Original Article

How scientific are we in treating symptomatic benign prostatic hyperplasia (BPH) ?

N. D. Perera, N. A. Mallikaarachchi, L. D. R. M. Namaratne and J. S. L. Silva
Department of Urology, National Hospital of Sri Lanka, Colombo.

Benign prostatic hyperplasia (BPH) occurs in elderly men who will occupy 15-25% of a population after next two decades. By the age of 60 years 50% are affected and approximately 50% of them would develop varying degree of lower urinary tract symptoms (LUTS) and other complications of bladder outlet obstruction. BPH and its related lower urinary tract symptoms cause significant level of morbidity and often have measurable decrement in the Quality of Life of those who are affected (1,2).

An important goal in treating men with BPH is to relieve bothersome symptoms and avoid complications and to increase the quality of life. Currently, mainstreams of management are transurethral endosurgical ablation of the adenoma or involution and relaxation of tissues by drugs such as finasteride and alpha adrenergic blockers respectively. Uncomplicated mildly symptomatic patients are also managed expectantly with lifestyle adjustments (3,4). It is observed that due to its minimal initial complications medical therapy has been offered to patients by a wide range of clinicians (apart from urologists) without proper assessment of the presenting problem or outcome of this relatively new therapeutic option.

Unfortunately, in Sri Lanka, selection of patients for the optimum treatment modality is still done on a very much subjective manner which depends heavily on the patient's often temperamental perception of his symptomatic bother and the clinician's personal experience which is often subjective to individual variation. Objective scoring systems such as International Prostate Symptom Score (IPSS) and basic urodynamics (post voidal residual and uroflowmetry) used in the west are not applied in Sri Lanka on a regular basis which could lead to faulty decision making (5,7,10).

The main purpose of the present study is to assess the applicability of an objective scoring system to the current decision making which is done mostly on clinical judgment. It was also attempted to find objectively the outcome of two main treatment modalities for BPH (namely medical and surgical therapy). Furthermore, an attempt was made to stratify patients according to the severity of the disease so that optimal treatment option could be decided more objectively.

Patients and methods

Data were collected using an interviewer-administered questionnaire after obtaining the informed verbal consent from subjects. The questionnaire consisted of three parts: socio-demographic data, objective pre and post interventional data and treatment details. Sinhala and Tamil translated version of the International Prostate Symptom Score (IPSS) and simple urodynamic studies using post void residue and uroflowmetry were used for assessment. Pilot study and pre testing with 20 patients led to few modifications such as changing the sequence of questions, new questions regarding the post interventional investigations.

Linguistic validation process was carried to translate the IPSS into native languages (Sinhala and Tamil).

All the data collectors used the same translation and scoring system and asked all questions as they were in the questionnaires and translation in order to reduce the interviewing bias.

Data analysis done by a database was created using *SPSS 15.0*. The collected data analyzed using t test, chi square and Spearman's correlation.

Ethical clearance was obtained from the ethical grants committee of the hospital.

Results

During the study period of two months out of 84 people who visited the BPH clinic for their follow up, 78 patients were taken for our study. Six patients were excluded according to our exclusion criteria such as presence of carcinoma, urethral strictures unrelated neuropathic bladders. Only 66 patients were taken for the analysis with all the investigation results. Patients who were not very cooperative were also excluded from the study. Out of 66 patients 33 patients had been managed with medical treatment and 33 were managed surgically. Mean age of the patients were 62.52 and 69.0 for medical and surgical management respectively.

For comparison purposes patients were divided into the following groups

- IPSS mild, moderate and severe symptom groups,
- PVR normal, insignificant and significant,
- Qmax normal, mild, moderate and severe impairment.

Table 1. Number and the percentage of patients after classification of the IPSS score

| (n=66) | | | IPSS grading | | | |
			Mild	Moderate	Severe	Total
Management Type	Medical therapy	Count	4	16	13	33
		% within IPSS grading	80.0%	64.0%	36.1%	50.0%
	Surgical therapy	Count	1	9	23	33
		% within IPSS grading	20.0%	36.0%	63.9%	50.0%
Total		Count	5	25	36	66
		% within IPSS grading	100.0%	100.0%	100.0%	100.0%

IPSS was also categorized as mild, moderate and severe when the total IPSS score become <7, 8-19 and 20-35 respectively.

Table 2. Number and the percentage of patients after classification of the PVR

| (n=66) | | | PVR grading | | | |
			Normal	Not significant	Significant	Total
Management Type	Medical therapy	Count	3	15	15	33
		% within PVR grading	100.0%	78.9%	34.1%	50.0%
	Surgical therapy	Count	0	4	29	33
		% within PVR grading	0.0%	21.1%	65.9%	50.0%
Total		Count	3	19	44	66
		% within PVR grading	100.0%	100.0%	100.0%	100.0%

PVR% was calculated as the percentage of the pre Voidal volume. Considered as significant when >30% and if its <30% as not significant, while 0% of PVR value was taken as normal.

Table 3. Number and the percentage of patients after classification of the Qmax

(n=66)			Pre Qmax Grading				Total
			Mild	Moderate	Normal	Severe	
Management Type	Medical therapy	Count	5	13	9	6	33
		% within pre Qmax Grading	62.5%	68.4%	56.3%	26.1%	50.0%
	Surgical therapy	Count	3	6	7	17	33
		% within pre Qmax Grading	37.5%	31.6%	43.8%	73.9%	50.0%
Total		Count	8	19	16	23	66
		% within pre Qmax Grading	100.0%	100.0%	100.0%	100.0%	100.0%

Qmax was categorized >15 ml/s, 10ml/s – 15ml/s, 5ml/s – 10ml/s and <5ml/s as normal, mild, moderate, severe.

Table 4. Spearman's correlation coefficient between pre interventional IPSS, QOL, Qmax and PVR

			Pre IPSS	Pre QOL	Pre Qmax	Pre PVR
Spearman's rho	Pre IPSS	Correlation Coefficient	1.000	.540(**)	-.249(*)	.239
		Sig. (2-tailed)	.	.000	.044	.054
		N	66	66	66	66
	Pre QOL	Correlation Coefficient	.540(**)	1.000	-.195	.173
		Sig. (2-tailed)	.000	.	.116	.166
		N	66	66	66	66
	Pre Qmax	Correlation Coefficient	-.249(*)	-.195	1.000	-.420(**)
		Sig. (2-tailed)	044	116	.	.000
		N	66	66	66	66
	Pre PVR	Correlation Coefficient	.239	.173	-.420(**)	1.000
		Sig. (2-tailed)	.054	.166	.000	.
		N	66	66	66	66

Table 5. Post treatment characteristics of the study population (n=66)

(n=66)		Post interventional IPSS	Post interventional QOL value	Post interventional Qmax	Post nterventional PVR
Management type					
Medical therapy	Mean	11.21	2.36	14.42	24.85
	Median	10.00	2.00	12.00	17.30
	Std. deviation	7.03	1.41	8.37	25.16
Surgical therapy	Mean	8.06	1.67	25.85	21.83
	Median	7.00	1.00	25.00	11.80
	Std. deviation	6.123	1.315	14.98	23.54

Table 6. Improvement in subjective assessment (IPSS) of the patients after treatment within the Severe IPSS group (n=36)

(N=36)			Improvement		Total
			not improved	improved	
Management Type	Medical therapy	Count	11	2	13
		% within cat	47.8%	15.4%	36.1%
	Surgical therapy	Count	12	11	23
		% within cat	52.2%	84.6%	63.9%

Discussion

Lower urinary tract symptoms are objectively assessed for management and outcome assessment by means of scoring systems out of which the most widely used is the International Prostate Symptom Score (IPSS) developed by American Urological Association (AUA) based on information regarding severity of symptoms (1-6). This also includes an assessment of quality of life (QOL) which is a reflection of degree of bother caused by patient's symptoms. QOL is a very important criterion because it reflects the concerns of the patient and real effect of symptoms on patients. Also it closely correlates with the IPSS (3,4,6). Although successfully tested in 26 different countries and languages, this is the first study which validated and applied IPSS in Sri Lanka (7).

In our study we used the questionnaire along with the Sinhala translation of the IPSS score which we developed after going through the linguistic validation process and grouped them in to mild, moderate and severe groups according to it (Table 1). The present study demonstrate that the translated version of IPSS has a highly significant correlation with the QOL both pre and post intervention (p<0.001), (Table 1,5). Overall pre interventional IPSS was higher in population who were managed surgically and pre interventional QOL was lower in surgically managed patients than those who were managed medically with a significant difference between these two groups (p<0.05) (Table 1). This demonstrates the fact that pure clinical judgment on which these treatment decisions are made, favours surgery for severely symptomatic patients disregarding

the urodynamic assessments (9). In spite of this fact out of thirty six patients in severe IPSS grading only 63.9% were managed surgically. In the same context 20% of patients with mild symptoms were subjected to surgery without clear reasons. It was observed that surgery has achieved better results in all post parameters in the present study. This is demonstrated by higher post interventional IPSS, lower QOL, lesser Qmax and PVR improvement observed in the medically managed population compared to surgically managed patients (Table 5). This observation was more intensified in severe IPSS group in which 11 patients improved after the surgery compared to only 2 patients improved on medically managed group (p=0.05) (Table 6).

These observations compare well with other studies done in foreign languages (8).

A similar superiority of surgical therapy was observed (Table 5) in urodynamic parameters. Mean Qmax was increased from 6.73ml/s to 25.85ml/s after doing surgery where as the mean PVR had lowered from 65.22% to 21.83% after surgical management. After managing conservatively with drugs the Qmax had changed from 9.87ml/s to 14.42ml/s. PVR value had decreased from 32.94% to 24.85% (Table 2). Present study affirms the fact that surgical ablation offers superior results to prolonged medical therapy both in symptomatic and urodynamic parameters. In the absence of objective assessment in the follow up of medically managed patients this fact may not be appreciated by the clinician, leading the patient to suffer in silence until a complication such as acute retention takes place.

When considering the fact of decision making based on simple urodynamic measures such as uroflowmetry and postvoid residual urine in the bladder it is interesting to find that the correlation between IPSS and the pre-management Qmax was very week. and there was no significant correlation between pre-management IPSS with the %PVR score itself. These findings suggest that isolated measurement of PVR and the Qmax were not correlated with the QOL of the patients prior to their management. Hence, decisions to treat based on these findings could be erroneous (9-14). These observations which are shared by others (15,17) are exemplified by the fact that 37.5% with mild Qmax which theoretically do not need surgery for outlet obstruction were treated surgically. In the same context 26% patients with severe urine flow impairment were treated with medical therapy which again would not be the best choice of treatment. This demonstrates the lack of standardisaton in decision making. Contrary to the judgment made by using pure clinical sense, we found that while the Qmax weakly correlated with IPSS

and QOL, PVR did not. (p=0.04 & p>0.05 respectively). Hence it is not advisable to use PVR or Qmax in isolation to make decisions. (r=0.228 p>0.005) (Table 4).

Conclusions

Traditional decision making based on non categorized symtomatology does not offer the patient the best method of treatment to improve his urological QOL. Standardization and uniformity in decision making to offer medical or surgical therapy needs a validated objective scoring system and pure clinical judgment could lead to errors in decision making. All clinicians who undertake treatment of symptomatic BPE should realize the complexity of pre treatment assessment to avoid offering a suboptimal treatment option. Most widely used symptom scoring systems such as IPSS can be translated and validated in native languages. Application of these scoring systems should be made mandatory in the initial clinical assessment, treatment decision making and in the follow up assessment. Simple urodynamic test though clinically useful when used alone do not predict the effect on QOL hence should not be used in isolation for treatment decision making. Severe symptom scores and urodynamic impairment are best treated with surgical therapy.

Stratification of patients according to the severity of symptomatic and urodynamic parameters in this study is more rational than just considering averages for comparison. We suggest wider application of this stratified comparison in future studies of this nature.

References

1. Ezz el Din K, Kiemeney LA, de Wildt MJ, Debruyne FM, de la Rosette JJ. Correlation between uroflowmetry, prostate volume, postvoid residue, and lower urinary tract symptoms as measured by the International Prostate Symptom Score. Urology; 1997; 49(1): 46-9.

2. Remigio V, et al. The impact of medical therapy on surgery for benign prostatic hyperplasia: a study comparing changes in a decade (1992-2002). British Journal of Urology International 2005; 196: 1045-48.

3. Goonawardene SAS. Benign Prostatic Hyperplasia: an appraisal of the indications for transurethral prostatectomy. Ceylon Medical Journal 1998; 43: 177-81.

4. Jayasekare G. Current concepts on prostatism – Physicians have a role in treatment. Journal of Ceylon College of Physicians 1996; 29(1): 1-6.

5. Rodrigues Netto N Jr, de Lima ML, de Andrade EF, et al. Latin American study on patient acceptance of the International Prostate Symptom Score (IPSS) in the evaluation of symptomatic benign prostatic hyperplasia. British Journal of Urology 1998; 81(1): 36-41.

6. Hansen BJ, Mortensen S, Mensink HJ, et al. Comparison of the Danish Prostatic Symptom Score with the International Prostatic Symptom Score, the Madsen-Iversen and Boyarsky symptom indexes. ALFECH Study Group. Neurourology and Urodynamics 2004; 23(2): 88-93.

7. Weiss JP, Blaivas JG, Tash Anger JA, Di Blasio CJ, Panagopoulos G, Gerboc J. Development and validation of a new treatment outcome score for men with LUTS. British Journal of Urology International 2001; 88(1): 21-5.

8. Quek KF, Low WY, Razack AH, Loh CS. Reliability and validity of the International Prostate Symptom Score in a Malaysian population. European Urology. 2001; 40 Suppl 1: 23-7.

9. Barry MJ. Evaluation of symptoms and quality of life in men with BPH. Urology 2001 Dec; 58(6 suppl 1): 25-32.

10. Fazil TA, Cem A, Nazmi B, Ilhan E, Haluk O. Prevalence of LUTS in a community based survey in men in Turkey. International Journal of Urology 2003; 10: 364-70.

11. Koji Y, Yoichi A, Kentaro I, Naoki T, Yosuke M, Kazutoshi O. Symptom specific QoL in patients with BPH. International Journal of Urology 2002; 9: 485-90.

12. Hideki I, Munekado K, Koji O, Osamu U, Akihiuro K, Tsuneharu M. Significant relationship of time dependent uroflowmetric parameters to LUTS as measured by the IPSS. International Journal of Urology 2006; 13: 1058-65.

13. Sharma DP. Management of BPH: a voice from third world. British Journal of Urology International 2006; 97: 671-72.

14. Hiroyoshi S, et al. Clinical impact of tamsulosin on generic and symptom-specific quality of life for benign prostatic hyperplasia patients: Using international prostate symptom score and medical outcomes. International Journal of Urology 2006; 13: 1202-06.

15. Hakenberg OW, Pinnock CB, Marshall VR. Preoperative urodynamic and symptom evaluation of patients undergoing transurethral prostatectomy: analysis of variables relevant for outcome. British Journal of Urology International 2003; 91: 375-79.

16. Michael M, Sonja A, Rolf K, Christopher G, Dieter H, et al. Peri-operative morbidity and changes in symptom scores after transurethral prostatectomy in Switzerland. British Journal of Urology International 2006; 98: 381-83.

17. Kuo HC. Clinical prostate score for diagnosis of bladder outlet obstruction by prostate measurements and uroflowmetry. Urology 1999 54(1): 90-6.

Authors

Neville D. Perera, MS (Col) FRCS (Eng) FRCS (Edin) DUrol (Lond)
Consultant Urological Surgeon

Department of Urology, National Hospital of Sri Lanka, Colombo, Sri Lanka.

N. A. Mallikaarachchi, Medical student

L. D. R. M. Namaratne, Medical student

S. J. L. Silva, Medical student

Faculty of Medicine, University of Colombo, Colombo, Sri Lanka.