Abstract of thesis entitled

“The evidence-based protocol on early removal of urinary catheters to promote early postoperative ambulation and reduce risk of urinary tract infection for patients who had undergone hysterectomy for benign gynecological diseases”

Submitted by

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Urinary catheters (UC) have been routinely used for 1 to 2 days after hysterectomy to assess urinary output and prevent urinary retention. The timing for UC removal after uncomplicated hysterectomies is generally based on tradition rather than evidence-based knowledge and thus varies significantly according to gynecologists’ preference. However, unnecessary prolong use of urinary catheters delays postoperative ambulation and is associated with increased risk of urinary tract infection (UTI). Delayed postoperative ambulation may lead to serious postoperative complications such as deep vein thrombosis and pulmonary embolism. UTI may increase patient morbidity, length of hospitalization and overall healthcare
expenditures. Therefore, the optimal duration for postoperative urinary catheterization should be considered to prevent unnecessary UC use and to minimize harmful postoperative outcomes.

An intervention for early removal of UC after uncomplicated hysterectomies may potentially improve the current practice and has been positively recommended in literatures. However, there was no published systematic review on postoperative outcomes of early UC removal for hysterectomy patients.

The dissertation, therefore, aims to evaluate the existing evidence on the postoperative influences of the early removal of UC (within postoperative 6 hours) for patient undergone uncomplicated hysterectomy for benign gynecological disease, to develop an evidence-based protocol, as well as to assess the implementation potential of the proposed protocol at a surgical unit of a public hospital in Hong Kong and to develop implementation strategies and evaluation plan.

Keyword search from electronic database PubMed and CINAHL Plus (EBSCOhost) and manual search from other resources was performed. Finally, 5 eligible randomized controlled trials (RCTs) were included and the data were extracted and summarized in the table of evidence. The internal validity and the overall methodological quality of the included studies were appraised by Scottish Intercollegiate Guidelines Network (SIGN) whereas two RCTs were graded as high
quality. The studies shown early removal of UC is associated with early postoperative ambulation and lower risk of UTI in patients who had undergone uncomplicated hysterectomy for benign gynecological diseases. With regular urination monitoring after catheter removal, no major complications was reported. As a result, an evidence-based protocol was developed.

The target patients and the local setting share similar characteristics to those in the included studies, suggesting that the proposed innovation is transferable. Staff competencies as well as organizational and administrative support ensure the success of the implementation of the proposed protocol. Cost-benefit analysis shown that implementing the proposed innovation was estimated to have an annual saving of HKD$752093 with minimal risk on patients. Therefore, the proposed innovation is effective and safe, as well as easy and economical to implement.

A 9-month implementation program, including the communication process, the pilot study and the evaluation, was designed. The effectiveness of the early removal of UC is determined by a decrease in the first postoperative ambulation time and the incidence of urinary tract infection.
The evidence-based protocol on early removal of urinary catheters to promote early postoperative ambulation and reduce risk of urinary tract infection for patients who had undergone hysterectomy for benign gynecological diseases

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A thesis submitted in partial fulfilment of the requirements for the Degree of Master of Nursing at The University of Hong Kong.

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Declaration

I declare that this thesis represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed _____________________

Kwan Tan Hung
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CHAPTER 1: INTRODUCTION

1.1 Background

Hysterectomy, which is the total or partly removal for uterus, has becoming a common surgery worldwide for women patients who have benign gynecological diseases such as uterine fibroids, dysfunctional uterine bleeding and cervical dysplasia. In Hong Kong, total abdominal hysterectomy is prevalent, accounted for more than half of the abdominal operations (HKCOG Tertiary-wide O&G Audit Report, 2004).

Urinary catheters (UC) have been commonly used during hysterectomy to maintain the urinary bladder empty, so as to improve surgical field exposure and prevent possible intraoperative injury to urinary bladder (Ghoreishi, 2003).

Keeping UC in-situ postoperatively for 1 to 2 days has been a routine practice for patients after hysterectomy to assess urinary output and prevent urinary retention. Urinary retention is the inability to completely empty the urinary bladder. Postoperative urinary retention may be harmful in the way that it may cause increased risk of urinary tract infection (UTI), detrusor instability and voiding difficulties in long term (Stanton, Ozsoy, & Hilton, 1983).

Urinary catheterization may possibly cause delayed postoperative ambulation due to discomfort or pain at urethral site and patient apprehension from the inserted
catheter (Ahmed et al., 2014; Alessandri, Mistrangelo, Lijoi, Ferrero, & Ragni, 2006; Dunn, Shlay, & Forshner, 2003). Delayed postoperative ambulation may lead to serious postoperative complications such as deep vein thrombosis and impaired pulmonary function (Gonzalez et al., 2004). In addition, prolonged UC use has shown to be associated with increased risk of UTI (Bouza, San Juan, Muñoz, Voss, & Kluytmans, 2001) which may in turn increase patient morbidity, length of hospitalization and overall healthcare expenditures (Foxman, 2003). Therefore, the optimal duration for postoperative urinary catheterization should be considered to prevent unnecessary UC use and to minimize harmful postoperative outcomes.

Early removal of UC after hysterectomy, which is within postoperative 6 hours, has been advocated as it may promote early postoperative ambulation, increase patient comfort, possibly reduce the risk of UTI and not associated with increased risk of postoperative urinary retention (Ahmed et al., 2014; Joshi, Aggarwal, Chopra, & Taneja, 2014). UC removal within postoperative 6 hours seems to be a more advantageous intervention for postoperative bladder management, compared with the traditional practice, delayed removal of UC at postoperative Day 1 to Day 2.

1.2 Affirming the Need

1.2.1 Clinical issue and current practice
Indwelling UC has been traditionally used postoperatively for patients with uncomplicated hysterectomy for urinary output assessment and prevention of postoperative urinary retention.

The current practice of the targeted surgical unit in the local public hospital is that the UC is removed 24 to 48 hours after uncomplicated hysterectomies. However, there was limited literature support for the use of indwelling UC for 24 to 48 hours after uncomplicated hysterectomies. The timing for UC removal after uncomplicated hysterectomies is generally based on tradition rather than evidence-based knowledge and thus varies significantly according to gynecologists’ preference. There is no evidence-based protocol regarding the use of UC after uncomplicated hysterectomies.

Prolong catheterization can delay postoperative ambulation and increase risk of UTI which may lengthen hospitalization (Ahmed et al., 2014; Alessandri et al., 2006). UTI has been a prevalent nosocomial infection and up to 75% of hospital acquired UTIs are related to UC use (Fernandez, Griffiths & Murie, 2003; Schiøtz & Tanbo, 2006). In addition, delayed ambulation may increase risk of deep vein thrombosis and pulmonary embolism which are morbid postoperative complications (Gonzalez et al., 2004). From observations in the local setting, approximately 18% cases developed UTI and prolonged their hospital stay from 4 to 5 days. Most patients with UC inserted complaint pain or discomfort at urethral site and had delayed ambulation after
operation. The local observations are congruent with the literature findings. Studies has shown that patients with placement of UC for 24 hours after gynecological procedures reported more pain and discomfort and delayed postoperative ambulation as compared to patients having early UC removal, that is within postoperative 6 hours (Dunn et al., 2003; Sekhayat, Farajkhoda, & Davar, 2008; Ahmed et al., 2014). Prolonged UC use seems to increase patient suffering, risk of UTI, morbidity, hospital stay and overall healthcare cost in the local setting. A change of current practice should be considered to minimize these undesirable outcomes.

In the local surgical setting, the incidence of urinary retention and the need for re-catheterization in patients who having UC removed 24 hours after hysterectomies is relatively low. Interestingly, studies has shown that patients with UC removal within 6 hours after uncomplicated hysterectomy had no significant difference in postoperative urinary retention and had other beneficial postoperative outcomes, such as early postoperative ambulation, lower risk of UTI and less discomfort at urethral site, as compared with whom with UC removed 24 hours after the operation (Ahmed et al., 2014; Joshi et al., 2014; Alessandri et al., 2006; Dunn et al., 2003). It may imply that the current practice in the local surgical unit that keeping the indwelling UC for at least 24 hours after uncomplicated hysterectomy to prevent urinary retention may be unnecessary. According to the Infectious Diseases Society of America, it is advocated
that UC should be removed as early as when they are considered to be unnecessary to reduce undesirable postoperative outcome (Hooton et al., 2010).

An intervention for early removal of UC may be considered in the local surgical unit.

1.2.2 Potential innovation

Removal of UC within the postoperative 6 hours after uncomplicated hysterectomies may potentially improve the current practice and has been positively recommended in literatures (Ahmed et al., 2014; Joshi, 2014; Alessandri et al., 2006; Dunn et al., 2003) because the intervention brings benefits towards postoperative ambulation and patient comfort without imposing significant risk on patients.

In order to optimize the benefits of the early UC removal, nurses should take the initiative role to implement appropriate interventions in the postoperative period, which include assessing the patients’ condition and fitness for the early removal of UC prior to catheter removal, providing relevant education, monitoring the urinary function after catheter removal, and observing for any complications arisen from early removal of UC. Nurse-initiated early removal of UC with urination monitoring in the postoperative period will probably decrease postoperative urinary complications and increase patient comfort and satisfaction.

1.2.3 The need of systematic review
To the best of my knowledge, there is no published systematic review on evaluating the effects of early UC removal after uncomplicated hysterectomies.

To formulate an evidence-based protocol regarding the early removal of UC after uncomplicated hysterectomies for benign gynecological disease, there is a need to perform a systematic review on existing literature to assembly and integrate the existing evidence.

Systematic review is performed to examine if the proposed intervention can benefit the target population and be transferred to the local setting.

1.3 Objectives and Significance

1.3.1 Objectives

To improve postoperative outcomes for patients having hysterectomy, a change of the current practice should be considered. The objectives of the thesis are listed as the followings:

1. To systematically review the existing literature on the postoperative influences of the early removal of UC (within postoperative 6 hours) for patient undergone uncomplicated hysterectomy for benign gynecological disease.

2. To critically appraise and synthesize the existing evidence of the proposed intervention.
3. To develop recommendations and evidence-based protocols on early removal of UC for post-hysterectomy patients.

4. To assess the implementation potential of the proposed protocol at a local setting in Hong Kong.

5. To develop an implementation plan and an evaluation plan of the proposed protocol.

1.3.2 Significance

The proposed intervention, early removal of UC after uncomplicated hysterectomies, may not only benefit patients, but also bring advantages to nurses and the institution.

For patients, early removal of UC reduces patients’ catheter-related apprehension and discomfort which may probably encourage early ambulation, promote patients’ comfort and satisfaction, decrease their pain perception, and at the same time, did not cause adverse effect on postoperative urinary retention, febrile morbidity and UTI, as shown in literatures (Joshi et al., 2014; Ahmed et al., 2014; Dunn et al., 2003). It appears that early removal of UC improves patients’ psychological and physical outcomes in the postoperative period.

For nurses, an effective evidence-based protocol of early removal of UC gives nurses a systematic approach and strong evidence-based support which facilitates the
implementation of the related nursing intervention and also maintains the consistency of nursing care, in-turns may increase nurse autonomy and increase nurses’ satisfaction to work.

For institution, early removal of UC after operation can be a cost-effective way to reduced hospital-acquired UTI. With decreasing UTIs, the duration of hospitalization may be shorten, less antibiotic may be used, and less super-infection may be projected. In the long term, the overall healthcare cost may be reduced.
CHAPTER 2: CRITICAL APPRAISAL

After identifying the clinical issue and affirming the need for early UC removal on hysterectomy patients, a systemic search on the current available literatures and critical appraisal will be performed in the following chapter.

2.1 Search and Appraisal Strategies

2.1.1 Search strategies

A systematic search was conducted from November 2015 to December 2015 to obtain related studies.

Electronic search

Electronic databases PubMed and CINAHL Plus (EBSCOhost) were searched with a combination of keywords to obtain publications. The keywords used in the search were “hysterectomy”, “catheter removal”, “catheter remove”, “device removal”, “urinary catheterization”, “foley catheterization”, “urethral catheterization”, “urinary catheterization”, “foley catheterization”, “urethral catheterization”, “urinary catheter”, “foley catheter” and “urethral catheter”.

Searching other resources

In addition to electronic database searching, the reference lists of the eligible studies were also checked to identify additional relevant articles.
2.1.2 Study selection

The titles and abstracts of all the potential studies identified from the search were firstly screened and assessed for relevancy based on the inclusion and exclusion criteria. The final decisions for the inclusion of the studies were made after the full text of the articles was read and justified if the eligibility criteria were met.

2.1.3 Eligibility criteria

Inclusion criteria

- The study should be a randomized controlled trial (RCT) that compared different timing for the removal of UC in the postoperative period of hysterectomy.

- The study groups were women undergone hysterectomies for benign gynecological disease.

- The outcomes were early postoperative ambulation, urinary tract infection, postoperative urinary retention or re-catheterization, pain or discomfort.

Exclusion criteria

- The study groups were women undergone hysterectomies for cancerous condition.

- Women underwent a complicated hysterectomies requiring strict fluid management postoperatively.

- Women required bladder suspension or colporraphy surgery.
Women had positive urine culture or signs and symptoms of UTIs before operation.

2.1.4 Appraisal strategies

The appraisal tool, the methodology checklist for randomized controlled trials, created by Scottish Intercollegiate Guidelines Network (SIGN), was adopted to critically assess the internal validity and the overall methodological quality of the included studies. After the assessment with the appraisal tool, each of the included studies was rated for the level of evidence. Details for appraisal of the five included studies by the methodology checklists are shown in Appendix 4.

2.2. Results

2.2.1 Search result

A total of 62 records were revealed by keyword search from electronic database PubMed and CINAHL Plus (EBSCOhost) and manual search from other resources. 59 records were remained after duplicates removed. After screening the titles and abstracts, 7 records were found relevant with available full text. Full text of the remaining records were retrieved and assessed for eligibility. Finally, 5 RCTs (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003) meeting the inclusion and exclusion criteria were included in the thesis.
Details of the database searching history and the process of study selection presented with “PRISMA 2009 Flow Diagram” were illustrated in Appendix 1 and Appendix 2 respectively.

2.2.2 Table of evidence

Data from the five included studies were extracted and summarized in the table of evidence with categories of study design, evidence level, sample characteristics, intervention, control, outcome measures and effect size. The table of evidence was shown in Appendix 3.

2.2.3 Summary of the appraisal results

Focused question

All the five included studies addressed appropriate questions, with the PICO well defined and clearly mentioned (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003).

Sample size

Sample sizes were ranged from 70 to 250 subjects. Three studies reported the sample size calculation and that they achieved an 80% statistical power (Ahmed et al., 2014; Chai & Pun, 2011; Dunn et al., 2003), while the remaining two studies did not mentioned about the power analysis (Joshi et al., 2014; Alessandri et al., 2006).

Randomization
All the five included studies were randomly assigned the subjects into intervention groups and control groups by computer generated randomization (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003).

Concealment

Four studies (Joshi et al., 2014; Chai & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003) mentioned the allocation was concealed by sealed envelopes. Ahmed et al.’s study (2014) did not mention the concealment method; bias in sample selection may be indicated.

Blinding

Blind to observers of outcome

Only two studies (Chai & Pun, 2011; Dunn et al., 2003) blinded the outcome observers. Although Joshi et al.’s study (2014) and Alessandri et al.’s study (2006) did not blinded the outcome observers and Ahmed et al.’s study (2014) did not mentioned about the blinding, it appears unlikely that the outcome parameters assessed in the studies were bias by the observers, regarding that the outcome measures, that are re-catheterization rate, symptomatic UTI, febrile event, time of first ambulation and length of hospital stay, were determined based on standard criteria; and pain is a
subjective measure reported by the participating subjects, which was also unlikely interfered by the outcome observers.

*Blind to subjects*

All five included studies did not mention if there were blinding done to the study participants (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003).

**Baseline differences**

All five studies reported clearly the baseline characteristics of the study groups and indicated that there was no baseline difference between the study groups (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003). Therefore, the intervention under investigation would be the only difference between study groups.

**Drop out**

Ahmed et al.’s study (2014) had 7 subjects (3.1%) dropped out before the study was completed. Although the dropout rate was low, it seemed that the study simply excluded the dropouts from their study without performing any intention to treat analysis. The remaining four studies (Joshi et al., 2014; Chai & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003) did not have study participants dropped out.

**Outcome measurement**
The outcome, postoperative urinary retention, was clearly stated and measured in a valid way in all five included studies (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003). The incidence of postoperative urinary retention was measured by the occurrence of re-catheterization event. When patient were unable to empty the bladder after catheter removal, urinary retention was indicated and a catheter was required. The incidence of re-catheterization was recorded. However the time for assessing the need for re-catheterization was different among the studies. Two studies (Ahmed et al., 2014; Alessandri et al., 2006) assessed the need at 6 hours after catheter removal; Joshi et al.’s study (2014) assessed the need at 12 hours after catheter removal; Chai & Pun’s study (2011) assessed the need at both 6 hours and 12 hours after catheter removal. Dunn et al. (2003) did not mention the time for the assessment in their study.

Other outcomes, symptomatic UTIs was measured in four studies (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011; Alessandri et al., 2006) and positive postoperative urine culture was assessed in three studies (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011). The criteria for measuring were mentioned clearly. Symptomatic UTI was measured on the criteria of the presence of bacteriuria with at least one of the following symptoms: fever, dysuria, increased urination frequency, urgency, suprapubic pain, burning sensation during urination. Bacteriuria was
indicated by the positive urine culture in which urine culture having an identified single uropathogen with at least $10^5$ colony-forming units per milliliter.

Febrile event was indicated by temperature greater than 38°C in Joshi et al.’s (2014) and Dunn et al.’s studies (2003).

Time to first ambulation, measuring from the end of operation to patient first walk supported by others, and length of hospital stay which was measured from the end of operation to hospital discharge, were clearly reported in Ahmed et al.’s (2014) and Alessandri et al.’s studies (2006).

Pain at urethral site was measured with standardized tools in Joshi et al.’s (2014), Dunn, et al.’s (2003) and Chai & Pun’s (2011) studies. The former two studies (Joshi et al., 2014; Dunn et al., 2003) assessed pain by a pictorial questionnaire, while Chai & Pun (2011) used visual analog scale for pain assessment.

All the outcomes in the included studies were measured in a standard, valid and reliable way with measuring tools or assessment criteria reported clearly.

**Level of evidence**

The five included studies are RCTs, therefore all the studies were rated as 1 according to SIGN. Finally, Ahmed et al.’s (2014) and Dunn et al.’s (2003) studies were rated as 1++ with high quality and low risk of bias indicated. Joshi et al.’s
(2014), Chai & Pun’s (2011) and Alessandri et al.’s (2006) studies were rated as 1+ in which moderate risk of bias may possibly be due to the relatively small sample size.

2.3 Summary and synthesis

2.3.1 Summary

All the five included studies (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003) were RCTs comparing the benefits and harms of the early removal and delayed removal of UC in the postoperative period after uncomplicated hysterectomy.

Patient characteristics

A total of 707 women, undergone uncomplicated hysterectomies for benign gynecological diseases which were mainly uterine fibroids and abnormal uterine bleeding, were included in the five studies (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003). The women patients in the five included studies did not have the following characteristics: recurrent UTI, preoperative positive urine culture, a complicated surgical procedure requiring postoperative strict bladder management, bladder suspension required and colporraphy surgery. Women with history of neurological disorder and urinary incontinence were also excluded in three studies (Ahmed et al., 2014; Chai & Pun,
The mean age of the women was mainly between their 40s and 50s.

All subject participants in Ahmed et al.’s (2014), Chai & Pun’s (2011) and Alessandri et al.’s (2006) studies, which contributed to 55% of the total samples, received general anesthesia for the operation, except that 43 cases in Alessandri et al.’s study (2006) received spinal anesthesia for vaginal hysterectomy. However, Joshi et al. (2014) and Dunn et al. (2003) did not mention clearly the mode of anesthesia in their studies.

In all included studies except Chai & Pun’s (2011), subject participants received prophylactic antibiotics preoperatively.

12 Fr UC was used in Ahmed et al.’s (2014) and Chai & Pun’s (2011) studies, while 16 Fr UC was used in the remaining three studies (Joshi et al., 2014; Alessandri et al., 2006; Dunn et al., 2003).

**Intervention**

For the intervention regarding the early removal of UC, there were different points of time for the UC removal in the five included studies. There were mainly two points of time which were immediately after operation (0h) and 6 hours after operation (6h).
In three studies (Joshi et al., 2014; Chai & Pun, 2011; Dunn et al., 2003), in which women with early catheter removal, the UC was removed immediately after the operation (0h). For Ahmed et al.’s (2014) and Alessandri et al.’s (2006) studies, there were two intervention groups regarding as early catheter removal, which were the removal of UC immediately after operation (0h) and the removal of UC at 6 hours postoperatively (6h).

**Control**

Delayed catheter removal, with UC removed at 24 hours postoperatively, was adopted as the control in all included studies; except for Alessandri et al.’s study (2006), in which women in the control group had UC removed at 12 hours postoperatively.

**Outcome**

*Urinary retention*

The impact of early and delayed removal of UC on postoperative urinary retention was compared and reported in all five included studies.

When comparing the immediate catheter removal (0h) with the delayed catheter removal, the findings for postoperative urinary retention were not consistent in the five included studies. Joshi et al.’s (2014) and Dunn et al.’s (2003) studies shown the removal of UC immediately after operation did not cause any significant increase in
the risk of postoperative urinary retention, as there was no statistically significant
difference in the re-catheterization incidence between the study groups. The clinical
difference was also non-significant with three more patients in the immediate catheter
removal group (0h) acquiring urinary retention which contributed to 2.4% and 8.5%
higher incidence of re-catheterization in Dunn et al.’s (2003) and Joshi et al.’s (2014)
studies respectively. Oppositely, Alessandri et al.’s (2006), Ahmed et al.’s (2014) and
Chai & Pun’s (2011) studies shown immediately catheter removal group (0h) had
significantly higher occurrence of re-catheterization with 18.8%, 16.4% and 20%
respectively, as compared with the delayed catheter removal group.

In Chai & Pun’s study (2011), it is observed that the incidence of urinary
retention after postoperative 6 hours was not significantly increased. Although the
immediate catheter removal group (0h) had a higher incidence of re-catheterization at
the time of sixth hour after operation, but the need for re-catheterization again in the
group (0h) after the first postoperative 6 hours was not statistical-significantly
different from that of the delayed catheter removal group, suggesting that
postoperative urinary retention may not be significant after 6 hours postoperatively.

The effect of catheter removal 6 hours after operation (6h) and delayed catheter
removal on postoperative urinary retention was also compared in Alessandri et al.’s
(2006) and Ahmed et al.’s (2014) studies. The results of the two studies were
consistent. The two studies shown that removal of UC at 6 hours postoperatively did not cause any significant adverse impact on postoperative urinary retention, supported by the non-significant statistical difference in re-catheterization incidence, as compared with the delayed catheter removal group. The clinical difference was also non-significant. None of the patients with catheter removal at 6 hours postoperatively (6h) had urinary retention in Alessandri et al.’s study (2006); while only two patients of the postoperative 6 hour catheter removal group (6h) in Ahmed et al.’s study (2014) had re-catheterization, accounting for a slightly higher incidence of 2.5% than the delayed removal group. Therefore, it was supported in Ahmed et al.’s (2014) and Alessandri et al.’s (2006) studies that the early removal of UC 6 hours after uncomplicated hysterectomy was more beneficial than the immediate and delayed removal of UC.

Symptomatic urinary tract infections

The outcome of the symptomatic UTI in the early catheter removal group and delayed catheter removal group was reported and compared in four studies (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006). Early UC removal significantly decreased the incidence of symptomatic UTIs in Ahmed et al.’s study (2014). It was also reported in Chai & Pun’s (2011), Alessandri et al.’s (2006) and Joshi et al.’s (2014) studies that women with immediate catheter removal had a
relatively lower incidence of symptomatic UTI than the delayed catheter removal group by 5.7%, 8.5% and 12.5% respectively, though statistical significance was not achieved.

**Positive postoperative urine culture**

Three studies reported the outcome of positive postoperative urine culture (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011). Ahmed et al.’s study (2014) shown that the incidence of positive urine culture in the early catheter removal groups were significantly lower than the delayed catheter removal group in the postoperative Day 2 and one week after operation. While in Joshi et al.’s (2014) and Chai & Pun’s (2011) studies, a relatively lower incidence of positive postoperative urine culture was found in the early catheter removal group, with effect size ranging from 14.3% to 17.2%, though statistically non-significant.

**Febrile event**

Two studies measured the outcome of febrile event and there was no statistically significant difference between intervention and the control groups (Joshi et al., 2014; Dunn et al., 2003).

**Time to first ambulation and length of hospital stay**

Two studies reported that early catheter removal significantly shortened the time to first postoperative ambulation and hospital stay with statistical significance
(Ahmed et al., 2014; Alessandri et al., 2006). It indicated that early removal of UC promotes early postoperative ambulation and hospital discharge.

*Pain at urethral site*

Joshi et al.’s (2014) and Chai & Pun’s (2011) studies shown non-significant difference in pain level at urethral site between the intervention and control groups. However, Dunn et al. (2003) shown delayed catheter removal may be significantly associated with higher pain perception in their study.

**2.3.2 Synthesis**

**Target group**

The target group of early UC removal intervention is suggested to be women undergone uncomplicated hysterectomies for benign gynecological disease, preferably under general anesthesia. Regarding that all the cases in Alessandri et al.’s study (2006) that acquired postoperative urinary retention received spinal anesthesia for vaginal hysterectomy, it appears that spinal anesthesia may possibly be a risk factor for postoperative urinary retention, which was also proven in other published study (Petros, Alameddine, Testa, Rimm, & Robillard, 1994). Therefore, women undergone hysterectomies under spinal anesthesia may not be the target population of the early UC removal intervention.

In addition, women with a complicated surgical procedure requiring
postoperative strict bladder management, requiring bladder suspension, colporraphy surgery or with history of neurological disorder may also not be the target group of the innovation as recommended in the studies (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003).

The innovation

Early removal of UC has been advocated in all the five included studies (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003), regarding its beneficial effects on postoperative patient outcomes, though the recommendation for the timing of early catheter removal was varied slightly among the studies. The variation on the timing recommended for UC removal may be mainly due to the variation of the interventions adopted for comparison among the included studies.

As mentioned in the previous section of summary, catheter removal at 6 hours postoperatively (6h), instead of immediate catheter removal after operation (0h), was recommended in Ahmed et al.’s (2014) and Alessandri et al.’s (2006) studies because catheter removal at 6 hours postoperatively (6h) was shown to have more benefits on preventing postoperative urinary retention and did not have a significant increased risk of UTIs. Besides, Chai & Pun’s study (2011) also shown that urinary retention and incidence of UTI after postoperative 6 hours was not significant. Although the
intervention about catheter removal at postoperative 6 hours (6h) was not adopted for investigation in Joshi et al.’s (2014) and Dunn et al.’s (2003) studies, the possible beneficial effect of the intervention on preventing postoperative urinary retention may not be rejected. As their studies concluded that immediate removal of UC (0h) did not cause any negative impacts on postoperative urinary retention (Joshi et al., 2014; Dunn et al., 2003), from this conclusion, it may imply that UC removal at 6 hours postoperatively may have even lesser adverse impact on the risk of postoperative urinary retention than immediate catheter removal, regarding the short-term effect of postoperative urinary bladder denervation (Weber, Walters, Schover, Church, & Piedmonte, 1999). Therefore, removal of UC at 6 hours postoperatively seems to be more beneficial than UC removed immediately after operations.

The overall effectiveness of the intervention, early removal of UC within 6 hours after uncomplicated hysterectomies, has been shown to be more beneficial than the delayed removal of UC, although the optimal timing recommended for early UC removal was slightly varied among the included studies. Early catheter removal promoted early ambulation after operation and shorter hospital stay (Ahmed et al., 2014; Alessandri et al., 2006), potentially reduced risk of symptomatic UTIs without imposing harmful impacts on postoperative urinary retention (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011; Alessandri at al., 2006; Dunn et al., 2003), and it
was shown to be associated with decreased incidence of postoperative positive urine culture (Ahmed et al., 2014; Joshi et al., 2014; Chai & Pun, 2011) and reduced perceived pain at urethral site (Dunn et al., 2003).

**Recommendations for practice**

There were recommendations for practice from the included studies.

Early removal of UC within 6 hours postoperatively is recommended in patients who have undergone hysterectomies under general anesthesia for benign gynecological disease as it is associated with earlier postoperative ambulation and lower risk of UTI.

Early removal of UC is recommended to implement with regular postoperative urination monitoring.
CHAPTER 3: IMPLEMENTATION POTENTIAL AND CLINICAL GUIDELINE

In the previous chapter, the postoperative benefits of early removal of UC for patients after hysterectomy have been illustrated with profound evidence. In the next chapter, the implementation potential for the new innovation will be explored and an evidence-based practice protocol will be developed.

3.1 Transferability

3.1.1 Target setting & Target audience

The target setting will be a gynecological surgical unit in a local hospital in Kowloon west cluster governed by the Hospital Authority (HA). There are 50 beds at the target gynecological surgical unit which mainly provides pre- and post-operative care to population living at Mongkok, Wong Tai Sin, Sham Shui Po, Kwai Ching and Tsuen Wan. In all the included studies, the intervention for early removal of UC after hysterectomy was implemented in gynecological surgical wards which were similar with the target setting.

The target audience will be patients who undergone hysterectomies for benign gynecological disease under general anesthesia and not requiring strict input and output measurement postoperatively. According to on-site observation of the targeted
gynecological surgical unit, there were approximately 196 patients admitted for hysterectomy in 2015, with about 95% receiving hysterectomy for benign gynecological diseases such as uterine fibroid and abnormal uterine bleeding. The mean age of the patients was mainly between 40s and 50s. Urinary catheters were inserted during hysterectomy and left in-situ postoperatively in the target surgical unit.

The demographic characteristics of the patients in the targeted surgical unit are similar with the study participants in the included studies in terms of age and indication for hysterectomy. In addition, study participants among the included studies were living in cities with similar economic background with the target audience. Although most of the studies are foreign studies (Ahmed et al., 2014; Joshi et al., 2014; Alessandri et al., 2006; Dunn et al., 2003) and only one study (Chai, & Pun, 2011) was conducted in Hong Kong, the willingness and acceptability for early removal of intervention may not possible affected by ethics as the intervention of early UC removal promotes patient comfort. Besides, the target audience shares similar postoperative urinary management with the subject participants in all the included studies.

Based on the above observation, the proposed innovation, the early removal of UC after hysterectomy fits in the local target setting.
3.1.2 The philosophy of care

The Mission and core value of the Hospital Authority (HA) in Hong Kong is always helping people to stay healthy. The HA aims to achieve its mission by promoting high quality, safe and effective patient-centered care with evidence-based knowledge. The HA promotes the implementation of continuous quality improvement measures to ensure the quality and safety of patient-centered care and encourages strategies which can motivate staff to provide high quality and effective patient-centered service.

The underlying philosophy of care and core value of the new innovation in the reviewed studies concurs with that of the HA, promoting people wellbeing, healthy people stay healthy and restoring people quality of life (Ahmed et al., 2014; Joshi et al., 2014; Alessandri et al., 2006; Dunn et al., 2003; Chai, & Pun, 2011).

3.1.3 Sufficient number of benefited patients

There were approximately 196 female patients admitted to the targeted gynecological surgical unit for hysterectomy in 2015 based on clinical observation, and about 95% receiving hysterectomy for benign gynecological diseases and were catheterized postoperatively. Assuming the patient population is similar in the coming years, it could be estimated that about 187 patients will be benefited from the innovation.
3.2 Feasibility

3.2.1 Potential resistance for the new innovation

Traditionally, surgeons’ or anesthetists’ order was required for the removal of UC after operation. The proposed innovation promotes nurse-initiated early postoperative UC removal with urination monitoring. Since the innovation involves changes in the current clinical practice and nurses in the target setting, based on observation, seems having difference level of adaptability, it may be possible that some frontline nursing staff may be reluctant to change due to uncertainty about the innovation and anticipated difficulty on implementing the new protocol. Some surgeons may be likely doubtful about the feasibility and safety of the new innovation as the post-hysterectomy urination management proposed may be different from the usual practice or preference of some surgeons.

Therefore gaining consensus among multidiscipline, nurses’ autonomy, staff training, staff reinforcement and post UC removal urination monitoring are important for the success of the new innovation.

3.2.2 Consensus among multidiscipline

Since the innovation involves changes in the current clinical practice, getting consensus and agreements from multidiscipline on the new protocol are essential.
A multidisciplinary committee, involving anesthetists, surgeons, medical officers, ward managers, advanced practicing nurses, nursing officers, would be formed for launching the innovation. The committee would be responsible for planning, training, implementing, as well as evaluating the protocol for the early UC removal for post-hysterectomy patients. Detailed and clear instructions on early UC removal and post-UC removal urination monitoring would be discussed and proposed with evidenced based support.

3.2.3 Nursing autonomy

With the clear evidence-based protocol, frontline nurses would be empowered to initiate the intervention with high level of autonomy. Nurses would also have the freedom to terminate the intervention once the intervention was considered as undesirable for patients. Advanced practicing nurses and nursing officers would provide training, supervision and support for frontline nurses on implementing the intervention. High level of autonomy facilitates nurses’ work and increases their satisfaction to work.

3.2.4 Staff training

No new specific nursing skills would be involved in the proposed innovation as removal of UC and the postoperative urination monitoring involving use of bladder scanners and urinary catheterization are common nursing procedures. However, the
innovation involves changes in current practice, all nurses in the target setting should be well equipped with knowledge on the new protocol. The protocol for early removal of UC would be introduced and explained clearly to facilitate frontline nurses to implement the innovation. Therefore all nurses in the target setting would be provided a 20-minute in-service educational training session during the briefing session at each shift. The education session involves explanation of the new protocol, the rationale and indication for early UC removal and instructions on post UC removal urination monitoring.

3.2.5 Reinforcement for nursing colleagues

Considering that some frontline nursing staff may be reluctant to change due to uncertainty and difficulty on implementing the new protocol, a step down approach on the implementation of the proposed protocol would be used. Advanced practicing nurses, nursing officers and senior nurses would be the initiators to carry out the intervention, set as examples for the nursing staff to follow, giving reassurance and reinforcement to the frontline nursing staff. All nurses are encouraged to consult advanced practicing nurses and nursing officers or attend surgeons when any difficulties or questions encountered during implementation of the intervention. Nurses are reassured that the innovation brings better patient postoperative outcome, promotes patient comfort, increase nurses’ autonomy and facilitates nurses’ work.
3.2.6 Post UC removal urination monitoring

Nurses are well-equipped on urination monitoring. Any urinary retention would be assessed by interviewing patient if any voiding or examine any residue urine by bladder scanners at 6 hours after UC removal. Intermittent catheterization or indwelling catheterization would be required if there were urinary retention according to the proposed protocol. Regular monitoring on urination after UC removal ensures the safety and the success of the early UC removal intervention.

3.2.7 Organizational and administrative support

The target setting promotes high quality, effective and efficient postoperative nursing care. The ward managers always encourage nursing staff to share the most updated evidence based knowledge and implement evidence based nursing practice. There is an existing sharing on newly published nursing journals during the briefing session at each shift. Therefore, the organizational and administrative support for the innovation would be likely gained with a clear and detailed evidence-based protocol proposal.

3.2.8 Equipment and resources

Regarding the equipment and resources for the innovation, no new or additional items are required. Bladder scanners and urinary catheters are available in the target settings.
3.2.9 Evaluation tools

There are appropriate measuring tools available for evaluating the effectiveness of the innovation. Time to first ambulation was measuring from the end of operation to patient first walk supported by others. UTI was assessed by postoperative urine culture and interviewing or assessing patients for signs and symptoms of UTI including fever, dysuria, increased urination frequency, urgency, suprapubic pain, burning sensation during urination.

3.3 Cost- benefit ratio of the innovation

3.3.1 Potential benefits of the innovation

The innovation of early removal of UC after hysterectomy benefits patients, nurses and the organization.

Patient benefits

For patients, early removal of UC reduces the duration of urinary catheterization, which promotes patient comfort, early postoperative ambulation and decrease postoperative complications, for example, urinary tract infection, deep vein thrombosis, and impaired pulmonary function. Enhancing patient’s comfort and satisfaction and reducing postoperative complications are essential elements of patient centered care in postoperative settings to maintain patient physical and psychological
health. Healthier and happier patients are always the organization strived for.

**Nurse benefits**

For nurses, the innovation increases their autonomy in work, allowing nurses to initiate and terminate the intervention with evidence-based support, which may increases nurses’ satisfaction to work. Besides, the innovation can reduce unnecessary workload which allows nurses provide more efficient, effective and higher quality nursing care and in turns increases staff morale.

**Institution benefits**

For institution, the innovation brings about fewer postoperative complications and can be a cost-effective way to reduce hospital-acquired UTI. With fewer undesirable postoperative outcomes, the duration of hospitalization may be decreased and the possibility of readmission due to postoperative complications may be minimized. In the long term, the overall healthcare expenditure may be largely reduced.

**3.3.2 Potential risk of the innovation**

Urinary retention after UC removal and re-catheterization may be the potential risk of the innovation. However, the rate of urinary retention and re-catheterization after early UC removal was not significantly high in literature findings (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003)
and from observation, reminder to void, encouraging fluid taking, and assisting ambulation can help reduce urinary retention. Besides, it was found that the rate of re-catheterization after early UC removal could be affected by the timing for postoperative UC removal in the literatures. Therefore, an optimal time for the early UC removal after hysterectomy needed to be justified.

3.3.3 Balance between risk and benefits

To balance between potential benefits and risks of the innovation, an optimal timing for the early removal of UC after hysterectomies may need to be considered.

From the literature (Ahmed et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006), both removal of UC immediately (0h) and at 6 hours after operation (6h) decrease UTI and promote early postoperative ambulation, but immediate UC removal after operation (0h) had significantly higher rate of urinary re-catheterization while UC removal at 6 hour postoperatively (6h) did not show any significant impact on urinary retention and re-catheterization. Therefore, it seems that UC removed at 6 hours after operation have more benefits on preventing re-catheterization when compared with the immediate catheter removal.

Making balance between the potential risk and benefits, removal of UC at 6 hours postoperatively seems to be more beneficial than UC removed immediately after operations.
3.3.4 Cost

The cost of implementing the innovation and the cost of not implementing the innovation are illustrated as below:

It is estimated that 180 cases undergone hysterectomy for benign gynecological disease in a year.

<table>
<thead>
<tr>
<th>Usual practice</th>
<th>Early removal of urinary catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 RN to perform urinary catheter care</td>
<td>1 RN to perform urinary output assessment after catheter removal:</td>
</tr>
<tr>
<td>HKD 179/hour</td>
<td>HKD 179/hour</td>
</tr>
<tr>
<td>-30 minutes for performing usual practice</td>
<td>10 minutes for performing the innovation</td>
</tr>
<tr>
<td>Total cost = 179x0.5x180=HKD$16110</td>
<td>Total= 179x1/6x180 =HKD$5370</td>
</tr>
</tbody>
</table>

| Increased Length of stay because of UTI:            | Re-catheterization: 2.5% patients                                    |
| 1 day hospital stay                                 | Urinary catheter cost: HKD$16                                        |
| HKD$4580                                            | 40 minutes for 1 RN performing re-catheterization and perform urinary |
| Approximately 18% patients acquired UTI and have a 5-day prolonged hospital stay | catheter care: HKD$119                                               |
| Total cost = 4580x5x180x0.18= HKD$741960            | Total cost = (16+119) x 180x2.5% = HKD$608                            |

| Total Cost                                           | HKD$5978                                                              |

It is estimated that implementing the innovation decrease an expenditure of HKD$752093.
3.4 Evidence-Based Practice Protocol

3.4.1 Name of EBP protocol

Evidence-based practice protocol on early removal of urinary catheters for patients who had undergone hysterectomy for benign gynecological diseases.

3.4.2 Aim

To promote early postoperative ambulation and reduce risk of urinary tract infection in patients who had undergone hysterectomy for benign gynecological diseases.

3.4.3 Protocol Objectives

- To describe evidence-based intervention strategies of early UC removal to promote early postoperative ambulation and minimize risk of urinary tract infection for patients following hysterectomy for benign gynecological diseases.
- To promote comfort and satisfaction for patients after hysterectomy.

3.4.4 Intended users

- Surgical ward nurses who take care for patients who had undergone hysterectomy for benign gynecological diseases.

3.4.5 Recommendations
The recommendation for protocol is developed based on the five reviewed articles (Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006; Dunn et al., 2003). The reviewed articles are graded according to the Level of Evidence (SIGN, 2011), and the recommendations suggested are graded according to the Grade of Recommendation (SIGN, 2011). The recommendations for practice are illustrated in Appendix 5.
CHAPTER 4: IMPLEMENTATION PLAN

After reviewing the implementation potential of the proposed innovation, the plan for communication, pilot study and implementation of the proposed protocol will be illustrated in this chapter. The basis for implementation of the proposed innovation will also be provided.

4.1 Communication plan

An effective communication plan helps getting agreement and support from stakeholders and which is crucial for the integrity and success of the implementation of the proposed protocol. Stakeholders are individuals or groups who can affect or be affected by the proposed innovation. Therefore identifying stakeholders is the foremost step in the communication plan.

4.1.1 Identification of stakeholders

For the early removal intervention of urinary catheter for post-hysterectomy patients, the stakeholders are the followings:

1. Management personnel include Chief of Service (COS) of the Gynecology & Obstetric Department, Departmental Operation Manager (DOM) of the Gynecology & Obstetric Department and ward manager of targeted gynecological surgical ward. They are policy makers who have the authority to approve the
implementation of hospital protocols and allocate resources.

2. Clinical supervisors who are nursing officers and advanced practiced nurses. They are usually responsible for providing training, supervision and support for the frontline nurses during the implementation of the intervention.

3. Frontline staff includes the targeted surgical ward nurses, medical officers, surgeons and anesthetists. Ward nurses are the protocol users whose opinion and support towards the intervention is essential for the quality and integrity of the protocol implementation. Cooperation from the medical officers, surgeons, anesthetists is very important because the postoperative urination management for clients having the new innovation may be different from the existing usual practice.

4. Target patients are patients who had undergone hysterectomy for benign gynecological disease under general anesthesia. Their attitudes towards the new intervention also have influence on the success of the protocol implementation.

4.1.2 Formation of an implementation committee

Firstly, the new innovation will be discussed with senior nurses, advanced practice nurses and nursing officers to seek their advice and invite them to form an implementation committee. With the support from senior nurses, surgeons and anesthetists will be then approached with a detailed presentation of the new
innovation and be invited to join the implementation committee. The committee will be responsible for communication with stakeholders, planning, training, implementing and evaluating the proposed protocol.

4.1.3 Getting approval from administrators

The new innovation will be firstly presented to the ward manager to seek administrative advice. Then, the proposed innovation will be presented in detailed to the Chief of Service (COS) and the Departmental Operation Manager (DOM) of the Gynecology & Obstetric Department in the Management meetings. The presentation will focus on the feasibility, the cost and benefit of the new innovation, resources analysis, the budget plan and the implementation plan. This information helps administrators have a clear idea about the implementation potential of the new innovation.

4.1.4 Training for frontline staff

After a formal approval is obtained from the Chief of Service (COS) and the Departmental Operation Manager (DOM) of the Gynecology & Obstetric Department, a 20-minutes in-service educational training will be arranged during the briefing session at each shift. The regular training will be last for 4 weeks. During the training session, the need for a change of the current practice regarding postoperative urination management on hysterectomy patients will be addressed and the significance of the
new innovation will be presented with evidence based support. The mission, vision, value and the philosophy of the new innovation will also be illustrated and the proposed protocol will be explained in detail. Frontline staff is encouraged to express their questions and concerns during the regular training sessions.

4.1.5 Sustaining the innovation

Advanced practice nurses, nursing officers and senior nurses will be the initiators to carry out the intervention, providing support and reinforcement for the frontline nurses. The implementation committee will help solving the questions or difficulties encountered during implementation and regularly assess frontline nurses’ compliance to the new protocol and their performance to ensure the protocol is implemented properly. The protocol will be available in the department intranet for reference and will also be put on the notice board of the surgical ward for easy access.

4.1.6 Timeline

The communication plan, from the formation of the implementation committee, getting approval from administrators to frontline staff training, will be last for 2 months.

4.2 Pilot study plan

After developed the communication plan, the pilot study will be carried out to
investigate the feasibility of the new innovation in the local surgical ward in order to prevent unpredictable problems, and to refine the proposed protocol through the evaluation of the results.

4.2.1 Objectives

The objectives of the pilot study are:

- Assess the flow for the implementation of the proposed protocol.
- Explore frontline staff response, opinions towards the proposed protocol and any difficulties during the implementation.
- Assess frontline staff compliance of using the proposed protocol.
- Evaluate patients’ satisfaction or opinion towards the new intervention.
- Evaluate the feasibility of the outcome assessment methods.

4.2.2 Timeline

From on-site observation of the targeted gynecological surgical unit, there were approximately 180 patients receiving hysterectomy for benign gynecological diseases under general anesthesia in the previous year. Therefore the pilot study will last for 1 month and 15 eligible patients will be enrolled for the pilot study by convenience sampling.

4.2.3 Process evaluation
The implementation committee will perform clinical audit every week to assess the compliance of frontline nurses, the appropriate use of protocol, the proper measurement of outcomes, and the accuracy of documentation. The case nurses will be interviewed for the satisfaction and opinions towards the proposed protocol and the outcome assessment method after the clinical audit. Patients’ satisfaction towards the new intervention will also be evaluated through interviews.

4.2.4 Protocol revision

The data collected from the process evaluation will be analyzed and the protocol will be revised based on the evaluation of the pilot results. The protocol revision will last for 2 weeks. The revised protocol will be then presented to the Chief of Service (COS) of the Gynecology & Obstetric Department for his final approval.

4.3 Evaluation plan

After exploring the feasibility of the proposed protocol by pilot study, an evaluation plan will be developed to examine the effectiveness of the new innovation by comparing the patient outcomes and healthcare provider outcomes before and after the implementation of the proposed protocol.

4.3.1 Outcomes

Patient outcome
The primary patient outcome is the postoperative ambulation time, which is measured from the end of operation to the time of patient first walk supported by healthcare workers or relatives.

Other patient outcomes, urinary tract infection, urinary retention, and satisfaction towards the new innovation will be assessed and recorded. Urinary tract infection will be measured by the presence of bacteriuria with at least one of the following symptoms: fever, dysuria, increased urination frequency, urgency, suprapubic pain, burning sensation during urination. Urinary retention will be measured by occurrence of re-catheterization event. Re-catheterization will be required when clients are unable to empty bladder 6 hours after removal of urinary catheters and bladder volume is greater than 500ml in bladder scan.

**Healthcare provider outcome**

The nurses’ satisfaction and competence towards the implementation of the proposed protocol will be the healthcare provider outcome.

**4.3.2 Nature and number of clients**

The target clients will be patients receiving hysterectomy for benign gynecological diseases under general anesthesia in the targeted gynecological surgical unit. The clients recruited will be followed after the operation till discharge.

As taking reference to Ahmed et al.’s study (2014), a sample size of 124 clients
enables the study had 80% power to detect a significant decrease in the first postoperative ambulation time at 0.05 level of significance. Therefore, 62 clients who had undergone hysterectomy under general anesthesia and without surgeons’ specific order for strict postoperative bladder management in the target unit will be recruited by convenience sampling to receive the new proposed protocol for the evaluation plan. All clients will be followed from the day of operation till discharge. Another 62 clients for comparison will be the clients receiving usual care as before the implementation of the proposed protocol.

4.3.3 Timeline

The proposed protocol will be implemented for a period of 6 months to obtain an adequate sample for evaluation.

4.3.4 Data collection and analysis

For patients receiving care based on the proposed protocol, the first postoperative ambulation time will be measured and documented by the case nurse, while the incidence of urinary tract infection, incidence of re-catheterization and any other undesirable outcomes will also be documented by the case nurses. Past data for the first postoperative ambulation time, urinary tract infection and re-catheterization will be obtained from the annual report of the department of Gynecology and Obstetrics, and will be compared with the data after the implementation of the proposed protocol.
The outcome data collected will be computerized and analyzed by a two-tailed paired t-test.

The clients’ satisfaction towards the new innovation and the nurses’ satisfaction and competence towards the implementation of the proposed protocol will be evaluated by self-reported questionnaires after each implementation. The data will be analyzed by descriptive methods.

4.4 Basis for implementation

After evaluation of the effectiveness of the proposed innovation, the basis determined whether the proposed protocol will be implement could be concluded. If the primary outcome measure, that is the postoperative ambulation time, is similar to that in the reviewed literatures (Ahmed et al., 2014; Alessandri et al., 2006), the new protocol could be regarded as effective and to be adopted for fully implementation.

According to the reviewed literatures, the first postoperative ambulation time was within 7 hours after the operation. Therefore, the proposed protocol will be fully implemented, provided that:

- the mean for the first ambulation time is within 7 hours after the operation
- the incidence of urinary tract infection and urinary retention is not significantly increased
the nurses are competent to implement the new innovation and are satisfied towards the proposed protocol
CHAPTER 5: CONCLUSION

5.1 Conclusion

Early removal of UC has been shown to be associated with early postoperative ambulation and lower risk of UTI in patients who had undergone uncomplicated hysterectomy for benign gynecological diseases. With regular urination monitoring after catheter removal, major complications may seldom happen. The intervention is effective and safe, as well as easy and economical to implement. To conclude, the proposed evidence-based protocol brings benefits to patients, healthcare providers and institutions and is strongly recommended for implementation.
REFERENCES


### APPENDIX 1: Database Searching History

**Searching database 1: PubMed**

<table>
<thead>
<tr>
<th>Search number</th>
<th>Search terms</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>hysterectomy</td>
<td>39231</td>
</tr>
<tr>
<td>#2</td>
<td>catheter remove OR catheter removal OR device removal</td>
<td>24189</td>
</tr>
<tr>
<td>#3</td>
<td>urinary catheter OR foley catheter OR urethral catheter OR urinary catheterization OR urinary catheterisation OR foley catheterization OR foley catheterisation OR foley catheterisation OR urethral catheterization</td>
<td>26954</td>
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<tr>
<td>#4</td>
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</table>

**Searching database 2: CINAHL Plus (EBSCOhost)**

<table>
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</tr>
</thead>
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<tr>
<td>S1</td>
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</tr>
<tr>
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</tr>
<tr>
<td>S4</td>
<td>S1 AND S2 AND S3</td>
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</table>
APPENDIX 2: PRISMA Flow Diagram

PRISMA 2009 Flow Diagram

Records identified through database searching (n = 60)

Additional records identified through other sources (n = 2)

Records after duplicates removed (n = 59)

Records screened (n = 59)

Full-text articles assessed for eligibility (n = 7)

Studies included in qualitative synthesis (n = 5)

Studies included in quantitative synthesis (meta-analysis) (n = 5)

Records excluded (n = 52):
- irrelevancy (n = 48)
- no full text (n = 4)

Full-text articles excluded (n = 2):
- not RCT (n=2)
- non recent 15 years publications (n=0)
1. Timing of urinary catheter removal after uncomplicated total abdominal hysterectomy: a prospective randomized trial

**APPENDIX 3: Table of evidence**

<table>
<thead>
<tr>
<th>Citation / Design</th>
<th>Sample characteristics</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmed, Sayed Ahmed, Atwa &amp; Metwally (2014) RCT (++)</td>
<td>1. Women</td>
<td>Group A: urinary catheter removal (0h) (n=73)</td>
<td>Group C: urinary catheter removal (24h) (n=67)</td>
<td>1. Urinary retention (re-catheterization required at 6 hours after removal)</td>
<td>1. Group A: 12 patients (16.4%); group B: 2 patients (2.5%); group C: 0% (p=0.001)</td>
</tr>
<tr>
<td></td>
<td>2. Age (years old) (mean +/- SD)</td>
<td></td>
<td></td>
<td></td>
<td>• Effect size: 16.4% [group A (0h) - group C (24h)]; 2.5% [group B (6h) - group C (24h)]</td>
</tr>
<tr>
<td></td>
<td>group A: 59.1 +/- 8.3</td>
<td>immediate after surgery (0h) (n=73)</td>
<td>Group B: 58.3 +/- 6.9</td>
<td>24 hours after surgery (6h) (n=81)</td>
<td>• group A (0h) showed significantly higher occurrence of urinary retention and group B (6h) shown similar incidence of urinary retention with group C (24h)</td>
</tr>
<tr>
<td></td>
<td>3. Surgery: TAH +/- salpingo-oophrectomy under GA (p=0.09)</td>
<td>Group B:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>group C: 61.3 +/- 10.5 (n=73)</td>
<td></td>
<td>Group B:</td>
<td></td>
<td>2. Symptomatic UTI (postoperative hospitalization period)</td>
</tr>
<tr>
<td></td>
<td>4. Indication for surgery: fibroid tumors (53%), abnormal uterine bleeding (36%), chronic pelvic pain (11%)</td>
<td>Group B: urinary catheter removal 6 hours after surgery (6h) (n=81)</td>
<td></td>
<td></td>
<td>2. Group A: 1 patient (1.4%); group B: 3 patients (3.7%); group C: 10 patients (14.9%) (p=0.008)</td>
</tr>
<tr>
<td></td>
<td>5. Fr 12 latex urinary catheter insertion during operation for continuous bladder drainage</td>
<td></td>
<td></td>
<td></td>
<td>• Group C (24h) showed significant higher incidence of UTI than Group A (0h) and B (6h) by 13.5% and 11.2% respectively</td>
</tr>
<tr>
<td></td>
<td>6. Single dose of prophylactic antibiotic before operation</td>
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<td></td>
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<td></td>
<td>3. Urinary symptoms one week after surgery (fever, dysuria, frequency, urgency, loin pain)</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>3. Group C: 22-26% had symptoms suggestive to lower UTI and 2.9% suggestive to nephritis; group A: 2 patients (2.7%) and Group B: 2 patients (2.4%) had symptoms of UTI (p=0.001)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>→ group C (24h) has statistically significant higher incidence of UTI than Group A (0h) and B (6h) in the postop one week time by at least 20%</td>
</tr>
<tr>
<td></td>
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<td>4. Positive postoperative urine culture</td>
</tr>
<tr>
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<td></td>
<td>4. i) Group A: 1 patient (1.4%); group B: 2 patients (2.5%); group C: 8 patients (11.9%) (p=0.001)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Group C (24h) had higher incidence of positive urine culture than group A (0h) and group B (6h) by 10.5% and 9.4% respectively</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ii) Group A: 0%; group B: 0%; group C: 14 patients (20.9%) (p=0.001)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Group C (24h) had higher incidence of positive urine culture than group A (0h) and group B (6h) by 20.9% respectively</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
<td>5. Time to postoperative first ambulation (hour) mean +/- SD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>5. group A: 4.1 +/- 1.8h; group B: 6.8 +/- 1.7h; group C: 10.3 +/- 2.5h (p=0.001)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• group C (24h) had significantly delayed first ambulation time than that of group A (0h) and B (6h) by 6.2 h and 3.5 h respectively</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6. Length of hospital stay (days) mean +/- SD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6. group A: 3.2 +/- 1.6 days; group B: 3.4 +/- 1.5 days; group C: 5.6 +/- 1.2 days (p=0.001)</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>• group C (24h) had significantly prolonged hospital stay than group A (0h) and B (6h) by 2.4 days and 2.2 days respectively</td>
</tr>
</tbody>
</table>

Diagnosis of symptomatic UTI: presence of significant bacteriuria with at least one of the following symptoms: Fever, dysuria, increased frequency of urination, urinary urgency, suprapubic pain, and burning micturition

TAH: total abdominal hysterectomy  
GA: general anesthesia
2. A prospective randomized controlled comparison of immediate versus late removal of urinary catheter after abdominal hysterectomy

<table>
<thead>
<tr>
<th>Citation / Design (Study quality)</th>
<th>Sample characteristics</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes (Assessment time)</th>
<th>Effect size (Intervention - Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joshi, Aggarwal, Chopra &amp; Taneja (2014) / RCT (+)</td>
<td>1. Age (years old) (mean +/- SD) intervention group: 46.8 +/- 6.9 (p=0.287)</td>
<td>Urinary catheter removal 24 hours after surgery (24h)</td>
<td>Urinary catheter removal immediate after surgery (n=35)</td>
<td>1. Urinary retention (re-catheterization required 12 hours after catheter removal or failure to void after 2 attempts)</td>
<td>1. Intervention: 3 patients (8.5%); Control: none (0%) (p=0.07)</td>
</tr>
<tr>
<td></td>
<td>2. Surgery: abdominal hysterectomy with or without salpingo-oophrectomy</td>
<td></td>
<td></td>
<td>2. Symptomatic UTI (postoperative hospitalization period)</td>
<td>2. Intervention: none (0%); Control: 3 patients (8.5%)</td>
</tr>
<tr>
<td></td>
<td>3. Indication for surgery: fibroid (59%), dysfunctional uterine bleeding (36%), adnexal mass (6%)</td>
<td></td>
<td></td>
<td>3. Positive postoperative urine culture</td>
<td>i) Intervention: 3 patients (8.5%); Control: 9 patients (22.8%) (p=0.22)</td>
</tr>
<tr>
<td></td>
<td>4. Fr 16 urinary catheter insertion during operation for continuous bladder drainage</td>
<td></td>
<td></td>
<td></td>
<td>ii) Intervention: 2 patients (5.7%); Control: 4 patients (11.4%) (p=0.532)</td>
</tr>
<tr>
<td></td>
<td>5. Single dose of prophylactic antibiotic before the operation</td>
<td></td>
<td></td>
<td>4. Febrile morbidity (2 consecutive oral temperature &gt; 100.4°F measured 6h apart)</td>
<td>i) Intervention: 2 patients (5.7%); Control: 6 patients (17.1%) (p=0.13)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>i) postoperative day 2</td>
<td>ii) postoperative day 3</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>5. Pain perception (assessed by a pictorial questionnaire)</td>
<td>5. Intervention: 14 patients (40%); Control: 16 patients (45.7%) (p=0.567)</td>
</tr>
<tr>
<td>Diagnosis of symptomatic UTI: presence of significant bacteriuria with at least one of the following symptoms: Fever, dysuria, increased frequency of urination, urinary urgency, suprapubic pain, and burning micturition</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Intervention group (0h) had higher re-catheterization rate than control group (24h) by 8.5% (i.e. 3 patients), but there is no statistically significant difference.

Control group (24h) showed higher incidence of UTI than intervention group (0h) by 8.5% (i.e. 3 patients) though not statistically significant.

Intervention group (0h) had lower incidence of positive urine culture than Control group (24h) by 14.3% (i.e. 6 patients) though not statistically significant.

Control group (24h) had higher incidence of positive urine culture than intervention group (0h) by 5.7% though not statistically significant.

Intervention group (0h) had lower incidence of febrile morbidity than control group (24h) by 11.6%.

Intervention group (0h) had lower incidence of febrile morbidity than control group (24h) by 11.4%.

Pain perception in intervention group (0h) is lower than that in control group (24h) by 5.7%.
<table>
<thead>
<tr>
<th>Citation / Design (Study quality)</th>
<th>Sample characteristics</th>
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<th>Control</th>
<th>Outcomes (Assessment time)</th>
<th>Effect size (Intervention - Control)</th>
</tr>
</thead>
</table>
| Chai & Pun (2011)/ RCT (+)        | 1. Age (years old)     | urinary catheter removal 24 hours after surgery | urinary catheter removal | 1. Urinary retention         | 1. i) At post-operative 6 hours:  
Intervention: 7 patients (20%); Control: none (0%) (p=0.011)  
- Intervention group (0h) had significantly higher re-catheterization rate than control group (24h) by 20% at postoperative 6 hours  
ii) At post-operative 12 hours:  
Intervention: 4 patients (11.4%); control: none (0%) (p=0.114)  
- No significant difference in re-catheterization rate between Intervention group (0h) and control group (24h) at 12 hours postoperatively |
|                                  | (mean +/- SD)          | (-/3.9)      | (-/-4.0) |                           |                                  |
|                                  | intervention group: 46.4 +/-3.9 | immediate after surgery (0h) (n=35) | 2. Surgery: TAH +/- salpingo-oophrectomy under GA | 2. Symptomatic UTI (postoperative hospitalization period) | 2. Intervention: 1 patient (2.9%); Control: 3 patients (8.6%) (p=0.607)  
- Control group (24h) has 5.7% higher incidence of symptomatic UTI as compared with intervention group (0h) though statistically non-significant |
|                                  | control group: 46.4 +/-4.0 | 24h (n=35)   |                           |                           |                                  |
|                                  | 2. Indication for surgery: symptomatic uterine fibroid (98.6%), adenomyosis (0.4%) |                           |                           |                           |                                  |
|                                  | 3. Fr 12 urinary catheter was insertion during operation for continuous bladder drainage |                           |                           |                           |                                  |
|                                  | 5. No prophylactic antibiotic was used before the operation |                           |                           |                           |                                  |

TAH: total abdominal hysterectomy GA: general anesthesia
### Study Description

A prospective, randomized trial comparing immediate versus delayed catheter removal following hysterectomy

<table>
<thead>
<tr>
<th>Citation / Design (Study quality)</th>
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<th>Control</th>
<th>Outcomes (Assessment time)</th>
<th>Effect size (Intervention - Control)</th>
</tr>
</thead>
</table>
| Alessandri, Mistrangelo, Lijoi, Ferrero & Ragni (2006) / RCT (+) | 1. Age (years old) (mean +/- SD) | Group A: urinary catheter removal immediate after surgery | Group C: urinary catheter removal 12 hours after surgery | 1. Urinary retention (recatheterization required 6 hours after removal) | **Group A: 6 patients (18.8%); group B: none (0%); group C: none (0%)**
|                                  |                        | Group A: group A: 47+/-5 | Group C: group C: 47+/-5 | **• Group A vs group B (p<0.001); group A vs group C (p<0.001); group B vs group C (non-significant)**
|                                  |                        | (p=0.631)                |                        | **• Group A (0h) showed significantly higher occurrence of re-catheterization than Group C (12h) by 18.8% and all the 6 patients had undergone vaginal hysterectomy in spinal anesthesia.**
|                                  |                        | (n=32)                   | (n=32)                | **• None of patients in group B (6h) and group C (12h) had urinary retention**
|                                  | 2. Surgery: i) AH under GA (0h) | Group B: 49+/-3.7 | Group B: 49+/-3.7 | 2. Symptomatic UTI (postoperative hospitalization period) | **Group A: 1 patient (3.1%); group B: 4 patients (13.3%); group C: 5 patients (15.6%) (non-significant)**
|                                  |                        | (n=32)                   | (n=32)                | **• Group A (0h) showed lower incidence of UTI than Group B C (12h) by 12.5% respectively but statistically non-significant**
|                                  |                        |                          |                      | **• Group B (6h) and group C (12h) showed similar incidence of UTI with group B (6h) having a 2.3% lower incidence (i.e. 1 patient)**
|                                  | 3. Indication for surgery: fibroids (63.5%), abnormal uterine bleeding (26.1%), cervical dysplasia (10.4%) | Group B: urinary catheter removal 6 hours after surgery (6h) | Group B: urinary catheter removal 6 hours after surgery (6h) | 3. Time to postoperative first ambulation (hour) | **Group A: 4.3+/-1.2h; group B: 6.5+/-1.5h; group C: 9.4+/-1.4h (p<0.05)**
|                                  |                        | (n=32)                   | (n=32)                | **• Group A vs group B (p<0.05); group A vs group C (p<0.05); group B vs group C (p<0.05)**
|                                  |                        |                          |                      | **• group A (0h) had significantly shorter ambulation time than that of group C (12h) by 5.1 h**
|                                  |                        |                          |                      | **• group B (6h) had significant shorter ambulation time than group C (12h) by 2.9 h**
|                                  | 4. Fr 16 latex urinary catheter was insertion during operation for continuous bladder drainage | Group B: 49+/-3.7 | Group B: 49+/-3.7 | 4. Length of hospital stay (days) | **Group A: 1.5 +/-0.1 days; group B: 2.1 +/-0.18 days; group C: 2.3 +/-0.16 days**
|                                  |                        | (n=32)                   | (n=32)                | **• Group A vs group B (p<0.05); group A vs group C (p<0.05); group B vs group C (non-significant)**
|                                  |                        |                          |                      | **• group A (0h) had significantly shorter hospital stay than group C (12h) by 0.8 days**
|                                  |                        |                          |                      | **• group B (6h) and group C (12h) had similar length of hospital stay with difference of 0.2 days**

AH: abdominal hysterectomy; LA VH: laparoscopic assisted vaginal hysterectomy; VH: vaginal hysterectomy; GA: general anesthesia; SA: spinal anesthesia

Diagnosis of symptomatic UTI: presence of significant bacteriuria with at least one of the following symptoms: Fever, dysuria, increased frequency of urination, urinary urgency, suprapubic pain, and burning micturition
5. Are in-dwelling catheters necessary for 24 hours after hysterectomy?

<table>
<thead>
<tr>
<th>Citation / Design (Study quality)</th>
<th>Sample characteristics</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes (Assessment time)</th>
<th>Effect size (Intervention - Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dunn, Shlay &amp; Forshner (2003)/ RCT (+++)</td>
<td>1. Age (years old): median=47 (range: 25-72)</td>
<td>urinary catheter insertion during operation for continuous bladder drainage</td>
<td>urinary catheter removal 24 hours after surgery</td>
<td>1. Urinary retention (recatheterization required for an additional 24 hours)</td>
<td>1. Intervention: 6 patients (4.8%); Control: 3 patients (2.4%) (p=0.17)</td>
</tr>
<tr>
<td></td>
<td>2. Surgery: abdominal hysterectomy and vaginal hysterectomy</td>
<td>Fr 16 urinary catheter was insertion during operation for continuous bladder drainage</td>
<td>Fr 16 urinary catheter removal 24 hours after surgery</td>
<td>2. UTI (determined by either microscopic abnormality or any patient symptoms)</td>
<td>2. Intervention: 3 patient (2.4%); Control: 3 patients (2.4%) (p=0.99)</td>
</tr>
<tr>
<td></td>
<td>3. Indication for surgery: fibroid tumor (58%), abnormal uterine bleeding (14%), cervical dysplasia (11%), uterine prolapse (17%)</td>
<td>Single dose of prophylactic antibiotic was used before the operation</td>
<td></td>
<td>3. Fever (temperature &gt;/= 38.5°C)</td>
<td>3. Intervention: 5 patients (4%); Control: 6 patients (4.8%) (non-significant)</td>
</tr>
<tr>
<td></td>
<td>4. Fr 16 urinary catheter was insertion during operation for continuous bladder drainage</td>
<td></td>
<td></td>
<td>4. Pain at urethral site or in bladder by a pictorial questionnaire (the Wong scale and the Self-report scale)</td>
<td>4. Vaginal hysterectomy</td>
</tr>
</tbody>
</table>
|                                   | | | | | Intervention group: mild pain (81.6%); moderate pain (19.4%); severe pain (0%)
|                                   | | | | | control group: mild pain (19%); moderate pain (54%); severe pain (27%) (p=0.0001)
|                                   | | | | | Abdominal hysterectomy:
|                                   | | | | | intervention group: mild pain (78%); moderate pain (22%); severe pain (0%)
|                                   | | | | | control group: mild pain (43%); moderate pain (37%); severe pain (20%) (p=0.0001)
|                                   | | | | | → patients in intervention group (0h) reported significantly less pain than patients in control group (24h) in both vaginal hysterectomy and abdominal hysterectomy |
APPENDIX 4: Methodology checklist

Methodology Checklist 2: Controlled Trials

Study identification  (Include author, title, year of publication, journal title, pages)

Before completing this checklist, consider:
1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

Section 1: Internal validity

In a well conducted RCT study...

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
</tbody>
</table>

| 1.1 The study addresses an appropriate and clearly focused question. | Yes ☑ No ☐ Can’t say ☐ |
|-----------------------------------------------------------------|
| The PICO is well defined and clear. 

| 1.2 The assignment of subjects to treatment groups is randomised. | Yes ☑ No ☐ Can’t say ☐ |
|-----------------------------------------------------------------|
| Randomization done by computer-generated random numbers. 

<p>| 1.3 An adequate concealment method is used. | Yes ☐ No ☑ Can’t say ☑ |
|-----------------------------------------------------------------|
| No concealment method. |</p>
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>Can't say</th>
<th>No</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4</td>
<td>The design keeps subjects and investigators 'blind' about treatment allocation.</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>No blinding is mentioned in the study</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>No baseline differences between groups by statistical testing</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>7 drop out in the study (3.1%)</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>Does not apply The drop outs are just simply excluded from the study</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>Does not apply</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

2.1 How well was the study done to minimise bias?  
Code as follows:  
High quality (++)
Acceptable (+)
Low quality (-)
Unacceptable – reject 0
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | The overall methodology in this study is clear. The randomization method is explained. It is better to mention the concealment method and blinding if used. The statistical power is clearly explained, all the data was provided with p-value in the study. Moreover, the sample size is adequate to prove if there is any effect of the treatment. However, the samples excluded in the study should be regarded as attrition and ITT analysis should be done. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes, the target population is also patient undergo uncomplicated hysterectomy for benign gynaecological disease and the intervention is similar |
| 2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | Early removal of the urinary catheter 6 hours after total abdominal hysterectomy appeared to be more beneficial with lower risk of urinary retention and urinary tract infection, early post-operative ambulation and shorter hospital stay. This study provides good evidence that support the use of the proposed intervention. However, the 7 samples excluded because of missed follow-up should be regarded as attrition and ITT analysis should be done on these samples. |
Methodology Checklist 2: Controlled Trials

**Guideline topic:**  
Key Question No:  
Reviewer:

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question  
2. Other reason (please specify):

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☑</td>
</tr>
<tr>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
</tr>
<tr>
<td>Yes ☑</td>
</tr>
<tr>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

| 1.2  | The assignment of subjects to treatment groups is randomised. |
| Yes ☑ | No ☐ |
| Can’t say ☐ | Randomization was done by computer-generated random table. |

| 1.3  | An adequate concealment method is used. |
| Yes ☑ | No ☐ |
| Can’t say ☐ | By sealed envelope. |

| 1.4  | The design keeps subjects and investigators 'blind' about treatment allocation. |
| Yes ☐ | No ☑ |
| Can’t say ☐ | Observers of outcomes were not blind to the randomization and the study did not mention about the subject blinding. |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes ☑ | No ☐  
|     | Can’t say □ | No baseline differences between groups by statistical testing |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes ☑ | No ☐  
|     | Can’t say □ |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes ☑ | No ☐  
|     | Can’t say □ |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | No drop out in the study. |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes ☐ | No ☑  
|     | Can’t say □ | Does not apply |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Yes ☐ | No ☑  
|     | Can’t say □ | Does not apply ☑ |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias?  
*Code as follows:*  
High quality (++), Acceptable (+), Low quality (-), Unacceptable – reject 0 | The overall methodology in this study is clear. The randomization method and the concealment were explained. It is better to mention if there was any blinding to the subjects. Although observers of outcome were not blinded to treatment allocation, it seems unlikely that the parameters evaluated in the study were biased by observers, considering that they were determined on the bases of standard criteria. The statistical power is clearly explained, all the data was provided in the study with p-value. Moreover, there was a clearly explanation on measurement tools for the outcomes. Though, there was relatively small |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | High quality (++), Acceptable (+), Low quality (-), Unacceptable – reject 0 | The overall methodology in this study is clear. The randomization method and the concealment were explained. It is better to mention if there was any blinding to the subjects. Although observers of outcome were not blinded to treatment allocation, it seems unlikely that the parameters evaluated in the study were biased by observers, considering that they were determined on the bases of standard criteria. The statistical power is clearly explained, all the data was provided in the study with p-value. Moreover, there was a clearly explanation on measurement tools for the outcomes. Though, there was relatively small |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes, the target population is also patient undergo uncomplicated hysterectomy for benign gynaecological disease and the intervention is similar. |
| 2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | Early removal of the urinary catheter (immediate removal) after total abdominal hysterectomy did not cause adverse outcome like significant rate of re-catheterization and high pain perception but may associated with a lower incidence of positive urine culture. This study provides evidence that support the use of the proposed intervention. However, more samples were needed to strengthen the result of the study. |
Methodology Checklist 2: Controlled Trials

Study identification  *(Include author, title, year of publication, journal title, pages)*

Guideline topic:  Key Question No:  Reviewer:

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question  □  2. Other reason □ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

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<tr>
<td><strong>1.1</strong></td>
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<td></td>
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<td><strong>1.2</strong></td>
<td>The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td></td>
<td>Can't say □ Randomization was done by stratified randomization via computer in a block of 4.</td>
</tr>
<tr>
<td><strong>1.3</strong></td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
<td>Can't say □ By sealed opaque envelopes.</td>
</tr>
<tr>
<td><strong>1.4</strong></td>
<td>The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
</tr>
<tr>
<td></td>
<td>Can’t say □ Reviewers were blinded but the study did not mention if the subjects were blinded.</td>
</tr>
<tr>
<td><strong>1.5</strong></td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
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<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
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**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
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| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? |

The overall methodology in this study is clear. The randomization method and the concealment were explained. Though blinding to reviewers is mentioned, it is better to mention if there were any blinding to the subjects. The statistical power is clearly explained, all the data was provided in the study with p-value. Moreover, the baseline characteristics were clearly explained, valid tools were used for measuring outcomes. However, there was not enough sample size to prove if there is any effect of the treatment. More sample size is needed for improvement.

<table>
<thead>
<tr>
<th>2.3</th>
<th>Are the results of this study directly applicable to</th>
</tr>
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<tr>
<td>Yes, the target population is also patient undergo</td>
<td></td>
</tr>
<tr>
<td>the patient group targeted by this guideline?</td>
<td>uncomplicated hysterectomy for benign gynaecological disease and the intervention is similar.</td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
</tr>
<tr>
<td>Delayed removal of urinary catheter may reduce incidence of post-operative urinary retention when compared with immediate removal. But the study showed that the re-catheterization rate of the immediate catheter removal group after post-operative 6 hours is not significantly different with the delayed removal group. It may indicate that early removal of urinary catheter at 6 hours post-operatively is also beneficial. The author also commented that the insignificant different of rate of urinary tract infection between study groups may be due to the relatively small sample size. It suggested a valuable suggestion on the size of urinary catheter used for total abdominal hysterectomy, especially for Chinese women. However, more samples were needed to strengthen the result of the study.</td>
<td></td>
</tr>
</tbody>
</table>
**Methodology Checklist 2: Controlled Trials**

**SIGN**

**Study identification**  *(Include author, title, year of publication, journal title, pages)*


**Guideline topic:** An evidence-based protocol on wet wrap therapy for patient with eczema to alleviate their severity

**Key Question No:**

**Reviewer:**

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question 2. Other reason (please specify):

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**Does this study do it?**

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<td>The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ☑ No ☐ Can't say ☐ By computer generated randomization list drawn up by a statistician</td>
</tr>
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<td>An adequate concealment method is used.</td>
<td>Yes ☑ No ☐ Can't say ☐ By a seal opaque envelope which kept by nurses</td>
</tr>
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<td>1.4</td>
<td>The design keeps subjects and investigators 'blind' about treatment allocation.</td>
<td>Yes ☐ No ☑ Can't say ☐ Blinding to observers was not done and...</td>
</tr>
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1.5 The treatment and control groups are similar at the start of the trial. | Yes ☑ | No ☐ | Can't say ☐ | blinding to subjects was not mentioned

1.6 The only difference between groups is the treatment under investigation. | Yes ☑ | No ☐ | Can't say ☐

1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Yes ☑ | No ☐ | Can't say ☐

1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | No drop out in the study

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes ☑ | No ☐ | Can’t say ☐ | Does not apply ☑

1.10 Where the study is carried out at more than one site, results are comparable for all sites. | Yes ☑ | No ☐ | Can’t say ☐ | Does not apply ☑

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias? *Code as follows:*  
High quality (++): ☑  
Acceptable (+): ☑  
Low quality (-): ☐  
Unacceptable – reject 0 ☐

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?  
The overall methodology in this study is clear. The randomization method and the concealment method were well explained. Also, statistical testing was done to prove there was no difference between two groups before the intervention. The statistical power was clearly explained with p-value provided for the outcomes. However, there was not enough sample size for the study.

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?  
Yes, the target population is also patient undergo uncomplicated hysterectomy for benign gynaecological disease and the intervention is similar

2.4 **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised
Early removal of urinary catheter (6 hours after operation) appears to be more advantage as compared to immediate and delayed catheter removal as it did not cause any urinary retention and had insignificant effect on increasing the incidence of urinary tract infection and had a relatively early postoperative ambulation. All the cases acquired postoperative urinary retention in the study were undergone the operation with spinal anesthesia. The author accounted the use of spinal anesthesia is possibly a risk factor of urinary retention. This study largely answered the research question and provided evidence of the proposed intervention. However, it is better to recruit more samples to strength the effect of the intervention.
### Methodology Checklist 2: Controlled Trials

#### Study identification
*Include author, title, year of publication, journal title, pages*


#### Guideline topic:
An evidence-based protocol on wet wrap therapy for patient with eczema to alleviate their severity

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<p>| 1.1 The study addresses an appropriate and clearly focused question. |
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|   | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? |
|   | The overall methodology in this study is clear. The randomization method and the concealment method were well explained. Baseline characteristic between study groups were clearly reported and indicated. There was no baseline difference. The magnitude of the p-value of the study outcome was not clearly stated although the non-significant result is reported. The sample size was adequate to detect difference between intervention group and control group. |

|   | Are the results of this study directly applicable to the patient group targeted by this guideline? |
|   | Yes, the target population is also patient undergo uncomplicated hysterectomy for benign gynaecological disease and the intervention is similar. |

|   | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |
|   | There was no significant difference on the risk of developing urinary tract infection, fever and need for |
Re-catheterization between early removal of in-dwelling catheter and in-dwelling catheter removed at 24 hours after operation. Meanwhile, the subjective pain score was significantly less in the intervention group. This study largely answered the research question and provided evidence of the proposed intervention. However, it is better to indicate clearly the time for assessment of urinary retention and re-catheterization taken place.
APPENDIX 5: Recommendation for Practice

Assessment

1.1 Assess patient’s medical history for absence of neurological disorder

Evidence: neurological disease can cause bladder dysfunction and may cause urinary retention. (Alessandri et al., 2006; Chai & Pun, 2011; Ahmed et al., 2014) (1+; 1+; 1++)

Grade of Recommendation: A

1.2 Assess patient’s surgical profile for any contraindications for the intervention.

Patients experiencing a complicated surgical procedure requiring postoperative strict bladder management or fluid replacement, patient with uterine prolapse, bladder suspension and colporraphy surgery are contraindicated.

Evidence: patients who had a complicated surgical procedure, bladder suspension and colporraphy surgery require an indwelling catheter to be kept postoperatively to monitor urine output strictly. (Alessandri et al., 2006; Dunn et al., 2003; Joshi et al., 2014) (1+; 1++; 1+)

Grade of Recommendation: A

1.3 Assess the mode of anesthesia for hysterectomy. Implement the intervention if hysterectomy is operated under general anesthesia.

Evidence:
The reviewed quality studies suggest early UC removal intervention to be implemented in patients receiving hysterectomy under general anesthesia. (Ahmed et al., 2014; Chai & Pun, 2011; Alessandri et al., 2006) (1++; 1++; 1+)

Spinal anesthesia may be a risk factor for postoperative urinary retention which may require an indwelling catheter to be kept for a considerable period of time. (Alessandri et al., 2006) (1+)

Grade of Recommendation: A

**Intervention**

2.1 Urinary catheter should be removed 6 hours after uncomplicated hysterectomy.

Evidence: The findings from the reviewed quality studies supported early UC removal 6 hours after uncomplicated hysterectomy promotes early postoperative ambulation, reduces risk of urinary tract infection and urinary retention. (Alessandri et al., 2006; Ahmed et al., 2014; Chai & Pun, 2011; Joshi et al., 2014) (1++; 1++; 1++; 1++; 1+)

Grade of Recommendation: A

**Urination Monitoring**

3.1 Assess urination 6 hours after removal of UC, intermittent catheterization required if unable to void within 6 hours after UC removal with bladder scan with residual urine > 500 ml; Assess urination at the next 6 hours, reinsert indwelling catheter if
unable to void with bladder scan with residual urine > 500 ml.

Evidence: Urination monitoring after UC removal is essential for preventing urinary retention. When patient was unable to empty the bladder and bladder volume greater than 500 ml in bladder scan suggesting urinary retention. (Alessandri et al., 2006; Chai, & Pun, 2011; Joshi et al., 2014; Ahmed et al., 2014) (1++; 1++; 1+; 1++)

Grade of Recommendation: A

Evaluation:

4.1 Assess patients any signs and symptoms of UTI that are fever, dysuria, increased urination frequency, urgency, suprapubic pain, burning sensation during urination.

Evidence: the reviewed quality studies assess signs and symptoms of UTI and show lower risk of UTI in patients with early UC removal after hysterectomy.

(Ahmed et al., 2014; Joshi et al., 2014; Chai, & Pun, 2011; Alessandri et al., 2006) (1++; 1++; 1+; 1+)

Grade of Recommendation: A

4.2 Record the time to first ambulation after operation, measuring from the end of operation to patient first walk supported by others.

Evidence: the reviewed quality studies measure the time from the end of operation to patient first ambulation and show that patients with early UC removal after
hysterectomy have a significant shorter time to first postoperative ambulation.

(Ahmed et al., 2014; Alessandri et al., 2006) (1++; 1+)

Grade of Recommendation: A