

The use of orthotopic neobladders in women undergoing cystectomy for pelvic malignancy

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Summary. Since June 1990, 21 women aged from 31 to 78 years (mean, 62 years) have undergone lower urinary tract reconstruction by means of an orthotopic Kock ileal reservoir following cystectomy. The indication for cystectomy included 15 patients with transitional-cell carcinoma of the bladder, 2 patients with urachal adenocarcinoma, 1 patient with cervical carcinoma, 1 patient with a mesenchymal tumor of endometrial origin, 1 patient with interstitial cystitis, and 1 patient with a fibrotic irradiated bladder. A total of four complications (two early and two late) have occurred in this group of patients. Excellent continence has been achieved during the day and night in 95% and 89% of the patients, respectively. In all, 16 of 20 patients void volitionally per urethra without a residual urine volume, whereas 4 patients require intermittent catheterization to empty the neobladder. All patients are completely satisfied. One patient died of metastatic transitional-cell carcinoma without a pelvic recurrence. Of the remaining 20 patients, 18 are currently alive without evidence of recurrent disease. Tumor recurrence has occurred in two patients: one patient with an extensive mesenchymal tumor developed a sigmoid recurrence necessitating conversion to a continent cutaneous diversion, and one patient developed a right iliac recurrence. This initial experience with lower urinary tract reconstruction in women has yielded extraordinary results, and we feel that the option of orthotopic reconstruction following cystectomy can safely be offered to selected female patients.

Since the early 1900s, innovative surgeons have persistently pursued how best to replace the original bladder removed for either benign or malignant disease. As we enter the mid-1990s, the ultimate goal of lower urinary tract reconstruction has become a means not only to divert urine but also to protect the upper urinary tract from the harmful effects of the diversion as well as an attempt to maintain a more natural voiding pattern per urethra. Over the past 45 years, the evolution of urinary diversion has subsequently developed along three distinct paths: a noncontinent cutaneous form of urinary diversion, a continent cutaneous form of urinary diversion, and, most recently, an orthotopic form of reconstruction to the urethra.

Beginning in 1950, Bricker [1] introduced the ileal conduit, which established a reliable form of urinary diversion and, even today, remains the "gold standard" with which all other forms of urinary diversion are compared. At the time of Bricker's introduction of the ileal conduit, Gilchrist et al. [4] independently reported on the concept of a continent cutaneous urinary diversion, utilizing the ileocecal valve as the continence mechanism and the distal ileum as a catheterizable stoma. However, Gilchrist et al.'s ileocecal reservoir gathered little support, whereas the Bricker procedure became the urinary diversion of choice for the next several decades.

The concept of a continent cutaneous diversion (introduced by Gilchrist et al.) was eventually popularized by Kock [5] and Skinner et al. [11] in the 1980s and revolutionized lower urinary tract reconstruction to a continent cutaneous form. This form of urinary diversion required catheterization of an abdominal stoma and relieved patients of the need for an external ostomy appliance. In 1979, Camey and Le Duc [2] reported their pioneering work with orthotopic neobladders to the native urethra. This was a substantial accomplishment in the evolution of urinary diversion that demonstrated the feasibility of lower urinary tract reconstruction of the urethra, with reasonable continence rates, in carefully selected men following cystectomy.

Since 1982 we have been dedicated to the continued improvement and progress of lower urinary tract reconstruction in patients undergoing cystectomy. The continent cutaneous urinary diversion via the Kock ileal reservoir subsequently became the procedure of choice in all patients requiring urinary diversion [11, 12]. Beginning in 1986, orthotopic lower urinary tract reconstruction to the urethra became the procedure of choice in carefully selected men undergoing cystectomy at our institution [13].

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Currently, over 90% of men requiring cystectomy undergo orthotopic lower urinary tract reconstruction at the University of Southern California.

However, prior to 1990, orthotopic reconstruction was limited to men and considered a contraindication in the woman undergoing cystectomy. Reasons for this included the observation that the urethra was routinely removed during cystectomy, as it was thought necessary to provide an adequate surgical cancer margin. In addition, it was believed that women would be incapable of maintaining their continence mechanism if orthotopic reconstruction were performed to the urethra. However, on the basis of an extensive pathologic review of female cystectomy specimens removed for transitional-cell carcinoma of the bladder [15], criteria are now available that may help safely identify appropriate female candidates for orthotopic diversion following cystectomy. In addition, elegant anatomic dissection of the female pelvis has provided a better understanding of the continence mechanism in women [3]. Consequently, in June of 1990 we began to offer selected women undergoing anterior exenteration the option of lower urinary tract reconstruction to the urethra by means of a Kock ileal reservoir [16].

Patients and methods

Patients

From June 1990 through January 1995, 21 women (17 from the University of Southern California, 4 from Innsbruck) aged from 31 to 78 years (mean, 62 years) underwent lower urinary tract reconstruction by means of a Kock ileal reservoir with bilateral ureteroileal urethrostomy following cystectomy. Bilateral pelvic iliac lymphadenectomy with en-bloc anterior exenteration was performed in 15 women with transitional-cell carcinoma of the bladder, 2 women with urachal mucinous adenocarcinoma of the bladder, and 1 woman with a mesenchymal tumor of the uterus. One patient underwent a total pelvic exenteration for squamous-cell carcinoma of the cervix and two women underwent a simple cystectomy: one patient with a fibrotic irradiated bladder and one for refractory interstitial cystitis.

Patient selection

The type of urinary diversion was dependent upon patient preference and was discussed in detail preoperatively. The patient was offered urinary diversion by means of an ileal conduit, continent cutaneous Kock diversion with intermittent catheterization or lower urinary tract reconstruction for volitional voiding by an orthotopic Kock diversion to the urethra. All women choosing lower urinary tract reconstruction underwent preoperative cystoscopy and biopsy of the bladder neck (vesicourethral junction) to rule out histologic evidence of atypia, carcinoma in situ, or overt carcinoma. Regardless, all patients were preoperatively marked for an appropriate stoma site by the enterostomal therapy nurse. All patients were shown how to catheterize themselves should this be necessary. In addition, all patients had the understanding that if the primary bladder or pelvic tumor involved the bladder neck as diagnosed by intraoperative frozen section of the urethrovesical junction, then lower urinary tract reconstruction by means of a Kock ileal urethrostomy would not be performed, and diversion by means of a cutaneous Kock or an ileal conduit would be performed, depending upon patient preference as discussed preoperatively. The presence of pelvic nodal disease or perivesical fat involvement away from the anterior vaginal wall or urethra did not preclude reconstruction by a Kock ileal urethrostomy.

Cystectomy

The technique of an en-bloc anterior exenteration with bilateral pelvic lymphadenectomy in women has previously been described in detail elsewhere [10]. However, specific mention should be made concerning preparation of the female urethra. This is the most important step of the surgical procedure, and strict attention to surgical detail is crucial to avoid damage to the proximal urethra and corresponding innervation during the final stages of the operation. Excessive dissection anterior to the urethra or along the pelvic floor may jeopardize the continence mechanism.

The posterior bladder wall should be sharply dissected off the anterior vaginal wall down to the area of the bladder neck. If there is any concern about a positive surgical margin at the posterior or base of the bladder, then the anterior vaginal wall may be removed en bloc with the cystectomy specimen. Vaginal reconstruction may subsequently be required. Regardless, it is emphasized that minimal dissection be performed anterior to the urethra or along the pelvic floor in close proximity to the urethra. In addition, we recommend that the pubourethral suspensory ligaments, which may also contribute to the continence mechanism, be left intact. These surgical maneuvers should help maintain the continence mechanism with orthotopic reconstruction in women.

Once the bladder has been freely dissection and remains attached only at the bladder neck and urethra, a curved clamp (Satinsky) is placed across the bladder neck. With gentle traction the urethra is transected, and 8-12 interrupted absorbable sutures are placed circumferentially in the urethra. These sutures will later be reanastomosed in a tension-free, mucosa-to-mucosa fashion to the neobladder at the end of the procedure. Frozen sections for pathologic examination should be taken from the transected end of the bladder neck to identify any tumor that would obligate subsequent urethrectomy and, ultimately, a cutaneous form of diversion.

Lower urinary tract and vaginal reconstruction

It is the authors' preference to use ileum (Kock ileal reservoir) in whole to construct the neobladder. Our vast clinical experience with orthotopic reconstruction to the urethra in over 300 men has subsequently been applied to selected women following cystectomy. The technique remains standard and has been described elsewhere [11, 13, 14].

Vaginal reconstruction may be required, depending upon the patient's desire for sexual function postoperatively along with the amount of vagina remaining following the anterior exenteration. Under most circumstances the entire vagina distal to the cervix may be preserved unless a deeply invasive posterior bladder-wall tumor is present. If the tumor is posterior and deeply invasive, however, the overlying portion of the anterior vaginal wall should be excised en bloc with the cystectomy specimen to provide an adequate surgical margin. If more than one-third of the anterior vaginal wall is excised, postoperative sexual dysfunction, particularly dyspareunia, may be encountered. The vagina may subsequently be closed in a vertical (side-to-side) or a horizontal fashion (clam-shell) if this is the case. In addition, other means of vaginal reconstruction may be considered, including a rectus myocutaneous flap, a detubularized cylinder of ileum, a peritoneal flap, or an omental flap. In all cases, a well-vascularized pedicle graft should be placed between the reconstructed vagina and the orthotopic neobladder so as to separate the suture lines. Our preference is a vascularized omental pedicle graft based on the gastroepiploic vessels.

Follow-up

Patients' follow-up consisted of a gravity cystogram ("Kocko-gram") to evaluate the neobladder and exclude reflux, performed twice during the 1st year and annually thereafter. The upper urinary tract was radiographically evaluated with either ultrasound or excretory urography and routine chemistry studies performed, along with serum determinations of blood urea nitrogen and creatinine levels, at 4 and 12 months postoperatively and annually thereafter. In addition, all women underwent an annual postvoid residual urine determination to ensure complete emptying of the neobladder.

A thorough pelvic examination, with particular attention being paid to the anterior urethra, was performed at each follow-up visit along with voided urine cytology for surveillance purposes of the retained urethra so as to exclude a urethral recurrence or help identify the development of a new urethral tumor at an early curable stage. We have not utilized panendoscopy of the retained urethra unless suspicious cells are reported on cytology or the patient notes burning, a bloody discharge, or some unusual sensation in the region of the urethra.

Data were analyzed according to early complications, late complications, voiding pattern and continence, urethral recurrence, and overall patient satisfaction. The voiding pattern, determined by a detailed questionnaire, was classified as an ability to void to completion without the need for catheterization; an inability to void without continuous intermittent self-catheterization; and, lastly, an ability to void that required intermittent catheterization no more than three times per day for only a small residual urinary volume. Daytime and nighttime continence was evaluated by McGuire's continence grading system [6] and was defined as follows: completely continent; incontinent with major effort and when upright; incontinent with minor effort only; and incontinenent without regard to effort, position, or activity. In addition, patients were surveyed concerning the interval from the operation until the achievement of initial and maximal continence as well as concerning overall satisfaction.

Results

The average operating time for performance of a complete bilateral pelvic lymphadenectomy with en-bloc anterior exenteration followed by lower urinary tract reconstruction by means of an orthotopic Kock ileal neobladder was 5 h and 20 min (range, 4.5-7 h). This is similar to the time required for construction of a cutaneous Kock ileal reservoir. One patient underwent a 7.5-h procedure for a total pelvic exenteration with simultaneous bowel (J-pouch), vaginal, and lower urinary tract reconstruction.

Early complications

There was no perioperative death in our group of patients. Two patients suffered an early complication that prolonged hospitalization, for an early complication rate of 9.5% (2 of 21 patients). One patient who received preoperative external-beam radiation therapy (5000 rads) for stage IIIB cervical cancer developed a prolonged case of postoperative ileus. Another patient developed bacterial cholangitis. Both patients were treated conservatively without further sequelae. The length of hospital stay for the remaining 19 patients averaged 8.5 days.

Late complications

Late complications requiring rehospitalization or reoperation occurred in two patients (9.5%). One patient developed Kock-pouch calculi requiring endoscopic removal on an outpatient basis without difficulty. Another patient developed stenosis of the urethroileal anastomotic site, which was successfully dilated without further sequelae.

Survival

As of January 1995, 19 of 21 patients are alive without evidence of disease. One patients are alive without evidence of disease. One patient with P4AN+M+ disease died of diffuse metastatic transitional-cell carcinoma, without a pelvic recurrence, at 7 months following surgery. Another patient developed a right iliac recurrence and is receiving external radiation therapy for this recurrence. Of the remaining 19 patients, 18 (95%) are currently alive without evidence of recurrence at an average follow-up of 19 months (range, 5-59 months). One patient with an extensive mesenchymal tumor of the uterus developed a pelvic recurrence in the region of the sigmoid colon at 24 months and subsequently underwent an exploratory celiotomy and excision of the tumor mass and colon with conversion of the orthotopic Kock ileal reservoir to a cutaneous Kock ileal diversion.

Continence

Complete daytime continence is reported by 18 of 19 patients (95%) without the need for protection; 1 patient reports daytime incontinence with major effort only, requiring 3 pads per day for protection. Continence was achieved in 9 patients immediately following removal of the catheter 3 weeks postoperatively. The remaining patients achieved continence at 1-24 months (median, 6 weeks) postsurgery. Overall, all 19 patients report complete satisfaction concerning daytime continence. Complete nighttime continence is reported by 17 of 19 patients (89%) without the need for protection; 1 patient reports minimal leakage of urine without the need for protection, and 1 patient requires 2 pads per night for protection. Overall, all patients are judged to have good nighttime continence with complete satisfaction.

Voiding pattern

Information regarding the voiding pattern was obtained from all patients. Of 20 patients, 16 (80%) are capable of voiding to completion by means of increasing intraabdominal pressure and relaxing their external sphincter. A total of 4 patients require intermittent self-catheterization to empty the neobladder 4-6 times daily; 2 of these 4 patients represent our early experience in which Burch suspension procedures were performed at the time of lower urinary tract reconstruction, which only contributed to urinary retention. Subsequently, 1 of these patients developed a sigmoid recurrence and was converted to a continent cutaneous Kock reservoir.

Satisfaction

All patients are completely satisfied with their voiding pattern, continence, self-image, and overall results obtained with the procedure.

Discussion

The development of lower urinary tract reconstruction following cystectomy has been a result of the persistent dedication of innovative and pioneering surgeons. The ultimate goal of urinary diversion is no longer simply to divert urine and protect the upper urinary tracts from significant damage but also to maintain the patient's ability to void volitionally per urethra in hopes of providing a positive body and self-image without a cutaneous stoma or an external ostomy appliance.

Only a decade ago, the standard Bricker ileal conduit remained the primary form of urinary diversion in the United States. Patients were required to wear an external collecting device and were hampered by both a negative body image as well as the long-term renal morbidity secondary to reflux of infected urine [8, 9]. These unfortunate sequelae of cutaneous conduits stimulated the need for improvement in lower urinary tract reconstruction and ultimately led to the development of a continent cutaneous catheterizable form of urinary diversion. This type of urinary diversion gained tremendous popularity in the early and mid-1980s and resulted in a plethora of different forms of reconstruction incorporating various intestinal and/or colon segments.

A natural extension of the continent cutaneous form of urinary diversion was the orthotopic reservoir anastomosed directly to the native urethra. Orthotopic urinary diversion has eliminated both the need for a cutaneous stoma and the often plagued continence mechanism (efferent limb), relying ultimately upon the intact external sphincter mechanism for continence. Orthotopic diversion has now become the ideal form of urinary reconstruction, as patients are capable of maintaining volitional voiding per urethra. This form of lower urinary tract reconstruction was initially performed in selected men and was not considered technically possible in women as total urethrectomy was traditionally performed during the cystectomy. In addition, a lack of understanding of the continence mechanism in women dampened the enthusiasm for orthotopic reconstruction in females.

Although the ideal bladder substitute remains to be developed, the orthotopic neobladder most closely resembles the original bladder in both location and function. Certain principles of all orthotopic urinary reservoirs should include a large-capacity, low-pressure, nonrefluxing (protecting the upper urinary tract), nonabsorptive surface that allows the patients to void volitionally per urethra. The continence mechanism is maintained by the external striated sphincter muscle (rhabdosphincter muscle) of the pelvic floor, whereas voiding is accomplished by a concomitant increase in the intraabdominal pressure (Valsalva maneuver) along with relaxation of the pelvic floor.

The literature is replete with particular opinions as to which bowel segment and/or reservoir is optimal for construction of the orthotopic neobladder. The small intestine, terminal ileum and cecum, large intestine, or a combination of these have been utilized to construct a urinary reservoir. It is the authors' preference to use the small bowel (Kock ileal reservoir) in whole, as it appears to provide less contractility, greater compliance, and improved continence rates as compared with large-bowel neobladders. In addition, mucosal atrophy with less reabsorption of urinary constituents appears to be more reliable in small-bowel than in large-bowel reservoirs [7]. Two important criteria must be fulfilled in the consideration of a patient for orthotopic lower urinary tract reconstruction. First, the external sphincter must remain intact to provide continence and to allow for conscious voiding per urethra. Second, the cancer operation must under no circumstance be compromised by the orthotopic reconstruction at the urethroenteric anastomosis, the retained urethra, or the surgical margins. If these two criteria can be safely maintained, the patient may then be considered for orthotopic reconstruction to the urethra following cystectomy.

Until recently, the continence mechanism in women was not well understood. However, recent neuroanatomic and histologic studies of the female pelvis and urethra in fetal specimens have provided a better understanding of the female urethra and continence mechanism [3]. These anatomic dissections have identified three layers of smooth muscle in the proximal two-thirds of the urethra. The innervation of this proximal urethral segment can be traced back to the pelvic plexus coursing along the lateral aspect of the uterus, vagina, and bladder neck. A gradual transition with intermingling smooth muscle to striated pelvic floor muscle can be identified in the middle to lower third portion of the urethra. This striated pelvic floor muscle, the so-called rhabdosphincter muscle, with its major portion on the ventral aspect of the urethra, is innervated from branches off the pudendal nerve that course along the pelvic floor posterior to the levator muscles. These anatomic dissections suggest that preservation of the distal half of the urethral musculature together with the corresponding nerve supply is crucial in maintaining the continence mechanism in women. Furthermore, cystectomy with en-bloc removal of the uterus and cervix effectively denervates the bladder neck and proximal urethral sphincter mechanism, rendering them ineffective as a continence mechanism.

These unique anatomy studies support the complete removal of the bladder neck with transection of the proximal urethra just beyond the urethrovesical junction since continence is maintained solely by the rhabdosphincter muscle of the lower urethra. Our growing experience in women with orthotopic reconstruction to the urethra has clearly demonstrated that these patients maintain a normal voiding pattern, with overwhelming day- and nighttime continence being reported by nearly all subjects [16].

A crucial aspect concerning orthotopic diversion to the urethra in patients undergoing cystectomy for pelvic malignancy is ensuring that the cancer operation is not compromised by the reconstruction. The indications for radical cystectomy for bladder cancer are well established; however, a concern of all patients undergoing orthotopic lower urinary tract reconstruction to the urethra is the risk of urethral or vaginal-wall recurrence. These concerns arise from the observations that the pathologic implications of sparing the female urethra have not been well studied and that urethrectomy has been routinely performed in women without sound scientific data. Unlike the man with prostatic urethral involvement, there is currently no known risk factor that predicts for urethral recurrence following cystectomy in the woman. With this in mind, a retrospective pathologic analysis of female cystectomy specimens was performed to define more clearly

the incidence of carcinoma involving the bladder neck and urethra in women [15]. This, in turn, should help identify which women may be appropriate candidates for orthotopic reconstruction to the urethra following dcystectomy for transitional-cell carcinoma of the bladder.

We pathologically reviewed 67 consecutive female cystectomy specimens removed for biopsy-proven transitionalcell carcinoma of the bladder between 1982 and 1990. Histologic evidence of tumor (carcinoma in situ or invasive carcinoma) involving the urethra was present in 9 patients (13%). In all cases, tumor was confined to the proximal or mid-urethra, and in no patient was the distal urethra involved with tumor. Most importantly, all patients with carcinoma involving the urethra had concomitant tumor involving the bladder neck. A total of 17 patients (25%) had tumor involvement of the bladder neck; all patients with an uninvolved bladder neck also had an uninvolved urethra. Tumor involving the bladder neck and urethra tended to be more commonly associated with high-grade and high-stage tumors as well as lymph-node-positive disease.

In addition to bladder-neck involvement, anterior vaginal-wall involvement with tumor was identified as a major risk factor for urethral tumor involvement. All patients with tumor extending into the anterior vaginal wall were also found to have bladder-neck involvement, and 50% of these specimens also demonstrated urethral tumor involvement. However, if the bladder neck was histologically free of tumor, then no patient demonstrated any urethral or vaginal-wall tumor.

This pathology study suggests that women without tumor involvement of the bladder neck and anterior vaginal wall may be considered appropriate candidates for orthotopic lower urinary tract reconstruction to the urethra with preservation of the anterior vaginal wall. Meticulous preoperative evaluation with bladder-neck biopsy and intraoperative frozen section of the proximal urethral margin of the cystectomy specimen is mandatory to exclude any tumor involvement at the anastomotic site or vaginal wall that would preclude orthotopic diversion. With proper selection, at least 75% of women undergoing cystectomy may be considered appropriate candidates for orthotopic lower urinary tract reconstruction.

Careful preoperative evaluation of all women considering orthotopic diversion following cystectomy is essential for proper selection of the appropriate candidate. This evaluation should include a bimanual pelvic examination using anesthesia, with particular attention being paid to the anterior vaginal wall and urethra. All patients should also undergo cystoscopy and biopsy of the bladder neck (vesicourethral junction) to exclude any overt tumor or carcinoma in situ. Any abnormality found by examination or biopsy would preclude orthotopic reconstruction to the urethra.

The patient should also have the understanding that if the bladder or pelvic tumor involves the bladder neck as diagnosed intraoperatively with frozen section of the proximal urethral margin, then lower urinary tract reconstruction should not be performed. In this case, a cutaneous form of diversion should be performed as based upon the patient's desires and discussed preoperatively. It is therefore important to involve the enterostomal therapy nurse during the preoperative period, to mark patients for an appropriate cutaneous stoma, and to instruct them how to catheterize should this be necessary.

With a better understanding of the continence mechanism in women as well as the realization that the urethra can safely be preserved in selected women undergoing radical cystectomy, orthotopic lower urinary tract reconstruction has now become a viable option. Our initial clinical experience with orthotopic reconstruction in women has subsequently yielded outstanding functional results [16]. With a growing number of women undergoing orthotopic reconstruction with longer follow-up, the results continue to be excellent. Continence is maintained during the day and night, with only a minority of patients requiring any form of catheterization to empty the reservoir. Interstingly, most women demonstrate complete continence immediately following removal of their urethral catheter (3 weeks postoperatively). We attribute this to the limited dissection performed anterior to the urethra and along the pelvic floor during the cystectomy.

Overall, these women are continent, have the luxury of voiding every 4-6 h with excellent voided volumes, retain a more routine micturition pattern, avoid the need for a cutaneous stoma or external urostomy appliance, and live a more normal life-style with a positive self-image. Careful preoperative counseling of all women considered as candidates for orthotopic lower urinary tract reconstruction should include the possible need for clean intermittent catheterization in the rare patient who is incapable of voiding with pelvic floor relaxation and Valsalva. In addition, the patient should understand the risk of a urethral recurrence and the need for continued long-term surveillance of the retained urethra. Careful follow-up will be necessary to define the true risk for urethral or vaginal-wall recurrence in these women. Presently, meticulous monitoring of the retained urethra by visual vaginal examination, careful palpation, and voided urine cytology should be performed on a regular basis in all patients at each follow-up visit.

In conclusion, we feel that the advent of orthotopic lower urinary tract reconstruction in women is a significant step in the continued progression of urinary diversion. With a better understanding of the continence mechanism in women and recent data suggesting that the urethra can be safely preserved in carefully selected women, orthotopic diversion can now be offered not only to men but also to women undergoing cystectomy. Now that it is possible to offer this form of lower urinary tract reconstruction, patients as well as their physicians may be encouraged toward an earlier and more aggressive form of therapy with cystectomy, when cure and, ultimately, survival is greatest.

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