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1	1 Early versus delayed urinary catheter removal after hysterectomy: A systematic rev					
2	and meta-analysis					
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18	Short title: Removal of urinary catheter after hysterectomy					
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20						

#### 21 Abstract

22 **Objectives:** In bladder drainage, an essential part of post-hysterectomy care, the optimal 23 timing for removing the urinary catheter is unclear. Our objective was to evaluate the risks 24 and benefits of early (<6 hours) vs delayed (>6 hours) catheter removal post-hysterectomy. 25 Study design: A systematic review searching MEDLINE, EMBASE and Cochrane 26 CENTRAL from inception till May 2019 for randomised trials of women undergoing 27 hysterectomy. We reported on urinary retention, positive urine culture, urinary tract infection (UTI) (defined by symptoms and/or antibiotic use), post-operative pyrexia, time to 28 29 ambulation, and length of hospital stay. We assessed risk of bias in included trials and used a 30 random-effect model to generate risk ratios (RR) for dichotomous outcomes and weighted 31 mean differences (WMD) for continuous outcomes, with 95% confidence intervals (CI). 32 Results: Of 1020 potentially relevant citations, we included 10 randomised trials (1120 33 women). Four trials had low risk of bias for randomisation and allocation concealment while 34 five had low risk for outcome assessment and selective reporting. Compared to delayed 35 removal, women in the early catheter removal group had a higher risk of urinary retention and needing re-catheterisation (10 RCTs, RR 3.61, 95%CI 1.21-9.21, I<sup>2</sup>=56%). There was 36 some reduction in the risk of post-operative UTI (6 RCTs, RR 0.42, 95% CI 0.18 to 0.96, 37  $I^2=0\%$ ), but we did not find a significant difference in post-operative pyrexia (6 RCTs, RR 38 0.73, 95% CI 0.43-1.24, I<sup>2</sup>=18%) or positive urine cultures (6 RCTs, RR of 0.56, 95% CI 0.27-39 40 1.12,  $I^2$ =55%). There was no significant difference in the average time to ambulation  $(3RCTs, WMD - 4.6, 95\% CI - 9.16 \text{ to } -0.18, I^2 = 98\%)$  and length of hospital stay  $(3RCTs, MMD - 4.6, 95\% CI - 9.16 \text{ to } -0.18, I^2 = 98\%)$ 41 WMD -1.05, 95% CI -2.42 to 0.31,  $I^2$ =98%). Our meta-regression on the provision of 42 43 prophylactic antibiotics did not show a significant effect on the reported outcomes. Our analysis was limited by our inability to adjust for potential effect modifiers such as the 44 45 surgical route.

46	<b>Conclusions:</b> Early removal of the urinary catheter <6 hours post-hysterectomy seems to
47	increase the risk of urinary retention and needing re-catheterisation, but may reduce post-
48	operative UTI.
49 50	Keywords: Hysterectomy, catheter, urinary, postoperative retention, systematic review.
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52	
53	

#### 54 Introduction

55 Hysterectomy is one of the commonest benign gynaecological procedures worldwide (1,2) with more than 400,000 hysterectomies performed in the USA yearly (3). Maintaining an 56 57 empty bladder during surgery is common practice to reduce the risk of urological 58 complications and promote enhanced post-operative recovery. Still, the optimal timing for 59 post-operative catheter removal remains unclear (4). Delayed removal of urinary catheter 60 postoperatively has been linked to increasing the risk of urinary tract infection (UTI), use of 61 antibiotics, longer time to ambulation and hospital stay. In contrast, early removal (<6 hours 62 post operatively) could also increase the risk of post-operative urinary retention and re-63 catheterisation (5,6).

64

65 A previous systematic review suggested that early catheter removal reduced the incidence of 66 postoperative UTI, positive urine culture, and the time to ambulation; however, it increased 67 the rate of re-catheterisation (7). This review, however, had several methodological 68 limitations; it included a non-randomised study in the meta-analysis and incorporated women 69 who had gynaecological surgery without a hysterectomy. Since its publication, two newer 70 trials were published (355 women) reporting contradictory results (8,9). To evaluate the optimal time for removing the urinary catheter post-hysterectomy we conducted a systematic 71 72 review and meta-analysis of all randomised trials on the topic.

73

### 74 Methods

75 We undertook this systematic review using a prospectively registered protocol (CDR

76 42019132213) and reported in accordance with the PRISMA guidelines.

77

78 Literature Search

We searched major electronic databases (MEDLINE, EMBASE and Cochrane CENTRAL)
for all randomised trials evaluating the timing of catheter removal following hysterectomy
from inception until May 2019. We combined the following MeSH search terms using the
Boolean operators to screen for relevant studies ("hysterectomy", "catheter", "catheters,
indwelling", "urine", "urinary retention") (Appendix 1). No search filters or language
restrictions were applied. We manually searched the bibliographies of relevant articles to
identify any additional studies not captured in the electronic search.

86

## 87 Study Selection

Two independent reviewers (MPR and IH) completed the study selection and inclusion
process in two stages. Any discrepancies were discussed and resolved in consensus with a
third reviewer (BHA). First, we screened titles and abstracts to identify potentially relevant
studies. Then, we reviewed the full texts of relevant articles against our inclusion criteria.
We included all primary randomised trials evaluating early versus delayed catheter removal
in women who underwent a hysterectomy via any modality (abdominal, laparoscopic or
vaginal). We excluded non randomised studies, animal studies, and review articles.

95

## 96 Data Extraction

Two reviewers (MPR and IH) extracted data in duplicate using a piloted electronic data
extraction tool. We collected data on study design, number of participants, inclusion and
exclusion criteria, length of catheterisation, clinical outcomes (symptoms of UTI, positive
urinalysis, positive urine culture, antibiotic administration for UTI, post-operative pyrexia,
re-catheterisation, time to ambulation (hours) and length of hospital stay (days)). Our primary
outcome was post-operative urinary retention following the removal of catheter. We also
reported on the following secondary outcomes which were planned *a priori:* post-operative

pyrexia and time to ambulation, length of hospital stay, positive urine culture, and UTI as acomposite outcome of urinary symptoms and/or use of antibiotics (10).

106

## 107 Assessment of risk of bias

108 The quality of published literature was assessed by two reviewers in duplicate (MPR and IH)

109 using the Cochrane Risk of Bias assessment tool. Studies were assessed in five domains:

110 randomisation and sequence generation, allocation concealment, outcome assessment,

111 completeness of outcome data, and selective outcome reporting. Due to the nature of the

112 intervention, we did not penalise unblinded trials, none of the trials blinded assessors.

113

## 114 Data synthesis

115 We reported on dichotomous outcomes using summary risk ratio (RR) with 95% confidence

116 intervals (CI) and on continuous outcomes using weighted mean difference (WMD). We

117 pooled data using a restricted maximum likelihood (REML) random-effect model (11). We

118 assessed the heterogeneity among included trials using the  $I^2$  statistics. We planned a

sensitivity meta-regression analysis to investigate potential effect modifiers where relevant.

120 All statistical analyses were conducted in Stata V13 (StataCorp, TX) and Open Meta-analyst

121 software (Brown University; Providence, RI, USA).

122

#### 123 **Results**

124 Characteristics of included studies

Our electronic search identified 1020 potentially relevant citations, of which 15 articles were deemed relevant and were assessed in full. We excluded five studies: three studies reported incomplete data, one reported on women undergoing pelvic surgery (8) and one was a nonrandomised study (12). In total, we included ten trials reporting on 1120 women who

129 underwent a hysterectomy (9,13–21) (Figure 1). Three studies were conducted in the USA and one study in each of the UK, Netherlands, Egypt, Italy, Hong Kong, India and Taiwan. 130 131 All studies randomised women to either early catheter removal (<6 hours post-operatively) or 132 delayed removal (>6 hours post-operatively), which ranged from 6 to 48 hours (Table 1). The median sample size of the included trials was 124 (range 70-250). There were variations 133 134 in the surgical routes to perform hysterectomy with four trials reporting on abdominal hysterectomy (4/10, 40%), two on laparoscopic or laparoscopy assisted hysterectomy (2/10, 135 136 20%), one on vaginal hysterectomy (1/10, 10%) and three on any surgical route (3/10, 30%). 137 Seven trials reported given prophylactic antibiotics pre-operatively (7/10, 70%) while three did not report on it. 138 139 140 Risk of Bias 141 The overall quality of the included studies was moderate (Figure 2, Appendix 2). Four studies 142 had low risk of bias for randomisation and allocation concealment (4/10, 40%). Half of the 143 included trials had low risk of bias for both outcome assessment and selective reporting (5/10, 50%), and majority had low risk of bias due to incomplete data (9/10, 90%) (Figure 2). 144 145 146 **Outcomes** Compared to delayed removal, women in the early catheter removal group had a higher risk 147 148 of urinary retention and needing re-catheterisation (10 RCTs, RR 3.61, 95%CI 1.21-9.21, 149  $I^2$ =56%). There was some reduction in the risk of post-operative UTI (6 RCTs, RR 0.42, 95% CI 0.18 to 0.96,  $I^2=0\%$ ), but we did not find a significant difference in post-operative 150 pyrexia (6 RCTs, RR 0.73, 95% CI 0.43-1.24, I<sup>2</sup>=18%) or positive urine cultures (6 RCTs, RR 151 of 0.56, 95% CI 0.27-1.12,  $I^2$ =55%). There was no significant difference in the average time 152

- to ambulation (3RCTs, WMD -4.6, 95% CI -9.16 to -0.18,  $I^2$ =98%) and length of hospital stay
- 154 (3RCTs, WMD -1.05, 95% CI -2.42 to 0.31,  $I^2$ =98%) in both groups.
- 155 We performed a meta-regression to evaluate the effect of prophylactic antibiotics on reported
- 156 outcomes. There was no significant effect on urinary retention (p=0.54), post-operative UTI
- 157 (p=0.30), positive urine cultures (p=0.58), or post-operative pyrexia (p=0.34). A meta-
- 158 regression was not possible for the two remaining outcomes due to the small sample size.

## 160 Discussion

161 *Summary of findings* 

162 Our meta-analysis indicates that early removal of urinary catheter (<6 hours) post-

163 hysterectomy might reduce the risk of post-operative UTI, however, it appears to increase the

164 risk of urinary retention needing re-catheterisation. There were no obvious benefits in other

165 reported measures including reducing time to mobilisation and the length of hospital stay. In

166 view of the cumulative evidence on the potential adverse effects of early catheter removal,

- 167 we deduce that such practice should not be routinely offered to women pending future
- 168 research.

169

170 *Strengths and limitations* 

171 We conducted this systematic review using a prospectively registered protocol and a

standardised methodology. We assessed the risk of bias in included studies and extracted data

173 in duplicate. We only included randomised trials and reported on clear time points (removal

174 of catheter before and after 6 hours) to reduce selection and performance bias.

175

176 Our findings are not without limitations. Women included had different background

177 morbidity and underwent different operative route for hysterectomy. The increased pain

178 associated with open abdominal surgery might lead to a higher risk of urinary retention in 179 contrast to laparoscopic hysterectomy. Several trials provided intravenous or intramuscular 180 antibiotics at the start of the surgery which could also reduce the risk of developing a UTI 181 postoperatively and the sensitivity of urine cultures.(Table 1) This varied across included 182 studies (using 1g ceftriaxone, 1.2g augmentin, 500mg cefazolin, 2g cefazolin or 183 doxycycline), still, our meta-regression did not show a significant effect of antibiotics on the 184 reported outcomes. The definition of UTI adopted by most authors was pragmatic including 185 symptoms and use of antibiotics. While this is consistent with established guidelines (10), 186 adopting a more stringent definition might reduce the event rate in both comparison groups. 187

188 The size of the urinary catheter used and the insertion technique were poorly reported which 189 could impact our estimates. Other factors such as the duration of the anaesthesia, the 190 operating time, and the post-operative pain relief could also impact the women's ability to 191 pass urine after removing the catheter. The threshold of 6 hours used by most authors is 192 somewhat arbitrary and the duration for delayed removal and the time of re-catheterisation 193 varied across included trials. Our inferences are subject to the inherent, unavoidable 194 heterogeneity in our meta-analyses. We believe our findings present the best available 195 pragmatic evidence to advise clinical practice pending future studies.

196

## 197 Implications for future practice

With the increasing numbers of minimally invasive interventions in gynaecology, adopting
the principles of enhanced recovery and early mobilisation is key to improve operative
outcomes and meet the patients' expectation for a speedy recovery (4). Early removal of the
urinary catheter is becoming routine practice especially since the introduction of same-day
discharge following laparoscopic hysterectomy (22). However, our findings suggest that

203	removing the catheter before 6 hours might increase post-operative complications. Therefore,					
204	careful mitigation of peri-operative factors (planned time of discharge, length of the					
205	procedure, patient co-morbidity, etc.) remains essential to formulate a safe and optimal post-					
206	operative care plan (23,24).					
207	Traditionally, prolonged and repeated catheterisation was deemed to be a contributing factor					
208	for post-operative UTIs. Still, the overall estimate in our meta-analysis shows minimal					
209	benefit of early vs delayed removal of catheter. Arguably, using an aseptic catheterisation					
210	technique with prophylactic IV antibiotic cover after anaesthetic induction and removal of th					
211	catheter less than 12 hours post-op might offer the optimal practice to reduce the risk of UTIs					
212	and post-operative pyrexia (25,26).					
213						
214	Future large trials are needed to evaluate the role of catheter removal in women planned for					
215	same-day discharge following total laparoscopic and laparoscopy assisted hysterectomy					
216	given their increased frequency and the potential for higher complications with early					
217	discharge. Future studies showed take into account the various effect-modifiers identified in					
218	this systematic review to aid translation into clinical practice.					
219						
220	Conclusions					
221	Early removal of the urinary catheter (<6 hours) post-hysterectomy seems to increase the risk					
222	of urinary retention needing re-catheterisation with some reduction in the risk of UTI.					
223						
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   308

# **Table 1:** Characteristics of included trials comparing early vs delayed removal of urinary

312 catheter post hysterectomy

313					
Study	Country	Numbers randomised	Inclusion Criteria	Exclusion Criteria	Use of prophylactic Antibiotic
Sandberg 2018	Netherlands	155	> 18 years old undergoing laparoscopic hysterectomy	Additional procedures to hysterectomy Incontinence	Not reported
Ahmed 2014	Egypt	221	Undergoing total abdominal hysterectomy	Neurological disorders, Pre- operative UTI, surgeons decision for catheter to remain longer than cohort assignment, urge incontinence	1g Intramuscular ceftriaxone
Dunn 2003	USA	250	Undergoing a hysterectomy	Anticipated complicated procedure Additional bladder procedure during hysterectomy	Single dose of unspecified antibiotics prophylaxis before the operation
Alessandri 2006	Italy	96	Undergoing a hysterectomy	Anticipated complicated procedure, Recurrent UTI Urinary incontinence, Neurological disorders	Single dose of unspecified antibiotics prophylaxis before the operation
Chai 2011	Hong Kong	70	Undergoing total abdominal hysterectomy	Recurrent UTI, urinary incontinence, neurological disorders, surgeons decision for catheter to remain, spinal anaesthesia and patient controlled analgesia	Not given
Lang 2018	USA	200	Undergoing hysterectomy via any surgical route and expected to be hospitalized for at least one day	None reported	Not reported
Dobbs 1997	UK	95	Undergoing total abdominal hysterectomy for non- malignant reasons	None reported	<ol> <li>1.2 g IV augmentin or alternative regime if allergic to penicillin</li> </ol>
Liang 2009	Taiwan	150	Laparoscopic assisted vaginal hysterectomy	Pelvic reconstructive surgery, stress incontinence, Urinary symptoms	500mg iv cefazolin
Summitt 1994	USA	99	Undergoing a vaginal hysterectomy	Procidentia, Stress incontinence, positive urine culture	2g Iv cefazolin or 200 mg IV doxycycline if penicillin allergic
Joshi 2014	India	70	Undergoing abdominal hysterectomy	Anticipated complicated procedure, bladder suspension/Colporrhaphy surgery, positive urine culture, co- morbidities requiring fluid balance	at the time of surgery and continued postoperatively as per department protocol.

## **Figure legends:**

- **Figure (1)**: Selection and inclusion process for trials in the systematic review comparing
- early vs delayed removal of urinary catheter post hysterectomy
- **Figure 2:** Risk of bias in included randomised trials comparing early vs delayed removal of
- 320 urinary catheter post hysterectomy
- **Figure (3)**: Forest plots of random effect meta-analyses for reported outcomes in trials
- 322 comparing early to delayed removal of the urinary catheter post hysterectomy
- 323
- 324
- 325