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Is placement of pelvic drain indispensable after radical cystectomy, extended lymph node dissection, and orthotopic neobladder substitution?

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Aim: To evaluate the necessity of leaving a pelvic drain after open radical cystectomy.

Materials and methods: Between January 2007 and January 2010, 58 patients with muscle-invasive bladder carcinoma were included. All patients underwent radical cystectomy, extended lymph node dissection, and orthotopic bladder (Studer pouch) substitution. Patients were randomized to have a pelvic drain catheter (Group 1, n = 22) or not (Group 2, n = 36). Ureteral catheters were removed at postoperative days 7 and 8. The pelvic drain catheters in Group 1 were removed when daily production was <100 mL. On postoperative day 21, the transurethral Foley catheter was removed after confirming no leakage on cystograms and cystostomy tubes were clamped, which in turn were removed on the next day after spontaneous voiding.

Results: Mean patient ages in Groups 1 and 2 were 62.82 ± 9.13 and 61.72 ± 11.22 (P = 0.968), respectively. The duration of pelvic drainage with a catheter was 9.86 ± 1.32 days in Group 1. No statistically significant difference was observed in the hospital stay, recovery of intestinal peristalsis, postoperative creatinine and BUN levels, and postoperative early and late complications between groups. The mean follow-up period was 17.57 ± 7.59 months.

Conclusion: Our limited experience shows that routine pelvic drainage seems not to be an indispensable part of open radical cystectomy and extended lymph node dissection with orthotopic bladder substitution, and it can safely be omitted.

Key words: Bladder cancer, pelvic drainage, radical cystectomy, transitional cell carcinoma

1. Introduction

Bladder cancer is the second most frequent genitourinary neoplasia and transitional cell carcinoma (TCC), representing approximately 90% of these cases (1). Although the majority of patients with bladder cancer present with superficial TCC, the disease can be infiltrative in 20% to 40% of those patients. In spite of the developments in chemotherapeutic agents for such cases, radical cystectomy (RC) remains the gold-standard treatment for muscle invasive bladder cancer (1). Following RC, orthotopic substitution for urinary diversion is currently well established. Similar to other diversion techniques, this procedure requires a bowel segment; however, it avoids an abdominal stoma and therefore offers an improved quality of life for patients undergoing RC (2). Over the last decade, this complex and time-consuming operation has been refined and standardized into a safe procedure, with a 1%–3% operative mortality rate (3). Moreover, the overall complication rate after open RC and urinary diversion could be as high as 25% to 35% (3).

Like other major abdominopelvic operations, insertion of a pelvic drain into the surgical field has become routine after RC with the assumption that drainage of urine, blood, lymph, and other body fluids will facilitate the healing process and reduce the risk of urinoma, infection, and/or lymphocele formation (4). However, many surgeons in different fields have questioned the necessity of routine drainage after surgery, claiming that a drain can increase the risk of infection and cause pain (5).

In this study, we evaluated the necessity of pelvic drainage with a Foley catheter inserted into the pelvis following RC and orthotopic bladder substitution.

2. Materials and methods

2.1. Patients

Between January 2007 and January 2010, 58 consecutive patients (56 males, 2 females) who were candidates for RC and Studer orthotopic neobladder operation for the surgical treatment of muscle invasive bladder cancer, and who agreed to participate in the study, were included. All

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patients had a negative metastatic workup with a chest X-ray and abdominal computed tomography (CT). Data on patient age, sex, clinical stage, surgical time, estimated blood loss, time to recovery of bowel movements, duration of hospital stay, and postoperative complications were recorded along with renal functions, which were monitored by blood urea nitrogen (BUN) and serum creatinine levels. Patients who underwent robot-assisted laparoscopic RC with other urinary diversions (e.g., ileal conduits), or who did not agree to participate in the study, were not included. All patients provided their informed consent and approval of the institutional review board was obtained.

2.2. Procedure

RC consisted of an infraumbilical incision with wide excision of the peritoneum, bladder, seminal vesicles, prostate, and distal ureters in men, and the bladder, uterus, ovaries, and anterior vaginal wall in women. Urinary diversion was performed with Studer's bladder substitute, which allows urethral preservation with normal renal function. For ureterointestinal anastomosis, Bricker's technique was used (6). Bilateral pelvic lymphadenectomy was also routinely performed using the following boundaries: the pubic bone distally up to 3 cm above aortic bifurcation proximally, and from the genitofemoral nerve laterally to the presacral area deep to the obturator nerve medially and inferiorly.

The patients were randomized with simple randomization (fair coin-tossing) to have a pelvic drain catheter (Group 1, n = 22) or not (Group 2, n = 36). In Group 1, a 20-F drainage catheter was placed below the neobladder through a stab incision. On the 7th to 8th postoperative days, the ureteric stents coming out through the anterior abdominal wall were removed. A cystogram was obtained on postoperative day 21, and after confirming that there was no leak from the pouch, the urethral catheter was removed. On the next day, the clamped cystostomy tube was removed after spontaneous voiding. Pelvic drains in Group 1 were removed when the drainage was less than 100 mL/day.

Postoperative electrolyte and hematocrit studies were performed on the day of surgery and on postoperative days 1, 3, and 7. Patients were discharged after tolerating a regular diet and resuming normal bowel movements.

The patients were followed at regular intervals every 3 months for the first year and at least once a year thereafter.

2.3. Statistical analyses

The primary end point of this study was the incidence of postoperative early and late complications. The chi-square test with application of Yate's correction was used to compare postoperative complication rates for those with (Group 1) and without (Group 2) a drain. Statistical significance level was set at $P < 0.05$.

3. Results

Of the patients, 22 (37.9%) and 36 (62.1%) were randomized to Group 1 (with pelvic drain) and Group 2 (without pelvic drain), respectively. Surgical and pathological characteristics of the patients are presented in Table 1. The mean patient age was 62.14 ± 10.4 (range: 28–80) years and all of the patients had TCC. There was no statistically significant difference in mean patient age, female/male ratio, clinical stage, surgical time, estimated blood loss, time to recovery of bowel movements, and duration of hospital stay in Groups 1 and 2 (Table 1). In

Table 1. Patient and surgical characteristics.

	Group 1 n = 22 (37.9%)	Group 2 n = 36 (62.1%)	Total n = 58 (100.0%)	P-value
Mean age ± SD (years)	62.82 ± 9.13	61.72 ± 11.22	62.14 ± 10.4	0.968
Sex (F/M)	2/20	0/36	2/56	0.14
Mean surgical time (min)	497.36 ± 97.71	484.44 ± 72.36	489.34 ± 82.3	0.968
Mean estimated blood loss (mL)	800.45 ± 323.6	905.56 ± 394.78	865.69 ± 370.03	0.298
Time need to return bowel sounds (days)	4.32 ± 1.46	4.36 ± 1.51	4.34 ± 1.48	0.803
Hospital stay (days)	12.68 ± 3.35	14.89 ± 7.18	14.05 ± 6.08	0.448
Clinical stage				
T2	14 (63.6%)	26 (72.2%)	40 (100%)	0.719
T3	7 (31.8%)	8 (22.2%)	15 (100%)	
T4	1 (4.5%)	2 (5.6%)	3 (100%)	

Group 1, the mean pelvic drains removal time was 9.86 ± 1.32 days (range: 8–13 days) postoperatively.

The mean follow-up period was 17.57 ± 7.59 months (range: 6–34 months). Preoperative and early postoperative mean BUN and creatinine levels were not different between the 2 groups (Table 2). Similarly, the 2 groups exhibited no significant differences in complication rates (P > 0.05).

Table 3 shows the peri- and postoperative complications in detail. Postoperative ileus was observed in 15 (25.86%) cases, all of which were resolved with conservative management. Acute renal failure (serum creatinine > 2.5/dL) was documented in 8 (13.79%) patients, 4 of which had a drain while the other 4 did not (P = 0.462). All of those patients were treated with transient hemodialysis, and chronic renal failure did not develop in any of these patients. Urinoma occurred in 7 (12.07%) patients (3 with drain, 4 without, P = 1.00). Of those patients, 1 (0.45%) in Group 1 and 4 (11.36%) in Group 2 had urine leakage from the incision after the urethral catheter removal. These patients were successfully treated by reinserting the urethral catheter and further percutaneous drainage was not required. However, for the remaining 2 patients in Group 1, a drain was percutaneously inserted under CT guidance and left to straight drainage.

Neither lymphocele nor hematoma was documented in any of the groups. Four (1 in Group 1 and 3 in Group 2) patients developed urinary retention after urethral catheter removal. They required catheter reinsertion and neobladder drainage for an additional week. A urethro-neobladder

Table 2. Preoperative and postoperative BUN and creatinine values.

	Postoperative days	Group 1 (n = 22)	Group 2 (n = 36)	Total (n = 58)	P-value
BUN	0	44.36 ± 21.97	35.77 ± 18.04	39.03 ± 19.88	0.133
	1	41.54 ± 22.40	33.02 ± 16.21	36.25 ± 19.07	0.173
	3	34.81 ± 15.77	29.83 ± 14.53	31.72 ± 15.07	0.214
	7	33.59 ± 16.12	29.08 ± 15.12	30.79 ± 15.52	0.301
Creatinine	0	1.15 ± 0.33	1.12 ± 0.31	1.13 ± 0.31	0.803
	1	1.27 ± 0.48	1.18 ± 0.37	1.22 ± 0.41	0.440
	3	1.12 ± 0.36	1.18 ± 0.39	1.16 ± 0.38	0.568
	7	1.25 ± 0.46	1.24 ± 0.35	1.25 ± 0.39	0.759

Table 3. Postoperative complications.

	Group 1 n (%)	Group 2 n (%)	P-value
Postop. ileus	8 (36.4)	7 (19.4)	0.153
Acute renal failure	4 (18.2)	4 (11.1)	0.462
Urinoma	3 (13.6)	4 (11.1)	1.00
Urinary retention	1 (4.5)	3 (8.3)	1.00
Stricture of ureteroenteric anastomosis	3 (13.6)	5 (13.9)	1.00
Stricture of urethro-neobladder (urethro-vesical) anastomosis	2 (9.1)	4 (11.1)	1.00
Wound infection	2 (9.1)	10 (27.8)	0.108

anastomotic stricture developed in 6 (10.34%) patients (2 in Group 1 and 4 in Group 2), all of which were successfully treated with an endoscopic incision of the anastomosis. Similarly, an uretero-neobladder anastomotic stricture was detected in 8 (13.79%) patients (3 in Group 1 and 5 in Group 2), and they were treated with anterograde double-J catheterization through the anastomosis under fluoroscopic imaging. These catheters were removed after 3 months with cystoscopy, and these strictures did not recur again. Wound infection was observed in 2 (9.09%) and 10 (27.78%) cases in Groups 1 and 2, respectively (P = 0.108). They were managed with conventional antibiotic therapy.

4. Discussion

RC remains the gold standard for the treatment of muscle invasive bladder cancer and the Studer orthotopic ileal neobladder is one of the most ideal orthotopic urinary diversion techniques (7). Similar to other major pelvic surgeries, pelvic drainage is also recommended after RC operations (7). Although this authority-based recommendation is not supported by strong evidence, most surgeons still prefer to insert a pelvic drain to prevent the intraabdominal blood, lymphatic fluid, or urine collection (8). Additionally, these drains are considered to be beneficial in the monitoring of and early management for postoperative bleedings, urinary leaks, and fistulas (8).

However, there are some potential complications directly related to the drains, such as increased risk of infection and pain, retention of drain fragments during removal, bleeding, abdominal wall hematoma, and pseudoaneurysm of the inferior epigastric artery (5,9–15). Infection is an especially well-established risk, since the drain may facilitate bacterial migration. An animal study showed that bacteria inoculated in the skin surface migrated through the drain tract to the intraperitoneal cavity as early as 6 h after placement of a drain (16). The authors demonstrated that the risk increases by the time, as it is 20% in 24 h and 56% in 7 h (16). Similarly, a drain may increase postoperative pain and may prolong postoperative recovery. Niesel et al. (5) investigated postoperative pain after radical prostatectomy and found that pain was attributable to the drain site in 42 of 179 (24%) patients. Retained fragments during drain extraction may sometimes require surgical exploration to remove the missing fragment (12), and the inferior epigastric artery can be injured on drain placement, which can result in pseudoaneurysm formation and may require intervention (15).

Therefore, the need for routine drainage after pelvic surgery has been questioned in nonurologic surgeries, and several studies demonstrated no statistically significant difference in the rate of complications between patients with and without drainage (17–19). For example, routine placement of intraperitoneal drains has been shown to be unnecessary after colon resection for cancer on a prepared bowel (20), perforated duodenum closure, open or laparoscopic cholecystectomy, elective liver resection (21), radical hysterectomy, pelvic (22) and retroperitoneal lymphadenectomy (9), and lumbar spinal fusion surgery (23). Moreover, it has been demonstrated that early removal of a pelvic drain independent of volume of drainage did not increase postoperative morbidity but decreased the length of the hospital stay, associated with a significant decrease in hospital-associated cost per case (24).

In the urology field, Savoie et al. (25) were the first to suggest that prophylactic drainage of the pelvis after radical prostatectomy may not be necessary because of improved surgical techniques. Other studies reported the possibility of radical retropubic prostatectomy, simple retropubic prostatectomy, partial nephrectomy, and conservative management of extraperitoneal bladder perforations without a pelvic drain (8,25–28). In those studies, not draining the pelvic cavity was not associated with a higher incidence of complications. Similarly, in our study we assessed the outcomes of patients who underwent RC–Studer orthotopic bladder substitution with and without pelvic drainage. Between the 2 groups, we compared the incidence of the most common complications of this operation (i.e. hemorrhage, anastomotic urine leakage, symptomatic lymphocele, postoperative ileus, urinary tract infection, wound infection, and dehiscence) (2,29). There was no remarkable difference in the types and rates of complications between our cases and previously reported series (2,29–31). Moreover, the types and incidences of complications were not different between patients with and without pelvic drainage, suggesting that routine drain placement must be questioned due to the potential risks of abdominopelvic drains.

We recognize that there are several limitations to this study. First of all, the number of patients was relatively small and the applied simple randomization technique (fair coin-tossing) resulted in imbalanced group sizes. Secondly, our assessment of complications was based on clinical symptoms and we did not routinely perform ultrasound to detect any intraabdominal fluid collection (i.e. hematoma, lymphocele, and urinoma formation). Thirdly, we did not compare the magnitude of postoperative pain between groups. Comparing patient reported outcomes regarding pain and overall satisfaction between 2 groups could have been of benefit in understanding the magnitude of problems caused by drains.

To our knowledge, this study is the first on the necessity of pelvic drain use after cystectomy published in English. Our limited experience shows that routine pelvic drainage seems not to be an indispensable part of open radical cystectomy and extended lymph node dissection with orthotopic bladder substitution, and it can safely be omitted.

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