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·Clinical Experience·

Targeted-cryosurgical ablation of the prostate with androgen deprivation therapy: quality of life in high-risk prostate cancer patients

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Abstract

Aim: To present preliminary results on health-related quality of life (QoL), prostate-associated symptoms and therapeutic effects of targeted-cryosurgical ablation of the prostate (TCSAP) with androgen deprivation therapy (ADT) in high-risk prostate cancer (PCa) patients. **Methods:** Thirty-four men with high-risk PCa features underwent TCSAP, and ADT was added to improve the treatment outcomes. High-risk parameters were defined as either prostate-specific antigen (PSA) ≥ 10ng/mL, or Gleason score ≥ 8, or both. The Genito–Urinary Group of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) with prostate-cancer-specific module (QLQ-PR25) was used for evaluating morbidities and PSA levels were recorded every 3 months. PSA failure was defined as the inability to reach a nadir of 0.4 ng/mL or less. **Results:** Although it was not statistically significant, the global health status scores increased after TCSAP with ADT. The scores for five functional scales also became higher after treatment. The most prominent symptom after treatment was sexual dysfunction, followed by treatment-related and irritative voiding symptoms. **Conclusion:** TCSAP with ADT appears to be minimally invasive with high QoL except for sexual dysfunction. Long-term follow-up of PSA data and survival is necessary before any conclusions can be made on the efficacy of this promising new therapeutic modality in the treatment of PCa. *(Asian J Androl 2006 Sep; 8: 629–636)*

Keywords: cryosurgery; prostatic neoplasm; prostate cancer; hormone antagonist; quality of life; targeted-cryosurgical ablation of the prostate; EORTC QLQ-C30

1 Introduction

The main treatment options for clinically localized prostate cancer (PCa) currently consist of radical prostatectomy and radiation therapy (external beam radiation therapy and/or brachytherapy). Unfortunately, both treatment modalities are not optimal in cancer treatment, especially in poorly differentiated tumors, and can result in significant morbidity, adversely affecting the quality of life (QoL) of the patients [1]. The shortcomings of these treatments have prompted the development of alternative approaches in the treatment of PCa, and cryosurgery has reemerged as an evolving technology and a minimally invasive treatment option.

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Early cryotherapy involved the use of liquid nitrogen based probes with poor control of the resultant ice-ball and a high rate of complications [2]. Improvement in transrectal ultrasound (TRUS) allowed the development of perineal delivery of cryotherapy probes. Further improvements integrating the Joule–Thompson effect in the development and application of urethral warming catheters and ultrathin 17 gauge cryoneedles on brachytherapy templates facilitated the emergence of the third generation cryotherapy. Its safety and therapeutic efficacy have been reported in several published studies [3–6]. QoL parameters are increasingly used as end points in clinical trials. The Genito–Urinary Group of the European Organization for Research and Treatment of Cancer (EORTC) will not accept any protocol that does not evaluate QoL. This seems especially true for PCa patients in whom improvements of surgical and non-surgical management, multiple treatment alternatives, early age at diagnosis, and bowel problems after treatment all underline the significance of QoL [7]. Cryosurgery is reported to result in a comparable QoL with standard treatments, such as radical prostatectomy (RP) and radiation therapy (RT) [7–11].

Androgen deprivation therapy (ADT) is the first line of treatment against advanced PCa and is also used as a neoadjuvant or adjuvant to local treatment of high-risk diseases [12]. Hormonal manipulation with RT has consistently demonstrated improved outcomes in patients with locally advanced PCa and those with high risk of early biochemical failure, compared with standard dose radiation therapy [13, 14]. Recent evidence suggests that adjuvant therapies might improve disease-free survival and overall survival in targeted-cryosurgical ablation of the prostate (TCSAP), especially in high-risk patients [6, 16].

If TCSAP with ADT proves to be a treatment at least as effective as the conventional treatment or solitary TCSAP in prolonging survival, and also contributes to an improved QoL. This treatment strategy might become a significant option for PCa patients. The primary end point of the present study was to describe the self-reported health-related QoL as well as sexual, urinary and bowel symptoms in men with high-risk PCa treated with TCSAP and the addition of ADT. The secondary end points were preliminary results on the medical and biochemical assessment of this TCSAP with ADT, which is ongoing, with follow-up projected to extend for at least another 5 years. These results should be supported by other reports with longer follow-up.

2 Materials and methods

2.1 Patient selection

Between December 2003 and May 2005, 34 patients underwent TCSAP for clinically localized or locally advanced PCa with high-risk features at Korea University Hospital. All patients had biopsy-proven PCa. High-risk parameters were defined with either a pretreatment prostate-specific antigen (PSA) level ≥ 10 ng/mL, or a pathology report indicating a Gleason score ≥ 8, or both of these two features. Patients who had undergone prior RP or RT for PCa were excluded from the present study. Preoperative Gleason scores, gland size and PSA were recorded. Clinical tumor staging was performed using digital rectal examination, TRUS imaging, and classified according to the 1997 TNM staging system. A bone scan was performed if PSA was above 10 ng/mL. Patients were required to have no evidence of metastatic disease by bone scan, computer-assisted tomography or endorectal coil magnetic resonance imaging. All patients received neoadjuvant ADT with luteiniing hormone releasing hormone (LHRH) analog plus anti-androgen prior to cryosurgery as a result of high-risk preoperative features. All patients were asked to complete the Korean translated Genito-Urinary Group of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire core-30 (EORTC QLQ-C30) and its prostate-cancer-specific module (QLQ-PR25) questionnaires before starting neoadjuvant ADT.

2.2 Cryosurgery technique

A brachytherapy template, 17 gauge cryoneedles (Galil Medical, Westbury, NY, USA), and the SeedNet Gold system (Galil Medical, Westbury, NY, USA) were used. The patients underwent a bowel preparation as for any large bowel procedure the evening before surgery. Under general anesthesia the patients were placed in an exaggerated lithotomy position. Perioperative intravenous cephalosporin in combination with an aminoglycoside was administered as for TURP. Cystoscopy was performed to assess the urethra. A Foley catheter was inserted to improve visualization of the urethra and bladder neck under TRUS when placing the needles. A multifrequency biplanar TRUS probe was used to assess the dimensions and shape of the prostate. An inflatable rectal stand off (brachyballoon) was used to enhance echogenecity. The 17 gauge cryoneedles

(1.47 mm in diameter; Galil Medical, Westbury, NY, USA) were then inserted under TRUS guidance, approximately 1 cm from the urethra, 5 mm from the prostate capsule and spaced 1 cm from each other. Depending on the size of the prostate, 10 to 12 needles were placed to outline the shape. Up to five thermosensors were placed. Two were placed on the left and right neurovascular bundles. Thermosensors at the level of the external sphincter and in Denonvilliers' fascia were used to minimize the risk of incontinence or rectourethral fistula. Thermosensors in the mid gland ensured that the required temperature of –40ºC was reached for effective cell killing. Two cryoneedles were placed just above the rectal wall for active rectal wall protection. Once the cryoneedles were placed, a flexible cystoscopy was performed to ensure that none of the needles had inadvertently pierced the urethra. With the flexible cystoscopy still in the urethra, a 0.038 inch diameter rigid guidewire was then inserted through the scope and into the bladder. After removal of the scope the urethral warmer was placed over the guidewire. Two freeze-thaw cycles were performed under TRUS guidance. During freezing the ultrasound was monitored continuously when the ice approximated the rectum. If the rectal temperature dropped below 0ºC or the ice ball margin extended into the rectal wall too far, active rectal wall protection needles were activated. Thawing was done in two stages, passive and active. In passive thawing the freezing cycle was turned off and we waited for 5 min or until a temperature "plateau" appeared. The "plateau" is defined as an absence of rise in temperature for 30 s. Once the temperature in the treatment zone rose to above 0ºC or was at a plateau, active thawing was initiated throughout all rows for 1 min, followed by 1 minute of passive thawing. This was repeated until the temperature was above 5ºC or rose continuously. The second freezing cycle was repeated in the same manner. After finishing the last freeze-thaw cycle the urethral warmer was left in place for at least 30 min before removal to minimize the risk of urethral sloughing. The cryoneedles were then removed and gentle pressure was applied to the perineum for 2 to 5 min to minimize bleeding. After completion of the procedure, a Foley catheter was inserted or the suprapubic tube was left open. Patients were generally discharged on the following day.

2.3 Questionnaires

In December 2005, 6–24 months after TCSAP with adjuvant ADT, all patients visited the outpatient office and were asked to personally complete the Korean translated EORTC QLQ-C30 version 3.0 and its QLQ PR25 module. QLQ-C30 and QLQ PR25 questionnaires were used with permission from the EORTC Data Center in Brussels, Belgium.

The EORTC QLQ-C30 is a widely used, reliable and validated instrument for measuring QoL in cancer patients. It was designed to be cancer specific, multidimensional in structure, appropriate for self-administration, applicable across a range of cultural settings, and suitable for use with additional site- or treatment-specific modules. The QLQ-C30 is composed of both multi-item scales and single-item measures; these include five functional scales (physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning), three symptom scales (fatigue, nausea and vomiting and pain), a global health status/QoL scale, and six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties). All of the scales and single item measures range in score from 0 to 100. A high score for a functional scale represents a high/healthy level of functioning and a high score for the health status/QoL represents a high QoL, but a high score for a symptom scale or item represents a high level of symptomatology or problems [16].

In addition to the QLQ-C30, all patients received a multidimensional, prostate-cancer-specific, self-administered instrument to supplement the core questionnaire. This supplement is composed of four scales, including sexual function, as well as urinary, bowel and treatment-related symptoms.

2.4 Clinical follow-up

By our protocol, all patients began long-term adjuvant ADT, continued for over 24 months after TCSAP, with LHRH-analog plus anti-androgen to improve treatment outcomes. Patients were followed with clinical examinations and serial PSA measurements at 3 month intervals. At each follow-up, the operating surgeon evaluated morbidities, including pelvic pain, irritative voiding symptoms, impotence and incontinence, defined as patient report of a lack of urinary control requiring more than one pad daily. The external genitalia and perineum were examined to determine the extent of swelling, obstruction, urethral sloughing and rectal fistula. Every 3 months, we measured serum PSA value for biochemical assessment and urinalysis for urinary tract infection.

Biochemical failure was defined as an inability to achieve and maintain a PSA value of less than or equal to 0.4 ng/mL.

2.5 Statistical analysis

The statistical software package SPSS 12.0 for Windows (SPSS, Chicago, IL, USA) was used for all statistical analysis. Paired *t*-test and Wilcoxon rank-sum test were used for comparison of means between pretreatment and posttreatment scores. The McNemar test was used to compare morbidities before and after treatment. $P < 0.05$ was considered statistically significant.

3 Results

3.1 Patient characteristics

Table 1 summarizes the preoperative characteristics of the study population. Mean patient age was 67.6 years (range 51 to 84). A total of 18 (52.1%) patients had significant comorbidity such as cardiopulmonary and/or cerebrovascular diseases, or solitary kidney as a result of previous radical nephrectomy for renal tumor. The mean age of the TCSAP patients who were without significant comorbidities or did not want a major operation was 71.2 years. Mean preoperative PSA was 15.6 ng/mL. A total of 22 (64.7%) patients had a preoperative PSA greater than 10 ng/mL. A total of 16 (43.6%) patients had a preoperative Gleason score of 8 or more (mean 7.3). A total of 22 (64.7%) patients were T2 and 5 (14.7%) were T3. Mean prostate size was measured as 29.1 g. Neoadjuvant ADT was performed in all patients prior to TCSAP for a mean duration of 2.6 months. Long-term adjuvant ADT was performed in all patients after TCSAP for a mean duration of 15.38 months (range 6–24 months). Long-term adjuvant ADT is scheduled in our protocol for over 24 months and is incomplete at the present time.

Table 1. Patient characteristics. DM, diabetes mellitus; PSA, prostate-specific antigen.

Items	Values	
Number of patients	34	
Mean/median age (range)	67.6/68.0	(51–84)
Number of comorbidity/Number of primary cryosurgery (%)	18/34	(52.1)
Cardiopulmonary	10	
D M	6	
Cerebrovascular	1	
Solitary kidney	1	
Number with Gleason score (%):		
2–6	5	(18.2)
7	13	(38.2)
8-10	16	(43.6)
Number with PSA (%):		
10 or less	12	(35.3)
Greater than 10	22	(64.7)
Number with T stage (%):		
T1	7	(20.6)
T2	22	(64.7)
T3	5	(14.7)
Mean prostate volume (SD)	29.1	(12.9)
Mean/median months of prior hormonal therapy(range)	2.6/1.2	(1–4)
Mean number with cryo-probes used (range)	11.4	(10–12)

3.2 Health-related QoL

All the 34 patients completed the questionnaires, before neoadjuvant ADT and after 6–24-month treatment (TCSAP + ADT). We defined pretreatment time point as pre-neoadjuvant ADT and post-treatment as post-TCSAP with ADT. The response rate was 100%. Figure 1 shows the global health status scores as well as the scores for the functional scales. Although it was not statistically significant, the global health status scores increased after TCSAP with ADT. The scores for five functional scales were also stable after TCSAP with ADT.

The scores for the three symptom scales and the six single items were low, indicating low severity of symptoms (Figure 2). No statistical differences were shown between pretreatment and posttreatment.

3.3 Prostate-cancer-specific symptoms

The most prominent and severe symptom after treatment was sexual dysfunction, followed by treatment-related and irritative voiding symptoms (Table 2). Table 3 shows morbidities and complications rate after TCSAP with ADT.

The scores of scales related to sexual functions increased significantly after TCSAP with ADT except items related to sexual intimacy. Post-treatment erectile dysfunction (ED) was reported in 88.2% (30/34) of patients but was not statistically significant ($P > 0.05$), as pretreatment rates had also been as high as 82.5% (28/34).

Irritative voiding symptom scores increased significantly after TCSAP with ADT. However, the number of patients complaining irritative voiding symptoms did not increase significantly with TCSAP with ADT. Treat-

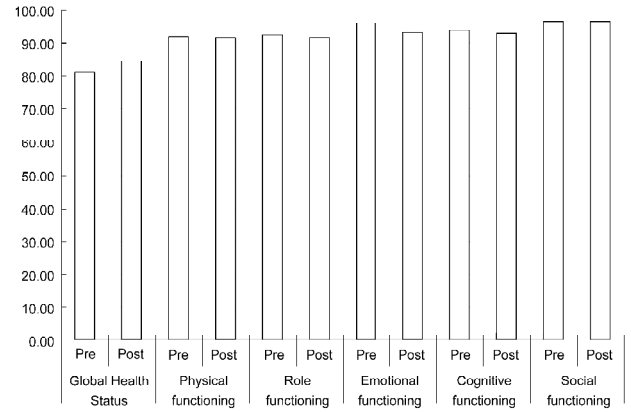

Figure 1. Summary of quality of life and functional scales comparing before and after TCSAP+ADT (targeted cryosurgical ablation of the prostate + androgen deprivation therapy). There was no statistical significance between the two groups in the scores of global health as well as functional scales. Pre: pre-neoadjuvant ADT. Post: post-TCSAP with ADT.

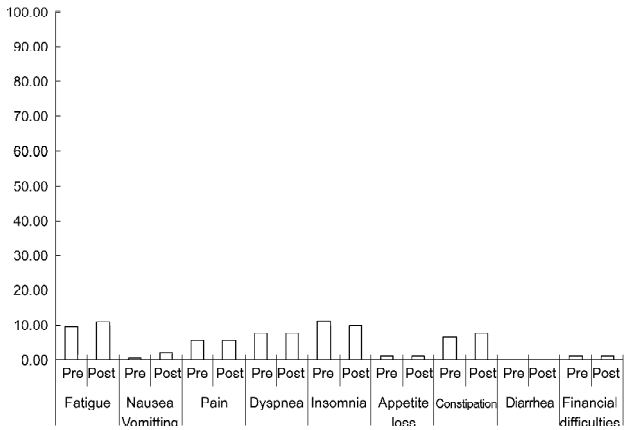

Figure2. Summary of three-symptom scales and single-symptom items comparing before and after TCSAP+ADT (targeted cryosurgical ablation of the prostate + androgen deprivation therapy). There was no statistical significance between the two groups in all scales and items. Pre: pre-neoadjuvant ADT. Post: post-TCSAP with ADT.

Table 2. Summary of prostate-cancer-specific symptom scales. Pretreatment: pre-neoadjuvant ADT. Posttreatment: post-TCSAP with ADT. ADT, androgen deprivation therapy; TCSAP, targeted-cryosurgical ablation of the prostate.

QLQ-PR25	TCSAP+ADT		
	Pretreatment score (SD)	Posttreatment score (SD)	*P*
Irritative symptom	10.6(2.2)	13.1(2.3)	0.046
Urinary incontinence	0.0(0.0)	0.0(0.0)	—
Painful voiding	0.0(0.0)	0.0(0.0)	—
Micturition problem	0.0(0.0)	0.0(0.0)	—
Defecation problem	3.3(1.9)	3.3(1.9)	—
Fecal incontinence	0.0(0.0)	0.0(0.0)	—
Hematochezia	0.0(0.0)	0.0(0.0)	—
Abdominal distension	0.0(0.0)	0.0(0.0)	—
Treatment-related side effect	3.5(1.1)	8.8(1.8)	< 0.01
Erection problem	72.3(6.1)	92.0(4.9)	< 0.01
Ejaculation problem	72.6(6.0)	90.5(5.4)	< 0.01
Sexual functioning	31.3(3.6)	21.1(1.6)	< 0.01
Sexual enjoyment	43.9(4.5)	20.8(2.1)	< 0.01
Sexual intimacy	15.5(3.6)	9.5(3.8)	0.283

Table 3. Summary of complication rate comparing pretreatment and posttreatment. McNemar test was applied in analysis. Pretreatment: pre-neoadjuvant ADT. Posttreatment: post-TCSAP with ADT. ADT, androgen deprivation therapy; TCSAP, targeted-cryosurgical ablation of the prostate.

Complications	TCSAP+ADT		
	Pretreatment number/total patients (%)	Posttreatment number/total patients (%)	*P*
Urethral sloughing	0/34 (0.0)	0/34 (0.0)	—
Rectourethral fistula	0/34 (0.0)	0/34 (0.0)	—
Incontinence (pads)	0/34 (0.0)	0/34 (0.0)	—
Scrotal swelling	0/34 (0.0)	3/34 (8.8)	—
Pelvic pain	0/34 (0.0)	2/34 (5.9)	—
Transient retention	0/34 (0.0)	1/34 (2.9)	—
Urinary tract infection	0/34 (0.0)	0/34 (0.0)	—
Erectile dysfunction	28/34 (82.5)	30/34 (88.2)	0.500
Irritative voiding symptom	7/34 (20.6)	10/34 (29.4)	0.250
Hot flush	0/34 (0.0)	5/34 (14.7)	—
Gynecomastia	0/34 (0.0)	2/34 (5.9)	—

ment-related symptom score, pertaining to hot flush or gynecomastia also showed statistically significant increase after TCSAP with ADT.

No major complications, such as rectourethral fistula, urethral sloughing and incontinence were noted. Low rates of penile paresthesia, pelvic pain and scrotal swelling were found and all cases were resolved through conservative management. Transient urinary retention in the

early postoperative period was noted in only one patient and was resolved after keeping a suprapubic cystostomy catheter for more than 1 week.

3.4 PSA follow-up

The mean duration of postoperative follow-up was 15.38 months (range 6–24 months). When the biochemical failure cut-off value was defined as PSA less than 0.4 ng/mL, overall 97.1% (33/34) of patients were free of biochemical recurrence. To date, no patient has demonstrated disease progression and the overall survival rate is 100%.

4 Discussion

Traditionally, the evaluation of a cancer treatment has been limited to overall and disease-free survival, local and distant recurrence, and treatment-associated toxicity. However, QoL is increasingly being recognized as an outcome measure in clinical trial, and many clinical trials groups see any evaluation of any treatment as incomplete without the assessment of its effect on QoL [16]. PCa is a good example of a malignancy in which death rates have decreased in the USA since 1991. Patients are diagnosed at a younger age, and alternative therapeutic options are available. When offering different options and informing the patient, physicians should be able to address typical side effects and QoL aspects, allowing a more informed decision regarding treatment.

The rationale for adjuvant or neoadjuvant ADT in high-risk patients of PCa who received TCSAP or RT is the theory that these patients eventually might experience early biochemical failure, recurrence, or metastasis because they already have local or distant micrometastatic disease at the time of diagnosis. On this basis, local control of disease will have very little impact on recurrence-free survival. There is also the distinct possibility that some patients likely develop metastatic disease because of inadequate local treatment. Adjuvant or neoadjuvant ADT with TCSAP or RT in high-risk patients, therefore, has become an important treatment strategy [6, 14, 15].

[illegible] *et al*. [13] showed, in a randomized, controlled trial in 1997, that when combined with radiation, the addition of ADT had a powerful potentiating effect with RT on survival for men undergoing primary curative treatment for localized PCa. Several reports on the oncologic outcome and QoL after TCSAP have been published [3–9]. However, studies on QoL and oncologic efficacy after TCSAP with ADT have not yet been reported.

Robinson *et al*. [7] determine the QoL of men enrolled in a Phase II clinical trial of TCSAP for the treatment of localized PCa. They find that the QoL outcomes of their study support the current renewed interest in cryosurgery. Compared with men who received the standard treatments of RP and RT, men treated with cryosurgery appeared to have a similar QoL, with perhaps the exception of decreased sexual function.

Table 4 gives an overview of previous studies on

Table 4. Reported studies on QoL using the EORTC QLQ-C30 questionnaire in patients with clinically localized prostate cancer. EORTC, European Organization for Research and Treatment of Cancer; RT, radiation therapy; TCSAP, targeted-cryosurgical ablation of the prostate; ADT, androgen deprivation therapy; QoL, quality of life; PF, physical functioning; RF, role functioning; EF, emotional functioning; CF, cognitive functioning; SF, social functioning.

	Borghede *et al.* [10]	Fransson *et al.*[11]	Anastasiadis *et al.*[9]	Present study
Number	186	108	81	34
Mean age (years)	67.5	71.3	72.8	67.6
Treatment	RT	RT	TCSAP	TCSAP+ADT
Mean time after treatment (months)	12-36	41	25.6	15.38
Mean scores				
QoL	75	69	76	84
PF	89	83	95	91
RF	92	79	90	91
EF	86	85	86	93
CF	88	85	87	92
SF	86	80	83	96

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patients with localized PCa using EORTC QLQ-C30 [9–11]. The studies allowed a comparison of patients after RT, TCSAP, and TCSAP with ADT. The overall QoL scores of the TCSAP with ADT group were higher than those in other groups. The scores for physical, role, emotional, cognitive and social functioning were also higher or comparable to previous reports. There was no statistical difference between pretreatment and post-treatment scores. When interpreting the data, however, one has to keep in mind that patients' race, age, PSA levels and pathologic stages were not standardized.

In addition to the QLQ-C30, the patients received a prostate-cancer-specific module, addressing sexual, urinary and bowel symptoms. ED is a significant adverse outcome of cryotherapy. Although some series have reported ED rates ranging from 40% to 47%, more contemporary series report rates greater that 80% [3–7]. ED is probably inevitable if the apex of the prostate and periprostatic tissue is aggressively frozen, as was the case in these high-risk PCa patients. Enervation of erectile function is provided by the cavernous nerve bundles that pass in close proximity to the prostatic apex. As one of the most likely areas for RP or TCSAP failure is the apex, any procedure that attempts to eradicate the entire gland and a rim of tissue is likely to cause ED [17]. Also, the loss of libido by ADT might have contributed to the high rate of ED in the present study.

Slow recovery of erections over time was expected after cryotherapy because of the observation that nerve regeneration is possible [3, 17]. A recent meta-analysis of the rates of ED after local treatments offers some data for comparison [18]. It reports the predicted probability of maintaining erectile functioning 1 year after various treatments as follows: (i) brachytherapy, 84%; (ii) RT, 67%; (iii) RP, 38%; and (iv) cryotherapy, 14%. In our study, 11.8% (4/34) of the patients had a recovery from ED and an additional 14.7% (5/34) were able to achieve erection with assistance of oral PDE5 inhibitor, bringing the overall total to 26.5% (9/34). We expect improvements on reevaluation after adjuvant ADT is completed. Also, in the present study, despite the fact that post treatment ED was as high as 84% and that sexual function related symptom scores were significantly higher after treatment, this did not affect the overall QoL. This might be attributed to the fact that the patient group in this study were relatively old and most patients had already had ED (82.5%) before treatment. The possibility of ED had also been expressed thoroughly before treatment.

Treatment-related symptom scales were also significantly increased with reports of hot flushes, gynecomastia and weight gain. These are thought to be side effects of ADT.

Litwin *et al.* [19] reported that patients with localized disease who were undergoing RP tend to have more sexual and urinary dysfunction than men undergoing RT, although both groups have more impairment in these areas than age-matched controls. Men undergoing RT have worse bowel function and more urinary distress from irritative voiding symptoms than men undergoing RP or age-matched controls. Pilepich *et al.* [20] also reported that in most instances of RT-related morbidity, the symptoms were recorded during the first several months to 1 year following completion of treatment, but late occurrences were not uncommon in certain types of RT-produced injuries, such as proctitis, hematuria and urethral strictures. In patients who develop symptoms of proctitis the probability of persistence of symptoms beyond the second year following occurrence has been estimated at 20–30%. In our study, there were no major complications such as urinary incontinence, rectourethral fistula and urethral sloughing. The scores of irritative voiding symptoms increased significantly, but did not influence the overall QoL. Also, there were few complaints related to bowel symptoms.

Han *et al.* [5] reported a multicenter experience of treatment of organ confined PCa with third generation cryosurgery. In their research, a total of 175 patients underwent third generation cryosurgery with at least 12 months of follow up and 81% of patients achieved a PSA nadir of 0.4 ng/mL or less at 3 months of follow-up, whereas 75% remained free from biochemical recurrence at 12 months with minimal morbidity. Most recently, Prepelica *et al.* [6] reported the efficacy of CSAP in patients with high-risk features. In their report, high-risk parameters were defined as either a PSA ≥ 10 ng/mL, or a Gleason score ≥ 8, or both. They reported that 83.3% of patients were free of biochemical recurrence after a median follow-up of 35 months (range, 4–77 months) using the American Society for Therapeutic Radiology and Oncology (ASTRO) definition of biochemical failure (3 consecutive increases in PSA level) and, overall, 87.3% of patients had a PSA nadir < 4.0 ng/mL. In their article, a 6-year Kaplan–Meier analysis revealed an 81.7% ASTRO survival probability. Our report on QoL is segregated from the biochemical assessment of TCSAP with ADT, which

is still ongoing. Our preliminary biochemical outcome showed that an overall 97.1% of patients were free of biochemical recurrence when the definition of PSA nadir was less than 0.4 ng/mL, with a mean of 15.38 months of postoperative follow-up (range 6–24 months). However, ultimate efficacy and durability of TCSAP with ADT could not be assessed as our study is limited with a short follow-up period after treatment and lack of a large scale randomized study comparing TCSAP+ADT with TCSAP alone.

In conclusion, TCSAP with ADT appears to have low morbidity and is minimally invasive with high QoL, excepting sexual dysfunction. Long-term follow-up of PSA data and survival are necessary before any conclusions can be made about the efficacy of this promising new therapeutic modality in the treatment of PCa.

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