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GENERAL UROLOGY
Original Article

Outcome analysis of transurethral resection versus potassium titanyl phosphate-photo selective vaporization of the prostate for the treatment of benign prostatic hyperplasia; a randomized controlled trial with 4 years follow up

Benign prostat hiperplazisinin tedavisinde transüretral rezeksiyona karşın potasyum titanil fosfat ile prostatın selektif vaporizasyonunun sonuç analizi; 4 yıllık izlem süreli randomize kontrollü bir çalışma

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ABSTRACT

Objective: Photovaporization of prostate (PVP) is a newer surgical modality of benign prostatic hyperplasia (BPH) which is gaining importance recently. There are a few randomized controlled trials that showed safety and efficacy of PVP in comparison with transurethral resection of prostate (TURP) with limited follow- up period (<2 years). Here, we are presenting a comparative study performed on potassium titanyl phosphate (KTP) PVP laser versus TURP for the treatment of BPH with long- term follow-up period.

Material and methods: After institutional ethical clearance, 150 patients were prospectively included in the study from January 2010 to March, 2012. Improvement of International prostate symptoms score (IPSS), Qmax, post- void residual (PVR) urine, International index of erectile function (IIEF)-5 score and complications were assessed at 12, 24, 36 and 48 months.

Results: Mean age of the study group was 65.3±7.86 years in the TURP and 63.6±8.12 years in the PVP groups (p=0.45). IPSS symptom score improved significantly in both TURP and KTP groups (p<0.003). There was improvement in Q max during follow- up in both groups (p<0.001) which was maintained at 48 months. Most of the patients in both groups were satisfied with symptoms and bothersome at 48 months. All the sexual parameters are similar to both groups except retrograde ejaculation. Overall complication noted in 23 patients (15.33%).

Conclusion: Both KTP Laser PVP and TURP afford durable relief from symptoms of BPH at 48 months follow- up. Both procedures are safe and associated with minimal complications. Both procedures do not have any detrimental effect on sexual function on long- term follow- up. Quality of life remains high even at 4 years in both groups.

Keywords: Prostate; hyperplasia; potassium titanyl phosphate; photovaporization; transurethral resection.

ÖZ

Amaç: Prostatın fotovaporizasyonu (PVP) benign prostat hiperplazisinde (BPH) son zamanlarda önem kazanmakta olan yeni bir cerrahi yöntemdir. Transüretral prostat rezeksiyonuna kıyasla PVP'nin etkinliğini gösteren kısıtlı izlem süreli (<2 yıl) az sayıda randomize kontrollü çalışma mevcuttur. Bu çalışmada BPH tedavisinde potasyum titanil fosfat (KTP) ve TURP'un uzun izlem süreli karşılaştırmasını içeren bir çalışma sunduk.

Gereç ve yöntemler: Kurumun etik kurulundan onay aldıktan sonra, Ocak 2010 ile Mart 2012 tarihleri arasında 150 hasta prospektif olarak çalışmaya dahil edildi. Uluslararası Prostat Semptom Skoru (IPSS), Qmax ve Uluslararası Erektil Fonksiyon-5 (IIEF-5) skorunda iyileşme, işeme sonrası rezidüel idrarda (PVR) azalma 12., 24., 36. ve 48. aylarda değerlendirildi.

Bulgular: Çalışma grubunda yaş ortalamaları TURP ve PVP gruplarında sırasıyla 65,3±7,86 yıl ve 63,6±8,12 yıl idi (p=0,45). Hem TURP, hem de KTP gruplarında IPSS semptom skorları anlamlı derecede düzelmişti (p<0,003). Her iki grupta izlem sırasında Qmax'ta iyileşme gözlenmiş ve 48. ayda da devam etmiştir (p<0,001). Her iki gruptaki hastaların çoğu 48. aylarda semptomlarının azalmasından memnundu. Retrograt ejakülasyon dışında tüm seksüel parametreler her iki grupta benzerdi. Toplamda 23 hastada (%15,33) komplikasyon gözlendi.

Sonuç: Kırk sekiz aylık izlemde hem KTP Lazer PVP hem de TURP BPH semptomlarında kalıcı bir düzelme sağlamaktadır. Her iki işlem güvenli olup minimal komplikasyonlara sahiptir. Her iki işlem uzun süreli izlemde cinsel işlevler üzerine olumsuz etki göstermemiştir. Her iki grupta yaşam kalitesi 4. yılda bile yüksek düzeyde kalmaktadır.

Anahtar sözcükler: Prostat; hiperplazi; potasyum titanil fosfat; fotovaporizasyon; transüretral rezeksiyon.

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Introduction

Transurethral resection of the prostate (TURP) is the globally dominant method of treatment for obstructive benign prostatic hyperplasia (BPH) and is *de facto* "gold standard" for all other similarly aspiring therapeutic measures.[1-3] Historically, this procedure was the most common active treatment for symptomatic BPH but potential morbidities, desire to shorten catheter dwell time and pressure to reduce length of hospital stay have stimulated the development of alternative procedures. The complications of TURP are not uncommon and occur in about 20% of the cases. [1] To overcome these complications, lots of energy sources are coming into the clinical practice for the treatment of BPH. Photovaporization of prostate (PVP) is one of them. There is a few randomized controlled trials (RCT) that showed safety and efficacy of PVP in comparison to TURP.[2,4,5] However, very scarce number of long- term follow- up studies have been performed on potassium titanyl phosphate photovaporization of prostate (KTP–PVP) versus TURP.[4-5] Here we are conducting a long term follow- up study of KTP-PVP laser versus TURP for the treatment of BPH.

Material and methods

One hundred and fifty consecutive patients have been prospectively included in the study from January 2010 to March, 2012. This study was approved by our instituitional ethical committee. All patients underwent either KTP PVP (n=57) or TURP (n=60). Patients with the following criteria have been included in our study: BPH leading to refractory urinary retention, recurrent urinary tract infections, lower urinary tracts symptoms (LUTS) refractory to medical treatment, renal insufficiency, bladder stones and recurrent hematuria. The International Prostate Symptoms Score (IPSS) and Q max were not available in patients (11 in TURP and 8 in KTP groups) who initially presented with urinary retention. According to American Urological Association (AUA) guidelines, BPH symptom score have been divided into three groups, ie mild (1-7), moderate (8-19) and severe (20-35). IPSS scoring system includes AUA symptom, and Quality of life scores. For patients who were sexually active, International Index of Erectile Function (IIEF) scores have been estimated and compared. IIEF is an internationally validated and self -administered scoring system that assesses overall sexual function. It is divided into five domains (i.e. intercourse satisfaction, orgasmic function, sexual desire and overall satisfaction). Total IIEF score has been calculated both in the pre-, and postoperative periods to assess sexual function. Prostate specific antigen (PSA) was measured before the procedure in all patients. Post-void residual (PVR) urine volume was recorded using abdominal ultrasound scan.

Exclusion criteria

Patients with the following criteria were excluded from the study: history of prostate, bladder, urethral, spinal surgery or spinal trauma, hypocontractile bladder on urodynamic study (UDS), diagnoses of prostate carcinoma, carcinoma of the bladder, urethral stricture and patients who did not give consent for the study.

Randomization

Because of the nature of the study, it was not possible to perform completely blind study. Patients and concerned surgeons were aware of the procedure to be performed (TURP/KTP) as per ethical approval. Computerized software was used to randomize all participants into 2 groups (TURP vs. KTP) which were unknown to the research team.

Patient's work up

Complete hemogram, serum creatinine, uroflowmetry, urodynamic study, transrectal ultrasound (TRUS) of prostate for prostate size, renal and bladder ultrasound, serum prostate- specific antigen (PSA) tests were performed during preoperative period for all eligible patient. Patients with abnormal digital rectal examination (DRE) or raised serum PSA levels were subjected to TRUS- guided prostate biopsy.

Primary endpoint

Differences in the degree of symptomatic improvement as measured by the changes in IPSS QOL (International Prostatic Symptoms Score-Quality of Life) scores and improvement in urinary flow parameters measured by uroflowmetry study at follow- up.

Secondary endpoint

Duration of operative time, and catheterization, improvement in sexual functions as measured by the changes in IIEF-5 scores, and complications.

Sample size

The sample size was estimated assuming type one error of 0.05 and a type two error of 20% to detect a difference in IPSS score of 3 points and dropout rate of 25% during the follow- up period. Minimum sample size of about 50 patients was needed in each group to detect statistically significant difference.

Surgical technique

All procedures were performed by experienced urologists under spinal anaesthesia. TURP was performed in the standard manner using Karl Storz 30 degree lens and 26 F continuous irrigation resectoscope sheaths. All TURP procedure was done using monopolar cautery and tungsten cutting wire loop at a setting of 160 W current for cutting and 80 W current for coagulation. A 0.5% glycine solution was used as the irrigating fluid. The resection was carried down to the surgical capsule from bladder neck up to the verumontanum.

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Photovaporization of prostate was carried out using the 120-W AMS Green Light laser High performance system (PVP 120 HPS). For PVP, 23F laser scope with continuous flow was used. A 30-degree lens and as an irrigant 0.9% sodium chloride were used. A 600- micron fiber, and 70 degree side firing laser fibre emitting green light at 532 nm were employed. At first the median lobe (if present) and then the lateral lobes were lased in a symmetrical manner. Tissue was vaporized down to the prostatic capsule until an unobstructed view of the trigone and a TURP like cavity was obtained. Vaporization was achieved by moving the laser fibre slowly and constantly in a "paint brush fashion" taking care to keep the fibre in "near contact" with the prostatic tissue. If any bleeding vessels were encountered during vaporization, coagulation was accomplished by defocusing the laser fibre (increasing working distance to 3-4 mm) or by reducing the power setting.

Operative time (calculated as time the resectoscope remained in the urethra), and intra- operative complications (if any) were recorded. In both groups patients were catheterized with a 22 Fr 3-way Foley catheter and the bladder was irrigated with normal saline till the effluent was clear on minimal irrigation so as to prevent clot formation. Foley catheter was removed once the effluent was clear on minimal bladder irrigation. Patients were discharged from the hospital after a successful voiding trial. Postoperative catheterization time and complications were recorded.

Follow-up

Functional results in terms of improvement of IPSS, Qmax, PVR (post- void residual urine) IIEF-5 score and complications were assessed at 12, 24, 36 and 48 months.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences 16.0 statistical software package (SPSS Inc.; Chicago, IL, USA). A p value of <0.05 was considered statistically significant. Student t test, X^2, and Fisher exact tests were used as appropriate.

Results

Out of 156 eligible patients, 150 included in the randomization process (6 patients did not give consent). Thirteen patients were lost to follow up (8 in TURP vs. 5 in KTP). Six patients died due to causes unrelated to prostatic surgery (2 in TURP vs. 4 in KTP groups). Fourteen patients required surgical intervention (8 in TURP vs. 6 in KTP groups) during the follow- up period. These 14 patients are considered as treatment failures. So 117 patients underwent final analysis with long- term follow- up data. Mean prostate volume was 69.6±16.3 cc in TURP and 70.3±15.5 cc in KTP groups, respectively. Minimum follow- up period was 48 months. Baseline demographic and clinical parameters are re-

Table 1. Baseline characteristics of the study population

Parameter	TURP group (n=57)	KTP group (n=60)	p
Age (Years)			
Mean±SD	65.3±7.86	63.6±8.12	
Range	(52-81)	(53-76)	0.45
Duration of symptoms before surgical intervention, (month)			
Mean±SD	19.2±3.2	18.7±3.4	
Range	(7-25)	(5-23)	0.44
IPSS score	(n=46)	(n=52)	
Mean±SD	25.9±5.2	26.1±4.8	
Range	20-30	19-31	0.28
IIEF	(n=33)	(n=38)	
Mean±SD	17.5±2.3	17.2±2.4	
Range	(17-18)	(18-25)	0.34
Q max (mL/sec)	(n=46)	(n=52)	
Mean±SD	8.3±2.4	8.5±2.7	
Range	(4.2-10.9)	(6.2-11.2)	0.43
PVRU, (mL)			
Mean±SD	213±23	238±31	
Range	(134-432)	(120-524)	0.57
Prostate volume, (cc)			
Mean±SD	69.6±16.3	70.3±15.5	
Range	(47-84)	(46-87)	0.56
Serum PSA (ng/mL)			
Mean±SD	4.24±3.3	4.78±3.8	
Range	0.45-28	0.24-31	0.44
QOL			
Mean±SD	4.3±1.3	4.4±1.2	
Range	3-6	3-6	0.32

TURP: Transurethral Resection of Prostate; KTP: potassium titanyl phosphate; SD: standard deviation; IPSS: International Prostate Symptom Score; IIEF: International Index of Erectile Dysfunction; PVRU: Post- Void Residual Urine Volume; PSA: Prostate- Specific Antigen; QOL: Quality of Life

Table 2. Intraoperative and postoperative characteristics

Parameters	TURP (n=57)	KTP (n=60)	p
Operative time, min (intraurethral resectoscope/ laser scope time)			
Mean ± SD	42.3±13.6	45.2±12.5	
Range	(27-63)	(32-68)	0.67
Duration of catheterization, hr			
Mean±SD	64.4±11.4	34±4.5	
Range	(60-72)	(24-36)	0.01
Postop Complications Early			
Blood transfusion	3	1	0.31
AUR	1	2	0.52
Hematuria	5	3	0.23
UTI	2	1	0.52
Late			
Urethral strictures	2	2	0.14
Bladder neck stenoses	2	1	0.77
Prostatic regrowth	4	3	0.33

SD: standard deviation; TURP: Transurethral Resection of Prostate; KTP: potassium titanyl phostate; AUR: Acute Urinary Retention; UTI: Urinary Tract Infection

corded in Table 1 without any statistically significant intergroup difference.

Mean age of the study group was 65.3±7.86 years in TURP and 63.6±8.12 years in PVP groups (p<0.003). Intraoperative and postoperative characteristics are depicted in Table 2. The mean operative time was shorter for TURP (42.3±13.6 min vs. 45.2±12.5 min) without any statistical significance (p=0.67). There was significant difference in duration of postoperative catheterization, irrigation and postoperative hospital stay between TURP and KTP PVP groups (p=0.01, p=0.03 and 0.01 respectively).

Postoperative outcomes are depicted in Table 3. There was a significant improvement in Q max values estimated during the follow- up period of both groups (p<0.001) relative to the preoperative values. The improvement in the Qmax was still maintained at 48 months. There was a significant reduction in

Table 3. Follow- up parameters

Parameter (Mean±SD)	TURP (n=57)	KTP (n=60)	p
	12 month		
Q max, mL	22.71±4.72	23.25±4.21	0.51
PVRU, mL	12.87±5.8	11.12±4.5	0.34
IPSS	10.5±2.5	13.87±3.1	0.13
IIEF	16.5±2.1	16.2±2.5	0.33
QOL	0.3±0.6	0.3±0.7	0.32
PSA. ng/ml	2.34±1.8	2.41±1.6	0.31
	24 months		
Q max, mL	20.8±3.56	21.6±3.67	0.43
PVRU, mL	13.34±4.6	14.27±3.8	0.27
IPSS	8.2±4.3	9.35±4.2	0.16
IIEF	16.4±1.6	16.5±2.3	0.44
QOL	0.5±0.4	0.4±0.3	0.36
PSA, ng/mL	2.33±2.1	2.4±1.88	0.29
	36 months		
Q max, mL	20.3±3.65	20.6±4.6	0.45
PVRU, mL	12.15±7.5	9.1±5.8	0.31
IPSS	7.1±4.3	6.4±5.1	0.21
IIEF	17.6±1.7	17.3±2.2	0.35
QOL	0.7±0.5	0.7±0.4	0.36
PSA, ng/mL	2.28±2.2	2.31±2.4	0.34
	48 months		
Q max, mL	19.18±5.2	18.19±4.7	0.35
PVRU, mL	17.15±6.8	12.6±7.2	0.27
IPSS	7.75±4.8	7.37±5.4	0.19
IIEF	16.28±1.8	17.0±1.6	0.32
QOL	0.2±0.4	0.3±0.4	0.41
PSA, ng/mL	2.32±1.78	2.27±2.13	0.31

PVRU: post- void residual volume; IPSS: International Prostate Symptom Score; IIEF: International Index of Erectile Dysfunction; QOL: Quality Of Life; PSA: Prostate Specific Antigen; TURP: Transurethral Resection of Prostate; KTP: potassium titanyl prostate; SD: standard deviation

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PVR (p<0.001) in both groups. IPSS symptom score improved significantly after surgery in both TURP and KTP groups compared to preoperative levels (25.9 vs. 10.5 and 16.1 vs. 13.87 respectively, p value <0.003). Out of 117 (TURP, n=57 vs. KTP, n=45) patients, 87 patients filled the preoperative IIEF-5 questionnaire forms. Among them, 71 (81.60%) patients (TURP, n=33 vs. KTP, n=38) were sexually active. There was no difference in IIEF scores between the groups. Retrograde ejaculation was noted in 23 (70%) in TURP and 11 (29.3%) in KTP groups.

Long-term complications include urethral strictures in 4 (TURP, n=2 vs. KTP, n=2) and bladder neck stenoses in 3 patients (TURP, n=2 vs. KTP, n=1). Strictures were managed with direct visual internal urethrotomy (DVIU) in 2 patients and endoscopic dilation in 1 patient. Bladder neck stenoses were managed with bladder neck incision (BNI). Symptomatic residual adenoma occurred in 7 patients (4 in TURP, n=4 vs. KTP, n=3) who required re- intervention and finally they were excluded from the analysis.

Discussion

A battery of modalities has been approved by United States Food and Drug Administration (US FDA) for the treatment of BPH. Despite a large number of alternative procedures are available, TURP remains the most effective surgical technique with good short- and long-term functional results. Although there have been technical improvements and a dramatic decrease of mortality and morbidity during recent decades, TURP always has been associated with a significant perioperative morbidity.[5] Factors like TUR-syndrome, hematuria, need for blood transfusion and longer hospital stay make investigators search for other prostatectomy alternatives.

Potassium titanyl phosphate laser has substantially more collimated beam with a potential to induce efficient tissue vaporization.[6] It has comparable efficacy and safety for short- term follow up less than 2 years but the long- term efficacy has not been compared with TURP.[5,7] In present study we attempt to compare the long term outcomes of American Medical System (AMS) Green Light HPS system with monopolar TURP in terms of long term safety and efficacy.

Urinary flow rates were similar in both groups except within the first 3 months postoperatively. The possible reason for increase in storage symptoms in KTP-PVP may be the exposure of remnant prostatic tissue to thermal injury which sloughs out postoperatively. This supports the previous study of Al-Anasri et al.[2] who had reported higher storage symptoms in the PVP group during the early postoperative period while some other studies did not find any difference in storage symptoms in the early postoperative period.[5,8] The average reduction in IPSS scores was 50-70% at 1-4 years compared to preoperative values. The improvement of lower urinary tract symptoms was consistent throughout the follow up period. At 4 years follow- up most of the patients were satisfied with their urinary flow rates.

The mean Q max was significantly higher in both groups compared to preoperative values. The average improvement in flow rate was 100-130% in both groups. There was no statistically significant difference between the two groups at baseline and 48 months follow- up which demonstrates that both procedures are very effective in improving the urinary flow rate in the long term. Thangasamy et al.[9] reported a meta-analysis comparing TURP versus KTP-PVP for the treatment of BPH. They have included nine trials with 889 patients who underwent TURP versus KTP-PVP (80 W in 5 trials and 120 W in 4 trials) from 2002 to 2012. In this analysis, they found shorter catheterization and hospital stay for PVP group and 19 minutes shorter operative time in the TURP group. Six trials found no difference in functional outcomes, while two trials favoured TURP and one trial PVP. Thangasamy et al.[9] concluded that there was no difference in functional outcomes between the KTP-PVP and TURP groups.

QOL score was paralleled the improvement in IPSS symptom scores. Most of the patients in both groups were satisfied with amelioration in symptoms and bothersome LUTS. The average improvement in QOL scores was 45-50% at 4 years. The improvement in QOL scores was not only significant but also consistent over follow -up period in both KTP and TURP groups.

Mishriki et al.[10] reported that TURP improved patients' QOL and bothersome LUTS symptoms over 12 years of follow-up which were associated with high patient satisfaction. Carter et al.[11] reported changes in QOL scores after KTP/Nd:YAG laser treatment of the prostate versus TURP in 204 patients. In this randomized trial, they found improvement in IPSS scores, and disease- specific BPH index was higher in TURP group at 6 weeks although there was no difference between the groups 6 months and one year later.

Sexual function was assessed with IIEF-5 score in those who were not catheterized and performing regular sexual activity before surgery. Sexual function score was not statistically significant in both groups compared to preoperative levels. Comparing with preoperative data there was not much change at 4 years of the follow-up period in none of the group. About 17% of the patients had deteriorated, 26% improved and 57% stable parametres of sexual function at 4 years of the follow- up period. All sexual parameters were comparable in both groups before and after surgery except retrograde ejaculation. Bouchier-Hayes et al.[4] performed a randomized comparative trial of PVP-KTP (80-W) laser ablation of the prostate and TURP in 120 patients.

Both groups were age-matched comparable but prostate volume was slightly higher in KTP-PVP group. They did not find any difference in sexual function (measured by Baseline Sexual Function Questionnaires) between the groups at one year follow-up.[4]

Retrograde ejaculation still remained to be a problem at 4 years of the follow-up period in 36%, and 15% of the patients in TURP, and KTP, respectively. Previous reports have shown that TURP may result in retrograde ejaculation in 70-100%, of the patients.[12] On the other hand KTP laser vaporization of prostate may lead to development of retrograde ejaculation in 15-26% of the patients.[7,13] KTP may be preferable to those who want to preserve their sexual function especially in younger population.

The durability of improvement in PVP group is not time-tested. Limited follow- up data are available in few of the randomized trials. In a study by Ruszat et al.[14] with 3 years of follow- up (with 80 watt KTP PVP) the researchers had detected reoperation rate (6.8%), urethral and bladder neck strictures (3.6% vs. 4.4%) in indicated percent of patients. Though it was not a randomized trial and did not use KTP 120 HPS, this is the only study of KTP PVP versus TURP with the longest follow-up. On the other hand TURP had 6-10% reoperation rate which is similar to our results.[15]

Percent reduction or change of serum PSA is a surrogate measure of the amount of tissue resected. Bouchier-Hayes et al.[4] reported decrease of serum PSA level after both TURP and KTP at 1 year follow- up. However, this decrease was not statistically significant in the KTP group. Our study shows 40-52% reduction of serum PSA which was maintained at 4 years in most of the patients. The reduction ijn serum PSA in the present study was similar for both groups. Few patients had raised serum PSA level. The increase in PSA and abnormal DRE lead to diagnosis of prostate carcinoma in 7 cases (3 in TURP vs. 4 in KTP). They were managed individually either with radical prostatectomy (5 patients) or hormonal therapy (2 patients).

Urethral stricture following instrumentation is a real concern nowadays. Stricture following TURP or KTP is mostly iatrogenic secondary to instrumentation, surgical technique and postoperative catheterization. The stricture rate was comparable between TURP and KTP arm. All patients were managed with DVIU. Bladder neck contracture is another long term complications of transurethral prostatic surgery. It has been reported in 2-10% in some studies.[13,16] Three patients (2.56%) developed neck contracture in our study. These were managed with bladder neck incision with good success rate. In our study 5.8% of (n=7) patients required re- intervention for residual adenoma over 4 years of follow- up. Rate of re-surgery were similar for both TURP and KTP. The patients who developed stricture had been found to have relatively larger prostate gland and longer operative times than rest of the patients (average prostate size-68.25 cc, operation time more than 59.2 min).

Large- sized prostate is better treated by holmium laser or open prostatectomy than TURP.[17] KTP laser is also not ideal for large-sized prostates but very promising for small- and medium- sized prostates.[14] This study showed that KTP PVP laser is a viable alternative of TURP for small to medium- sized prostates. The outcomes were maintained at 4 years follow up. The drawback of KTP PVP is non- availability of prostate tissue for histopathological examination which is not a problem with TURP.

In conclusion, both KTP Laser PVP and TURP afford durable relief from symptoms of BPH at 4 years of follow- up. Both procedures are safe and associated with minimal complications. KTP Laser PVP is associated with shorter duration of postoperative irrigation, shorter length of catheterisation and postoperative hospital stay. Both procedures do not have any detrimental effect on sexual function in previously sexually active men at 48 months of follow- up. Quality of life remains at a high level even at 4 years in both groups.

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