Prostate capsule sparing radical cystectomy: oncologic safety and clinical outcome

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Abstract:

Objectives: Prostate capsule sparing radical cystectomy (PSRC) is a modification of the traditional surgical approach to radical cystectomy and neobladder, which offers the prospect of improved preservation of erectile function and continence.

Methods: This is a review of the literature regarding the oncologic and quality of life outcomes of this approach for transitional cell carcinoma of the bladder, and a comparison of these results to conventional cystoprostatectomy and neobladder.

Results: There are a limited number of studies addressing prostate capsule or prostate sparing cystectomy. All are retrospective, non-comparative and not uniform in terms of patient selection and technique. Long-term follow-up is lacking. The incidence of synchronous and or metachronous prostate cancer and TCC of the prostatic urethra is lower than that found in conventional cystoprostatectomy. This is likely due to pre-operative patient selection, restricting the procedure to those with no evidence of prostatic involvement by either disease. The local recurrence rate is 5%, comparable to standard cystoprostatectomy. Recurrence free and overall survival rates are comparable.

Keywords: bladder cancer, radical cystectomy, prostate sparing

Introduction

Radical cystoprostatectomy and neobladder has a significant impact on many quality of life (QOL) related domains. Body image perception, day and nighttime continence and erectile function are affected. The introduction of orthotopic bladder replacement has reduced the effects on body image. However, erectile function is still commonly affected, and incontinence, particularly nocturnal, is common. Nerve sparing cystectomy is associated with a relatively low rate of erectile function preservation [Schoenberg *et al.* 1996].

Prostate sparing radical cystectomy (PSRC) has been proposed as a viable treatment option for superficial refractory or muscle-invasive TCC. Different authors have described different techniques, with several common motifs. All preserve a portion of the prostatic capsule, the seminal vesicles and the vasa deferentia, but vary in the types of prostate resection and neobladder configuration [Tal and Baniel, 2005; Botto *et al.* 2004; Colombo *et al.* 2004; Muto *et al.* 2004; Vallancien *et al.* 2002; Spitz *et al.* 1999].

All authors describe removal of a portion of the prostate to variable degrees. The two main techniques are (a) removal of the prostatic adenoma using Millen's technique of simple retropubic prostatectomy, excising the tissue containing the prostatic ducts and acini, but leaving the surgical capsule and seminal vesicles intact [Millin, 1945], and (b) a transverse excision through the proximal prostate, leaving the distal prostate, including the distal adenoma and seminal vesicles and utricle intact [Spitz *et al.* 1999]. In both cases, the peri-prostatic portion of the neurovascular bundle; the distal sphincteric complex; and the continuity of the vasa, seminal vesicles, and ejaculatory duct, remain undisturbed.

Radical cysto-prostatectomy is the current gold standard for the management of patients with invasive bladder cancer. There has also been a shift towards early cystectomy for high risk T1 disease, due to the high rate of progression to invasive cancer, at which point occult metastatic disease is more likely to be present [Chang and Cookson, 2005]. The dilemma, particularly in

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young patients, is the trade off between the adverse quality of life effects and the survival benefits of cystoprostatectomy. Prostate sparing cystectomy appeals to patients in several ways. It may reduce the risk of erectile dysfunction, making early cystectomy more palatable. An additional benefit may be the facilitation of laparoscopic cystectomy if the entire prostate does not require removal [Arroyo *et al.* 2005]. Further, avoiding the prostatectomy part of RCP shortens the procedure and may reduce the blood loss [Tal and Baniel, 2005]. Finally, leaving the prostate or prostate capsule intact facilitates the surgical anastomosis between the neobladder and the urethra. The rationale for prostate sparing cystectomy is therefore to improve the QOL after surgery and to facilitate the operation without compromising cancer control.

Technique

Patient selection is a critical component of the procedure. Patients at significant risk for prostatic urethral involvement should be excluded. This involves several steps. Patients should be candidates for a neobladder on the basis of age, co-morbidity, and extent of disease. T4 disease should be excluded. The primary cancer should not directly involve the bladder neck or prostatic urethra. Associated multifocal CIS increases the risk of prostatic involvement and is a contra-indication. (Focal CIS in the peri-tumoral area is not a contra-indication.) Transurethral biopsies of the prostatic urethra should be performed, ideally at the time of the initial TUR, to identify occult ductal involvement of the prostate. Multiple biopsies should be taken, with particular attention to the distal prostate just proximal to the ejaculatory duct, where the highest concentration of ducts occurs.

Patients should have no evidence of underlying prostate cancer. They should have a normal DRE, normal TRUS, and a prostate-specific antigen (PSA) consistent with a relatively low risk of prostate cancer. In patients in whom prostate cancer is suspected, a 10–12 core TRUS guided biopsy of the prostate is warranted.

Some authors have advocated a full TURP and/or extensive prostate biopsies prior to the procedure (regardless of PSA and DRE findings) to exclude either TCC of the prostatic urethra or underlying prostate cancer [Colombo *et al.*

2004; Vallancien *et al.* 2002]. These are likely unnecessary. They subject the patient to an additional procedure, and have a low incremental utility compared to the strategy described above.

The proposed procedure

To reduce the risk of tumor spillage, maximal tumor cytoreduction by TURBT should be performed prior to surgery. The bladder is approached by a median subperiumbilical laparotomy. The lateral vesical peritoneum is divided bilaterally up to the internal inguinal ring. The vas deferens are bilaterally identified, isolated and preserved. The ureters are identified and transected bilaterally at their entry to the bladder. The umbilical arteries are then divided, followed by the division of the posterior and lateral pedicles of the bladder. The peritoneum is transversally incised at the level of the cul-de-sac. A plane is created between posterior bladder wall and both seminal vesicles and deferential ampullae. Sharp dissection of the bladder from seminal vesicles, ejaculatory ducts and deferential ampullae is performed. Closure of the (proximal) bladder neck before final dissection of the bladder from the prostate should be performed to reduce tumor spillage. The anterior prostatic capsule is transversally incised. The plane between the adenoma and the surgical capsule is then dissected sharply and bluntly, as described by Millen's technique for simple retropubic prostatectomy [Millin, 1945]. The goal is a complete adenectomy. The adenoma should remain attached at the bladder neck; this is generally not difficult (Figures 1 and 2).

In men without prostatic enlargement, the plane between the surgical capsule and adenoma may not be readily dissectable. In those cases, the transverse incision should be extended throughout the entire prostate about 1 cm superior to the apex, leaving the apical tissue, including the veru and seminal vesicles. Where possible, the prostatic capsule should be spared superiorly.

The residual posterior pedicles are then divided and the bladder and prostatic adenoma removed. The bladder neck and prostatic capsule are examined in frozen section to exclude malignancy. A positive distal margin warrants complete resection of the residual prostate.

Extended lymphadenectomy is performed without complete skeletonization of the medial and

Figure 1. Surgical technique of prostate capsule sparing: Note plane of dissection between capsule and adenoma.

Figure 2. Gross appearance following prostate capsule sparing adenoma. Arrow points to prostate adenoma attached to bladder.

deep surface of the internal iliac artery to avoid damage of the *nervi erigentes* at their origin (the area between this artery and the external side of the rectum is where the *nervi erigentes* arise from the pelvic plexus). An ileal neobladder is then

created and anastomosed to the prostatic capsule with interrupted stitches. The capsular sutures should be placed close to the prostatic apex.

Oncologic concerns

Prostatic involvement by TCC

The impetus for traditional cystectomy including en bloc dissection of the entire prostate arose because of reports that occult TCC and prostate cancer were prevalent in the prostate of these men. In unscreened patients, the incidence of prostatic involvement by TCC in cystectomy specimens is 20–48% (Table 1) [Pettus *et al.* 2006; Weizer *et al.* 2006; Kefer *et al.* 2005; Revelo *et al.* 2004; Montie *et al.* 1989]. These figures include CIS and severe dysplasia, as well as ductal or stromal involvement. Apical involvement has been described in 15–33% [Pettus *et al.* 2006; Revelo *et al.* 2004].

The critical questions are (a) whether prostatic involvement can be identified prior to or during surgery, and (b) when, in spite of appropriate patient selection, superficial, that is, ductal or acinar involvement is present, a capsule sparing approach where the adenoma and glandular elements are largely resected, provides an adequate oncologic outcome.

The evidence suggests that the answers are affirmative. Prostatic involvement tends to occur in a stepwise fashion, from urethral, to ductal, to stromal involvement. Excluding patients with cancer at the bladder neck will select a group at lower risk of prostatic involvement. Extensive sampling of the prostatic urethral, particularly proximal to the veru montanum (where the ducts are concentrated) is likely to identify urethral and ductal involvement. Gross involvement of the prostate is often palpable. A recent study of 128 radical cystoprostatectomy specimens (1988–2003), where 39% had prostatic involvement, found that 78% were detected by prostatic urethral biopsy. Of the remainder, 14% had direct extension into the prostate and 14% had extracapsular or seminal vesicle involvement. Most of these were suspected on DRE. Finally, frozen section of the prostatic apex will identify patients whose prostatic urethral involvement had still not been identified.

Eleven recent series of PSRC where patients were screened for prostatic involvement for TCC

Table 1. Incidence of prostate urethral TCC and prostate cancer in prostates removed during cystoprostatectomy.

Author	N	TCC Prostatic involvement	% Urethra/ducts	% Stroma	% PCa	% Sig PCa
Montie <i>et al.</i> 1989	72	–	–	–	46	7
Revelo <i>et al.</i> 2004	121	48	37	11	41	20
Kefer <i>et al.</i> 2006	171	32	19	15	36	25
Pettus <i>et al.</i> 2006	122	32	9	23	47	12
Shen <i>et al.</i> 2005	214	32	14	5		
Weizer <i>et al.</i> 2006	35	23	14	9	47	12

report an incidence of local recurrence of about 3%; considerably lower than cystoprostatectomy series in unscreened patients (Table 2) [Simone *et al.* 2008; Thorstenson *et al.* 2008; Wunderlich *et al.* 2006; Martis *et al.* 2005; Min *et al.* 2005; Botto *et al.* 2004; Colombo *et al.* 2004; Muto *et al.* 2004; Terrone *et al.* 2004; Vallancien *et al.* 2002].

Occult prostate cancer

Co-existent prostate cancer likely exists in patients with invasive bladder cancer at roughly the same frequency as in normal men. There is no evidence to suggest that the risk of prostate cancer incidence or mortality is any higher in bladder cancer patients than in the normal population. In the context of the aggressive lethality of invasive bladder cancer, the mortality risk of co-existent prostate cancer, which is likely to be slow growing even if clinically significant, is small. In addition, with appropriate screening (including PSA, TRUS, and 10–14 core biopsy where indicated), most patients with clinically significant disease are likely to be identified. In the unusual case where clinical prostate cancer arises in a patient who has had a capsule sparing cystectomy and neobladder, salvage options exist.

Coexistent prostate cancer (PC) in RCP specimens has been reported in 23–47% of men undergoing cystectomy (Table 1). The majority of these cancers were clinically insignificant. DRE was the only pre-RCP screening test. Important tumors were defined as curable or advanced based on the extent of extracapsular extension and the presence of seminal vesicle invasion or lymph node metastases.

In contrast, synchronous or metachronous PC in series of PSRC, where patients were screened for pre-existing prostate cancer, occurs in 2–4% (Table 2) [Simone *et al.* 2008; Thorstenson *et al.*

2008; Wunderlich *et al.* 2006; Martis *et al.* 2005; Min *et al.* 2005; Botto *et al.* 2004; Colombo *et al.* 2004; Muto *et al.* 2004; Terrone *et al.* 2004; Vallancien *et al.* 2002]. Occasionally, even with this thorough screening, PC may develop. In Vallancien's study [Vallancien *et al.* 2002], 3/100 men developed prostate cancer postoperatively (two pathologic errors and one de novo within 5 years of follow-up). In 11 reported series of prostate sparing cystectomy, 12/369 (3%) were found to have prostate cancer. Further, the prostate cancers diagnosed after a negative initial screen are likely to be smaller volume and more indolent. Thus appropriate screening appears to identify almost all men with occult prostate cancer. In the small minority who have disease missed by screening, the disease is likely to be indolent relative to the natural history of invasive bladder cancer.

Recurrence rates

In radical cystectomy series, recurrence occurs in about 30% at 5 years and 40% at 10 years [Stein and Skinner, 2006]. Effective local control is achieved by cystoprostatectomy. Local recurrence occurs from 5 to 19%. Local and systemic recurrence rates after prostate sparing cystectomy is reported in 0–3% of patients in the 11 series in the literature. Summarizing the world experience, local recurrence has occurred in 12/369 patients (3.3%) and systemic recurrence in 48/369 (13%). Bearing in mind the critical role of patient selection in determining recurrence rates, this rate is clearly comparable to other cystectomy series.

Controversy exists regarding the interpretation of this literature. A limitation of the existing data is that the mean follow up has been ≤ 3 years in 9 of the 11 series in the literature. The low recurrence rate may reflect the modest duration of follow up. Two series have long follow up. Terrone [Terrone *et al.* 2004] reported 27 patients

Table 2. Incidence of local and distant recurrence of TCC, and concurrent prostate cancer, in prostate sparing cystectomy series.

Author	N	Stage $\leq$ pT2%	% Local	% Distant	% PCa
Vallencien <i>et al.</i> 2002	100	64	3	14	5
Botto <i>et al.</i> 2004	34	65	3	12	3
Muto <i>et al.</i> 2004	61	98	0	19	2
Colombo <i>et al.</i> 2004	27	96	0	0	0
Terrone <i>et al.</i> 2004	27	93	0	15	0
Abuzied <i>et al.</i> 2005	45	100	7	9	
Min <i>et al.</i> 2005	12	100	0	17	
Martis <i>et al.</i> 2005	32	47	0	0	0
Wunderlich <i>et al.</i> 2006	31	84	3	0	0
Thorstensen <i>et al.</i> 2008	25		0	20	16
Simone <i>et al.</i> 2008	20	100	20	30	
Total	369	193	3.3	13	2

Table 3. Functional outcome of prostate sparing cystectomy.

Author	N	% Day cont	% Night cont	% Potency
Vallencien <i>et al.</i> 2002	100	97	95	82
Botto <i>et al.</i> 2004	42	80	80	90
Muto <i>et al.</i> 2004	61	95	31	95
Colombo <i>et al.</i> 2004	27	100	100	100
Terrone <i>et al.</i> 2004	27	100	77	93
Abuzied <i>et al.</i> 2005	20	100	100	90
Arroyo <i>et al.</i> 2005	25	100	100	84
Martis <i>et al.</i> 2005	32	98	83	80
Wunderlich <i>et al.</i> 2006	31	94	94	87
Thorstensen <i>et al.</i> 2008	25	85	50	95
Simone <i>et al.</i> 2008	20	100	100	100

with a mean follow up of 90 months, and Muto [Muto *et al.* 2004] described 61 patients with mean follow up of 68 months. One literature review of 7 series involving 306 patients with T2 or less disease calculated a similar systemic recurrence rate of 13%, but concluded that this was two times higher than the rate expected from classical cystoprostatectomy [Hautmann and Stein 2005].

While the low rate of local and systemic recurrence in the published series of prostate sparing cystectomy relative to the rate in comparable cystoprostatectomy series may reflect careful patient selection, these low rates are reassuring. The likelihood that the retained prostate tissue would be the source of recurrence will be low if one adheres to the following principles.

- (1) Minimize the chances that the prostate which is left behind contains TCC by adequate screening.
- (2) Perform an adequate extended lymph-node dissection.

- (3) Adhere to strict principles of avoiding intra-operative spillage.
- (4) Perform meticulous frequent post-PSRC follow-up, including voided urine cytology.

Functional results following prostate sparing cystectomy

Orthotopic neobladder with cavernous nerve sparing technique represents a major advance compared to ileal conduit. However, erectile function and incontinence are both common. Preservation of erectile function is reported in 13–50% of patients undergoing nerve sparing cysto-prostatectomy [Maderbascher *et al.* 2002; Henningsohn *et al.* 2003; Lebrete *et al.* 2000; Hautmann *et al.* 1999]. The main goals of prostate capsule sparing cystectomy are to improve erectile function and continence. In very few patients, fertility sparing may also be a goal. Remarkably, all 11 published series of prostate sparing cystectomy report 80% or greater rates of potency preservation, and 6 describe 90% or greater preservation (Table 3). Since the capsule

sparing approach leaves the entire prostatic neurovascular region intact and undissected, these results are not overly surprising

Preservation of the distal sphincteric mechanism in the prostatic capsule would be expected to improve urinary control, and this is borne out by the reported results. The rate of day and night time continence following standard cystoprostatectomy and ileal neobladder is 90% and 80% respectively. The prostate sparing series appear to achieve a higher level of continence. Nine series report daytime continence rates of 94% or greater. Night time continence was achieved in 94% or more in 7 series, and only Muto reported a rate of night time incontinence >50%. Six series report daytime and night time incontinence rates of 100%!

These studies assessed continence by physician reporting in most cases, and did not use validated questionnaires or other more objective means of assessment. This is a significant limitation of the database. However, results are encouraging.

Other benefits

Patient acceptance of cystectomy can be difficult because of the impact on quality of life. Bladder preservation strategies may be preferred by patients, with the attendant risks of understaging, disease progression, late recurrence in the bladder, and perhaps increased prostate cancer mortality. The morbidity and quality of life effects also drive attempts at conservative management of borderline disease, particularly high grade T1 disease. A definitive surgical approach to invasive bladder cancer which better preserves quality of life, particularly continence and erectile function, supports the palatability of a more aggressive approach to these difficult cases. This may translate into improved cancer specific survival [Herr and Sogani, 2001].

Patient selection

This is critical, and will determine the long term success of this strategy. Several disease characteristics are correlated with prostatic involvement by TCC. In particular, multifocal CIS of the bladder is associated with prostatic involvement in about 1/3 of cases [Nixon *et al.* 2002]. A high degree of tumor multifocality is also a risk factor.

In contrast, patients who have no CIS, multifocality, or bladder neck involvement have an extremely low rate of prostatic urethral involvement; 0 of 40 patients in one series [Kefer *et al.* 2005].

The ideal patient

Patients should have either high grade T1 TCC, or a single T2 tumor. Ideally the bladder neck should not be involved, and multi-focal CIS should be absent. (A small area of peri-tumoral CIS is a common feature associated with invasive bladder cancer, and should not preclude a prostate capsule sparing approach.) Prostatic urethral biopsies should show no evidence of TCC.

Prostate cancer should be excluded by selecting patients who have a normal DRE and PSA less than age adjusted norms, or else a negative 10–14 core biopsy. A low PSA threshold should be used for indicating a TRUS guided biopsy. TRUS is also useful in planning the surgical approach. In patients with significant prostatic enlargement, a Millen type of adenectomy can be readily performed. In patients with small prostates (<30 cc), a distal apical sparing approach may be more feasible.

Prostate capsule sparing cystectomy is only warranted in patients who are in a position to enjoy the quality of life benefits. Younger candidates should have normal erectile function and an orthotopic bladder replacement must be planned.

Since there are quality of life benefits involving trade-offs, selected patients who do not fulfill all of the ideal criteria may also be offered a prostate capsule sparing approach. This would include patients who have co-existent CIS of the bladder, erectile dysfunction, or T3a disease, with negative extensive prostatic urethral biopsies.

Another difficult area is the patient found to have a few microfoci of low grade prostate cancer on biopsy. Most would agree that the presence of any prostate cancer on TRUS biopsy (with co-existent invasive bladder cancer) should be managed with cystoprostatectomy. Indeed, the '2 for 1' concept of eradicating 2 cancers with one operation is surgically and clinically appealing. However, it stands to reason that patients with small-volume low-grade prostate cancer have a small risk of prostate cancer mortality and may be candidates for a prostate sparing approach. In these cases, a trade off between

the functional benefits of prostate sparing and the oncologic benefits of cystoprostatectomy must be balanced.

Conclusion

Prostate capsule sparing cystectomy is an appealing modification of conventional cystoprostatectomy. The current published series, which comprise 369 patients in 11 publications, suffers from the limitations of short follow up, patient heterogeneity, and variable inclusion criteria and surgical modifications. Nonetheless, the evidence to date suggests that in properly selected patients, this procedure can be performed safely, with a low rate of local recurrence. Preservation of the capsule, which includes the neurovascular bundle and components of the distal sphincter mechanism, appears to result in an improved functional outcome, with superior rates of preservation of erectile function and continence. Improved quality of life makes cystectomy a more acceptable treatment option to patients, thereby avoiding the risks inherent in conservative management of borderline cases. Patient selection is critical. Prostatic involvement by TCC or prostate cancer must be ruled out by appropriate diagnostic maneuvers prior to the operation. This experience suggests that by minimizing the probability that the prostate which is left behind contains TCC, performing an extended lymph-node dissection, avoiding intra-operative spillage, and incorporating meticulous follow-up, the odds that the retained TCC free prostate will be the source of recurrence are low, while patients enjoy an improved quality of life.

Conflict of interest statement

None declared.

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