

Evaluation of outcome of transurethral needle ablation for treating symptomatic benign prostatic hyperplasia: A 10-year experience

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Abstract

Aim: The aim of this study is to report our 10-year experience with transurethral needle ablation (TUNA) to evaluate its outcome on long-term basis.

Patients and Methods: A total of 351 patients' records who underwent TUNA procedure for the management of benign prostatic hyperplasia were reviewed. The International Prostate Symptom Score (IPSS) and peak urinary flow rate were evaluated before the procedure, at 3 and 6 months postoperatively, and then yearly for 10 years. For patients complaining of *de novo* erectile dysfunction, the International Index of Erectile Function-5 was evaluated. Postoperative complications, number of patients who required additional therapeutic modality/other TUNA sessions, or those dropped out during follow-up were all recorded.

Results: Three hundred and fifty-one patients who underwent TUNA with fulfillment of our selection criteria were included in the study. The yearly records of included patients showed that patients' baseline IPSS was significantly improved all over the follow-up years. Similarly, the maximum flow rate of the patients was significantly improved during the next 8 years. About 96.4% of patients who underwent TUNA did not require additional therapeutic modality/other TUNA sessions during the 1st-year follow-up. However, by 10 years, 26.4% of patients were offered another TUNA session and shifted to either medical therapy or other minimally invasive therapies. Mild hematuria was the most common complication (85.7%). Urinary retention, urethral stricture, and *de novo* erectile dysfunction were developed in 15.1%, 1.7%, and 6.8% of patients, respectively. There were no cases of retrograde ejaculation.

Conclusion: TUNA can be considered as a relatively effective technique with a good safety profile. The current study demonstrated both significant subjective and objective improvements over 10 and 8 years of follow-up, respectively. It can be considered as a preferable option for patients who prefer surgical option with preservation of their sexual function and fertility.

Keywords: Benign prostatic hyperplasia, transurethral needle ablation, transurethral resection of the prostate

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INTRODUCTION

Benign prostatic hyperplasia (BPH) is a benign condition affecting the prostate that frequently leads to the development

of group of symptoms known as lower urinary tract symptoms (LUTS). These symptoms affect the daily life activities and subsequently reduce the quality of life (QOL).^[1,2]

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There is a wide range of therapeutic options that range from simple medical management to invasive surgery.^[1,3-5] Medical therapy often represents the initial and most preferable option to improve LUTS.^[6-9] However, some patients are reluctant to continue with medication, and sometimes, they are obliged to stop because of either treatment failure or due to the development of side effects.^[1,5]

Transurethral resection of the prostate (TURP) is still considered the gold standard therapeutic option against which all other modern treatment options are compared.^[1,4,10] However, TURP is not an appropriate option for some patients who are not suitable candidate for this relatively invasive procedure.^[1,3,11]

For this category of patients, several minimally invasive therapies (MITs) have been developed to provide an alternative treatment option.^[12] Among these, transurethral needle ablation (TUNA) is a technique that creates controlled tissue necrosis in the prostate using low-level radiofrequency energy.^[13-15]

This procedure was first introduced in 1993.^[16,17] Several studies have shown its effectiveness in the treatment of LUTS.^[18-21] Other studies compare that TUNA and TURP showed its efficacy in improvement of both subjective and objective parameters with less side effects than TURP. However, the major limitation for all minimally invasive options including TUNA is the shortage of long-term evaluation studies.^[22,23] In this study, we present our 10-year experience with TUNA to assess its outcome on long-term basis.

PATIENTS AND METHODS

Records of 351 patients who underwent TUNA procedure, during the period from June 2005 to December 2014, for the management of BPH were reviewed.

Only records of patients with transrectal ultrasonography (TRUS)-detected prostate volume of 40–70 ml were included in the study. Exclusion criteria included patients whose records showed nonpharmacological prostate treatment, bleeding disorder, renal or hepatic impairment, associated urolithiasis, urethral strictures, and an enlarged median lobe or those with neurogenic bladder disorder.

TRUS was performed for all patients. All procedures were performed with the patients in lithotomy position, and intraurethral anesthesia with lidocaine gel 2% was used. This was followed by cystourethroscope to rule out any

associated lesion in the bladder or median lobe enlargement of the prostate.

We performed the procedure using both a device and a technique that is similar to what we described in our series previously.^[24] The TUNA system (TUNA[®], Medtronic, Inc., Minneapolis, Minnesota) consists of a radiofrequency generator, TUNA catheter, handle, and 0° telescope. The generator delivers a low power of radiofrequency energy at 460 KHz. The catheter tip has two needles at the end. Each needle has a retractable shield for protection of the urethra. The needles can be deployed to a length ranging from 12 to 22 mm according to the transverse diameter of the prostate that was obtained from the TRUS of the prostate. The TUNA catheter was advanced under vision with 0° telescope. The length of the needle deployed (L) was calculated using this formula: $L \text{ (length of the needle)} = 1/2TD \text{ (transverse diameter in mm)} - 6$. This formula is sufficient for the tip of the needle to be 6 mm away from the prostatic capsule. Both needles were inserted into the prostate and heated to 110°C. Approximately one lesion was performed every 1 cm in each lobe starting with the bladder neck to reach a point above the verumontanum by 1 cm. There is a thermosensor at the end of the TUNA catheter which measures the temperature of the urethral mucosa. The urethra should be irrigated with cold saline before its temperature reaching 43°C.

After finishing the procedure, patients typically catheterized for 1–7 days. All patients received antibiotic and anti-inflammatory coverage for 3–5 days postoperatively. Discomfort was rated by our patients intraoperatively according to pain scale from 0 (no pain) to 10 (the worst). According to local policy, all patients undergoing TUNA are strictly followed up and maximum urinary flow rate (Q_{max}) is evaluated by uroflowmetry at 3 and 6 months and then yearly. Those with deteriorating symptoms were offered another TUNA session or shifted to either medical therapy or other MITs.

For all patients, postoperative complication records as well as the baseline and yearly changes in the International Prostate Symptom Score (IPSS) and prostate-specific antigen (PSA) were evaluated. For patients complaining of *de novo* erectile dysfunction, the International Index of Erectile Function-5 was evaluated.

The number of patients who required another TUNA session and shifted to either medical therapy or other MITs or those dropped out during follow-up were all recorded and were excluded from the next year follow-up evaluation.

Data were organized, tabulated in groups according to the length of follow-up duration (in years), and presented as mean \pm standard deviation. Yearly clinical changes were statistically analyzed using ANOVA test. The statistical analyses were processed using Statistical Package of Social Sciences (SPSS Inc., Chicago, Illinois, USA) software for windows version 18. Differences were considered significant when P value was <0.05 .

RESULTS

Over the selected duration, 351 patients who underwent TUNA with fulfillment of our selection criteria were included in the study (range of 27–42 procedures/year). The duration of follow-up ranged from 1 to 10 years with a mean of 4.6 years (± 2.8). By the end of the study, 19 patients had full annual records for 10 years. As our last record evaluation was at 2015, some of our patients who were done after 2005 had not completed the 10-year follow-up. Furthermore, some patients' records were not available (dropped out) during follow-up period. Causes of dropout included malignant changes in the prostate (confirmed by TRUS biopsy), nonprostate-related severe morbidity/mortality, or unknown cause [Table 1]. In addition, 60 (26.4%) patients were shifted to other therapeutic modality or required redoing TUNA session during the follow-up period.

The patients' age at the time of diagnosis ranged from 54 to 75 years with a mean age of 61.89 years (± 5.7). The prostate size ranged from 41 to 70 g with a mean weight of 57.97 g. At presentation, the PSA results were in normal range according to age and prostate size.

The immediate complications encountered in patients' files during the 3- and 6-month follow-up were not severe. Mild hematuria was the most common complication that developed in 301 patients (85.7%) due to the needle puncture. In most cases, it subsided spontaneously with

the increased fluid intake except in 11 patients (3.4%) where irrigation was necessary. After catheter removal, urinary retention was developed in 53 patients (15.1%) who were treated by recatheterization for 2 or 3 more days. Six patients developed urethral stricture (1.7%). Twenty-four patients developed *de novo* erectile dysfunction (6.8%). There were no cases of retrograde ejaculation or TURP syndrome.

IPSS was reported to be 12.4 ± 3.5 and 12.7 ± 3.4 at 3 and 6 months after TUNA, respectively, which was statistically significant as compared to the baseline value (20.5 ± 1.6). It was also recorded for available patients in each follow-up year (nondropped outpatients) that also still showed significant improvement over all the follow-up years as compared to the baseline value [Figure 1a].

Similarly, Q_{max} of the patients was reported to be 13.5 ± 2.8 and 13.3 ± 2.6 at 3 and 6 months after TUNA, respectively, which was statistically significant as compared to the baseline value (8.4 ± 3.1 ml/s). When recorded for available patients in the follow-up years, it also still showed a significant improvement during the next 8 years. However, for the 9th- and 10th-year records, the Q_{max} was not significantly better than the baseline values [Figure 1b].

Regarding patients who underwent other TUNA sessions or shifted to other therapeutic modality, about 96.4% of patients who underwent TUNA did not require additional therapeutic changes/other TUNA sessions during the first-year follow-up. However, by 10 years, 26.4% of patients were offered another TUNA session or were shifted to either medical therapy or other MIT [Figure 2].

DISCUSSION

Treatment options for LUTS due to BPH have been expanded dramatically in the last decade. From these

Table 1: 10-year follow-up after transurethral needle ablation

Follow-up duration (years)	Number of patients' records reviewed	Dropped out			Number of patients required medical treatment	Number of patients shifted to another MIT	Number of patients underwent TUNA session
		Nonprostate morbidity/death	Cancer prostate	For unknown cause			
1	351	2		19	2	7	3
2	293	2		18	2	6	2
3	243	1	1	15	4	6	1
4	187	2		17	2	5	2
5	138	1	1	13	1	3	1
6	100	1	1	8	1	2	0
7	78	2		7	2	-	1
8	57	-		8	2	1	-
9	37	1		2	1	-	1
10	21	1		1	1	1	-

MIT: Minimally invasive therapy, TUNA: Transurethral needle ablation

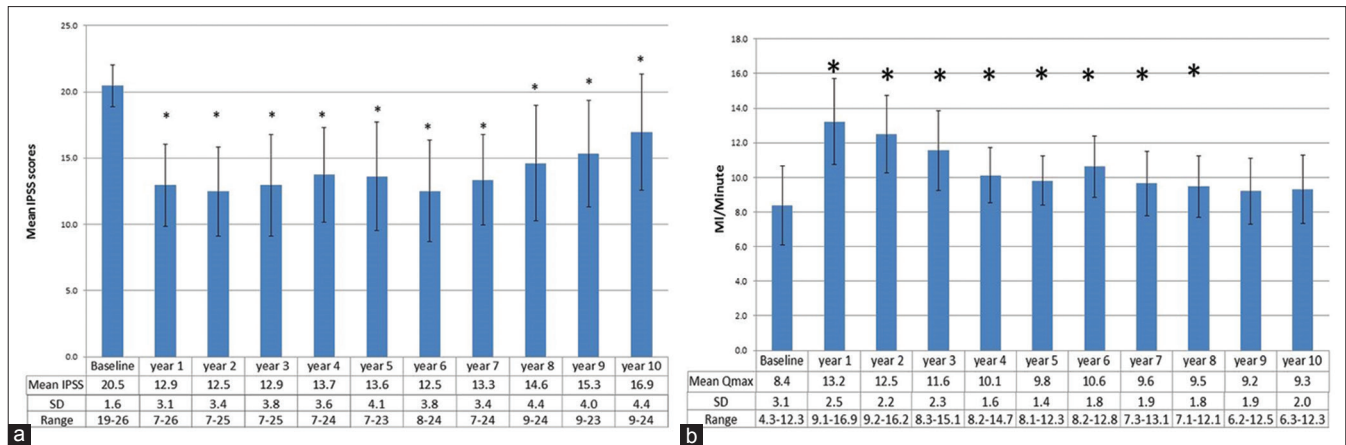


Figure 1: Different clinical changes over 10-year follow-up. (a) International Prostate Symptom Score changes and (b) Q_{max} changes

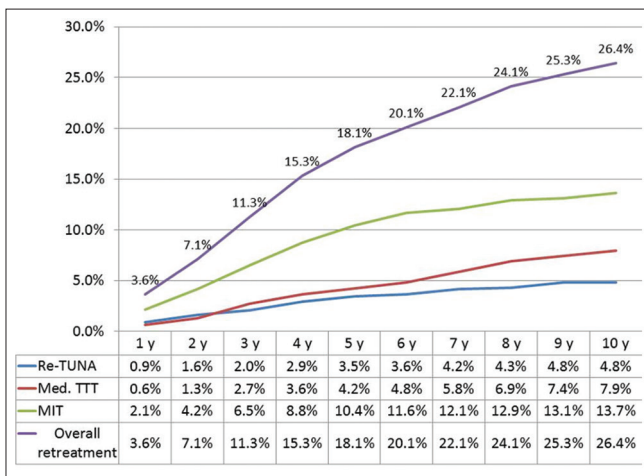


Figure 2: Percentage of patients requiring retreatment or shift to other therapeutic modalities

options, MITs are shown to be a preferable alternative option owing to its safety as compared to TURP.^[25]

Several studies have demonstrated that TUNA is an effective technique in terms of significant subjective (based on IPSS) and objective (based on Q_{max}) improvements of LUTS with variable follow-up duration. In a meta-analysis study, it was reported that the mean IPSS at 1 year became half that of the baseline and this effect persisted for 5 years.^[12] Similarly, at 5-year follow-up in another study, IPSS had 55% average improvement over baseline.^[21]

Furthermore, in most of the studies, Q_{max} has been improved by 70% over baseline, and at 1-year follow-up, the mean approached or exceeded 15 mL/s.^[12] However, with extended follow-up, there was a tendency of Q_{max} for slight decline. Zlotta *et al.* reported an improvement of Q_{max} (from 8.6 ml/s to 12.1 ml/s) that was in accordance with other studies with 5-year follow-up in which mean Q_{max} has been improved from 8.8 to 11.4 ml/s.^[20,21]

However, evaluation of the long-term efficacy of interventional technique is a major concern that has a paramount importance for both patients and health authorities to document its durability.^[25] The major issue regarding the efficacy of TUNA was related to the lack of its long-term evaluation.^[26]

Our current study supported that the durability of the response achieved and demonstrated a significant improvement in IPSS over all the follow-up years and in Q_{max} over 8 years of follow-up.

If the efficacy of TUNA compared with that of TURP, it is not surprising that TURP demonstrates better results than TUNA owing to its powerful relief of bladder outlet obstruction by direct excision of the adenomatous tissue.^[21]

However, both techniques have comparable efficacy, especially in terms of symptom relief and QOL scores before 1 year. When the follow-up was extended to and beyond 12 months, IPSS, QOL, and Q_{max} were statistically better in the TURP arm, with the difference in efficacy becomes more apparent across time.^[21,27]

When addressing the issue of retreatment after TUNA, several studies reported an overall accepted retreatment rate around 20%.^[22,27]

Zlotta *et al.* reported in their 5-year follow-up on 176 patients that < 25% of the patients needed additional treatment.^[20] In our series, by 10 years, 26.4% of patients were offered another TUNA session or were shifted to either medical therapy or other MITs.

On the other hand, several studies demonstrated that TUNA is superior to TURP regarding associated adverse events particularly for postoperative bleeding and sexual

dysfunction. In the literature, the most frequent adverse event following TUNA is hematuria that in most of cases is mild. Overall, only 16 cases of severe hematuria were reported in the literature, with only one patient requiring transfusion.^[27] In our series, mild hematuria was the most common complication (85.7%). In another study, all patients had also mild hematuria with no cases required blood transfusion in both studies.^[24]

On the other hand, postoperative bleeding in TURP patients was described as a more common feature with one reporting that up to 10.5% of patients needed transfusion.^[28]

Many studies reported that sexual dysfunction was greater in TURP than in TUNA. Cimentepe *et al.* reported deterioration in sexual function in 61% of patients in the TURP arm while no cases were reported in the TUNA arm.^[29]

Hill *et al.* reported impotence in 3.1% of patients following TUNA versus 21.4% incidence following TURP. Similarly, in our series, only 6.8% of our patients developed *de novo* erectile dysfunction. Moreover, Hill *et al.* reported 41% incidence of retrograde ejaculation in TURP group with no cases reported in the TUNA group that is similar to our finding.^[21]

In our study, urinary retention was developed in 15.1% of our cases that is similar to our previous study that reported its incidence in 13.3% of patients.^[24] However, in one study in Europe with 1-year follow-up, it was recorded in 51% of patients when the patients were not immediately catheterized after the procedure.^[20]

Furthermore, the incidence of stricture urethra and incontinence is greater in TURP than TUNA.^[21] In our series, urethral stricture was recorded in 1.8% of patients that is also similar to our previous study that reported its incidence in 1.7% of patients.^[24]

TUNA can be considered as a valuable option for patients who are poor candidates for surgery if compared with TURP as it has fewer anesthetic requirements and its shorter operative time. However, all mentioned potential advantages of TUNA must be balanced against its lower efficacy and higher rate of retreatment if compared to TURP.^[27]

CONCLUSION

TUNA can be considered as a relatively effective technique with a good safety profile. The current study demonstrated

both significant subjective and objective improvements over 10 and 8 years of follow-up, respectively. It can be considered as a preferable option for patients who prefer surgical option with preservation of their sexual function and fertility.

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Conflicts of interest

There are no conflicts of interest.

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