

A prospective randomized trial to compare side effects of early versus late removal of Foley's catheter and vaginal pack following vaginal hysterectomy

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ABSTRACT

Background: There is a controversy about the ideal time for removal of catheter and vaginal pack following vaginal hysterectomy. The present study was undertaken to compare post-operative morbidity in early and late removal of Foley's catheter and vaginal pack. The aim of this study is to compare post-operative morbidity in early and late removal of Foley's catheter and vaginal pack following vaginal hysterectomy.

Methods: This was a prospective randomized study with n=100 of those women who were undergoing vaginal hysterectomy with or without pelvic floor repair and fulfilled the inclusion criteria. After informed written consent, they were assigned to Foley's catheter and vaginal pack removal group in 6 hours (group I, n=50) or 24 hours removal group (group II, n=50). Primary parameters used to assess were urine routine and microscopy, urine culture and sensitivity on post-operative day 2, need for re-catheterization and repacking, febrile morbidity, ambulation, vault infection and post-operative hospital stay duration were analyzed in both groups.

Results: Febrile morbidity was found in 6% and 8%, Positive urine culture was found in 10% and 20%, Rate of re-catheterization was 10% in group I and group II respectively. Vaginal bleeding after pack removal and repacking was in 6% in group I whilst none had in group II.

Conclusions: Early removal was associated with less incidence of urinary tract infection, and increased rate of re-catheterization and repacking. Needs larger comparative studies to support the practice of early removal.

Keywords: Foley's catheter, Recatheterization, Urinary infection, Vaginal pack

INTRODUCTION

Hysterectomy is one of the most common gynecological surgeries performed worldwide with 600,000 hysterectomies being performed in United States itself per year.¹

Traditionally abdominal hysterectomy is the common approach worldwide. However today there are several

different methods of performing hysterectomy, such as total laparoscopic hysterectomy, laparoscopic assisted vaginal hysterectomy (LAVH), robotic assisted vaginal hysterectomy and vaginal hysterectomy. Over the years Vaginal Hysterectomy (VH), LAVH and robotic assisted VH are gaining popularity and are replacing abdominal hysterectomy. American college of obstetricians and gynecologists strongly recommend vaginal hysterectomy be the route of choice, wherever feasible for women with

benign pathology in whom hysterectomy is indicated.² The reasons in advocating so are more favorable outcomes when compared to abdominal hysterectomy such as shorter operative duration, speedier recovery, less pain and better quality of life.³ The common conditions in which vaginal hysterectomy is indicated are Fibroid <16 weeks, Adenomyosis, Dysfunctional Uterine Bleeding and Utero-Vaginal prolapse. The choice of this route is multi-factorial, as it not only depends on the recommendations and indications of VH, but also surgeon's expertise and training, their level of confidence and comfort in performing VH and the extent of uterine descent.⁴

It has been a routine practice to place a vaginal pack following VH to prevent reactionary hemorrhage and also continuous bladder drainage with Foley's catheter to assess urinary output and to prevent post op. urinary retention. But this is accompanied with increased risk of urinary tract infection (UTI), inconvenience for patients, higher costs and prolonged hospital stay. In VH, nerve supply is not much disturbed, so short-term catheterization is being tried. The best way to prevent catheter related UTI is to avoid catheterization if possible or removal of catheter as early as possible. There is a controversy about the ideal time for removal of catheter after surgery as the decision of the duration of catheter post operatively is based more upon the hospital protocols, surgeon's preference, evidence-based knowledge rather than any strict guideline.⁵ Studies have shown 3 to 10% increased risk of bacteriuria per day of catheterization.⁶

Present study was done to compare the complications and outcome when the vaginal pack and urinary catheter were removed after 6 hours or after 24 hours post operatively.

Objectives were to:

- To assess febrile morbidity, urinary tract infection, re-catheterization, pain perception, voiding difficulty, vaginal bleeding and duration of hospital stay.
- To compare the incidence of the complications in the two groups of women in whom the urinary catheter and vaginal pack removal after 6 hours and 24 hours.

METHODS

This was a prospective randomized comparative study. Patients were recruited for the study after informed and written consent and the study was conducted at MGMCH and RI over a period of fifteen months (December 2015–March 2017). All the patients who were fulfilling the inclusion criteria underwent pre-operative evaluation for surgery such as haemogram, urine examination, blood urea, blood sugar, ECG and serology for HIV and HbsAg. Pre-operative urinary infection was excluded by urinary microscopy and culture wherever indicated. Pap smear for all and endometrial sampling was

done in indicated cases to exclude cervical and endometrial malignancy. Vaginal hysterectomy was done by standard technique under spinal anesthesia.

Inclusion criteria

Women undergoing vaginal hysterectomy with or without repair for benign gynecological conditions like utero vaginal prolapse, DUB, Adenomyosis, fibroid uterus <16 weeks size, cervical dysplasia etc.

Exclusion criteria

Women having UTI with pre-operative positive bacterial culture, urinary incontinence of any type-stress, urge or mixed, Comorbid illnesses like diabetes mellitus, chronic renal disease etc.

Any condition, which requires prolonged catheterization or prolonged IV fluid administration, like Kelly's stitch, iatrogenic bladder injury etc.

Cases were randomized using computer generated random number table into two groups:

- Group I: Foley's catheter and vaginal pack were removed 6 hours after surgery
- Group II: Foley's catheter and vaginal pack were removed 24 hours after surgery.

All patients received same type of prophylactic antibiotic Injection cefuroxime 1.5 grams I.V, 30-60 minutes before surgery.

All patients received spinal anesthesia and amount of blood loss and duration of surgery were noted for each patient. Hospital stay duration postoperatively for patients of both groups was recorded.

Pain was assessed using visual analog scale where score of 0-2 was mild, 3-6 was moderate, 7-8 was severe pain and 9-10 worst pain possible. Pain score was recorded 6 hours after surgery.

All patients were given Injection Ketorolac 30 mg i.m (Thrice a day), Injection Tramadol 100 mg i.v (twice a day) in the post-operative period for the first 24 hours.

Parameters studied in both groups were: incidence of symptomatic UTI, rates of re-catheterization and repacking. Subjective pain assessment was done using visual analog scale. Febrile morbidity was defined as two consecutive oral temperature readings of >100.4 degrees Fahrenheit measured 6 hours apart.

After urinary catheter removal and vaginal pack patients were encouraged to mobilize and void spontaneously. Time of first voiding was recorded, and pain scale was recorded 4 hours after surgery. Need for re-catheterization was assessed by ability to pass urine at the

end of 8 hours. If they were not able to void after 8 hours they were re-catheterized.

The diagnosis of symptomatic UTI will be based on the presence of significant bacteriuria accompanied by at least one of the following symptoms like fever, dysuria, increased frequency of micturition, urinary urgency and supra pubic pain.

On second postoperative day a midstream urine specimen was sent for microscopy and where pus cells were ≥ 5 , sample for urine culture and sensitivity was sent.

Patients with positive urine culture sensitivity were treated according to sensitivity and duration of hospital stay noted

Statistical Analysis

All data was entered into Microsoft excel 2011 and was analyzed using SPSS windows version 16. Need of repacking and re-catheterization at the end of 8-12 hours – Chi square test. Subjective pain assessment (Visual Analog Scale) at 8hours post operatively for all patients – Chi square test. Febrile morbidity- 2 reading of >100.4 -degree F 6 hours apart – Chi square test. Duration of hospital stay post-operatively – Mean, SD, student t-test.

RESULTS

Age, menopausal status and duration of surgery were almost same in both groups. The most common indication for VH was fibroid uterus (32%) in group I and Adenomyosis (30%) in group II.

Table 1: Indications for hysterectomy.

Indications for hysterectomy	Group I (n=50)	Group II (n=50)	p value
Abnormal uterine bleeding	7 (14.0%)	8 (16.0%)	
Fibroid	16 (32.0%)	10 (20.0%)	
Adnenomyosis	9 (18.0%)	15 (30.0%)	
Dysplasia	7 (14.0%)	4 (8.0%)	0.415
Genital prolapse	11 (22.0%)	13 (26.0%)	

Vaginal Hysterectomy with pelvic floor repair (VH with PFR) was done in 26% and 45% of patients in group I and group II respectively.

Postoperative fever of >100.4 -degree Fahrenheit was found to be 6% and 8% in group I and II respectively, which was not statistically significant.

UTI with pus cells >5 was found in 20% and 52% of group I and group II respectively and was statistically significant. *Escherichia coli* was commonest organisms in both groups.

Table 2: Urinary tract infection (number of pus cells).

Pus cells	Group I	Group II	p value
0-5	40 (80%)	24 (48%)	
>5	10 (20%)	26 (52%)	
Total	50	50	0.0008

Table 3: Urine culture and sensitivity.

Urine culture and sensitivity	Group I	Group II	p value
Culture not sent (0-5 pus cells)	40 (80%)	24 (48%)	
Sterile	5 (10%)	10 (20%)	
Bacteria present	5 (10%)	16 (32%)	0.003

Urine culture and sensitivity was positive in 10% and 32% of patients in group I and II respectively which was statistically significant.

Rate of recatheterization was high in group I (10%) and none in group II.

Table 4: Recatheterization.

Recatheterization	Group I	Group II
Not recatheterized	45 (90%)	50 (100%)
Recatheterized	5 (10%)	0

Pain during the first voiding episode, first voiding time and urinary discomfort was almost similar in both groups.

Vaginal bleeding after pack removal was found in 3 patients who required repacking in group I and none in group II and there was no vault infection in either group. Ambulation time was similar in both groups. Hospital stay was less in group I compared to group I.

Table 5: Hospital stay duration post operatively (in days).

	N	Mean	SD	p value
Group I	50	3.48	0.544	
Group II	50	3.98	0.714	0.000

DISCUSSION

Present study was done to compare Foley's catheter and vaginal pack removal in patients undergoing VH in 6 hours and 24 hours postoperatively. Traditional practice of keeping the urinary catheter and vaginal pack for prolonged duration post-operatively has changed with time as it became evident that prolonging the duration did not have any additional benefit, but it increased urinary tract infection and hospital stay. The best way to prevent urinary tract infection is to avoid putting the catheter if possible or to remove it as early as possible.

The removal of catheter immediately after surgery had the disadvantage of difficulty in immediate ambulation and voiding due to the residual effect of regional anesthesia. To overcome the problem urinary catheter and vaginal pack were removed 6 hours after surgery and it was compared with removal 24 hours later of the same. Sample size in this study was 100, randomized into two groups.

The mean age of the patient in the present study was 47.90 years in-group I and 50.18 years in group II. No variations were seen in indications for surgery, menopausal status or type of surgery. The commonest indication for vaginal hysterectomy in the present study was fibroid uterus 26% followed by utero vaginal prolapse in 24% of cases. 37% had vaginal hysterectomy with pelvic floor repair and 63% had vaginal hysterectomy alone.

Utero- vaginal prolapse was the commonest indication in studies by Sekhavat et al and Glavind et al.^{7,8} Summit et al above included only vaginal hysterectomy cases without pelvic floor repair whereas studies by Rajan et al and Glavind et al included cases with or without pelvic floor repair similar to the present study.^{9,10}

Febrile morbidity was almost similar in both groups in present study, 6% and 8% in group I and II respectively. Summit et al in their study found much higher incidence of postoperative febrile morbidity of 24.5% in 24 hours group versus. 8% in no catheterization group.⁹ Rajan et al study morbidity was 7% and 4% in 3 hours versus 24 hours group respectively.¹⁰

In the present study urinary tract infection was 20% and 52% in group I and group II respectively and statistically significant indicating longer duration of catheterization resulted in higher incidence of urinary tract infection.

Table 6: Urinary tract infection.

Studies	Percentage
Ahmed ¹¹ (Immediate versus 6hours Versus 24 Hours)	1.4% versus 3.7% versus 15%
Nahed ¹² (12-24 hours versus 48-72 hours)	6% versus 24%
Rajan ¹⁰ (3hours versus 24 hours)	26% versus 26%
Shrestha ¹³ (24hours versus 72 hours)	18% versus 30%
Shahnaz ¹⁴ (24hours versus 72 hours)	22.9% versus 34.3%
SummittError! Bookmark not defined. (no catheter versus 24 hours)	28% versus 16.3%
Present study (6 hours versus 24 hours)	20% versus 52%

Most of the studies reported higher incidence of urinary tract infection, when urinary catheter was kept for a longer time similar to present study except in Summit et

al study observed incidence of urinary tract infection in women in whom post-operative indwelling catheter was not kept.⁹

In the present study *Escherichia coli* was isolated in the majority of positive cultures being 60% versus 62.5% in the group I and group II respectively. Thakur et al, Shrestha et al, Joshi et al in their study also found *Escherichia coli* to be the most frequent organism in the positive urine cultures.^{13,15,16}

Summit et al observed that none of the patients required re-catheterization in no catheter group compared to catheterization group, among whom two patients required re-catheterization following vaginal hysterectomy.⁹ The study concluded that indwelling catheterization is not required after routine uncomplicated vaginal hysterectomy. After vaginal surgery patient may be unable to pass urine on her own and may have retention of urine due to post-operative tissue swelling, pain, transient bladder atony, hematoma and also due to the hemostatic vaginal pack.

In the present study re-catheterization rate was 10% in group I and none in group II. In the present study, visual analog scale was used to assess pain experienced during first voiding episode. Both 6 hours and 24 hours group experienced moderate amount of pain, which was statistically insignificant.

Duration from removal of catheter post operatively to patient voiding spontaneously was taken as First void time. In the present study majority of patients voided within first 5 hours of catheter removal in both groups. Mean duration in hours was 4.07 hours±0.931 in group I and 4.3 hours±1.129 in group II.

Table 7: Rate of recatheterization.

Studies	Percentage
Rajan ¹⁰ (3hours versus 24hours)	10% versus 4%
Shrestha ¹³ (24hours versus 72 hours)	6% versus 0
Summit ⁹ (immediate versus 24 hours)	0 versus 2
Shahnaz ¹⁴ (24hours versus 72 hours)	31.4% versus 25.7%
Present study (6 hours versus 24 hours)	10% versus 0%

Patients undergoing vaginal hysterectomy with pelvic floor repair were more likely to develop post-operative voiding dysfunction, which may be due to anterior colporrhaphy and bladder mobilization. In the present study majority experienced moderate discomfort whilst other studies found that majority experienced only mild amount of discomfort.

In the present study there was no incidence of vault infection in either of the groups. Vaginal repacking was

required in 6% of patients in group I and none in group II. The patients who required repacking had undergone vaginal hysterectomy with pelvic floor repair.

Subramanya et al study found no particular benefits of placing vaginal pack post operatively in patients undergoing vaginal hysterectomy.¹⁷

Rajan et al reported no patient experienced vaginal bleeding following pack removal, however, in the 24-hour removal group 1% had to be repacked. This observation was in contrast to present study.⁹ Thiagamoorthy et al recommended in their study to pack the vagina post operatively suggesting it might reduce hematoma formation post operatively.¹⁸

There was no significant difference in the operation time and ambulation time in both the groups of present study. Mean ambulation time after catheter removal in present study was 10.32 hours in group I and 10.10 hours in group II. Ouladsahebmadarek et al (immediate versus 24 hours) found mean of 15.53 hours versus. 24.36 hours respectively.¹⁹

Duration of hospital stay post operatively in present study was 3.48 versus 3.98 days in group I and group II respectively. Choudhary et al found hospital stay of 4.68 days in short duration compared to 6.98 days in longer duration catheterization.²⁰ Nahed (12-24hrs group) reported that majority ambulated within 4-8 hours versus. 48-72 hours where majority ambulated in 14-18 hours.¹²

Sample size was small in the present study and it also excluded comorbidities like diabetes mellitus, hypertension etc. The study included women who underwent vaginal hysterectomy with and without pelvic floor repair.

CONCLUSION

The question of how long urinary catheter and vaginal pack should remain in-situ after vaginal hysterectomy with or without pelvic floor repair has been debated for several years and has not yet been resolved. Risks and benefits have to be weighed. Early removal of urinary catheter was associated with less risk of urinary tract infection but with slightly increased risk of re-catheterization.

Early removal of vaginal pack was associated with increased risk of vaginal bleeding requiring repacking in case of vaginal hysterectomy with pelvic floor repair. Best way to prevent catheter related morbidity is to remove it as early as possible.

Vaginal pack may be necessary in cases of vaginal hysterectomy with pelvic floor repair when vaginal oozing is anticipated. Further large comparative studies are necessary to support the practice of short-term catheterization of 3-6 hours.

Recommendations

Early removal of Foley's and vaginal pack is recommended in uncomplicated Vaginal Hysterectomy to reduce post-operative morbidity.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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