



## SURVEY BY UROLOGICAL SOCIETY OF INDIA (USI) TO UNDERSTAND PRACTICE PATTERNS IN DIAGNOSIS AND MEDICAL MANAGEMENT OF VOIDING LUTS SECONDARY TO BENIGN PROSTATIC OBSTRUCTION (BPO)

### Urology

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### ABSTRACT

To ascertain practice patterns and attitude of Indian Urologists with regard to voiding LUTS in men due to BPO, a questionnaire was prepared & validated by USI, and was sent to 2100 member urologists by email & response was collected online. The response rate was 29.9%. Of these, 20.4% were academic and 79.6% in community/private practice. Almost all urologists routinely used ultrasound (85.2%) and digital rectal examinations (81.1%) for lower urinary tract symptoms diagnosis. 55.9% of Indian urologists preferred  $\alpha$ -blockers as the therapy of first choice for all patients, while 44.1% prescribed 5 $\alpha$ -reductase inhibitors in combination with an  $\alpha$ -blocker to patients with clinically enlarged prostates (weight >50 g) at the outset.

**Summary:** Indian urologists consider  $\alpha$ -blockers as primary treatment for all patients of LUTS due to BPO. Although practice pattern is consistent with published guidelines, there are variations which need to be addressed in forming Indian guidelines.

### KEYWORDS

Lower urinary tract symptoms,  $\alpha$ -blockers, survey

### INTRODUCTION

Benign prostatic hyperplasia (BPH), one of the most common cause of lower urinary tract symptoms (LUTS), has a reported prevalence of 6.7–14% in hospital and community studies from India.<sup>[1]</sup> The LUTS burden increases from 18% in the age group of 40–49 years to 50% in 70–79 years.<sup>[2]</sup> 89% of men with BPH were noted to have LUTS in a study from a tertiary care centre in Andhra Pradesh.<sup>[1]</sup>

In India, the number of transurethral resection of prostate (TURP) has decreased from 95.8% in 2008 to 74.5% in 2012.<sup>[2]</sup> There have also been reports from several countries indicating a dramatic decline in hospitalizations for TURP with a concomitant rise in the intensity of prescription medications for the treatment of BPH.<sup>[3,4]</sup> This indicates adoption of new therapeutic modalities for the treatment of LUTS secondary to Benign Prostatic Obstruction (LUTS/BPO).<sup>[5,6]</sup> However, new therapeutic modalities have also been accompanied by controversy about the optimal treatment. Arguments also exist about applying international guidelines directly to the management of Asian patients, as their clinical characteristics are different from those of western populations (e.g. similar LUTS incidence with smaller prostate volume).<sup>[7,9]</sup>

In such an environment, variation in medical practice is expected as patient preference and personal opinions may be considered in taking treatment decisions. India does not have any well-structured practice guidelines on managing LUTS associated with BPO. Hence objective of this survey was to understand how urologists in India approach & offer medical treatment to the patients with LUTS due to BPO. Whether Indian Urologist's practice differ from the existing guidelines such as American, European or Singapore...etc. The survey results would also be beneficial if there is any need for formulating Indian guidelines & healthcare policy on LUTS associated with BPO.

### METHODS

#### About the survey

A cross-sectional, observational questionnaire-based survey was conducted among Indian urologists between August and November 2017. The questionnaire was developed to assess multiple aspects of self-reported practices regarding the management of LUTS associated with BPO.

**Survey instrument:** The survey instrument (questionnaire) was developed by the lead author. This questionnaire was then reviewed by

English language expert to modify the language to remove any potential bias in expected answers. The questionnaire was then sent to 50 urologists to understand the following aspects:

- 1) See if there was any confusion in understanding the question
- 2) If any question could have been better worded
- 3) If any option of answers have similar meaning & hence dilemma in answering
- 4) If any question has inadequate answers & hence difficulty in choosing the option.

Based on the feedback received the questionnaire was finalised.

The first part of the survey dealt with demographic details (speciality, practice setting and geographical area). The second section comprised of 15 questions related to diagnosis and management of patients with BPO including diagnostic modalities, strategy for medication, and urologist's preference for medical therapy. The survey instrument did not focus on BPO associated storage symptoms as well as its surgical treatment (Figure 1).

**Survey methods:** All existing Urological Society of India (USI) members with valid email id (n=2100) were eligible to participate in the survey. They were mailed a link of the survey instrument on working e-mail addresses with a cover letter, specifying the purpose of the study and a statement indicating that all responses are anonymous and confidential. Institutional Review Board approval and patient consent were not required, as the survey did not involve patients or patient data.

**Analysis:** Statistical analysis was completed using computer R software version 3.1.3. Responses that generated continuous distribution was summarized by medians and interquartile ranges, and those with categorical distribution were summarized by proportions and number of respondents. All responses were further characterized based on practice duration as Resident Urologist, Urologist with less than 5 years, 5-15 and more than 15 years of experience (practice groups). Comparison of responses by physician or practice characteristics was assessed using the chi-square test. Probability value of less than 0.05 was considered to be statistically significant.

### RESULTS

A total of 628 Urologists- members of Urological Society of India - completed the questionnaire. Incomplete responses were not considered.

### Participant demographics, qualification and experience

Amongst the participants, 28.5% had been practicing as urologist for more than 15 years, 23.9% for 5-15 years and 27.2% for less than 5 years. 20.38% were resident urologists (RU). A majority (51.1%) of respondents practiced in private settings, 28.5% were working for corporate non-teaching hospitals, 14.0% were students pursuing Magister Chirurgiae (MCh) course and 6.4% were students pursuing Diplome in National Board (DNB) course in various institutes.

### Respondent geography and response rates

Respondents were from every part of India, which gives strength to the survey and makes it representative of entire country. 91 (14.58%) responses were recorded from Maharashtra followed by Gujarat (66; 10.6%), Karnataka (57; 9.1%) and National Capital Territory (49; 7.9%). Responses from Arunachal Pradesh and Andaman and Nicobar Islands contributed only 0.3% of the cohort (1 response from each state) as shown in figure 2. This is because of less number of urologists in these regions.

### Initial evaluation of men with suspected BPH

More than 80% of urologists preferred ultrasound (USG; 85.2%) and digital rectal examination (DRE; 81.1%) as diagnostic tests of first choice, followed by uroflowmetry (49.9%) for initial assessment of LUTS/BPO in 75-100% of their patients. Only 24.6% urologists used International Prostate Symptom Score (IPSS) for initial assessment but preferred using USG/DRE during the follow-up period. Urologists who had worked for less than 5 years were less inclined to use uroflowmetry for diagnostic assessments than those who were more experienced ( $p=0.001$ ).

### Pharmacological management of LUTS

Study results indicated that 55.9% of the urologists preferred  $\alpha$ -blockers as first choice treatment while 44.1% prescribed 5 $\alpha$ -reductase inhibitors (5-ARI) in combination with  $\alpha$ -blocker.

### Choice among $\alpha$ -blockers

50.6%, 21.0% and 30.3% of urologists preferred tamsulosin, silodosin and alfuzosin, respectively for the management of LUTS. There was unanimity across the practice groups that at least 30 days treatment period should be considered for evaluating efficacy of the  $\alpha$ -blocker.

The factors for choosing the  $\alpha$ -blockers, as rated on 5-point Likert scale, were severity of symptoms (average rating 4.1), sexual activity (4.0), age (4.0), co-morbidities (3.9), complications (3.8), drug cost (3.8), erectile dysfunction (ED; 3.7), prostate size (3.7), drug availability (3.7), and IPSS (3.6). Most respondents stated that only 10-20% of their BPH patients were less than 60 years of age. Senior urologists with >15 years' experience were less likely to use the IPSS score as a determinant in their choice of  $\alpha$ -blocker ( $p=0.000$ ).

Majority of urologists were more likely to choose alfuzosin in patients less than 60 years (83.3%), those who were sexually active (91.5%) and those with small prostate (29.0%) as compared to both tamsulosin and silodosin. Although, similar in efficacy, urologists preferred silodosin (65.5%) over tamsulosin for elderly patients (>60 years) and tamsulosin was preferred over silodosin for patients (36.9%) with larger prostate glands (weight 25-50g) as shown in table 1. Residents were more inclined to prescribe silodosin in elderly patients (> 60 years) than other practice groups ( $p=0.037$ ). Almost all respondents stated that they did not notice a perceptible difference in efficacy or safety when switching from one  $\alpha$ -blocker to another. Experienced urologists were less inclined to associate severity of disease with their decision of choosing silodosin ( $p=0.010$ ). While prescribing silodosin, consultants were more likely to disregard age of the patient as compared with residents ( $p=0.037$ ).

### Reasons for using combination therapy

Prostate size (weight >50 g) was selected as a most important criteria for prescribing the combination of  $\alpha$ -blocker with 5-ARI. The factors as rated on 5-point Likert scale, found average rating of 4.5 for prostate size, followed by the severity of symptoms (3.9), complications (3.9) and age of the patients (3.5) (Figure 3).

As compared to other practice groups, urologists with >15years of experience were more conservative in prescribing combination therapy (59.3%) reserving the combination for glands  $\geq 75$ g ( $p=0.000146$ ) as compared with RU (35.9%), urologists with <5years practice (38.0%) and urologists with 5-15years practice (46.9%).

Urologists who had worked for less than 5 years, most frequently applied IPSS scoring (96.1%) before making the final decision for combination therapy ( $p=0.012$ ).

### Continuation of pharmacological management

55.8% of respondents recognized the need for long term medication in patients with BPO. However, 21.5% of respondents stated that their patients stopped medications after initial relief, and 22.7% stopped medications due to cost, non-availability or other individual reasons. Subjective improvement of symptoms as per patient's feedback was considered as the main criteria (55.2%) for assessment of success of pharmacological management of LUTS, followed by objective evidence of improvement in uroflowmetry parameters (23.4%).

In patients not responding to  $\alpha$ -blockers for 3 months or more, 39.9% of respondents preferred surgery, 20.4% persisted with  $\alpha$ -blockers, while 14.7% considered combination therapy with 5-ARI. However, senior urologists (5-15y, >15y) appeared less convinced regarding surgery for BPO ( $p=0.044$ ).

### DISCUSSION

This first nationwide questionnaire-based USI survey provides insights into the current medical Management of patients with LUTS due to BPO. Although having different opinions, Indian urologists don't seem to have sharply polarized attitudes in approach towards both diagnosis and medical management of LUTS.

In this survey, it was found that most respondents used USG (85.2%) and DRE (81.1%) for initial work up of patients with BPO, while uroflowmetry (49.9%) and IPSS (24.6%) were used less often. This is in contrast to recommendations made by various guidelines as practice guidelines of both, the European Association of Urology and the American Urological Association (AUA) recommend evaluating symptom severity with a symptom score as an important part of the assessment of male LUTS.<sup>[10]</sup> Singapore Urology Association (SUA) guidelines have given grade A recommendation for the use of quality of life (QoL) score along with IPSS to quantify the severity of LUTS and in guiding treatment options.<sup>[11]</sup>

Tomaskovic I, et al. conducted a survey in Croatia and showed that DRE, USG, prostate-specific antigen (PSA), urinalysis, and IPSS were performed by 100.0%, 100.0%, 100.0%, 81.0% and 31.0% of respondents for the initial assessment of BPO, respectively.<sup>[12]</sup> Another study from China found that recommended diagnostic tests, such as IPSS, DRE, urinalysis, PSA, ultrasonography and uroflowmetry were used by 58.8%, 67.5%, 92.5%, 88.8%, 92.7% and 31.2%, respectively.<sup>[13]</sup> In a study from Korea it was observed that IPSS, DRE, urinalysis, PSA, uroflowmetry and trans rectal ultrasound (TRUS) were used by majority of urologists for initial evaluation of BPH.<sup>[14]</sup> These variations might be due to differences in national or institutional guidelines, variations in human resources, availability of medical technology, cultural differences or socioeconomic factors. Our survey showed more reliance on IPSS score in younger practice groups than senior urologists. The difference might be attributable to a greater familiarity of younger graduates with the scoring system.

The time from initiation of therapy to the first assessment varies according to the pharmacological agent prescribed in patients with BPO. The present survey results showed that the most commonly utilised follow up interval of 7 to 30 days was consistent with American Urology Association (AUA) guidelines that recommend an interval of two to four weeks for  $\alpha$ -blockers.<sup>[15]</sup> However, the optimal treatment duration before  $\alpha$ -blocker discontinuation has not yet been determined, although the results of two studies indicate that discontinuation may only be suitable for patients with mild to moderate symptoms, as many of those with severe baseline symptoms deteriorated after  $\alpha$ -blocker withdrawal.<sup>[16]</sup>

This survey shows that most of the Indian urologists choose  $\alpha$ -blockers as the first choice of treatment, followed by combination of  $\alpha$ -blocker and 5-ARI for the management of patients with moderate to severe LUTS associated with BPO. This is consistent with the current guidelines as well as practice in most countries.<sup>[12-14]</sup> Thus the current management is appropriately focused on a rapid relief of symptoms. A Spanish study found statistically lower QoL in patients with older age, severe LUTS and greater size of prostate.<sup>[17]</sup> Similarly in the current survey, severity of LUTS was regarded as being the most important reason for prescribing  $\alpha$ -blocker, followed by sexual activity and age of the patients.

Although some studies suggest that silodosin might be the most efficacious  $\alpha$ -blocker in men with LUTS due to BPO, most urologists in the survey preferred (50.6%) tamsulosin, followed by silodosin (30.3%) and alfuzosin (21.0%) as  $\alpha$ -blocker of first choice. This may be attributable to the lower incidence of ejaculatory dysfunction, differences in cost and/or differences in availability of the two drugs.<sup>[18,19]</sup> Further, a randomized crossover study by Watanabe et al. comparing patient preference for tamsulosin and silodosin in 84 (n = 42 per group) Japanese patients over 4 weeks, concluded that patients preferred tamsulosin over silodosin.<sup>[20]</sup> Thus, it is possible that patient's preference may also have influence on selection of  $\alpha$ -blocker by Indian Urologists.

American, European or Singapore Urological Associations guidelines do not outline any criteria, indications or preference for alfuzosin, silodosin or tamsulosin.<sup>[11,15]</sup> However, choice among  $\alpha$ -blockers could depend on the patient's comorbidities, side effect profile and tolerance of each drug as all the drugs seem to have similar efficacy.<sup>[17,21,22]</sup> The current USI survey demonstrated preference of Indian urologists for alfuzosin for patients less than 60 years of age, with high sexual activity and prostate size less than 25 g, for silodosin for elderly patients (>60 years) with co-morbidities while for tamsulosin for patients with prostate glands weighing 25-50g. A randomised trial comparing tamsulosin and silodosin from Kolkata showed that postural hypotension was less likely with the latter possibly conferring an advantage in the elderly male.<sup>[19]</sup> However, another randomized study from Bengaluru found syncope only in the silodosin arm. Of note, this study did not find any significant difference in the adverse events between alfuzosin, tamsulosin and silodosin. However, the study was not designed to detect this difference and might have been under-powered for this.<sup>[23]</sup> Most cited reason for preference of tamsulosin in patients with enlarged prostate (25-50 g) were fewer adverse events compared to other  $\alpha$ -blockers.<sup>[24]</sup>

The use of 5-ARI in combination with  $\alpha$ -blockers is a mainstay of treatment for LUTS patients with enlarged prostates (>30 g) and is affirmed by most clinical guidelines.<sup>[11,25,26]</sup> In contrast, majority of the Indian Urologist's reserved combination therapy for patients with prostate size >50g. In 2008, the CombAT trial showed significantly greater improvements in symptom and bother scores as well as QoL with combination therapy (dutasteride and tamsulosin) than with either monotherapy regimen.<sup>[27]</sup> These preferences may reflect the greater cost-benefit ratios with advancing prostate size for a therapy that is intended to be long term. Indian urologists were not inclined to use phytotherapy. This is in line with existing guideline recommendations. In contrast, studies have shown a greater inclination of urologists from other nations to use these therapies.<sup>[12]</sup>

The surgical treatment for BPH has gradually decreased in India during recent decades. In the present survey, approximately 75.0% urologists preferred medical therapy. Patients being treated by senior urologists in this survey have been found willing to avoid surgery and prefer medical therapy. Similar results have been reported by Emberton M, et al in the Prostate Research on Behaviour and Education (PROBE) Survey. PROBE survey conducted in 5 European countries found that majority of patients preferred therapy that reduces the need for surgery and its complications in conjunction with slowing of disease progression.<sup>[28]</sup>

Close-ended questions in USI survey may have limited the strength of the responses. The practice patterns may also differ according to the stage of the disease, which is not covered in this survey. The response rate may appear low, but it is better or comparable to other web-based surveys of health providers. Finally, the data represents a snapshot in time and therefore may be subjected to recall bias. It is also important to highlight that current survey instrument did not focus on BPH associated storage symptoms and its treatment.

Despite these limitations, this study has important implications. It is the first nationwide, population-based Indian study with good geographical distribution, which demonstrated the differences in BPH management practices.

**CONCLUSION**

This first nationwide questionnaire-based survey provides insight into the current medical management of patients with lower urinary tract symptoms secondary to benign prostatic obstruction. Indian urologists considered  $\alpha$ -blockers as an appropriate treatment for all patients with LUTS/BPO irrespective of their prostate size. However, they currently prefer prescribing combination of  $\alpha$ -blockers with 5-ARI at the outset in patients with an enlarged prostate (weight >50 g). Examinations, tests & selection of medical therapy in men with suspected BPO in many aspects are consistent with published guidelines, however there are significant deviations based on duration of practice of the urologists. This survey provides potentially valuable information that

suggests that Indian guidelines or health care policies are necessary to bring uniformity in approach for management of LUTS associated with BPH.

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**CONFLICTS OF INTEREST**

None declared

**TABLES**

**Table 1: Prescription of  $\alpha$ -blocker for different age groups**

	Alfuzosin			Silodosin			Tamsulosin		
	Age								
Urologists	<60y (%)	>60y (%)	NI (%)	<60y (%)	>60y (%)	NI (%)	<60y (%)	>60y (%)	NI (%)
RU	83.3	6.3	10.4	15.2	73.9	10.9	16.8	54.7	28.4
<5y	90.2	3.0	6.8	6.8	66.7	26.5	20.6	41.2	38.2
5-15y	79.8	3.1	17.1	10.1	62.8	27.1	16.9	44.6	38.5
>15y	79.7	9.8	10.5	11.9	61.2	26.9	19.1	42.7	38.2
Mean	83.3	5.5	11.2	10.7	65.5	23.8	18.5	45.1	36.4
	Sexual activity/Erectile dysfunction								
Urologists	Active	NI	NA	Active	NI	NA	Active	NI	NA
RU	89.4	7.5	3.2	15.4	23.1	61.5	12.6	33.7	53.7
<5y	94.7	2.3	3.0	23.1	27.7	49.2	12.2	38.2	49.6
5-15y	90.9	7.4	1.7	13.2	34.7	52.1	18.3	40.8	40.8
>15y	90.0	9.2	0.8	14.6	36.6	48.8	20.7	38.8	40.5
Mean	91.5	6.4	2.1	16.8	31.0	52.3	16.1	38.1	45.8
	Co-morbidities								
Urologists	No	NI	Yes	No	NI	Yes	No	NI	Yes
RU	22.8	35.9	41.3	7.0	24.2	69.2	20.4	28.0	51.6
<5y	22.3	33.9	43.8	4.9	18.0	77.0	15.0	30.9	54.2
5-15y	16.2	45.3	38.5	4.2	45.4	50.4	15.3	42.4	42.4
>15y	7.1	37.5	55.4	6.8	31.4	61.9	4.3	31.0	64.7
Mean	17.0	38.2	44.8	5.6	30.0	64.4	13.4	33.3	53.2
	Prostate size								
Urologists	<25g	25-50g	NI	<25g	25-50g	NI	<25g	25-50g	NI
RU	24.7	45.5	28.2	13.1	39.3	29.8	14.0	45.4	29.1
<5y	32.2	31.3	34.6	17.9	32.1	44.6	16.7	39.5	41.1
5-15y	30.9	30.9	33.0	17.9	27.7	34.8	23.2	28.6	32.5
>15y	27.0	35.0	29.0	14.4	35.6	33.7	16.2	36.2	34.3
Mean	29.0	34.6	31.5	16.0	33.3	36.2	17.8	36.9	34.5

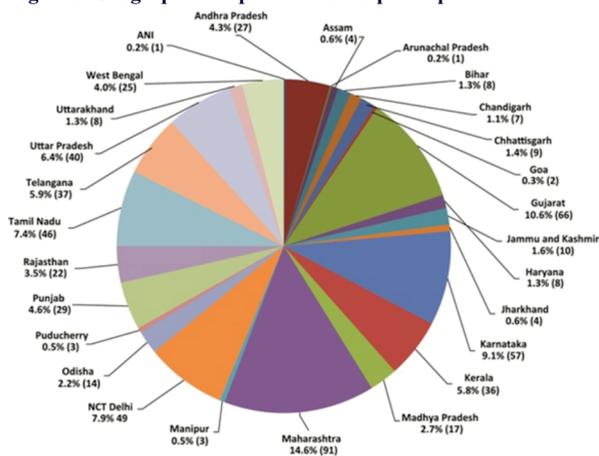
RU: Resident Urologists; NI: Not important; NA: Not applicable

**FIGURES**

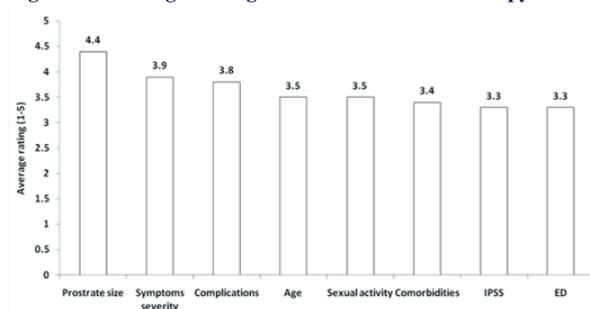
**Figure 1: Survey Instrument**

1. Doctor, what is your primary medical specialty?
2. Which of these locations correctly represent your primary practice settings?
3. In which state or union territory of India do you practice?
4. Out of your current patients you prescribed an anti-BPH medicine, what percentage of patients are prescribed:
  - a. Alpha-blockers
  - b. Combination of Alpha-blockers and 5ARI
5. How often do you carry out the below mentioned tests:
  - a. IPSS
  - b. IRE
  - c. Uroflowmetry
  - d. Ultrasound
6. Please rate the importance of the following reasons for prescribing combination therapy (Alpha-blockers & 5ARI) to your patients?
  - a. Prostate size
  - b. Age of the patient
  - c. Severity of the symptoms
  - d. Complications
  - e. Co-morbidities
  - f. Sexual activity
  - g. IPSS Score
  - h. Erectile dysfunction
7. While prescribing combination therapy, if prostate size is one of the main criteria, then for which prostate size will you prefer combination therapy?
  - a. <25 g
  - b. 25-50 g
  - c. 50-75 g
  - d. >75 g
8. Out of your current patients to whom you prescribe single alpha blocker, what is the patient share in the following molecules?
  - a. Tamsulosin
  - b. Alfuzosin
  - c. Silodosin
9. While deciding on which alpha-blocker to prescribe to your anti-BPH patients, how important are the following parameters to you?
  - a. Prostate size
  - b. Age of the patient
  - c. Severity of the symptoms
  - d. Complications
  - e. Co-morbidities
  - f. Sexual activity
  - g. IPSS Score
  - h. Erectile dysfunction
  - i. Drug cost
  - j. Drug availability
10. Please select the patient attributes (Age, Sexual activity/ED, Concomitant conditions, IPSS score and Prostate size) which you associate with the following molecules?
  - a. Alfuzosin
  - b. Silodosin
  - c. Tamsulosin
11. For your patients not responding as expected to 3 months of alpha-blocker therapy, what action do you take?
  - a. Switch to other alpha-blockers
  - b. Switch to combination-respective of size of gland
  - c. Consider for intervention-TURP/TUIP
  - d. Do urodynamic study
  - e. Others
12. In case where you switch from one alpha-blocker to another, in what % patients do you get the desired benefit?
  - a. <20%
  - b. 20-40%
  - c. >40%
13. Generally in your clinical practice, how long do patients continue to take an anti-BPH therapy:
  - a. As long as you advise even >3 years
  - b. Stop after they get initial relief
  - c. Stop because of cost
  - d. Stop and go for surgery because symptoms reappear
  - e. Stop because of non-availability
  - f. Others
14. In sexually active patients having BPH with mild ED, what is your preferred therapy
  - a. Alpha-blockers with Tadalafil
  - b. start with Tadalafil and then add Alpha-blocker
  - c. Alpha-blocker and on demand sildenafil
  - d. Others
15. What do you consider as the success of medical management for BPH?
  - a. Subjective improvement of symptoms -as per your assessment
  - b. Subjective improvement of symptoms -as per patient's feedback
  - c. Objective evidence of improvement in uroflowmetry parameters
  - d. Others
16. What % of your patients who are on medical therapy eventually go for surgical intervention?
  - a. <25%
  - b. 25-50%
  - c. 50-75%
  - d. >75%
17. Doctor, generally what is the initial duration (test duration) of first prescriptions of alpha-blockers that you prescribe?
  - a. 1-7 days
  - b. 1-15 days
  - c. 1-30 days
  - d. Others
18. How often do you get young patients (<60 yrs) with BPH symptoms?
  - a. <5%
  - b. 5-10%
  - c. 10-20%
  - d. >20%

**Figure 2: Geographical representation of participants**



**Figure 3: Factors governing choice of combination therapy**



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