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Gynecologic-Tract Sparing Extra Peritoneal Retrograde Radical Cystectomy with Neobladder

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ABSTRACT

Objective: We report on a series of female patients with transitional cell carcinoma of the bladder who underwent extra-peritoneal retrograde radical cystectomy sparing the female reproductive organs with neobladder creation.
Materials and Methods: 14 female patients between the ages of 45 and 72 years who underwent gynecologic-tract sparing cystectomy (GTSC) with neobladder between 1997 and 2002 were retrospectively reviewed. Our surgical technique is also described. Radical cystectomy is accomplished by a retrograde method sparing the uterus, adnexa, vagina and distal urethra. An orthotopic neobladder was constructed using small bowel or sigmoid colon, brought extraperitoneally, and anastomosed to the distal urethra.
Results: Operating time ranged from 4.5 to six hours with a mean of 5.3 hours. Ten patients were able to void satisfactorily while four required self-catheterization for complete emptying of the bladder. Seven patients were continent day and night and another 7 reported varying degrees of daytime and nighttime incontinence. One patient died of metastases and another of pelvic recurrence. There were no urethral recurrences. Patient satisfaction with the procedure was high.
Conclusions: Gynecologic-tract sparing cystectomy with orthotopic neobladder is a viable alternative in female patients with muscle invasive traditional cell carcinoma of the bladder, providing oncological safety with improved quality of life. Our extraperitoneal technique, which is an extension of our successful experience with retrograde extraperitoneal radical cystectomy in men, minimizes intraoperative complications and simplifies the management of post-operative morbidity with the neobladder.

Key words: *female; bladder neoplasm; carcinoma, transitional cell; cystectomy; urinary diversion*
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INTRODUCTION

Over the past decade, radical cystectomy with orthotopic neobladder has become a popular treatment for muscle-invasive bladder cancer in females (1). This change has occurred due to a better understanding of the anatomy of the bladder neck, urethra, and continence mechanism in females and improvements in surgical technique. Recently there has been considerable interest in preservation of the gynecological tract to maintain sexual function without compromising oncological principles. It is clearly established that the continence mechanism in females depends on the striated sphincter and sexual function on the maintenance of adequate vaginal length and intact nerve supply to clitoris. Furthermore, an intact uterus with its adnexa allows reproductive function to be preserved in young patients who undergo radi-

cal cystectomy. The issue of oncological safety of a urethra-sparing cystectomy has been addressed by several authors (2,3) and is feasible and safe. We undertook refinements in our extra-peritoneal retrograde technique of cystectomy in males and extended it to females to preserve the gynecologic tract. The authors report their experience of extra-peritoneal retrograde radical cystectomy sparing the female reproductive organs (gynecologic tract) with orthotopic neobladder.

MATERIALS AND METHODS

Of the 237 patients who underwent radical cystectomy at our institution for muscle invasive transitional cell carcinoma of the bladder between January 1997 to December 2002, 178 patients were males and 59 were females. Of the 59 female patients, 14 underwent gynecologic-tract sparing cystectomy (GTSC) while the other 45 had ileal conduits. Age ranged from 45 to 72 years. All patients had biopsy proven muscle-invasive transitional cell carcinoma of the bladder with no evidence of lymphadenopathy or extravesical spread on clinical evaluation and imaging studies. Patients with diffuse carcinoma-in-situ or tumors involving the bladder neck were excluded, as were patients with a poor performance status. Other exclusion criteria were patients who were unable to perform self-catheterization due to obesity; problems with manual dexterity or lack of suitable assistance were also excluded. Patient motivation was assessed and only patients who understood the implications of a neobladder and were willing to self catheterize were included. All patients were continent prior to cystectomy. Patients in whom close follow-up was difficult were also excluded. Informed consent was obtained from all patients. All patients had a serum creatinine of less than 1.8 mg%. A thorough pre-operative gynecological checkup including a vaginal Pap smear to rule out any co-existing gynecological condition was done in all patients. All 14 patients underwent gynecologic-tract sparing cystectomy and creation of a neobladder as described below. Post-operatively the urethral catheter was removed at 3 weeks and patients were started on a regimen of clean intermittent self-catheterization 5-6 times per day, which was later discontinued in patients who voided satisfactorily.

Patient voiding patterns and continence were assessed by means of a questionnaire and personal interviews as well as a voiding diary. As no quality of life questionnaire had been validated for use in the subset of Indian female patients, we created a physician-administered questionnaire in the regional language. A patient was considered continent if she required no more than one pad for the loss of small quantities of urine during the night (from going to bed to getting up in the morning) or the day. Post-void residual urine was assessed by means of self-catheterization after spontaneous voiding.

Surgical Technique

Our technique of gynecologic-tract sparing cystectomy (GTSC) and neobladder was based on our experience gained in the performance of radical cystoprostatectomy by the retrograde method in male patients as reported previously (4). Bowel preparation is started on the morning of the day before operation and includes the administration of two liters of polyethylene glycol solution and oral antibiotics. A site for a stoma is marked in conjunction with the stoma therapist in case it becomes necessary to create a conduit. The patient is placed in the supine position on the table with her legs slightly abducted on the table allowing access to the urethral meatus. A 18F Foley catheter is passed and the balloon inflated to 20 cc. Betadine soaked pack is inserted in the vagina. Abdomen is opened through an infra-umbilical midline incision and the transversalis fascia incised. The peritoneum is swept cephalad and extra peritoneal space is explored. Bilateral pelvic lymphadenectomy is performed from the common iliac artery bifurcation all along the external iliac artery and vein to the femoral canal distally and obturator nerve medially. Frozen section examination is used only when the tissue appears highly suspicious. Further, if frozen section reveals positive nodes the lymphadenectomy is extended to the level of the inferior mesenteric artery. The bladder is retracted cephalad and fibrofatty tissue is removed from the retropubic space to expose the bladder neck (Figure-1). The dorsal venous

complex is ligated and divided and the endopelvic fascia incised on both sides. By sharp dissection, the urethra is dissected from its attachments to the vagina 2 cm below the bladder neck and is hooked with a right angle clamp (Figure-2). The anterior wall of the urethra is incised 1-2 cm below the bladder neck, the catheter removed, clamped proximally to prevent balloon deflation, and divided and then the posterior wall of urethra is divided. Six to eight 3-0 vicryl sutures are placed in the distal cut end of the urethra with the needles on the luminal surface and retained for later anastomosis to the neobladder. The proximal urethral end is held with the catheter and by gentle traction, the urethra with the bladder neck is dissected off the vaginal vault. Continued traction on the catheter prevents leakage of urine from the bladder into the operative field. There is generally fibro-fatty tissue between the vagina and bladder neck, which requires sharp and blunt dissection. Carefully without injuring the vault of vagina and paravaginal tissues, the bladder is lifted off the anterior vaginal wall and uterus (Figure-3). The vascular pedicles to the bladder are ligated and divided in retrograde fashion. Bladder with its fascia is next lifted off the peritoneum over the uterus, or in patients who have had a previous hysterectomy over the vault of the vagina and the rectum. The dissection proceeds further proximally and paravesical tissues and obliterated hypogastric pedicles are ligated and cut. The ureters are divided last and the cut ends are sent for frozen section examination. The urachus is ligated and divided and the specimen removed. In many instances, it is possible to remove the bladder without opening the peritoneum; if peritoneum is adherent to the dome of the bladder or when the tumor involves the dome of the bladder, it may be excised with the specimen. After the specimen is removed, wedges of tissue from the bladder neck and urethral cut margin are sent for frozen section examination. The peritoneum is opened for a short distance if not previously done and a segment of ileum extending 60 cm proximally from a point 15 cm proximal to the ileocecal junction is isolated on a vascular pedicle and

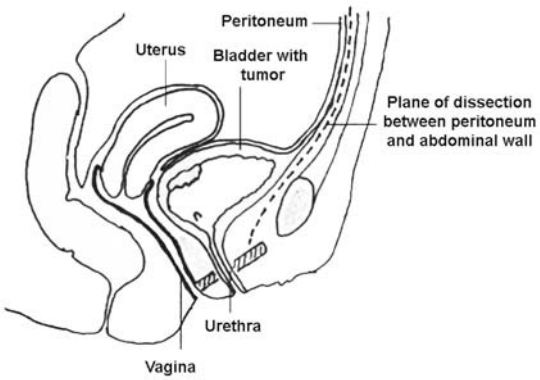

Figure 1 *– Relevant anatomy showing initial plane of dissection.*

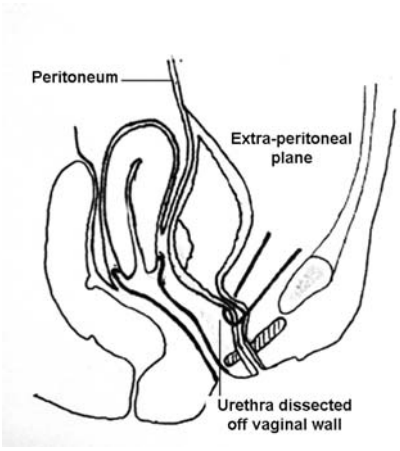

Figure 2 *– Anterior dissection dissecting urethra from anterior vaginal wall.*

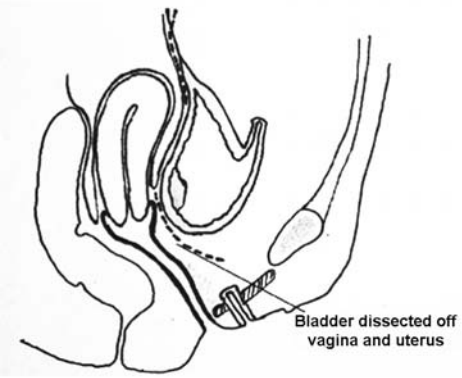

Figure 3 *– Dissection proceeding, lifting bladder from vagina and uterus.*

bowel continuity restored by end-to-end anastomosis, after ensuring that the segment reaches the urethra. The peritoneum is closed around the pedicle of the ileal segment, thus isolating it from the peritoneal cavity. The neobladder is then created as described by Hautmann. Briefly, the bowel is detubularised and sutured in a W configuration to create a plate and the ureters are implanted creating serosa-lined extra-luminal tunnels. In all cases, ureteric length was sufficient to allow easy reimplantation. In one patient a sigmoid colon neobladder, as described by Reddy (5) was created because of a previous medical history of ileocecal tuberculosis.

The neobladder is anastomosed to the urethra using the pre-placed vicryl sutures over a 20F Foley catheter, and lies extraperitoneally (Figure-4). Drains are placed and the incision closed.

During dissection of the urethra, care is taken not to dissect anterior and distal to the level of the transection, to ensure preservation of the pubo-urethral and urethropelvic ligaments. While dissecting lateral to the bladder it is advisable to avoid injury to paravaginal tissues so that the branches of the pelvic nerve plexus, which course laterally to the vagina, can be preserved.

RESULTS

Follow-up ranged from 18 to 71 months with a mean of 32.5 months. Operative time was between 4.5 and 6 hours with a mean of 5.3 hours. In one patient who had undergone a previous hysterectomy for menorrhagia the vagina was preserved. In all other patients the vagina, uterus and adnexa were preserved. Blood loss ranged from 300-1500 cc and three patients received transfusions. No patient suffered early or late complications requiring intervention. There was no perioperative mortality.

One patient with T3bN2 grade tumor died of metastases 13 months after surgery. Another patient with T2bN1 grade tumor was diagnosed as having a pelvic recurrence and died at 26 months. The recurrence was on the lateral pelvic wall and distant from the urethra. Of the remaining 12 patients, 10 are alive and well with no evidence of disease, while 2 are lost to follow up. None of these had urethral recurrences. Details of patients are given in Table-1.

Ten patients were able to void satisfactorily, with post-void residual volumes ranging from 0-100 cc. Four of these patients required self-catheterization twice daily to empty completely the bladder and six voided with insignificant post-void residue. Remaining four patients are unable to void, requiring regular self-catheterization to empty their neobladders.

Seven of the 14 patients are continent by day and night. Of the remaining 7 patients, 3 have significant daytime and nighttime incontinence, 2 report nighttime wetness only which is managed using pads, and 2 have significant daytime-only incontinence.

Asymptomatic bacteriuria occurred in 9 patients. Two patients had recurrent episodes of clinically significant urinary tract infection that required institution of long-term antibiotic prophylaxis. One patient developed a rise of serum creatinine to 2.3 mg% from a baseline level of 1.6 mg%. Renal function in all other patients remained stable on follow-up.

Patient satisfaction after the operation was high, with most patients happy that they had opted for a neobladder as against an ileal conduit.

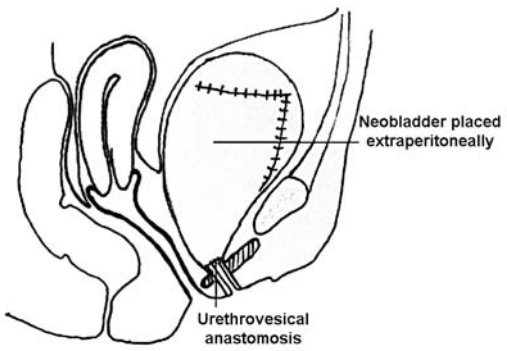

***Figure 4** – Neobladder in extraperitoneal pelvic space.*

COMMENTS

Orthotopic neobladder has become an increasingly popular form of urinary diversion in male patients with muscle invasive bladder cancer who are candidates for radical cystectomy. However, female

Table 1 *– Summary of patients.*

Pte	Age	Neo-bladder	Pathology	Daytime Continence	Nighttime Continence	Voiding	CISC	Comments	Follow-up (months)
1.	68	Ileal	T2N0	no	no	Spontaneous	Yes	NED	65
2.	62	Ileal	T1N0	yes	yes	Hypercontinent	Yes	NED	36
3.	72	Ileal	T3N2	yes	no	Spontaneous		Died of mets at 13 months	13
4.	65	Ileal	T3N1	no	yes	Spontaneous	Yes	NED	29
5.	65	Ileal	T3bN1	yes	yes	Spontaneous		NED	29
6.	58	Ileal	T2N1	yes	no	Spontaneous	Yes	NED	27
7.	45	Ileal	T4N0	yes	yes	Hypercontinent	Yes	NED	27
8.	63	Ileal	T2N0	no	no	Spontaneous		NED	23
9.	62	Ileal	T2N1	yes	yes	Hypercontinent	Yes	Died at 26 months	26
10.	70	Ileal	T2N0	yes	yes	Hypercontinent	Yes	NED	20
11.	68	Ileal	T2N0	no	yes	Spontaneous		NED	18
12.	65	Ileal	T2N0	yes	yes	Spontaneous	Yes	NED	17
13.	64	Ileal	T2bN0	no	no	Spontaneous		NED	12
14.	55	Sigmoid	T3N0	yes	yes	Spontaneous		NED	12

NED = no evidence of disease; CISC = clean intermittent self catheterization.

patients with the same disease have traditionally been offered continent cutaneous stomas or ileal conduits. Although the literature on quality of life following radical cystectomy is divided on the relative benefit of cutaneous diversion vs. orthotopic diversion, some authors have shown that quality of life is better preserved after orthotopic diversion (4). The reasons why orthotopic diversion was not previously offered are two-fold. Traditionally radical cystectomy in female patients included total urethrectomy as a part of optimum oncological clearance. However, pathological studies in female radical cystectomy specimens have demonstrated that the urethra is rarely involved in the absence of extensive carcinoma in situ (6). In a literature review, Stein et al. identified bladder neck involvement and anterior vaginal wall involvement as risk factors for urethral involvement (7), this has allowed a subset of female patients to be identified in whom the distal 2 cm of the urethra can be preserved at radical cystectomy, allowing an orthotopic reconstruction to be performed. Subsequent experience with female neobladders has confirmed the oncological safety of sparing the urethra. Recent understanding of the continence mechanism and voiding in females has led to an increasing number of investigators creating neobladders with excellent results (6-8). Furthermore, Chang et al. (9) reported preservation of the anterior wall of vagina to provide better support to the distal urethra leading to better continence and decreased incidence of prolapse of the neo bladder and lower incidence of neo bladder-vaginal fistula. Additionally vaginal length helped better sexual function.

In the past, radical cystectomy in females included an anterior exenteration i.e. removal of the bladder, urethra, uterus, fallopian tubes, ovaries and anterior wall of the vagina. Recently the oncological

necessity for removal of the internal genital organs has been questioned. Groutz et al. examined the cystectomy specimens of 37 patients with bladder cancer and found uterine involvement by transitional cell carcinoma in only 1 patient (10). Chang et al. (11) looked at the involvement incidence of the internal genitalia in 40 anterior exenteration specimens; traditional cell carcinoma was identified in 2 of them, and in both gross involvement had been identified during operation. In one patient uterus showed the presence of a low-grade stromal sarcoma. They concluded that in the absence of clinical suspicion removal of the uterus and its adnexa rarely improves cancer control. More recently in a series of 609 female radical cystectomies, Ali-El-Dein et al. (12) reported a 2.6% rate of concomitant gynecologic organ involvement by bladder cancer and a 0% rate of primary genital cancer. The preservation of the uterus and its adnexa is desirable in a younger patient who wants to retain reproductive function. Moreover, Chang et al. (9) suggested that preservation of the uterus and its supports may prevent the dead space that otherwise would be filled by small bowel which in some may produce anterior enterocele following cystectomy as was reported by Anderson et al. (13). Horenblas et al. (14) reported on "sexuality preserving cystectomy" in 3 female patients with bladder cancer, using a retrograde method. No patient had a local recurrence, and all patients achieved satisfactory daytime and nighttime continence. One patient developed a vaginal urinary fistula and was converted to a continent catheterizable stoma. Vaginal lubrication and orgasmic feeling were reported to be normal after surgery. Preservation of branches of the pudendal nerve to the clitoris is essential for normal sexual sensation, and the uterus has been reported to have a role in orgasmic sensation (15). Several authors have described radical cystectomy by a retrograde technique. Hautmann (16) has used this approach in female patients during anterior exenteration while sparing the anterior vaginal wall and urethra preparatory to neobladder creation. More recently, Dhar et al. have reported nerve sparing radical cystectomy and orthotopic bladder replacement in female patients (17).

The oncological outcome in our group of patients was satisfactory, with 2 deaths out of 14 at a mean of 32 months. Notably no patient suffered a recurrence in the region of the urethra. As most urethral recurrences in male patients following radical cystectomy have been shown to occur within 19 months (18), this seems to indicate that urethral recurrence in the future will be unlikely. As shown by Stein et al. (6), patients with an uninvolved bladder neck rarely have urethral involvement. However, for greater safety they advise intraoperative frozen section biopsy of the distal surgical margin, which we follow. While the utility of sparing the uterus and ovaries in older female patients may be questioned, it is emphasized that the aim of sparing the uterus in this group is not reproductive ability but voiding function by preventing sagging of the pouch.

In our series 72% (10/14) patients were able to void spontaneously, while 28% (4 /14) unable to void. Four out of the 10 patients who were able to void were advised self-catheterization twice daily for complete bladder emptying. None of these patients reported urinary leakage and all expressed satisfaction that they were able to perform their daily activities without fear of wetting. Compliance with self-catheterization was adequate and pouch infections were not a problem. 64% of patients were continent by day: the remainder had low-volume leaks that could be easily managed by pads. A similar number who had nocturnal leakage of urine could manage their low-volume incontinence using pads. Though a 36% incontinence rate may seem high, management with pads is low cost and acceptable compared with the external appliances required with an ileal conduit, which in a developing country are unaffordable to many and not easily available in many areas. A majority of patients expressed satisfaction with the functional outcome.

We in the past reported our extra peritoneal retrograde approach for radical cystectomy in males (19) with the aim of complete closure of the peritoneal hiatus thus separating the GI tract from neobladder or ileal conduit. Bowel handling is minimized and the need to pack the bowels into the upper abdomen using towels is obviated. The morbidity is reduced and the management of urinary leak is simplified. Moreover, the left ureter does not cross the sigmoid mesentery reducing the incidence of left uretero ileal anastomotic stricture and improved preservation of the left upper tract. We extended the same technique of extra peri-

toneal retrograde approach for radical cystectomy in females followed by neobladder. This approach in 14 patients gave us excellent results in terms of minimal post-operative morbidity and long-term benefits. Retrograde approach for cystectomy has been reported by others using the trans-peritoneal route. However, we have been using the extra-peritoneal route as described previously and we are quite satisfied with the oncological safety and benefit of a peritoneal surface separating the GI tract from the neobladder resulting in reduction in morbidity, leak, and early return of peristalsis. Uretero-enteric anastomotic stenosis or neobladder-vaginal fistula has not been observed in our series mainly because of intact vaginal vault and no crossing of the left ureter.

CONCLUSION

We have here described a technique of performing radical cystectomy with orthotopic neobladder in selected female patients by a retrograde method with preservation of the internal genital organs. Early results are promising with regard to voiding function and patient satisfaction.

CONFLICT OF INTEREST

None declared.

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EDITORIAL COMMENT

Cystectomy has been the mainstay of aggressive bladder cancer treatment for years. Classic radical cystectomy in women involves en bloc removal of the bladder, uterus, ovaries, anterior vaginal wall and urethra. Acceptable oncological and functional results of orthotopic urinary diversion in men and better understanding of the female continence mechanism have, in the past decade, led to the fact that orthotopic neobladder has been established as an oncologically and clinically safe and good acceptable option of urinary diversion in appropriately selected women. With proper patient selection, preservation of the female urethra has been shown to be safe, although it was an initial oncological concern. Over the years, we have learned that bladder neck involvement, increased grade and stage, and lymph node involvement by tumor are a major risk factor for urethral involvement. However, gynecological-tract sparing cystectomy furthermore remains permanently discussed. The potential menace of insufficient cancer control and secondary malignancies of preserved gynecologic organs persists. In this group of patients the oncological outcome was satisfactory.

On the other hand, in properly selected female patients, preserving the uterus, ovaries and anterior vaginal wall may improve the functional results. By preserving the anterior vaginal wall and pubo-urethral ligaments, the occurrence of neobladder descent and pelvic prolapse is decreased. The preservation of the uterus may be beneficial to prevent a chronic retention (hypercontinence) by providing proper back support to the neobladder.

Finally, more importantly, the nerves, which are essential for a normal sexual response, are usually removed and damaged in standard cystectomy, and the surgery leads to the loss of proper sexual function.

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EDITORIAL COMMENT

The authors describe their technique in women with bladder cancer of retrograde radical cystectomy with sparing of the anterior vaginal wall and, when present, the uterus and ovaries, followed by an extraperitonealized orthotopic neobladder. Increasingly, efforts are made to avoid the traditional anterior pelvic exenteration, where radical cystectomy in the female is combined with total hysterectomy and bilateral salpingo-oophorectomy. Transitional cell carcinoma involves the uterus, vagina, or cervix in less than 3% of women with bladder cancer, all of whom have grossly locally advanced disease (1-3). The preservation of the vagina and uterus can have tremendous benefits to the clinical outcome and health-related quality of life (HRQOL) of the patient. Too often the sexual concerns of women are overlooked. Sexual dysfunction following radical cystectomy in the female is correlated with the magnitude of vaginal preservation. Furthermore, the risk of potentially devastating postoperative complications such as neobladder vaginal vault prolapse, enterocele formation, and neobladder-vaginal fistula, that occasionally mandate conversion to cutaneous diversions, may be reduced with preservation of the uterus and vagina (4). Similarly, extraperitonealization of the orthotopic neobladder may reduce the incidence of both bowel and urinary complications, or at the very least, reduce their severity when they occur. The authors' technique carries the promise of improved perioperative outcomes with the potential for better long-term HRQOL than standard procedures.

However, we must consider the findings of this study in the context of its own limitations: the absence of a comparison group and the use of physician-centered outcomes. I agree that intuitively, the major considerations in this technique, namely preservation of the gynecologic organs and extraperitonealization of the diversion, likely enhance patient-centered outcomes. Yet as we advance clinical care, we are obligated to validate our progress. Beyond utilization of comparison groups, we have yet to elucidate the HRQOL measures that calibrate a patient's satisfaction following radical cystectomy and urinary diversion. Many analyses have attempted to compare continent to incontinent diversions, with mixed results (5-9). The author's difficulty identifying an appropriate questionnaire with which to assess their patients highlights the difficulty in measuring HRQOL in this population. Can one instrument compare HRQOL across urinary diversions and patient gender?

The authors present a technique that may improve both perioperative and long-term clinical outcomes following radical cystectomy for bladder cancer. Yet the article also underscores the need for studies that employ experimental methods and appropriate measures of surgical results.

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EDITORIAL COMMENT

Two elements stand out in this study on cystectomy in females.

In the first place the preservation of all internal genital organs and secondly the retrograde extraperitoneal approach.

Standard cystectomy in females comprises of the complete removal of internal genitals together with a part of the vagina. While this may have been oncologically sound in older days, it seems over treatment at this moment. Involvement of the genital tract by urothelial cancer in contemporary series is a very rare event. In all cases, preoperative staging reveals invasion of the genital tract by urothelial cancer. This has been documented by a variety of authors as described in this paper. In addition, risk factors for urethral involvement and therefore a contraindication for this type of surgery have been defined with great certainty. Despite these rational arguments in favor of this type surgery, daily practice remains so far largely unchanged.

I see at least one reason. Bladder cancer, especially muscle invasive bladder cancer, has a poor long-term survival even in the most favorable conditions. Local recurrences should be avoided at all cost, as they portend a lethal end in almost all cases. Fear of local recurrences has withheld many colleagues to embark on this type of surgery. While this may seem reasonable, recent reports like this one testify to the safety of "sexuality preserving cystectomy". In a comparison, done at our institute, no more local recurrences were found in the group of patients treated with a "sexual preserving cystectomy" compared to patients undergoing a standard cystectomy (submitted for publication). With a follow up of more than 10 years now, I consider this type of surgery in well selected patients oncologically safe.

Also interesting is the extraperitoneal approach used by the authors. Some details caught my attention.

In the first place the closure of the peritoneum around the mesentery of the neobladder. While no scientifically sound comparison was done between this method and the standard closure, this could very well be a factor of importance in decreasing the postoperative complications.

The retrograde fashion leads to early dissection of the bladder neck. The authors use the inflated balloon to decrease the risk of tumor spill. I would suggest two other measures in order to further decrease this risk: closure of the bladder neck around

the balloon and early transection or clipping of the ureters.

Although the authors should be applauded for adding new proof of safety for this type of surgery, I am somewhat concerned about the functional results.

In the first place no information on sexual functioning is given. This was apparently not assessed. In the second place the incontinence rate of more than 35%. This needs to be analyzed as, also in underdeveloped countries, this rate of incontinence is in need of improvement.

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