DCR, ten women, all allocated to the ICR group, could not void within 6 hours (13.5%). However, seven of these women could void spontaneously within 9 hours after catheter removal without additional intervention. Regarding the secondary outcomes, eight women from the delayed group requested earlier catheter removal because of complaints (9.9%). Three women with ICR (4.1%) had a urinary tract infection postoperatively versus eight women with DCR (9.9%). Women with ICR mobilised significantly earlier [5.7 hours (range 0.8–23.3) versus 21.0 (range 1.4–29.9), $P \leq 0.001$]. No significant difference was observed for hospital stay, postoperative pain or patient satisfaction.

Strength and limitations

Limitations of our study were that neither patients nor caregivers were blinded to the catheter policy, which could result in biased reporting outcomes. This could be particularly the case for outcomes related to patients, as psychological factors might be of influence.¹⁵ Yet, for this topic, a double-blinded study would not have been possible. Strengths of the study include its randomised controlled design and the inclusion of a large population of women undergoing LH. To our knowledge, no other RCT specific for LH has been conducted. Furthermore, the trial was performed in six different hospitals, which adds to the generalisability of the outcomes.

Interpretation

Although the majority of the hospitals in the Netherlands leave the urinary catheter in place until the next day after LH, the scientific support for this management is absent. Indeed, the few available studies on this topic all favour immediate removal after different types of hysterectomy.^{4,6,16} The potential drawback of immediate catheter removal is the increased risk of urinary retention, which has been reported to be up to 34% after LAVH.⁴ The

retention rate in our study was in line with a prospective cohort study that demonstrated a retention rate of 14% after analysing 140 women undergoing LH with ICR.⁵ Nevertheless, our study did not meet the predefined margin of non-inferiority. Yet, of the ten women with voiding dysfunctions, only three required re-catheterisation. The other seven voided spontaneously within 9 hours without additional interventions. It is therefore debatable if all voiding difficulties were clinically relevant and should be actually classified as urinary retention. In literature, several definitions are in use to define 'urinary retention'. If considering only those women requiring re-catheterisation, the urinary retention rate for the ICR group would be 4.1% in our study. Yet, also with this definition, the outcome would not meet the non-inferiority margin (risk difference 4.1, range -1.7 to 12.3). As a result, in the future, it would be interesting to study the risk of urinary retention when removing the catheter a couple of hours after surgery.

In the context of same-day discharge after LH, it is important to take into consideration that a proportion of women with ICR voided with delay. Indeed, a recent systematic review demonstrated that a reduced time before voiding after catheter removal was directly associated with a successful same-day discharge.¹⁷ For instance, it might be too late to discharge patients on the same-day if they can only void between 6 and 9 hours after surgery. A study demonstrated that it was difficult to predict preoperatively who is at risk of voiding dysfunction.¹⁸ Although our study was not designed to study the risk factors associated with urinary retention, we observed that women who were confronted with voiding difficulties had significantly more intra-operative blood loss. Numbers did not allow us to determine a cut-off.

Another aspect to consider when determining the optimal moment to remove the catheter is the risk of urinary tract infections. Studies have shown that the overall risk of urinary tract infection with an indwelling catheter is 3%–7% per day of catheterisation.^{7,19} Similarly to the RCT of Liang et al.⁴ reporting on voiding outcomes of 150 women undergoing LAVH, we did not observe a statistically significant difference in the risk for urinary tract infections up to 6 weeks after surgery. However, it was interesting to observe that already during the short time of admission, four women from the DCR group were diagnosed and treated for urinary tract infections (4.9%) compared with none in the ICR group. It is important to realise that healthcare providers were not blinded to the use of a catheter and therefore there was a bias toward the concern for dysuria in women because DCR cannot be excluded.

Direct catheter removal has also been associated with early mobilisation after surgery.^{6,16} This was also observed in our study; women with ICR mobilised significantly earlier compared with women with DCR, with a difference in

medians of 15 hours. Patients with ICR are forced to get out of bed to void, which is a positive side effect of this regimen because early mobilisation has been associated with quicker recovery and decreased morbidity.¹¹ In theory, patients with an indwelling catheter in place could also start mobilising, but they often have no incentive to do so. Despite the faster mobilisation, ICR did not, in our study, result in earlier hospital discharge. This is in contrast with previously published studies and might be related to the fact that in all hospitals that participated in this study, it is currently standard care to discharge patients 1 day after LH.⁶

Finally, it is relevant to assess patient's wellbeing on catheter removal. Studies have reported that patients experience more urethral or vesical pain with prolonged catheterisation.⁹ In our study, eight women (9.6%) from the DCR group requested catheter removal a few hours after surgery because of unbearable discomfort, which is from a patient's perspective an important finding against prolonged catheterisation. On the other hand, women who had a catheter in place until the next morning reported on average a low VAS specific for the catheter (2.9, SD 2.9). In addition, the overall pain scores were not clinically different for the group without catheter. It seems therefore that the degree of discomfort varies according to the individual.

Compared with open surgery, LH has been associated with many well-known advantages such as quicker hospital discharge and faster recovery.²⁰ Although catheter management is probably not the main priority of a surgeon, the consequences of a suboptimal regimen may undo the benefits associated with the minimally invasive approach. The consequences of a poor catheterisation policy might significantly impact patient's postoperative recovery as well as lead to increased hospital costs, aspects that are increasingly being considered in our era of Value-Based Health Care.

Conclusion

In conclusion, the non-inferiority of immediate catheter removal could not be demonstrated in terms of urinary retention 6 hours after procedure. However, 70% of the women with voiding difficulties in the ICR group could void spontaneously within 9 hours after LH without further interventions. It is therefore questionable if all observed urinary retention cases were clinically relevant. ICR was also associated with faster mobilisation and, although not significant, with lower rates of treatment for urinary tract infections (4.1% versus 9.9%). Furthermore, 9.9% of the women from the DCR group requested earlier removal because of discomfort. As a result, the clinical advantages of immediate removal may still outweigh the risk of bladder retention and should be considered after uncomplicated LH.

Disclosure of interests

EM Sandberg reports receiving a research grant from Bronovo Hospital Fund (The Hague, the Netherlands). The funding source had no involvement during the conduction of the research and/or preparation of the article. The other authors report no conflict of interest. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

ES and ARHT were responsible for the acquisition, analysis and interpretation of data, as well as the drafting and finalisation of the manuscript. CvM, HSK, KG, WK, HTC/N, LCFH and KK were responsible for the randomisation of the patients in their hospital, the acquisition of data as well as the finalisation of the manuscript. NvG contributed to the statistical analysis and interpretation of the data as well as the finalisation of the manuscript. FWJ was responsible for the conception of the study and contributed to the acquisition and interpretation of data and the finalisation of the manuscript. All authors take responsibility for this study and its findings.

Details of ethics approval

The protocol was approved by the Ethics Committee of Leiden University Medical Centre (LUMC) in Leiden, the Netherlands on 6 April 2016; reference number P15.382/NL55504.058.15. The trial was registered in clinical.gov.org (NCT02742636).

Funding

None.

Acknowledgements

We thank Dorien Berends-van der Meer, Ada van der Ster, Gerlies van den Heuvel and Thekla Jansen-Werkhoven for their help during the conduct of the study.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Detailed overview of the women with voiding dysfunction compared with women without from the immediate catheter removal group.

Table S2. Baseline characteristics and surgical outcomes – per-protocol analysis.

Table S3. Primary and secondary outcomes of the trial – per-protocol analysis.

Appendix S1. Questionnaire. ■

References

- 1 Guideline on Minimally Invasive Surgery (in Dutch). [http://www.aneesthesiologie.nl/uploads/openbaar/RL_Minimaal_Invasieve_Chirurgie_2012.pdf]. Accessed 1 October 2017.
- 2 Laparoscopic techniques for hysterectomy, interventional procedures guidance. [<https://www.nice.org.uk/guidance/ipg239/resources/laparoscopic-techniques-for-hysterectomy-1899865344377797>]. Accessed 1 October 2017.
- 3 Sandberg EM, Leinweber FS, Herbschleb PJ, Berends-van der Meer DMA, Jansen FW. Urinary catheterisation management after laparoscopic hysterectomy: a national overview and nurse preference survey. *J Obstet Gynaecol* 2018;8:1–6.
- 4 Liang CC, Lee CL, Chang TC, Chang YL, Wang CJ, Soong YK. Postoperative urinary outcomes in catheterized and non-catheterized patients undergoing laparoscopic-assisted vaginal hysterectomy – a randomized controlled trial. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:295–300.
- 5 Ghezzi F, Cromi A, Uccella S, Colombo G, Salvatore S, Tomera S, et al. Immediate Foley removal after laparoscopic and vaginal hysterectomy: determinants of postoperative urinary retention. *J Minim Invasive Gynecol* 2007;14:706–11.
- 6 Alessandri F, Mistrangelo E, Lijoi D, Ferrero S, Ragni N. A prospective, randomized trial comparing immediate versus delayed catheter removal following hysterectomy. *Acta Obstet Gynecol Scand* 2006;85:716–20.
- 7 Hooton TM, Bradley SF, Cardenas DD, Colgan R, Geerlings SE, Rice JC, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. *Clin Infect Dis* 2010;50:625–63.
- 8 Schumm K, Lam TB. Types of urethral catheters for management of short-term voiding problems in hospitalised adults. *Cochrane Database Syst Rev* 2008;16(2).
- 9 Zhang P, Hu WL, Cheng B, Cheng L, Xiong XK, Zeng YJ. A systematic review and meta-analysis comparing immediate and delayed catheter removal following uncomplicated hysterectomy. *Int Urogynecol J* 2014;26(5):665–74.
- 10 Dunn TS, Shlay J, Forshner D. Are in-dwelling catheters necessary for 24 hours after hysterectomy? *Am J Obstet Gynecol* 2003;189:435–7.
- 11 Barber EL, Van LL. Enhanced recovery pathways in gynecology and gynecologic oncology. *Obstet Gynecol Surv* 2015;70:780–92.
- 12 <http://www.consort-statement.org/extensions?ContentWidgetId=555>. Accessed 1 October 2017.
- 13 Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. *Qual Saf Health Care* 2010;19:132–7.
- 14 Chang ISF. Exact test of equivalence and efficacy with a non-zero lower bound for comparative studies. *Stat Med* 1998;17:1403–13.
- 15 Sakakibara R, Uchiyama T, Awa Y, Liu Z, Yamamoto T, Ito T, et al. Psychogenic urinary dysfunction: a uro-neurological assessment. *Neurourol Urodyn* 2007;26:518–24.
- 16 Ahmed MR, Sayed Ahmed WA, Atwa KA, Metwally L. Timing of urinary catheter removal after uncomplicated total abdominal hysterectomy: a prospective randomized trial. *Eur J Obstet Gynecol Reprod Biol* 2014;176:60–3.
- 17 Korsholm M, Mogensen O, Jeppesen MM, Lysdal VK, Traen K, Jensen PT. Systematic review of same-day discharge after minimally invasive hysterectomy. *Int J Gynaecol Obstet* 2017;136:128–37.
- 18 Won HR, Maley P, Chetty N, Chan K, Abbott J. Bladder dysfunction after gynecologic laparoscopic surgery for benign disease. *J Minim Invasive Gynecol* 2012;19:76–80.
- 19 Givens CD, Wenzel RP. Catheter-associated urinary tract infections in surgical patients: a controlled study on the excess morbidity and costs. *J Urol* 1980;124:646–8.
- 20 Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BW, et al. Surgical approach to hysterectomy for benign gynaecological disease. *Cochrane Database Syst Rev* 2015;(8):CD003677.