Open Prostatectomy Versus Transurethral Resection of the Prostate, Where Are We Standing in the New Era?

A Randomized Controlled Trial

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Purpose: To compare peri-operative and short-term complications of open transvesical prostatectomy (OP) as well as its functional outcomes with transurethral resection of the prostate (TURP) in management of benign prostatic hyperplasia with prostates sized 30 to 70 g.

Materials and Methods: Hundred patients who were candidate for the prostate surgery with prostates between 30 to 70 g randomly underwent OP or TURP. Secondary endpoints included international prostate symptom score, residual urine volume, surgical complications, and patients' quality of life. Patients were followed up for 6 to 12 months after the operation.

Results: Fifty-one and 49 patients underwent OP and TURP, respectively. Median (interquartile range) of peak flow rate improvement was 11.1 (7.6 to 14.2) and 8.0 (2.2 to 12.6) in OP and TURP groups, respectively ($P = .02$). International prostate symptom score improvement did not reveal statistically significant difference between treatment groups. Re-operation due to residual prostate lobe, urethral stricture, and urinary retention was performed in 8 patients in TURP group versus no patient in OP group ($P = .006$). Dysuria was more frequent in patients that underwent TURP ($P < .001$). Hospitalization duration was slightly longer in patients that underwent OP ($P = .04$). Patients' quality of life was better in the OP group ($P = .04$).

Conclusion: Open transvesical prostatectomy is an acceptable operation for the prostates sized 30 to 70 g. Higher peak flow rate improvement, better quality of life, less frequent dysuria, less need to re-operation, and its ease of learning make open prostatectomy a suitable option to be discussed in patients parallel to TURP.

Keywords: open prostatectomy, transurethral resection of prostate, lower urinary tract symptoms, randomized controlled trial

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INTRODUCTION

Open transvesical prostatectomy (OP) and transurethral resection of the prostate (TURP) are two old surgical procedures performed for patients with benign prostatic hyperplasia (BPH). Currently, TURP is considered as the reference or standard treatment for the prostate less than 70 to 80 g.[1-3] Nevertheless, OP is still being performed for operations of the prostates that are candidate for TURP in many developing and even developed countries, as the percent of OP in the late 1990's and early 2000 in Sweden,[4] France,[5] Italy,[6] and the Mediterranean

coasts[7] ranged from 14% to 40%.

In the 21st century, with advances in surgical methods and anesthesia, the complications of OP have decreased relative to the reports of the old times. Besides, patients are satisfied with OP regarding its functional outcome and durability. Open transvesical prostatectomy is not currently recommended for moderate-sized prostates while, as mentioned above, a large percent of such operations are performed through the open approach. Some authors considered comparing OP with newer methods unethical[8] while there has not been good quality evidence for the comparison of OP with TURP.[3,9] We aimed to compare the peri-operative and short-term complications of OP as well as its functional outcomes with TURP that is considered as the standard treatment for 30 to 80 g prostates and based this comparison with objective measurements like peak flow rate (PFR).

MATERIALS AND METHODS

Hundred patients who had referred to urology outpatient clinic of Shahid Labbafinejad Medical Center (a tertiary referral hospital in Tehran, Iran) between 2005 and 2007, and were candidates for the prostate surgery were enrolled in this study.

Indications for the prostate surgery included lower urinary tract symptoms despite maximal medical therapy, frequent urinary tract infections, hematuria unresponsive to medical therapy, high serum creatinine that decreased with urethral catheter placement, and urinary retention despite medical therapy.

Taking the history and physical examination, including digital rectal examination, were performed by a urologist. Laboratory evaluations included serum level of creatinine, serum level of prostate-specific antigen (PSA), urine analysis, and urine culture. Ultrasonography of the kidneys, the bladder, and the prostate were also performed. Thereafter, patients were referred to the operating room for cystoscopy and transrectal ultrasonography of the prostate to assess the prostate size.

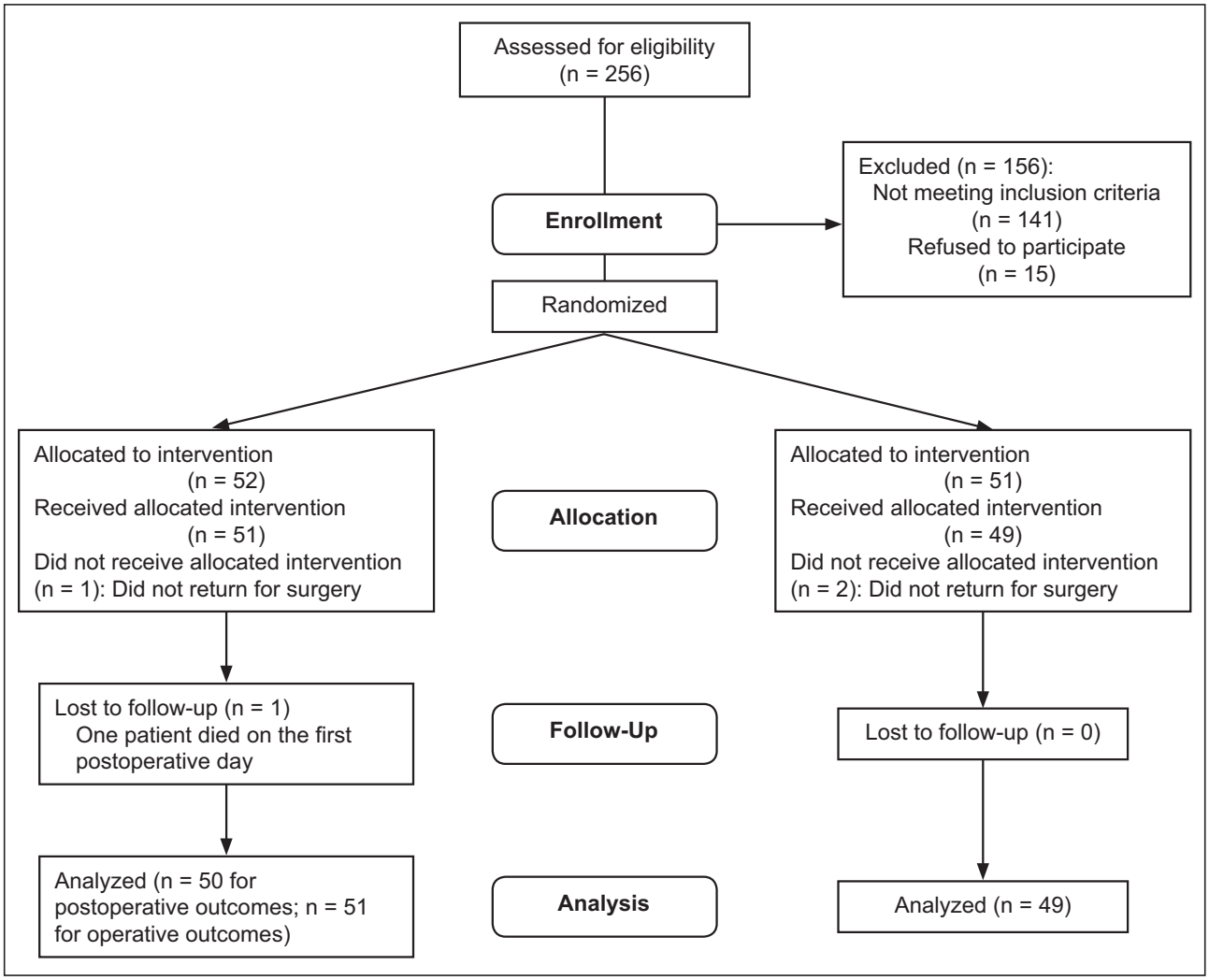
Patients with high serum level of PSA underwent transrectal ultrasound guided biopsy of the prostate (5 cores from each lobe). If the prostate size in transrectal ultrasonography was within the 30 to 70 g and the posterior urethra revealed obstructive pattern in cystoscopy, patients were assigned to treatment groups based on the allocation protocol. The random allocation protocol was based on randomly produced numbers stratified on the surgical American Society of Anesthesiology (ASA) risk score. Random numbers were produced by Epi Info software and were used to allocate subjects in each of the ASA risk scores (I to III) separately.

Patients with a bladder stone larger than 2 cm, large bladder diverticula, previous urethral surgery, suspicious mass in digital rectal examination, history of the prostate operation, the prostate size outside the range of 30 to 70 g in transrectal ultrasonography, and those with pathology report other than BPH in transrectal prostate biopsy were excluded from the study. Finally, 100 patients remained for the analysis (Figure).

Open transvesical prostatectomy was performed as described by Freyer[10] by two senior urology residents supervised by attending urologists. Transurethral resection of the prostate was carried out with 25 F Wolf resectoscopes by two surgeons with more than 10 years of experience. The obvious different nature of surgeries (OP versus TURP) made blinding impossible both for the surgeon and the patients.

Data were collected during the operation, postoperative hospitalization, and when patients referred to the clinic at 8 to 12 months postoperatively. In the clinic visit, complications after discharge from the hospital, including dysuria, episodes of cystitis, epididymitis, retrograde ejaculation, and re-operation as well as international prostate symptom score (IPSS) and patients' quality of life were recorded and their PFR was measured.

The patients' quality of life was assessed by a single question as suggested by Batista-Miranda and colleagues.[11] The primary endpoint of interest was improvement in patients



Flow diagram of patients.

postoperative PFR compared to their pre-operative values (postop PFR– preop PFR). Secondary endpoints were IPSS improvement (preop IPSS – postop IPSS), residual urine volume reduction, re-operation, dysuria, episodes of cystitis, epididimytis, retrograde ejaculation, incontinence, and patients' quality of life at 8 to 12 months after the operation.[11-14]

The objective of this study was to show at least 2.5 mL/s improvement in PFR in patients who underwent OP compared with subjects that underwent TURP. Considering a power of 0.9, 0.05 type I error and 3.7 mL/s standard deviation for PFR,[14] 46 samples were needed for each treatment group. To compensate for a presumed 10% loss to follow-up, 102 total samples were needed.

This study was approved by the Ethics Committee of Urology and Nephrology Research Center, which has adopted codes of ethics to guide human experimentations. All the patients were informed about the study objectives and interventions. A written informed consent was obtained from each patient.

Statistical analysis was done by SPSS software (Statistical Package for the Social Science, version 16.0, Chicago, Illinois, USA). Categorical variables were analyzed by Chi-square or Fisher exact test as appropriate. Quantitative variables were analyzed by *t* test or Mann-Whitney test. Intention to treat analysis was considered for all analyses. No subgroup analysis was planned. Two-sided *P* values less than .05 were considered statistically significant.

RESULTS

The flow chart of patients has been outlined in Figure. Fifty-one and 49 patients underwent OP and TURP, respectively. Patients' demographic characteristics before the operation are presented in Table 1. The only statistically significant difference in pre-operative variables was for age with a mean difference of 10 years between OP and TURP groups. American Society of Anesthesiology risk score categories 1, 2, and 3 were observed in 4, 31, and 16 patients in the OP group versus 3, 29, and 17 patients in the TURP group ($P > .05$).

Peri-operative and late postoperative data are presented in Table 2. Early postoperative complications (during hospitalization) were observed in 4 patients in OP group (urinary leak after suprapubic catheter removal in 3 patients and gastrointestinal bleeding in 1 patient) and in 3 patients in TURP group (gross hematuria with clot passage in 2 patients and 1 case of suprapubic catheter insertion because of urinary retention after urethral catheter removal and failure to insert another urethral catheter). No episodes of transurethral resection syndrome and no documented thromboembolic events were observed.

One patient in OP group died the day after the operation. He was a 73-year-old man, who was candidate for surgery because of medical therapy failure. He had history of palpitations and his ASA risk score was III (high). His pre-operative electrocardiogram revealed poor R progression. Operation duration was 55 minutes and he received one unit packed cell intra-operatively. Pre-operative and postoperative serum level of hemoglobin was 13.1 and 12.1 mg/dL, respectively. Postoperative creatinine level was 1.2 mg/dL. His postoperative pulse rate and blood pressure were within the normal limits. Bladder irrigation output was light bloody washing serum and discontinued on the first postoperative day (16 hours after the surgery). He complained of heart burn on the first postoperative day and received ranitidine tablets. He fainted on his way to the toilet and had cardiac arrest, which did not respond to cardiopulmonary resuscitation. The patient's family did not agree with an autopsy to reveal the cause of death.

During 8 to 12-month follow-up, re-operation was performed in 8 patients in TURP group as follows: 4 patients underwent repeated TURP, 2 patients were operated for urethral/bladder neck stricture, and suprapubic catheter was inserted in 2 patients because of urinary retention and failure to pass a urethral catheter. No re-operation was performed for OP patients. Urge incontinence was observed in 2 patients in each group. In the OP group, incontinent patients recovered 3 and 6 months after the operation. In the TURP group, one patient recovered 6 months after the

Table 1. Patients' characteristics in OP and TURP groups before the operation.

Variable*	OP patients (N = 51)	TURP patients (N = 49)	*P*
Age, years	71.7 ± 7.3	61.0 ± 8.0	< .001
Body mass index	24.6 ± 3.3	24.4 ± 3.2	NS
Prostate size in TRUS, g	47.9 ± 12.2	44.4 ± 8.9	NS
IPSS	27.1 ± 7.1	27.1 ± 7.7	NS
Peak flow rate, mL/s	7.0 (0 to 9.4)	8.1 (2.8 to 10.4)	NS
Prostate-specific antigen, mg/dL	2.6 ± 1.0	2.3 ± 1.0	NS
Urinary incontinence	19 (37)	17 (35)	NS
Surgery indication			NS
Medical therapy failure	31 (61)	34 (69)	
Retention	18 (35)	12 (24)	
Frequent UTI	1 (2)	0 (0)	
Hematuria	0 (0)	1 (2)	
Creatinine rise	0 (0)	3 (6)	
Residual urine volume, mL	62 (25 to 110)	47 (19 to 93)	NS

OP indicates open transvesical prostatectomy; TURP, transurethral resection of the prostate; TRUS, transrectal ultrasonography; IPSS, international prostate symptom score; and UTI, urinary tract infection.
*Data are presented as N(%), mean ± SD, or median (interquartile range).

Table 2. Comparing operative and postoperative variables in OP and TURP patients.

Variable	OP patients (N = 50)*	TURP patients (N = 49)	*P*
Anesthesia: Spinal/General	50/1*	49/0	NS
Opioid administration, mg	7.2 ± 9.2†	7.9 ± 10.6†	NS
Transfusion	4 (8)	5 (10)	NS
Clot retention	0 (0)	6 (12)	.01
Resected prostate weight, g	34.5 ± 11.6	31.0 ± 15.2	NS
Postoperative fever	3 (6)	5 (10)	NS
Time to catheter removal, days	7 (5 to 10)	5 (3 to 7)	NS
Time to work, days	14 (14 to 30)	14 (9 to 23)	NS
Re-operation	0 (0)	8 (16)	.003
Incontinence	0 (0)	1 (2)	NS
Impotence‡	3 (6)	1 (2)	NS
Cystitis	2 (4)	2 (4)	NS
Epididymitis	4 (8)	6 (12)	NS
Retrograde ejaculation	17 (34)	19 (39)	NS
Dysuria	14 (28)	35 (71)	< .001
IPSS improvement	22.3 ± 7.4	20.4 ± 8.3	NS
PFR improvement, mL/s	11.1 (7.6 to 14.2)	8.0 (2.2 to 12.6)	.02
RUV reduction, mL	60 (25 to 110)	47 (19 to 90)	NS
QOL score at 6 to 12 months	2.3 ± 1.0	2.8 ± 1.4	.04

OP indicates open transvesical prostatectomy; TURP, transurethral resection of the prostate; IPSS, international prostate symptom score; PFR, peak flow rate; QOL, quality of life; and RUV, residual urine volume.
Data are presented as N (%), mean ± SD, or median (interquartile range).
*One patient in the OP group died the day after the surgery; therefore, follow-up is available on 50 patients.
†Opioid administration to control pain after the operation was necessary in 23 patients (45%) in OP group and 27 patients (55%) in TURP group (*P* > .05).
‡New impotence that was observed after the surgery.

operation and the other one complained from urge incontinence 12 months after the operation. He used one pad every day.

Early postoperative complications (clot retention and postoperative fever) and late complications (incontinence, cystitis, epididymitis, retrograde ejaculation, and dysuria) are presented in Table 2. Hospitalization duration was slightly longer in patients that underwent OP (Table 2). Patients' overall quality of life at 8 to 12 months after the operation was better in the OP group compared with the TURP group.

DISCUSSION

Open transvesical prostatectomy is currently regarded as the only procedure that completely relieves prostatic obstruction.[2,9,15] It is usually used for large prostates or when another pathology necessitating open intervention such as multiple bladder stones coexists.[16] Previously, TURP was the most commonly used operation for obstruction relief and accounted for 60% to 97% of the prostate operations.[4-7,17] The use of OP is now mostly confined to less developed countries with little expertise or experience in endoscopy.[18]

Currently, laser vaporization technology and Holmium laser enucleation of the prostate are revolutionary techniques with little morbidity and equivalent success to OP or TURP, and are promising to be the new gold standard treatments of BPH, irrespective of the prostate size.[19-21] But the main drawbacks for laser technology are its high cost and difficult learning curve[20,21] that make it unsuitable. Currently, few centers in the Middle East offer Holmium laser enucleation of the prostate.

Transurethral resection of the prostate has been declared as the reference or standard treatment for the prostates less than 70 to 80 g;[1-3,22] however, it has been clearly stated that TURP has not passed the formal pathways of a new surgical method evaluation[23] and its comparison with OP has been based on retrospective, open, and single center series.[3,23]

Since the indications for TURP and OP are

different, best comparisons are possible only through randomized controlled trials (RCT).[14] To the best of our knowledge, only one RCT has compared OP with TURP,[9,12,13,24,25] which was done in the pre PSA era and included the following limitations: 1) Almost 15% of patients in each group were proved to have malignant pathology. The rate of complications (both early and late) and poor outcomes were substantially higher in patients with a malignant histology. Today, the prostate cancer that is screened by PSA measurement is a contraindication for OP. 2) Transurethral resection of the prostate was performed by experienced urologists while OP was done by 8 registrars and 3 urologists. 3) The rate of some reported complications were totally different from later reports. For example, urethral stricture was reported higher in OP patients while many later studies reported higher stenosis/stricture in TURP patients.[3,26,27] 4) The attrition rate in 5-year follow-up was high, which was unequally distributed between treatment groups (25.6% for TURP patients and 6.3% for OP patients).

A later report by Jenkins and colleagues considered any clinical trials comparing OP versus TURP unethical.[8] Their argument was based on the reported higher mortality rate of OP (around 10%)[28,29] versus TURP (less than 3%) in older patients, especially those over the age of 80 years. However, recent large series reported no difference in mortality or myocardial infarction between OP and TURP.[26,30-32] Mortality rate for OP in the most recent series is less than 1%.[14,26] Therefore, we think that recruiting patients for the prostate surgery in a clinical trial for comparing OP versus TURP is *no longer unethical* and such comparison has been done recently for OP and laser[33] or photoselective enucleation.[34]

We think that although OP is associated with more morbidity[9,14] regarding scar line and more hospitalization stay, but it results in better IPSS, PFR improvement,[2,9,15] less re-operation rate,[3,14,26,35] and less dysuria.[9,12,24] Postoperative dysuria is bothersome and refractory to treatment.[12]

In this study, patients in OP and TURP groups were comparable at baseline except for age. Age was associated neither with primary nor with secondary outcomes evaluated in this study. Nevertheless, we cannot exclude the possibility that difference in age might affect the observed differences of this study. The average PFR improvement in patients that underwent OP was 3.1 m/s higher than TURP group ($P = .02$). Restricting Meyhoff and associates' study results to patients with benign histology, both PFR and mean urinary flow rates were also higher in OP group.[13] Other retrospective studies support the higher PFR improvement in patients who underwent OP.[3]

We did not observe statistically significant improvement in IPSS or residual urine volume between the two study groups. Some reports support better IPSS improvement and less residual urine volume in OP operations.[2-3,12,14,24] We observed no statistically significant association between the prostate size and the magnitude of PFR, IPSS, or residual urine improvement in either group.

Immediate postoperative complications in OP group were mostly related to leakage after suprapubic catheter removal (3 subjects) and were managed conservatively by keeping urethral catheter for a longer time. Postoperative complications in patients that underwent TURP were mostly related to bleeding (2 subjects) and clot retention (6 subjects).

Higher re-operation rate has been reported in patients who underwent TURP due to a higher stenosis/stricture rate in this group. Re-operation rates less than 5% have been reported in one-year follow-up.[3,26,30,35,36] In this study, the re-operation rate during one-year follow-up (16%) is higher than Western reports, but a recent Slovakian study reported an immediate (up to 4 weeks after operation) complication rate of 38% and 13% complication rate during one-year follow-up,[37] which is close to our findings.

Another important finding in this study is the higher frequency and duration of dysuria in patients that underwent TURP (the latter was not statistically significant). Dysuria duration was reported higher by Meyhoff and colleagues in patients who underwent TURP, but was not

statistically significant.[24] Higher dysuria and irritative symptoms have been noticed by other investigators in patients undergoing TURP.[9] Persistent irritative symptoms have been reported to be a major problem in operations that leave the heated damaged tissue in situ[9] as these symptoms are more resistant to treatment.[12]

In economic points of view, the costs of OP and TURP were almost the same with less than 0.5% difference.[38] Even in Western countries, where the cost of TURP is higher than OP, it has been suggested that this benefit will be overbalanced five years after the operation, due to higher re-operation rate in TURP patients.[27]

In summary, although OP seems more invasive due to the low midline incision (that is extraperitoneal, without incising any muscles), but on the other hand, the following advantages should also be considered: 1) Open transvesical prostatectomy in this study and also in Meyhoff and associates' study was performed by senior residents while TURP was performed by expert urologists.[25] Nonetheless, the results were better with OP; 2) Extra morbidity associated with OP is not considerable as indicated before;[9] 3) Open transvesical prostatectomy is associated with less re-operation rate bringing forward the suggested issue that "Is a little more morbid operation better or another less invasive operation that needs more re-operation?";[9] 4) Less clot retention and re-bleeding;[25] 5) Specially, better improvement in PFR (which is the main goal in management of patients with BPH) and IPSS; 6) Equivalent short-term and probably less long-term cost. We think that OP should be offered in any consultation with patients for the prostate operations.

CONCLUSION

Open transvesical prostatectomy is a safe operation in 30 to 70 g prostates with few complications in comparison with TURP. Open prostatectomy is accompanied by better outcome in relieving obstruction and less dysuria and re-operation. The authors believe that OP can be learned easily and recommend it as a suitable surgical option to be discussed parallel with TURP in patients with 30 to 70 g prostates.

CONFLICT OF INTEREST

None declared.

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