

# Evaluation of the improved tubeless cutaneous ureterostomy technique following radical cystectomy in cases of invasive bladder cancer complicated by peritoneal metastasis

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**Abstract.** Radical cystectomy, as the most common surgical treatment for patients with invasive bladder cancer (IBC) complicated by peritoneal metastasis, is usually accompanied by a urinary diversion procedure. In this study, we evaluated the improved tubeless cutaneous ureterostomy technique by comparing the resulting clinical effects with either a traditional ureterostomy and an ileal conduit urinary diversion. Clinical data from 85 patients who underwent 1 of the 3 procedures between April 2012 and April 2015 were analyzed retrospectively. In total, 30 patients underwent improved tubeless cutaneous ureterostomy, 28 patients underwent a traditional cutaneous ureterostomy and 27 underwent an ileal conduit urinary diversion following radical cystectomy. The incidence of complications, including stoma infection, nipple atrophy, terminal necrosis, urine leakage, external orifice stenosis, uronephrosis and ureterectasia in the group of patients treated with the improved tubeless ureterostomy technique was significantly lower than that of the patients in the other 2 groups, and the difference was statistically significant ( $P < 0.05$ ). In addition, the duration of the surgery, intra-operative bleeding, the duration of the hospitalization period and the time to extubation in the patients treated with the improved tubeless ureterostomy technique were significantly decreased ( $P < 0.05$ ) compared with the patients in the other 2 groups. Finally, the health-related quality of life of the patients treated with the improved tubeless ureterostomy technique was significantly higher ( $P < 0.05$ ) than that of the patients in the other 2 groups. The findings of our

study demonstrated that the use of the improved tubeless cutaneous ureterostomy technique following radical cystectomy in patients with IBC complicated by peritoneal metastasis resulted in improved clinical effects. Thus, improved tubeless cutaneous ureterostomy may be a promising alternative for enhancing the quality of life of patients with IBC.

## Introduction

Bladder cancer is a malignancy with a very high incidence in China, and is particularly prevalent amongst individuals between 50 to 70 years of age (1). More than 90% of cases are urothelial tumors (transitional cell carcinoma) (1). According to the TNM staging method proposed by the Union for International Cancer Control (UICC), bladder cancers are divided into non-muscle invasive bladder cancer (IBC; Tis, Ta, of T1) and muscle IBC (above T2) (2). IBCs are generally highly malignant. Treatment methods include radical cystectomy, pelvic lymph node dissection and urinary diversion (2).

Ideally, permanent urinary diversion should be able to prevent post-operative complications, preserve renal functions, and enable patients to lead normal lives (3). Cutaneous ureterostomy is achieved by connecting the bladder-detached ureters to the skin surface, creating a stoma (3). Urinary diversion can either be permanent or temporary. A cutaneous ureterostomy is easier to perform than a bowel bladder replacement and it avoids the risks of any injuries to the abdominal organs. It is often used in patients with a poor general physical condition or with intestinal tract lesions (4). Multiple clinical studies have confirmed that cutaneous ureterostomy is an excellent urinary diversion method that can fully maintain the quality of life of patients (3-5). Nevertheless, traditional cutaneous ureterostomy may lead to a series of adverse effects, such as additional abdominal incisions, deeper wounds, more severe trauma, uneven skin surrounding the stoma, urine leakage and dermal papilla, ureter elongation and increased tension of the ureter (6). Based on the above-mentioned facts, this study focused on evaluating the clinical effects of an improved tubeless cutaneous ureterostomy following radical cystectomy for the treatment of patients with IBC complicated by peritoneal metastasis, with the aim to provide much needed information on this method and to confirm its clinical future applications.

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## Patients and methods

**Patients.** A total of 85 male patients diagnosed with IBC and peritoneal metastasis during the period from April 2012 to April 2015 at the First Affiliated Hospital of Harbin Medical University, were enrolled in this study. All the patients had clear indications for laparoscopic surgery. After obtaining the approval of the Ethics Committee of our hospital and written informed consent from all the participating patients and their relatives, an improved cutaneous tubeless ureterostomy was performed on 30 patients (improved group), a traditional cutaneous ureterostomy was performed on 28 patients (traditional group), and an ileal conduit urinary diversion on 27 patients (ileum group). The age of the patients in the improved group ranged from 48 to 72 years (average age,  $63.5 \pm 9.3$  years), that of the patients in the traditional group ranged from 49 to 73 years (average age,  $63.2 \pm 10.5$  years) and that of the patients in the ileum group ranged from 47 to 75 years (average age,  $63.8 \pm 9.7$  years). There was no significant difference in the age of the patients between the 3 groups ( $P > 0.05$ ).

The inclusion criteria for the patients enrolled in the present study were as follows: i) an age of  $\geq 18$  to  $< 80$  years; ii) a normal structure and function of ureters, normal renal function, the absence of skin wounds; and iii) patients must have received a first treatment, good compliance, the complete clinical data must be available and patients must have the ability to complete the given questionnaire. The exclusion criteria for enrolling patients in this study were as follows: i) patients who underwent a 'difficult' surgical resection, those who had serious medical conditions, those who were diagnosed with a poor prognosis or with a survival period of  $< 12$  months; and ii) patients with primary tumors in other organs, or those who were intolerant to surgery or anesthesia and those with autoimmune diseases and skin allergies.

**Radical cystectomy under laparoscopy.** All the surgical procedures were performed under a general anesthesia, and the patients were maintained in a supine position, with a raised hip (10 cm) and lowered head by  $15\text{--}20^\circ$ . The procedures were performed as follows:

**Laparoscopic 5-port method.** The first puncture point was located in the inferior margin of the cord where a 10-mm cannula was inserted. The second and third puncture points were located beside the left and right rectus abdominis separately, 2-3 cm under the umbilicus, with a 10-12 mm cannula. The fourth and fifth puncture points were located 2-3 cm above the left and right anterior superior iliac spine, respectively, inserting a 5 mm cannula into each. The pneumoperitoneum pressure was maintained at 10-15 mmHg.

**Bilateral pelvic lymph node dissection.** As previously described (7), an ultrasonic knife was used to cut open the posterior peritoneum alongside the surface of the right external iliac blood vessels. The external iliac vein and artery were isolated separately. The lymph and adipose tissue in the internal genitocrural nerve ahead of the external iliac artery, and the lymph and adipose tissue between the external iliac vein and artery and in the obturator muscle were cleared away. The obturator nerve was left intact and was protected, clearing from 1 cm above the iliac vessel bifurcation to the inguinal ligament. The same method was used to clear away the left pelvic lymph nodes.

**Bilateral ureter isolation.** Each ureter was found in the bifurcation of the internal and external iliac arteries, and it was isolated down to the external bladder wall. An ultrasonic knife (Harmonic GEN300, Johnson & Johnson, New Brunswick, NJ, USA) was used to separate the ureter from the bladder. The length of the ureter was preserved as much as possible, avoiding producing tension when suturing it with the urine reservoir, and affecting healing.

**Seminiferous duct, seminal vesicle and prostate posterior wall isolation.** The peritoneum was cut open in the front wall of the bottom of the bladder rectum pit, exposing the seminiferous ducts. Each duct was cut off and raised to separate the seminal vesicle. The Denonvilliers' fascia was cut open, and the perisinusoidal space was separated to expose the prostate and seminal vesicles. The rectum was then isolated.

**Anterior bladder wall isolation.** Under a state of a mildly full bladder, the contour of the bladder and the peritoneal reflection ahead were exposed. The bilateral peritoneum was cut open on its outskirts, and an ultrasonic knife was then used to cut off the median umbilical ligament and peritoneal reflection. The retropubic space was isolated and the endopelvic fascia cut open. The incision was expanded towards the direction of the pubis to the symphysis pubis, and the puboprostatic ligament was exposed. The dorsal venous complex was transfixed and cut off.

**Isolation of the ligaments on the bladder and prostate sides.** An ultrasonic knife was used to isolate the ligaments on the bladder and prostate sides, and the nerve vascular bundles were retained as much as possible. The urethral canal was divided close to the apex of the prostate, and the prostate capsule was retained 0.5-1 cm on the apex of the prostate.

**Traditional cutaneous vesicostomy.** A median incision of the lower abdomen was performed. The middle and lower segments of the bilateral ureters were separated behind the peritoneum through the abdominal cavity. A tangential clamp was used to clamp the ureter close to the bladder, the ureter was cut off above the clamp, and an F8 ureter stent was inserted until the renal pelvis on the proximal end and fixed on the broken end of the ureter. A silk thread (No. 4; Shanghai Tian-Qing Trading Co., Ltd., Shanghai, China) was used for purse string ligature on the distal end. A blunt separation was made on the front of the promontory and the back of the mesocolon pelvium. A channel was formed and the ureter was pulled with a small pipe diameter to the opposite side through the channel. A ureter end-to-side anastomosis was made 10 cm to the broken end of the contralateral ureter. A 4-0 thread was used to suture (interrupted sutures, full thickness) the back wall. The stent drainage tube was placed into the lower segment of the contralateral ureter through the anastomotic stoma and inserted out the broken end. The primary fixation thread of the drainage tube was cut away. A silk thread (No. 4; Shanghai Tian-Qing Trading Co., Ltd.) was used to fix the 2 drainage tubes onto the broken end of the thick ureter side. The front wall of the anastomotic stoma of the ureter was sutured. The external coat of the ureter of the anastomotic stoma was intermittently sutured. The abdominal incision was extended on one side of the ureter stoma in an S shape. The length and width of the 2 trapezoid skin flaps were 4 cm, the upper margin was 2.5-3.0 cm, and the midpoint of the S shaped incision was equivalent to the superior border

Table I. Comparison of duration of surgery, intra-operative bleeding, duration of the hospitalization period and time to extubation.

| Group       | Duration of surgery (min) | Intra-operative bleeding (ml) | Duration of hospitalization period (days) | Time to extubation (days) |
|-------------|---------------------------|-------------------------------|-------------------------------------------|---------------------------|
| Improved    | 26.3±7.2                  | 23.4±5.2                      | 12.7±3.6                                  | 1.5±0.4                   |
| Traditional | 45.7±12.3                 | 42.7±13.6                     | 16.5±4.2                                  | 2.3±0.5                   |
| Ileum       | 53.2±16.8                 | 46.8±15.9                     | 18.2±4.7                                  | 2.5±0.4                   |
| F-value     | 4.627                     | 4.725                         | 4.218                                     | 4.936                     |
| P-value     | 0.035                     | 0.033                         | 0.039                                     | 0.027                     |

Improved group (n=30), patients underwent improved tubeless cutaneous ureterostomy; traditional group (n=28), patients underwent traditional cutaneous ureterostomy; ileum group (n=27), patients underwent ileal conduit urinary diversion.

of the iliac crest. A full-layer flap was isolated, and the surface of the external oblique aponeurosis surrounding the flap was stripped. The vertical edge of the aponeurosis was cut open, and the muscle incision was equivalent to the level of the superior border of the iliac crest. A silk thread was used to suture the external oblique aponeurosis on the wound margin of the muscle membrane of the transversus abdominis. The aponeurosis was sutured on both sides and muscle incisions using a silk thread (No. 4; Shanghai Tian-Qing Trading Co., Ltd.), forming a button-shaped passage. The ureter was pulled outside of the abdominal wall. A thread (No. 3; Shanghai Tian-Qing Trading Co., Ltd.) was used to pass through the external coat of the ureter from the proper site and was fixed in the margin of the buttonhole. A relaxation suture was made using a thread (No. 10; Shanghai Tian-Qing Trading Co., Ltd.) on the wound margin on both sides of the flap base, and the stitches passed through the external oblique aponeurosis on both sides of the buttonhole. The suture stitch was taut and knotted. A no. 1 thread was used to suture the wound margin of the skin and to form a skin tube enveloping the ureter. The terminal of the ureter and the flap margin were sutured intermittently and the drainage tube was fixed to the ostomy pouches (2115 Alternat; Coloplast, Humlebaek, Denmark). A relaxation suture was then performed on the abdominal skin if the tension of the incision was too large. The abdominal incision of the other side was sutured closed.

*Improved tubeless cutaneous ureterostomy.* A median incision of the lower abdomen was chosen. The skin was cut off, starting from the superior border of the symphysis pubis, about 15 cm. The subcutaneous tissue and the anterior sheath of the rectus abdominis were also cut open. The rectus abdominis muscle was separated in the 2 sides, and the pyramidalis muscle was cut open. The lower segments of the bilateral ureters were found outside the peritoneum and transversed bilaterally, suturing the distal ends by means of a no. 4 silk thread. The lower segment and middle segment of the bilateral ureters were isolated separately. A 0.6 cm round incision was made on the bilateral middle abdomen separately, and the subcutaneous tissues were removed. An incision of the same size and shape was made on the external oblique aponeurosis to pierce through the internal oblique muscle and the transversus abdominis muscles, to extract the bilateral ureters out of the body through the round incisions on both sides. The wall of the ureter and

external oblique aponeurosis were discontinuously sutured with a 4-0 absorbable thread to fix the ureter. The wall of the ureter and round skin incision were discontinuously sutured with a 5-0 absorbable thread. The ureter was cut open by 0.5 cm longitudinally, and the terminal of the ureter was turned inside out and folded. The terminal of the bilateral ureters exhibited a nipple-like shape and protruded 0.5 cm from the skin surface, where a single J stent (4F Alterna, Coloplast) incubation was performed on both sides.

*Observation index.* The patients were followed-up and observed for complications related to the surgical procedures, such as stoma infection, nipple atrophy, terminal necrosis, urine leakage, stenosis of the external orifice, uronephrosis, ureterectasia, as well as others. The individual assessment scale scores were used to keep track of the duration of the surgery, intra-operative bleeding, the duration of the hospitalization period and time to extubation, as well as the general health-related quality of life (HRQOL) of the patients. The HRQOL assessment scale consisted of 3 parts: i) functional assessment scale (Karnofsky performance scale) (8), ii) tumor common character scale [functional assessment of cancer therapy-general (FACT-G)] (9), and iii) tumor-specific character scale [basal-cell cancer (BSS)]. FACT-G included 7 entries of physical well-being, 7 entries of social well-being, 6 entries of emotional well-being, 7 entries of function well-being and 9 entries of BSS, with each entry ranking from 0-4 points, for a total of 144 points. The higher the scores, the higher the HRQOL.

*Statistical analysis.* SPSS 19.0 (SPSS, Inc., Chicago, IL, USA) statistical software was used to analyze the data. The data are presented as the means ± standard deviation. Analysis of variance was applied for inter-group comparisons, and enumeration data were presented as a percentage (%). The  $\chi^2$  test was also applied for inter-group comparisons. A value of P<0.05 was considered to indicate a statistically significant difference.

**Results**

*Comparison of the incidence of complications.* The patients in the improved group (n=30) were followed-up for a period of 6 months to 3 years, with a median follow-up time of 1.7 years. A total of 4 patients (13.3%) suffered from complications,

Table II. Comparison of HRQOL scores.

| Groups      | KPS       | PWB      | SWB      | EWB      | FWB      | BSS      |
|-------------|-----------|----------|----------|----------|----------|----------|
| Improved    | 83.4±15.6 | 23.5±7.2 | 21.7±6.6 | 19.8±5.7 | 24.5±8.3 | 30.2±9.3 |
| Traditional | 66.4±14.3 | 14.7±6.9 | 13.2±5.9 | 11.4±5.3 | 13.6±7.9 | 16.7±7.8 |
| Ileum       | 59.7±12.7 | 13.6±6.4 | 12.8±5.7 | 10.8±5.1 | 13.5±7.7 | 15.9±7.6 |
| F-value     | 5.324     | 5.624    | 5.937    | 5.323    | 4.978    | 5.934    |
| P-value     | 0.029     | 0.027    | 0.024    | 0.031    | 0.034    | 0.017    |

Improved group (n=30), patients underwent improved tubeless cutaneous ureterostomy; traditional group (n=28), patients underwent traditional cutaneous ureterostomy; ileum group (n=27), patients underwent ileal conduit urinary diversion. HRQOL, health-related quality of life; KPS, Karnofsky performance scale; PWB, physical well-being; SWB, social well-being; EWB, emotional well-being; FWB, function well-being; BSS, basal-cell cancer.

including 1 stoma infection, 1 urine leakage, 1 stenosis of the external orifice and 1 ureterectasia. The patients in the traditional group (n=28) were followed-up for a period of 4 months to 3.3 years, with a median follow-up time of 1.9 years. A total of 9 patients (32.1%) suffered from complications, including 2 stoma infections, 1 nipple atrophy, 1 terminal necrosis, 1 urine leakage, 2 cases of stenosis of the external orifice, 1 uronephrosis and 1 ureterectasia. The patients in the ileum group (n=27) were followed-up for a period of 5 months to 2.9 years, with a median follow-up time of 1.5 years. A total of 13 patients (48.1%) suffered from complications, including 2 stoma infections, 2 nipple atrophy, 2 terminal necrosis, 2 urine leakage, 2 cases of stenosis of the external orifice, 1 uronephrosis, 1 ureterectasia and 1 case of septic shock. The incidence of complications in the patients in the improved group was significantly lower than that of the patients in the other 2 groups, and the difference was statistically significant ( $\chi^2=8.160$ ,  $P=0.017$ ).

*Comparison of duration of surgery, intra-operative bleeding, duration of hospitalization period and time to extubation.* The duration of surgery, intra-operative bleeding, the duration of the hospitalization period and time to extubation in the patients in the improved group were significantly lower than those of the patients in the other 2 groups, and the differences were statistically significant ( $P<0.05$ ; Table I).

*Comparison of HRQOL scores.* The HRQOL scores of the patients in the improved group were significantly higher than those of the patients in the other 2 groups, and the difference was statistically significant ( $P<0.05$ ; Table II).

## Discussion

Radical cystectomy is usually carried out simultaneously with urinary diversion and urinary tract reconstruction (10). At present, the methods of urinary diversion mainly include two categories: uncontrollable urinary diversion and controllable urinary diversion. Uncontrollable urinary diversion includes 2 types, cutaneous ureterostomy and intestinal urinary diversion. Cutaneous ureterostomy is applicable to all urinary diversions following radical cystectomy, and is particularly suitable for older patients and for patients with advanced

cancer combined with renal inadequacy. The surgical procedure is simple, and the abdominal cavity is not involved, thus greatly reducing the incidence of abdominal complications (11). Intestinal urinary diversion can be carried out in two ways: small intestine-constructed new bladder, including the jejunum and ileum, and partial large intestine-constructed new bladder. Ileal conduit mainly involves the partial ileum in its distal end. It is the simplest output duct diversion mode. Its major complications include urine leakage, sepsis, acute pyelonephritis, wound infection, wound dehiscence, paralytic ileus, intestinal obstruction, metabolic acidosis and volvulus (12). Controllable urinary diversion includes two types: *in situ* urethral anastomosis and controllable urinary catheterization urinary reservoir. Thus far, the application of these urinary diversion methods is limited. However, since these methods can be used to retain the autonomous urination function of the patients to a large extent, they are likely to be the new directions for future studies (13).

The use of ostomy pouches resulted in great inconvenience for the patients enrolled in this study. The bags require frequent disinfection and replacement, and patients cannot practice handstands, strenuous exercises or lie on their stomach (14). As the technology of ostomy pouches becomes more advanced, the compatibility of ostomy pouches with tissue is also improving, and the occurrence of skin irritation becomes increasingly less common and adverse effects are also becoming less frequent (15). The improved tubeless cutaneous ureterostomy procedure evaluated in this study had the following features (16): i) during ureter isolation, tissues on the periphery of the ureter were retained as much as possible to avoid damaging the supply vessels of the ureter; ii) ureter isolation spanned approximately 10 cm from the abdominal wall stoma, and the anastomotic stoma was enlarged; iii) the external coat of the ureter on the abdominal skin stoma side was fixed onto the abdominal wall to avoid placing excessive tension on the ureter; iv) a total of 2 single J tube stents were left in the ureter to avoid anastomotic stoma stenosis and urine leakage. The results of this study showed that the incidence of complications of the 'improved' group was significantly lower than that of other 2 groups. Furthermore, the duration of the surgery, intra-operative bleeding, the duration of the hospitalization period and the time to extubation of the patients in the 'improved' group were significantly decreased compared

with the patients in the other 2 groups. Finally, the HRQOL scores of the patients in the improved group were significantly higher than those of the patients in the other 2 groups. The noted differences amongst the groups were all statistically significant ( $P < 0.05$ ).

In conclusion, the findings of our study demonstrate that the improved tubeless cutaneous ureterostomy technique clearly produces better clinical results following radical cystectomy in patients with IBC complicated by peritoneal metastasis, and its application is worth advocating and promoting.

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