Effectiveness of Vaginal Douching on Febrile and Infectious Morbidities after Total Abdominal Hysterectomy : A Multicenter Randomized Controlled Trial

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Abstract

Objective : To evaluate the effectiveness of vaginal douching with 1 per cent povidone-iodine in reducing febrile and infectious morbidities after total abdominal hysterectomy (TAH).

Method : The authors conducted a randomized controlled trial in 300 patients undergoing elective TAH in three hospitals in Northeast Thailand: a university, a regional and a general hospital. The patients were randomly allocated to the intervention or control groups. Patients in the intervention group received pre-operative vaginal douching with 1 per cent povidone-iodine while patients in the control group did not. External evaluators not apprised of the intervention assessed febrile and infectious morbidities.

Results : 300 patients were enrolled in the study. The incidences of febrile morbidity in patients with and without pre-operative vaginal douching were 25 and 35 per cent, respectively, though not statistically significant (risk difference -9.6%, 95% CI -19.9%, 0.8%, adjusted odds ratio 0.6, 95% CI 0.3%, 1.0%). A statistically significant difference in infectious morbidity was found between the groups (8 *vs* 19%, risk difference -10.0%, 95% CI -17.8%, -2.2%, adjusted odds ratio 0.4, 95% CI 0.2%, 0.9%).

Conclusion : Pre-operative vaginal douching with 1 per cent povidone-iodine significantly reduces infectious morbidities after TAH.

Key word : Total Abdominal Hysterectomy, Vaginal Douching

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Total abdominal hysterectomy (TAH) is the most common major gynecologic operation the world over. In the USA, roughly 600,000 hysterectomies are performed annually[1], while the UK rate is about 20 per cent of women aged 55[2]. In Khon Kaen University Hospital, Thailand, about 300 TAHs are performed annually[3].

The two most common complications after TAH are febrile and infectious morbidities[4,5]: the incidence of febrile morbidity varying between 5 and 50 per cent[4,6] and common infectious morbidities being urinary tract, abdominal wound and vaginal cuff infections and pneumonitis[7]. Potential risk factors for febrile and infectious morbidities are advancing age, obesity, diabetes mellitus, anemia, prolonged surgery and lack of prophylactic antibiotics[6-8].

Since the vaginal canal must be breached, when performing TAH, routine vaginal douching is recommended[9]. A survey conducted in 80 major hospitals in Thailand indicated that almost all (79 of 80) practiced pre-operative vaginal douching, usually once the night before surgery then again on the morning of the surgery[3].

Many antiseptic solutions are used for vaginal douching, including povidone-iodine, chlorhexidine, chlorhexidine plus cetrimide and normal saline [3]. To our knowledge, there have been no reports of randomized controlled trials evaluating the effectiveness of vaginal douche in preventing febrile and infectious morbidities after TAH. Recent meta-analysis indicated that no conclusive randomized controlled trial was found and most of the studies had severe methodological problems thereby making them descriptive rather than conclusive[10]. Although vaginal douching is not very costly, it is time-consuming and discomforting to patients : so the authors aimed to evaluate its effectiveness in reducing febrile and infectious morbidities after TAH.

MATERIAL AND METHOD

Between November 1999 and September 2000, 300 patients in three hospitals scheduled for elective TAH for benign conditions were enrolled in the study. All of them were free of underlying medical disease and obvious gynecologic infection. The patients were excluded if the pathology indicated a malignancy or if only a subtotal hysterectomy was performed. One hundred patients from each of Khon Kaen University (Srinagarind) Hospital, Khon Kaen Regional Hospital and Kalasin General Hospital gave written informed consent and were randomly allocated to receive (intervention group) or not receive vaginal douching (control group) before TAH. A sealed envelope containing a computer generated random number was used for randomization process. Patients assigned to the intervention group had two vaginal douches with 1000 ml of 1 per cent povidone-iodine solution (prepared by the pharmacy at Srinagarind Hospital), on the night before surgery and again on the morning of surgery. TAH was performed by either senior residents or faculty members using standard operative procedures[11]. Gynecologists not apprised of the intervention performed per vaginal examination on each patient to assess for vaginal cuff infection both, the day before hospital discharge (usually 5 and 7 days after TAH) and four weeks after surgery. The incidence of febrile morbidity after TAH from the present pilot study was 20 per cent. To detect a 15 per cent difference (20 *vs* 35%), at 5 per cent α error, 20 per cent β error, two sided test, the authors required a sample size of at least 138 patients per group[12].

The main outcome measurement was febrile morbidity defined as the presence of an oral temperature $\geq 100.4^{\circ}F$ ($38^{\circ}C$) on two occasions at least 4 hours apart in the post-operative period prior to hospital discharge, excluding the first 24 hours[7,13] and infectious morbidity defined by the presence of a urinary tract, abdominal wound or vaginal cuff infection and pneumonia. Patients with post-operative infections were treated according to the standard treatment at the respective hospitals. A urinary tract infection was recorded if patients had symptoms of infection and a mid-steam urine specimen showed bacterial growth $\geq 10^5$ bacteria/ml of urine[7]. Surgical wound infection was defined as redness, tenderness and infiltration or abscess[7]. Pneumonitis was defined by fever, physical and radiological findings of consolidation[7]. Vaginal cuff cellulitis or infection was defined as redness, tenderness and infiltration or abscess at the vaginal cuff[7].

The intention-to-treat principle was strictly adhered to. Data analysis was performed using STATA 6. The effectiveness of vaginal douching was evaluated by comparing the incidences of febrile and infectious morbidities between the two groups. Risk difference, odds ratio and their 95 per cent confidence intervals, adjusted for potential confounding factors by multiple logistic regression were calculated.

The Ethics Committee of Khon Kaen University approved the present study.

RESULTS

Three hundred patients were recruited in the study between November 1999 and September 2000, 150 in the intervention group and 150 in the control, Fig. 1. Each hospital had 50 intervention and 50 control subjects by randomization. One patient allocated to the control group at the university hospital was excluded because myomectomy was performed rather than hysterectomy as scheduled, so 299 patients were available for data analysis. The baseline characteristics of patients in both groups were comparable. The distribution of indicators were similar between the intervention and control groups. Table 1.

The most common indication for TAH was myoma uteri (76%) followed by benign ovarian tumor and cervical intraepithelial neoplasia 8.7 and 6.0 per cent, respectively, Table 2. The incidence of febrile morbidity in patients with and without pre-operative vaginal douching was 25.3 (38 in 150 cases) and 34.9 per cent (52 in 149 cases), respectively, Table 3. No statistically significant difference was found between the two groups (risk difference -9.6%, 95% CI -19.9%, 0.8%, adjusted odds ratio 0.6, 95% CI 0.3%, 1.0%). Patients in the intervention group had significantly lower infectious morbidity than the control group, 8.0 (12 in 150) *vs* 18.8 per cent (28 in 149), (risk difference -10.0%, 95% CI -17.8%, -2.2%, adjusted odds ratio 0.4, 95% CI 0.2%, 0.9%), adjusted for age, BMI, prophylactic antibiotics, operative time, estimated blood loss, vaginal cuff closure technique at 3 different hospitals, Table 4.

Thirteen patients could not be followed-up at the fourth post-operative week (9 subjects in the intervention group and 4 in the control). Sensitivity analysis was performed, but the results did not change.

The most common early infectious morbidity was abdominal wound infection while vaginal cuff infection was the major cause of late infectious morbidity, Table 3.

Multiple logistic regression analysis was carried out to determine the effectiveness of vaginal douching and infectious morbidity. After adjusting for potential confounding factors (age, BMI, prophylactic antibiotic, surgeon, operative time, estimated blood

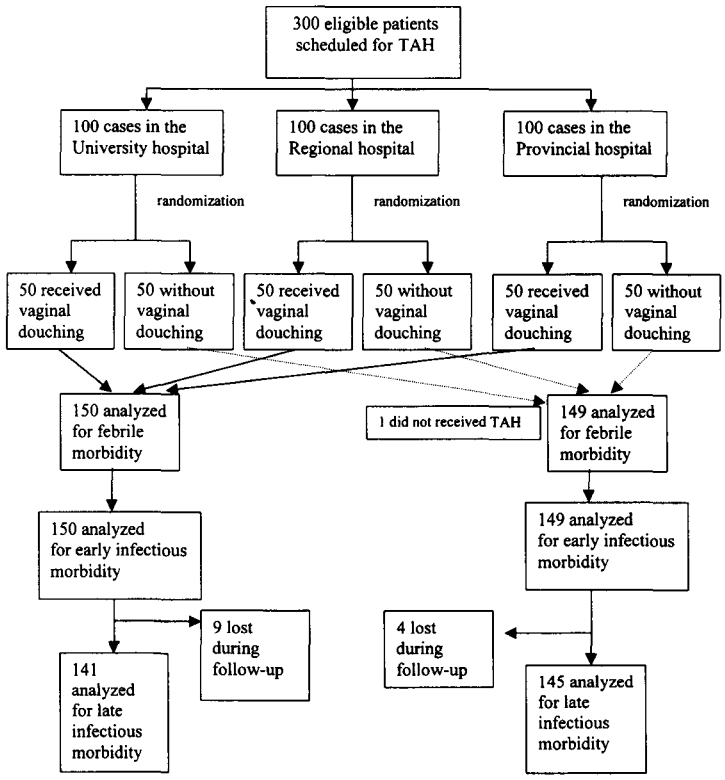

Fig. 1. Flow of participants.

Table 1. Baseline characteristics of patients.

Characteristics	Intervention group (with vaginal douching) n = 150	Range	Control group (without vaginal douching) n = 149	Range
Age (yr)	43.9 ± 7.7	25-74	44.0 ± 7.2	25-71
Weight (kg)	58.9 ± 10	40-90	59.7 ± 9.3	38-89.5
Height (cm)	155.2 ± 4.7	142-169	155.7 ± 4.9	144-168
BMI (kg/m^2)	24-4 ± 3.8	16.7-34.9	24.6 ± 3.4	16.2-36.8
Prophylactic antibiotics (%)	79.4		76.5	
Surgeons				
Faculty member (%)	81.3		85.2	
Resident (%)	18.7		14.8	
Operative time (min)	87.0 ± 36.9	40-305	90.15 ± 36.6	30-235
Estimated blood loss (ml)	294.6 ± 173.5	50-1,000	285.2 ± 171.3	50-1,200
Vaginal cuff suture				
Open technique (%)	37.3		43.6	
Close technique (%)	62.0		56.4	
No record (%)	0.7		0	
Hospital stay (day)	7.5 ± 2.2	4-15	7.2 ± 2.6	4-22
Loss to follow-up (person)	9		4	

Table 2. Indications for TAH.

Indications	Intervention group (with vaginal douching) n = 150		Control group (without vaginal douching) n = 149	
	Number	%	Number	%
Leiomyoma	113	75.3	114	76.5
Benign ovarian tumor	18	12	8	5.4
Cervical intraepithelial neoplasia (CIN)	8	5.3	10	6.7
Endometrial hyperplasia	0	0	6	4.0
Abnormal uterine bleeding	2	1.3	8	5.4
Adenomyosis	4	2.7	2	1.3
Endometriosis	1	0.7	0	0
Pelvic pain	1	0.7	0	0
Others	3	2	1	0.7
Total	150	100	149	100

loss, vaginal cuff closure technique and 3 different hospitals, pre-operative vaginal douching with 1 per cent povidone-iodine was found to significantly reduced infectious morbidity in TAH patients (adjusted odds ratio 0.4, 95% CI 0.2%, 0.9%).

DISCUSSION

The incidence of febrile morbidity in patients with and without pre-operative vaginal douching was 25.3 and 34.9 per cent, respectively, not statistically significant (risk difference -9.6%, 95% CI -19.9%, 0.8%), similar to other studies of febrile morbidity[6, 14]. The incidence of infectious morbidity in patients with and without pre-operative vaginal douching was 8.0 and 18.8 per cent in the intervention and control groups, respectively (risk difference -10.0%, 95% CI -17.8%, -2.2%). Infectious morbidity in the control group was higher than it was in other studies[6,15] indicating that pre-operative vaginal douching with 1 per cent povidone-iodine solution significantly reduced infectious morbidity after TAH. The most common early infectious morbidity was from abdominal wound infection while the most common late infectious morbidity was from vaginal cuff infection. The number needed to treat based on the authors' data was 10. The incidence of UTI was lower than in other

Table 3. Febrile and infectious morbidities after TAH.

Type of infections	Intervention group (with vaginal douching) N = 150	%	Control group (without vaginal douching) N = 149	%
Febrile morbidity	38	25.3	52	34.9
Infectious morbidity				
Early infection (occurred in 1st week)	5	3.3	9	6.0
Abdominal wound infection	2	1.3	5	3.4
UTI	1	0.7	0	0
Pelvic collection	1	0.7	0	0
Vaginal cuff infection	0	0	4	2.7
UTI + pelvic collection	1	0.7	0	0
Late infection (assessed at 4th week)	7 (n = 141)		19 (n = 145)	
Vaginal cuff infection	7	5.0	18	12.4
Peritonitis (detected 3rd week)	0	0	1	0.7
Total	12/150	8.0	28/149	18.8

Table 4. Febrile and infectious morbidities after TAH.

Outcomes	Intervention (n = 150) (%)	Control (n = 149) (%)	Risk diff (95% CI) (%)	Adjusted odds ratio# (95% CI)
Febrile morbidity	25.3	34.9	-9.6 (-19.9, 0.8)	0.6 (0.3, 1.0)
Infectious morbidity	8.0	18.8	-10.0 (-17.8, -2.2)	0.4 (0.2, 0.9)

Adjusted for age, BMI, prophylactic antibiotic, surgeon, operative time, estimated blood loss, vaginal cuff closure technique and 3 different hospitals.

studies[6] perhaps because a urine culture was performed only for those patients with abnormal simple urinalysis.

Povidone-iodine was used as an antiseptic solution because it is a broad-spectrum antiseptic solution[16]. Goldenheims did not observe any significant difference in wound healing among burn patients using 1, 5 or 10 per cent povidone-iodine solution[17].

Eason et al[14] conducted a cohort study of 158 women who were treated with vaginal povidone-iodine gel before TAH and 317 historical control subjects. Patients in the treatment group had significantly lower febrile morbidity (adjusted odds ratio 0.52, 95% CI 0.31, 0.89). However, the non-randomized nature of the present study limits its significance. Vinkomin conducted a randomized, controlled trial in 30 patients scheduled for elective TAH. All patients received routine pre-operative vaginal and perineal cleansing with 10 per cent povidone-iodine[15] the evening before surgery. In the intervention group the vagina of 15 patients was swabbed for 3 minutes prior to surgery with 10 per cent povidone-iodine. Post-operative bacterial infections were reduced though not statistically significant. Blackmore conducted a randomized controlled trial in 103 patients undergoing abdominal hysterectomy or vaginal hysterectomy. Fifty-one patients in the intervention group received 7.5 per cent povidone-iodine[18] vaginal pessaries every 8 hours for at least 36 hours pre-operatively and their abdomen was prepared with a 10 per cent povidone-iodine at the time of operation. In the control group, 52 patients had their abdomen prepared with 0.015 per cent chlorhexidine preparations and 0.15 per cent cetrimide in water for vaginal cleansing. The incidence of vaginal vault infection in the study and control groups was 41 and 21 per cent, respectively, though not statistically significant.

In the present study, 13 patients could not be followed-up, 9 subjects from the intervention group and 4 from the control. Even if they were all assigned

as having infectious morbidities, the statistical analysis still showed a borderline significant protective effect (adjusted odds ratio 0.6, 95% CI 0.3, 1.1) ; it is unlikely, however, that all 13 would have infectious morbidities. The protective effect of vaginal douching with 1 per cent povidone-iodine is therefore likely statistically significant.

A randomized controlled trial with a sufficient sample size to detect clinically significant outcomes, using a proper random allocation method to ensure concealment and following the intention-to-treat principle, are the strengths of the present study. The limitation was that we used only clinical findings were used to diagnose vaginal cuff infections. The authors tried to limit the detection bias that might occur by standardizing and not apprising the gynecologists doing the pelvic exam to detect vaginal cuff infection at about one week and 4 weeks after the operations. The authors also included infectious morbidity at 4 weeks after the operation as an outcome variable. Without this outcome the authors would not have detected the beneficial effect of vaginal douching.

The authors searched MEDLINE between 1966 and 2001 but found no randomized controlled trial evaluating the effectiveness of vaginal douching for the prevention of febrile or infectious morbidities after TAH. The present study is perhaps the first randomized controlled trial to show that pre-operative vaginal douching effectively reduces infectious morbidities after TAH.

Well-trained gynecologists using standard operative procedures performed all TAH in the present study. The indications for TAH were common diseases mainly myoma uteri, similar to other reports (1-3). Since 1 per cent povidone-iodine is not expensive, the authors recommend routine pre-operative vaginal douching with this solution for patients scheduled for elective TAH. The economical effectiveness of pre-operative vaginal douching with 1 per cent povidone-iodine should therefore be generalized to other hospitals.

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ประสิทธิภาพของการสวนล้างช่องคลอดต่อภาวะไข้และการติดเชื้อหลังการผ่าตัดมดลูกออกทางหน้าท้อง : การศึกษาแบบสุ่ม

ประนอม บุพศิริ, พบ, โฉมพิลาศ จงสมชัย, พบ, MHS*, นารีรักษ์ วงศ์พราวมาศ, วทบ*, จรรยาภรณ์ อุ่นชัย, พบ**, บรรพจน์ สุวรรณชาติ, พบ***, ภิเศก ลุมพิกานนท์, พบ, วทม**

วัตถุประสงค์ : เพื่อประเมินถึงประสิทธิภาพของการสวนล้างช่องคลอดด้วย 1% povidone–iodine ในการลดภาวะไข้และภาวะการติดเชื้อหลังการผ่าตัดมดลูกออกทางหน้าท้อง

วิธีการ : ได้ทำการศึกษาแบบสุ่มในผู้ป่วยจำนวน 300 รายที่ได้วางแผนไว้จะทำการผ่าตัดมดลูกออกทางหน้าท้องในโรงพยาบาล 3 ระดับ ในภาคตะวันออกเฉียงเหนือ คือโรงพยาบาลมหาวิทยาลัย โรงพยาบาลศูนย์ และโรงพยาบาลจังหวัด ผู้ป่วยจะถูกสุ่มจัดแบ่งไปอยู่ในกลุ่มที่ได้รับการสวนล้างช่องคลอดด้วย 1% povidone–iodine ก่อนผ่าตัด และกลุ่มที่ไม่ได้สวนล้างคลอดอย่างละเท่า ๆ กัน ผู้ประเมินภายนอกจะเป็นผู้ประเมินภาวะไข้ และภาวะการติดเชื้อหลังผ่าตัด

ผลการศึกษา : อุบัติการณ์ภาวะไข้หลังผ่าตัด ในกลุ่มที่ได้รับการสวนล้างช่องคลอด และไม่ได้รับการสวนล้างช่องคลอด เป็นร้อยละ 25 และ 35 ตามลำดับ และไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (risk difference –9.6%, 95% CI –19.9%, 0.8%, adjusted odds ratio 0.6, 95% CI 0.3%, 1.0%) แต่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติของภาวะการติดเชื้อหลังผ่าตัดในกลุ่มที่สวนล้างช่องคลอดและไม่ได้สวนล้างช่องคลอด (8% *vs* 19%, risk difference –10.0%, 95% CI–17.8%, –2.2%, adjusted odds ratio 0.4, 95% CI 0.2%, 0.9%)

สรุป : การสวนล้างช่องคลอดก่อนทำการผ่าตัดมดลูกออกทางหน้าท้องด้วย 1% povidone–iodine สามารถลดภาวะการติดเชื้อหลังผ่าตัดได้อย่างมีนัยสำคัญทางสถิติ

คำสำคัญ : การผ่าตัดมดลูกออกทางหน้าท้อง, การสวนล้างช่องคลอด

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