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A Prospective Randomized Study Comparing Voiding Time Between Suprapubic Catheterization and Intermittent Self-Catheterization Following Radical Hysterectomy and Pelvic Lymphadenectomy for Cervical Cancer

Prapaporn Suprasert MD,
Jatupol Srisomboon MD,
Chailert Phongnarisorn MD.

Division of Gynecologic Oncology, Department of Obstetrics & Gynecology, Faculty of Medicine, Chiang Mai University, Chiang Mai 50200, Thailand

Abstract

Objective To compare the voiding time between intermittent self-catheterization (ISC) and suprapubic catheterization (SPC) in cervical cancer patients undergoing radical hysterectomy and pelvic lymphadenectomy (RHPL).

Design Prospective randomized study.

Setting Division of Gynecologic Oncology, Department of Obstetrics & Gynecology, Faculty of Medicine, Chiang Mai University.

Subjects & Methods Between September 1998 and June 1999, 71 patients with stage IB-IIA cervical cancer undergoing RHPL were prospectively randomized to receive either ISC (38 cases) or SPC (33 cases) for managing post operative bladder dysfunction. Intermittent self-catheterization every 4 hours after voiding was initiated on day 7 post-operatively in the ISC group, whereas in the SPC group, the catheter was clamped on 7th post operative day. The duration for clamping in the SPC group was 4 hours and was released after self voiding to check the residual urine. Both ISC and SPC were discontinued when post voiding residual urine was less than 75 ml for 2 consecutive voids. Patients in the SPC group were switched to perform ISC if they could not void normally at day 30 postoperatively. The voiding time, the frequency of urinary tract infection, perioperative data and morbidity were recorded.

Results Both groups were similar regarding age, body mass index (BMI), tumor histology, stage, size and gross appearance of the tumors. There was no difference between groups in respect of operative time, need for blood transfusion, perioperative morbidity, need for adjuvant chemoradiation and the frequency of urinary tract infection. Twenty-five (65.8%) patients in the ISC group and 23 (69.7%) in the SPC group had voiding time less than 30 days. Mean voiding time in the ISC group was significantly less than that in the SPC group (13.1 days vs. 17.3 days respectively, P = 0.02).

Conclusion Patients performing ISC after RHPL for invasive cervical cancer can resume bladder function earlier than those undergoing SPC without significant difference in the frequency of urinary tract infection and perioperative morbidity

Key words: Cervical cancer, radical hysterectomy, voiding time, suprapubic catheterization, intermittent self-catheterization

Radical hysterectomy and pelvic lymphadenectomy (RHPL) continues to play a major role in the treatment of early stage cervical cancer. Due to extensive dissection of cardinal ligament combined with isolating the ureters and mobilizing the bladder during the operation, lower urinary tract dysfunction is the most common complication associated with radical hysterectomy.[1-4] The incidence of significant bladder dysfunction may be as high as 50%.[3,4] Many operative techniques were used to reduce this problem by preservation of nervous part of the cardinal ligament.[4-6] However, dysfunction of bladder still occurred. To solve this problem, either prolonged bladder catheterization with suprapubic catheterization (SPC) or transurethral indwelling catheter has been used as the method of postoperative urinary drainage to prevent bladder overdistension.[7,8] The use of suprapubic bladder catheterization has advantage over transurethral catheter because the patient can conduct intermittent voiding trials without the necessity of removal or replacement of the catheter. For such trials, the suprapubic catheter is clamped for brief periods until the urge to void returns. However, intermittent self - catheterization (ISC) is an acceptable technique for urinary drainage to avoid long term indwelling catheter use.[7,8] Some authors believed that prolonged catheterization acts as chronic irritant and prevents the bladder from expanding and emptying in its usual function while ISC achieves a state relatively free of catheter and permit bladder filling to act as a stimulus for return of reflex bladder contractility.[8,9] Chamberlain et al[9] reported that the ISC patients had short voiding time when compared with the SPC patients in the past. Thus far, there is no randomized control trial comparing the voiding time between these 2 techniques.

This prospective randomized study was conducted to determine whether there is the difference between the voiding time of the ISC and the SPC techniques after RHPL for invasive cervical cancer.

Materials and methods

Cervical cancer patients who underwent RHPL at Chiang Mai University Hospital between September, 1998 and June, 1999, were enrolled to enter the study. The enrolled patients should have normal preoperative bladder function and urinary analysis. The patients who had one of the following criteria, i.e. urinary tract infection more than 2 times per year, history of renal stone, bladder calculi, urinary incontinence, intra operative bowel or urinary tract complication or inability to perform ISC were excluded.

A Piver-Rutledge type III radical hysterectomy was performed following bilateral pelvic lymphadenectomy[10] by the same team of surgeons. Sampling of paraaortic nodes was performed when there were enlarged pelvic nodes or suspicious of metastasis. Neither retroperitoneal drainage nor peritonization was done.

At the end of the RHPL operation, the patients were allocated immediately into 2 groups, i.e. the ISC or the SPC group before abdominal closure which were assigned by computerized randomization and sealed in the envelope. The ISC group was managed by indwelling transurethral Foley's catheter for 7 days. On day 6, the patient was instructed to do ISC until she could confidently perform by herself. When the Foley's catheter was removed on day 8, the ISC was performed every 4 hours after each voiding and the post voiding residual urine (PVR) was recorded. In the SPC group, suprapubic catheter was placed through a small bladder incision and exited through a separated skin incision. The catheter in this group was clamped on day 7 post operatively for 4 hours and was released after self-voiding to check the PVR.

In both groups, ISC and SPC were discontinued when the PVR was less than 75 ml for 2 consecutive voids. Patients in the SPC group were switched to perform ISC when they retained the SPC more than 30 days because some cases were assigned to receive adjuvant chemoradiation according to one or more of the following pathologic findings: positive pelvic or paraaortic nodes, parametrial invasion, positive vaginal margin or deep stromal invasion with lymph vascular space invasion (LVSI). The chemoradiation consisted of cisplatin (75 mg/m2) intravenous infusion

at weekend every 3 weeks for 4 courses combined with external radiation (200 CGy/day) given on weekdays until reaching 5,000 Cgy. The 2-4 times of high dose rate (HDR) were added in case of positive vaginal margin.

Urine analysis was performed weekly until the ISC or SPC was discontinued. Bacteriuria was defined as urinary culture showed the organism more than 105 colonies/ml and was treated by oral or parenteral antibiotic according to drug sensitivity.

All patients received the same antibiotic prophylaxis as a single oral dose (2 gm) of tinidazole 12 hours before surgery and ampicillin infused intravenously 1 hour prior to the operation. In the post operative period, ampicillin was given at 6- hour interval until the patients could take the oral form of 2 gm per day. Ampicillin was continued for another 5 days. The patients were assessed on a daily basis postoperatively, and then weekly after being discharged from the hospital to check bladder function and any possible complications.

Basic data, perioperative complication, febrile morbidity, the voiding time and rate of urinary tract infection were recorded. Prolonged bladder dysfunction was defined as the voiding time was longer than 30 days. Febrile morbidity was defined as two consecutive oral temperatures greater than or equal to 38˚ C, at least 6 hours apart excluding the first 24 hours after operation. Bimanual pelvic examination was performed at 6- week postoperative visit and then every 3 months for the first year of follow up, every 4 months in the second year and every 6 months thereafter.

Based on previous study, the estimated incidence of patients who could successfully void within 1 month after RHPL operation in the SPC was 56% while in the ISC was 88%.[11] For a type 1 error of 0.05, type 2 error of 20% and a power of test of 80%, the calculated number of patients required in each group was 25. Data was analyzed using the data package SPSS for window. Chi square or Fisher exact test was used to evaluate the difference of demographics and perioperative complications between the two groups. Comparison of mean values between groups was performed by using the Student t test or Mann-Whitney U test. P value of less than 0.05 was judged statistically significant.

Results

During the study period, 81 patients had undergone RHPL, 10 cases were excluded due to injury of large bowel (2 cases) and urinary tract injury (5cases), history of renal stone (1 case), allergy to penicillin (1 case) and usage of another preoperative antibiotic (1 case). Seventy one patients were eligible to the study. Thirty-eight and 33 cases were randomized to the ISC group and SPC group respectively. Clinical characteristics of the patients are presented in Table 1. There was no significant difference between the two groups. Most of the patients were in FIGO stage IB1 of squamous cell cervical carcinoma.

Table 2 shows the surgical characteristics, perioperative complications. No significant difference was found in terms of operative time, blood loss, blood transfusion, post operative ileus, adjuvant chemoradiation and perioperative complications including the incidence of urinary tract infection and the number of patients who was able to void within 30 days after the operation.

Left hypogastric artery injury, left common iliac vein injury and left obturator nerve injury occurred in one patient each respectively in the ISC group while stomach serosal injury occurred in 1 case of the SPC group.

Three cases in the ISC group and two cases in the SPC group developed post operative complications. Infected surgical wound,[2] bowel ileus from hypokalemia[1] occurred in the ISC group while bilateral hydronephrosis[1]and lymphocyst[1] occurred in the SPC group.

Six patients in the ISC group developed febrile morbidity from atelectasis,[2] acute pyelonephritis[3] and cystitis.[1] Four patients in the SPC group developed febrile morbidity from edema of left leg with right psoas abscess,[1] acute pyelonephritis[1] and cystitis.[2] Twelve

cases in each group received post operative chemoradiation.

Bacteriuria was detected in 44% and 34.8% of the ISC and SPC groups respectively which did not differ significantly. The most common organism was E. coli.

Twenty- five (65.8%) patients in the ISC group and 23 (69.7%) in the SPC group were able to void within 30 days after the operation. However, among these patients, the mean voiding time of the ISC group was significantly less than that of the SPC group (13.1 days vs. 17.3 days respectively, P=0.02). Non parametric significance testing of the mean voiding time was performed by the Mann-Whitney U test with type I error chosen at the 0.05 level due to the number of patients in each group was less than 30 and the data of both groups were not normally distributed.

Table 3 shows the voiding time in patients who had prolonged bladder dysfunction. Among 23 patients who had voiding time more than 30 days, 11 (47.8%) could normally void at day 31-40 postoperatively. The maximum voiding time was 1 year after the operation. Ten of these 23 patients received postoperative chemoradiation. Four of 6 patients who had voiding time more than 90 days had received postoperative chemoradiation.

Table 1. Clinical characteristics of the patients

Characteristics	ISC (N = 38)	SPC (N = 33)	P value
Age (years)			
Mean ± SD (range)	42.9 ± 7.6 (30-57)	46.7 ± 11.0 (30-67)	0.09
BMI			
Mean ± SD (range)	24.3 ± 3.4 (17.9-33.0)	23.6 ± 3.2 (18.3-30.1)	0.40
Parity			
Mean ± SD (range)	2.9 ± 3.8 (1-6)	2.6 ± 1.8 (0-7)	0.62
FIGO stage (N)			0.88
IB1	36 (94.7%)	31 (93.9%)	
IIA	2 (5.3%)	2 (6.1%)	
Pathology			0.32
Squamous cell CA	26 (68.4%)	24 (72.7%)	
Adenocarcinoma	10 (26.3%)	9 (27.3%)	
Small cell NE	2 (5.3%)	-	

BMI = Body mass index
CA = Carcinoma
NE = Neuroendocrine

Table 2. Surgical characteristics and perioperative complications

Characteristics	ISC (N=38)	SPC (N=33)	P value
Operative time (hours)			
Mean ± SD (range)	3.5 ± 0.6 (2.1-5.0)	3.8 ± 0.6 (3.0-5.2)	0.05
Blood loss (ml)			
Mean ± SD (range)	718.4 ± 509.2 (200-2,500)	560.6 ± 411.5 (200-2,500)	0.16
Paraaortic node sampling	6	5	1.00
Return of bowel sounds (days)			
Mean ± SD (range)	1.5 ± 0.6 (1-3)	1.5 ± 0.5 (1-2)	0.57
Intraoperative complications	3 (7.8%)	1 (3%)	0.62
Postoperative complications	3 (7.8%)	2 (6.1%)	1.00
Febrile morbidity	6 (15.8%)	4 (12.1%)	1.00
Adjuvant chemoradiation	12 (31.6%)	12 (36.4%)	0.67
Voiding time < 30 days	25(65.8%)	23 (69.7%)	0.70
Bacteriuria*	11 (44%)	8 (34.8%)	0.20
Mean voiding time (days) ± SD (range)	13.1 ± 5.7 (8-30)	17.3 ± 7.1 (8-30)	0.02

Bacteriuria* = The number of patients whose urine culture within 30 postoperative days showed the organism > 10^5 colonies/ml

Table 3. Voiding time in patients with prolonged bladder dysfunction

Voiding time (days)	Number
31-60	14
61-90	3
>90	6
Total	23

Discussion

Bladder dysfunction remains the most common adverse event encountered following radical hysterectomy.(1-4) Most patients experience early hypertonic bladder dysfunction attributed to muscle trauma, followed by decreased bladder sensation secondary to denervation. Suprapubic catheterization (SPC), intermittent self-catheterization (ISC) and prolonged transurethral catheterization are recommended as postoperative drainage to prevent excessive bladder distension and to assess the resumption of bladder function.[8,7] SPC is associated with a low incidence of infection, and can be removed as soon as the patient consistently achieves a post void residual urine of less than 75-100 ml. ISC every 4-6 hours is simple and can be performed until the target residual urine volume is achieved. Long term retention of transurethral catheter may cause patient discomfort from urethral irritation and increase the incidence of urinary tract infection.[6,9]

Although the percentage of patients who could normally void urine within 30 days after the operation

in the ISC group (65.8%) and in the SPC group (69.7%) did not significantly differ, the mean voiding time in the ISC group was significantly less than that in the SPC group (13.1 days vs. 17.3 days, respectively). Chronic irritation of the catheter balloon may interfere the voiding system in the SPC group while patients in the ISC group are free of foreign body in the bladder which allows normal bladder filling and contractility.[9] Chamberlain et al reported that resumption of bladder function within 30 days was more frequent in the ISC group (88.4%) when compared with their experience with SPC (56%) in the past.[9] This difference compared with our study may result from difference in surgical technique and radicality of the operation. The more radicality of parametrial excision, the higher incidence of prolonged bladder dysfunction. Preservation of the neural part of the cardinal ligaments could reduce the bladder problem.[3-6]

In addition to the radicality of the operation, postoperative radiation may effect bladder voiding system. Bandy et al and Farquharson et al reported the higher incidence of bladder dysfunction in patients who received both radical hysterectomy and postoperative radiation when compared with those who underwent the operation alone.[11,12] Among the 23 patients who had voiding time more than 30 days, 10 (43.5%) received postoperative chemoradiation. Comparison of voiding time in patients with or without adjuvant radiation could not be carried out because those who retained SPC more than 30 days were switched to perform ISC.

Urinary tract infection (UTI) was not significantly different in both groups. However, when compared to the incidence of UTI in the other studies, the incidence of the SPC group (34.8%) was lower than that of 60-70% in the previous report.[13,14] While the incidence in the ISC group (44%) was higher than that of 21% reported by Hayasaki.[14] These may result from various factors, i.e. the operative technique, degree of bladder injury, duration and technique of bladder catheterization, the incidence of hospital-acquired infections, host factors, etc.

In conclusion, patients performing ISC after RHPL for invasive cervical cancer can resume bladder function earlier than those undergoing SPC without significant difference in the frequency of urinary tract infection and perioperative morbidity .

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