

A randomized clinical trial to compare immediate versus delayed removal of foley catheter following abdominal hysterectomy and laparotomy

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ABSTRACT

Objective: Indwelling urinary catheters are frequently used after surgery to prevent urinary retention. There is controversy about the ideal time to remove the catheter after surgery. This study compares the early and late Foley catheter removal following hysterectomy and laparotomy.

Methodology: In a clinical trial, 200 women candidate for hysterectomy or laparotomy were randomized to early removal of Foley catheter immediately or 24 hours after surgery. Early and late outcomes such as pain, fever, symptomatic urinary tract infection (UTI), the rate of re-catheterization and patients' satisfaction were compared in two groups.

Results: There were no significant differences between two groups in symptomatic UTI, re-catheterization rate and reinsertion of Foley catheter. The mean time of hospital stay were lower in the early removal group ($P < 0.05$). The patients were more satisfied when the catheter was removed early.

Conclusion: Immediate removal of Foley catheter seems to be more beneficial and satisfying for the patients than delayed removal.

KEY WORDS: Hysterectomy, Laparotomy, Urinary Catheter.

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INTRODUCTION

Indwelling transurethral Foley catheters are used as a standard method in non-complicated gynecologic surgeries for prevention of post surgical problems of bladder. However, there is a little support for use of Foley catheter for 24 hours after hysterectomy. Besides, use of Foley catheter is associated with increased bacteria and positive urine culture. Although use of urinary catheter for urine output control satisfies clinicians, there is little information about the benefits for patients.^{1,2}

On the other hand, it has been shown that significant percent of nosocomial infections result from urinary tract infections and a notable part of these infections are because of indwelling catheters. Increased rate of nonsocomial infections can lead

to longer hospitalization, physical and mental disturbances of patients and finally extra costs for patients and health system.¹⁻³

We designed this research to compare the outcomes of early and late removal of Foley catheter after hysterectomy and laparotomy.

METHODOLOGY

In this randomized clinical trial 200 women at Alzahra Teaching Hospital in Tabriz,Iran who were candidates for laparotomy or abdominal hysterectomy were enrolled into two groups from 2009 to 2010. The Ethics Committee of Tabriz University of Medical Sciences approved the study protocol.

In intervention group (100 patients) Foley catheter removed after surgery during recovery and in control group indwelling catheter remained 24 hours after surgery. Patients were randomly assigned to early and late removal of Foley catheter after hysterectomy and laparotomy. The randomization procedure was password protected, web-based, using permuted blocks and stratified by study center and invasive procedure.

Inclusion criteria were elective abdominal hysterectomy or laparotomy for benign pathology (fibroma, AUB, chronic pelvic pain, ovarian cysts,...) under general anesthesia and taking written informed consent. Patients who had intraoperative bleeding more than one liter, operation length > 2 h, severe endometriosis, dense pelvic adhesions, bladder suspension and underlying medical problems were excluded from the study. Foley catheter No. 14 under sterile condition was inserted in operating room before initiation of surgery and the ballon filled with 15 cc distilled water. Cephazoline 1gr iv half an hour before surgery started and continued every 6 hours until 2 doses. In intervention group, patients controlled for ability to void every 4 hours after surgery and if the patient could not void, Nelaton catheter used every 4 hours upto 2 times. In the case of urine retention or residual urine volume exceeded 150 ml after 12 hours which measured by ultrasonography, indwelling Foley catheter was inserted for 24 hours. The same approach was applied for control group 12 hours after removal of Foley catheter.

Urine analyses before , 24 and 48 hours after surgery were done. A check list was filled out for each patient 30 hours after surgery. The primary outcome of this study was pain score which was measured by visual analog scale. Assuming that 30% of patients in the control group would have the primary outcome, a sample size of 91 would allow

80% power to detect a 20% reduction in risk of that outcome in the intervention group. The sample size was inflated by about 10% to account for failure to return study diaries for a final intended sample size of 100 patient.

Baseline assessments and outcome parameters were summarized using simple descriptive statistics. Variables were expressed by their mean and standard deviation if normally distributed. The main analysis focused on a comparison between the trial groups of the primary outcome. The primary outcome was additionally analyzed using Chi-square test or Independent samples T test , when appropriate. Secondary outcome parameters such as rate of recatheterization, need for indwelling Foley catheter,mean time to ambulation and defecation, fever, dysuria, frequency, urine analysis and patient’s convenience variables, were analyzed by SPSS.15 software using the Chi-square test (including OR estimates with 95% CI), two group t-test or Mann-Whitney test, when appropriate. P-value < 0.05 considered significant.

RESULTS

There was no significant difference between two groups in demographic features (Table-I). Sixty-three and 37 patients in intervention group underwent laparotomy and abdominal hysterectomy respectively. In control group laparotomy was done for 57 and hysterectomy for 43 patients (P= 0.38). The mean times of operation in two groups were not significantly different (1.67 ± 0.35 hour in immediately removed group vs. 1.76 ± 0.38 h in delayed removal group, P= 0.087).

Operation to discharge duration was shorter in intervention group (2.17 ± 0.68 day vs. 2.69 ± 0.75 d, P< 0.0001). Patient’s ambulation occurred significantly earlier in immediately removal catheter group (15.53±6.45 hour vs. 24.36±4.66 h; P< 0.001). Defecation after surgery was earlier in intervention group (34.68 ± 12.87 h. vs. 45.60 ± 16 h; P< 0.001).

Table-I: Some demographic features of two studied groups.

<i>Characteristics</i>	<i>Early removal (N=100)</i>	<i>Delayed removal (N=100)</i>	<i>P value</i>
Age (y)	37.48 ± 8.85	39.48 ± 9.54	0.12
Weight (kg)	67.87 ± 10.77	68.68 ± 13.41	0.63
BMI (kg/m2)	26.41 ± 4.15	26.93 ± 5.38	0.44
Parity	2.68 ± 1.53	2.99 ± 1.66	0.39

Urethral burn was reported in 4% of immediately removal vs. 14% of delayed catheter removal group (OR 3.97; 95% CI 1.24 - 12.32). Subjectively, patients in the intervention group reported lower severity of pain (6.46 ± 1.25 vs. 7.03 ± 1.29 ; $P= 0.002$). Fever (≥ 38.5 degrees C) occurred more frequently in control group (OR 3.97; 95% CI 1.62 - 9.75).

Nelaton catheter was used only for six patients in case group (once in 3 cases and twice in the remaining) ($P= 0.129$). Reuse of indwelling Foley catheter was in 3% of case group ($P= 1$). Urine analysis before surgery did not show any significant difference in two groups ($P= 0.285$) but hematuria was observed higher in control group 24 hours after surgery (OR= 2.67; 95% CI 1.46 - 4.84).

Although symptomatic urinary tract infection was not different between groups (3 vs. 9; $P= 0.074$), dysuria at the beginning of urination was significantly higher in delayed catheter removal group (4 vs. 14; $P= 0.013$). Patients were more convenient of early removal of catheter (70% vs. 30% ; $P< 0.04$).

DISCUSSION

In this study we compared delayed versus immediate removal of Foley catheter following laparotomy or abdominal hysterectomy. According to our findings, immediate removal of catheter after surgery leads to earlier ambulation, shorter hospitalization, lower incidence of fever and dysuria and less pain score. The higher frequency of reported fever (during first 24 hours after surgery) in delayed removal group may be due to other factors like reaction to anesthetic drugs and antibiotics or atelectasia.

There are few randomized clinical trials about catheter removal after abdominal hysterectomy or laparotomy. Recently a RCT on 70 patients who underwent TAH for benign diseases revealed no difference in the pain assessment and symptomatic urinary tract infection between immediate and delayed catheter removal groups but re-catheterization was significantly higher in early removal group (20 vs. 0%; $P= 0.011$).⁴

Dobbs and colleagues studied 100 women who underwent abdominal hysterectomy and found significantly higher rates of recatheterization in early removal and bacteriuria in delayed removal of catheter.⁵ Summit and colleagues in their study on 100 patients with vaginal hysterectomy concluded that indwelling Foley catheter after surgery was not needed although it did not increase the postoperative morbidity.⁶ In contrast to Summit, an other study in 2007 on 233 women who underwent

vaginal hysterectomy or laparoscopic assisted vaginal hysterectomy showed voiding problems in 21% of patients with immediate removal of urinary catheter and mentioned it as a risk factor for urinary infection and longer hospitalization.⁷ The important negative point for this study was lack of control group.

Our findings corresponds with Alessandri and Dunn studies.^{8,9} In another study 270 cases of cesarean section were compared in two groups with and without Foley catheters. There was no difference in complications but hospital stay was shorter in group without urinary catheter.¹⁰ In a Cochrane database systematic review in 2007, twenty six trials about the strategies for the removal of short-time indwelling urethral catheters were reviewed. There was no significant difference in need for recatheterisation.

Early catheter removal was associated with higher risk of voiding problems and a lower risk of UTI and shorter hospital stay. The authors concluded midnight removal of urinary catheter is beneficial.¹¹ Transurethral urinary catheters are consistent with patients discomfort and the high incidence of urinary tract infections.¹² However, bacteriuria has been reported in fewer cases of intermittent catheterization group compared with indwelling catheter group (RR 2.90; 95% CI 1.44 to 5.84).¹³

Early removal of Foley catheter following uncomplicated abdominal hysterectomy and laparotomy seems to be associated with more patients' satisfaction, less pain and shorter hospital stay.

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Authors Contribution:

Elaheh Ouladsahebmadarek: substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, drafting the article and revising it and final approval of the version to be published.

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