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Editor's Choice

Medical treatment of benign prostatic hyperplasia: physician and patient preferences and satisfaction

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SUMMARY

Practice guidelines acknowledge the importance of patient preferences in determining the appropriate treatment of benign prostatic hyperplasia (BPH). Recent literature suggests that patient and physician perspectives and satisfaction with BPH treatment management may differ; this may have an impact on clinical outcomes and patient compliance. This review evaluates patients' and physicians' preferred treatment options for managing BPH and patient satisfaction with therapy. A Medline-based systematic review using the terms 'Benign prostatic hyperplasia' + 'Patient preference/perception/satisfaction' or 'Physician/urologist preference/perception' was performed. Patients prefer therapies affecting long-term disease progression over those that provide short-term symptom improvement, which contrasts with the beliefs of their physicians. The prescribing behaviour of urologists and primary care physicians can be very varied. Studies of patient satisfaction with specific treatments generally show a high level of overall satisfaction, but cross-study comparisons are limited because of heterogeneity in study design. The evidence to date suggests that patients' views and beliefs and those of their physician may not always be in agreement. Improved physician–patient communication will help determine the best treatment option for patients with BPH and may ensure greater compliance and treatment success.

Review Criteria

A systematic review of the literature was carried out in Medline using the search terms 'Benign prostatic hyperplasia' + 'Patient preference/perception/satisfaction' or 'Physician/urologist preference/perception' for articles published up to June 2008. Seven survey studies were identified that examined benign prostatic hyperplasia (BPH) treatment preferences, and six studies were identified that assessed satisfaction with specific medical treatments for BPH. It was not deemed appropriate to assess study quality because of heterogeneity in study designs.

Message for the Clinic

It is vital that physicians assess and fully understand their patients' satisfaction with benign prostatic hyperplasia (BPH) treatment, as well as knowing their preferred treatment options and expectations. Improved physician–patient communication will help determine the best treatment option for patients with BPH and may ensure greater compliance and treatment success. Large-scale studies such as Combination of Avodart® and Tamsulosin will provide further valuable information on patients' treatment preferences and long-term benefits of patient-reported health outcomes.

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Mark Emberton has acted as a paid consultant to GlaxoSmithKline and has received lecture fees from GlaxoSmithKline. He is also a UK Principal Investigator for the GlaxoSmithKline REDUCE study.

Introduction

Patient preferences are vital components of the appropriate treatment of benign prostatic hyperplasia (BPH), particularly as the symptoms of the disease and their impact on patients are heterogeneous and therefore difficult to predict (1). This is reflected in practice guidelines that highlight the importance of assessing preferences for one treatment over another in addition to the patient-reported health outcomes that result from those treatments (2).

A clear understanding of patient and physician perspectives and satisfaction with BPH treatment management has been limited by the lack of data in this field. Recent data from the Prostate Research on Behaviour and Education (PROBE) survey (3) and the Combination of Avodart® and Tamsulosin (CombAT) study (4) have provided a better understanding of preferences and satisfaction with BPH treatments, suggesting that patient and physician preferences may not always be aligned. In addition, prescribing practices differ somewhat between primary care physicians (PCPs) and urologists.

Guidelines from the American Urological Association and European Association of Urology describe treatment options for patients with BPH. The treatment strategy for BPH involves the improvement of lower urinary tract symptoms (LUTS) and the reduction in the risk of acute urinary retention (AUR) and BPH-related surgery, as well as improvement in quality of life (2,5). Watchful waiting is

recommended for patients with mild–moderate BPH symptoms that are not bothersome. For patients with bothersome mild–moderate BPH symptoms, medical treatment is recommended, which involves two principal drug classes: the α-adrenergic receptor antagonists (α-blockers) and the 5α-reductase inhibitors (5ARIs). The response to treatment is also an important factor to consider; symptom worsening under treatment is a strong predictor of AUR and surgery (6,7).

Adrenoceptors on the smooth muscle in the bladder neck and the prostate are the target for α-blockers, and the relaxation of the muscle tone that ensues from this receptor blockade provides rapid symptomatic relief (8,9), although central actions may also contribute to the effect (10,11). α-Blockers do not inhibit the growth of the prostate or slow the natural progression of BPH, therefore the advantages of α-blocker therapy primarily extend to the improvement of BPH symptoms and not to reduce the risk of complications such as AUR and BPH-related surgery.

5α-Reductase inhibitor inhibit the conversion of testosterone to dihydrotestosterone, and by reducing prostate volume they provide long-term symptom improvement and reduce the risk of serious complications such as AUR and surgery (8,12–14). Data from the Medical Therapy of Prostatic Symptoms study (8) and the CombAT study (15) have shown that combination therapy with an α-blocker and a 5ARI leads to significantly greater improvements in symptoms than with either agent alone.

This review examines the available data for preferences and satisfaction with medical treatment of BPH; a better understanding of patient preferences should allow a more tailored treatment approach that may have benefits for improved patient compliance and therapeutic outcomes.

Evidence acquisition

A systematic review of the literature was carried out in Medline, using the search terms 'Benign prostatic hyperplasia' + 'Patient preference/perception/satisfaction' or 'Physician/urologist preference/perception'. All clinical trials, retrospective analyses and surveys, in English, were included, in which patient or physician preferences and satisfaction regarding BPH and its treatment (medical not surgical) were assessed (published up to June 2008).

The quality of each study could not be formally rated, as no measure was deemed to be appropriate because of the nature of the studies and heterogeneity in study design.

Evidence synthesis

Treatment preferences

A total of seven survey studies have examined BPH treatment preferences (Table 1). Of these, one study examined preferences in the general population, two studies examined preferences in patients, two studies examined preferences in physicians and two studies examined preferences in both patients and physicians.

General population

A random selection of 208 men in the UK aged ≥ 40 years completed questionnaires on their opinions of potential treatment with an α-blocker or 5ARI using trade-off techniques (16). The predefined list of factors investigated, developed in conjunction with urologists, included time to symptom improvement, sexual and non-sexual side effects, risks of AUR and surgery, cost and decrease in prostate size.

The potential treatment side effects, particularly impotence, decreased libido and dizziness, were most important for determining preference for one treatment over another. Time trade-off analysis showed that men would wait 13 months for symptom improvement in exchange for decreased prostate size, but only 2 and 8 months for symptom improvement in exchange for an absolute 1% decrease in the risks of AUR and surgery respectively. Men who reported moderate symptoms of BPH according to the International Prostate Symptom Score (IPSS) were less concerned about sexual side effects, time to symptom improvement and risk of AUR than those who reported mild BPH symptoms.

Patients

Patient treatment preferences were evaluated in 87 hospital outpatients undergoing preliminary diagnostic assessment for BPH (17). Three treatment strategies were described: watchful waiting, α-blocker therapy and transurethral resection of the prostate (TURP). The treatments were presented to the patient in pairs, with information on the chance of symptom improvement and the chance of risks (including immediate complications, death, urinary incontinence, impotence and need for future prostate surgery), and the patient selected which of the two would be the more favourable option. Probability trade-off techniques were then used to assess the strength of the respondent's preference for the treatment ranked in first place. Six subgroups were identified, based on the order of the preferred treatment options of each patient. Most patients (63.2%) were in the two subgroups placing TURP as the least favoured option – these patients reported

Table 1 Surveys in which patient or physician overall preferences regarding BPH treatment were elicited

Study	Study design	Survey population	Method of eliciting preferences	Summary
Watson et al. (16)	Interview-based survey in the UK	Men aged ≥ 40 years selected at random from the general population (n = 208)	Discrete choice trade-off experiment based on characteristics of a hypothetical α-blocker and 5ARI (pretreatment assessment)	Men would wait longer for symptom improvement in exchange for decreased prostate size (13 months) than they would in exchange for an absolute 1% decrease in the risks of AUR (2 months) and surgery (8 months)
Llewellyn-Thomas et al. (17)	Interview-based survey of hospital outpatients in Canada	Men aged 51–95 years (mean age 68 years) undergoing initial diagnostic assessment for BPH (n = 87)	Probability trade-off between three hypothetical treatment options: watchful waiting, treatment with an alpha blocker or TURP (pretreatment assessment)	More patients rated watchful waiting as a first choice vs. α-blocker therapy (47% vs. 34% respectively)
Piercy et al. (18)	Assessment of a shared decision-making programme for patient education in Canada	Men with symptomatic BPH (n = 635). Median age 63 years. 31.1% had mild BPH symptoms, 47.3% had moderate symptoms and 21.6% had severe symptoms	Question relating to preference for surgical or non-surgical treatment (patient answered 'definitely prefer surgery', 'probably prefer surgery', 'no preference', 'probably prefer non-surgical therapy' or 'definitely prefer non-surgical therapy') (pretreatment assessment)	59.4% of patients had a definite or probable preference for non-surgical therapy, while only 9.1% of patients expressing a preference for surgery; however, patients with severe symptoms were more than twice as likely to prefer surgery then those with mild or moderate symptoms
Kaplan and Naslund (19)	National telephone survey in the USA	Men aged 50–79 diagnosed with enlarged prostate (n = 419). 52% had mild/no symptoms, 48% had moderate/severe symptoms Urologists (n = 100) PCPs (n = 100)	Questionnaire covering issues including choice of treatment (physician), recollections of treatment decisions (patients) and attitudes to treatment (patients/physicians). 74 questions for patients with enlarged prostate, 58 questions for PCPS/urologists (pretreatment assessment)	Most of the men were more worried about long-term risks of BPH than with immediate symptom relief (70%); however, few physicians (31–37%) believed that patients were more concerned with long-term effects than immediate symptom relief
Emberton et al. (PROBE study) (3)	Interview-based study in five European countries	Patients aged 45–80 years receiving prescription medication for BPH (n = 502) Urologists (n = 100)	Questionnaires (physician- or patient-oriented) covering beliefs and perceptions about BPH and its treatment. Part 1 of the questionnaire involved 18 questions (plus some sub-questions) on initial experiences regarding diagnosis and management of BPH. Part 2 involved nine questions (plus some sub-questions) relating to awareness and understanding of BPH treatments. Patients had to have consulted with a physician in the past 12 months for BPH or enlarged prostate, and be receiving medications for their prostate problem at the time of interview	In general, reducing progression to surgery was favoured over symptom relief regardless of whether patients were receiving an α-blocker or 5ARI 63% of urologists reported prescribing drug therapy to more than 70% of their patients; α-blockers were prescribed for most of the patients who received medical therapy
Stoevelaar et al. (20)	Questionnaire-based survey of urologist preferences in the Netherlands	Urologists (n = 39) 13.3% of patients had a PV of < 20 ml; 68.4% had a PV of 20–49 ml and 18.3% had a PV of ≥ 50 ml	Questionnaire of 23 diagnostic conditions to be rated as 'for' or 'against' the use of watchful waiting, surgery, finasteride or an α-blocker, based on data from 670 patients. Pretreatment assessment, which was then compared against actual choice of treatment	The preference of the treating urologist had a 'considerable influence' on the actual treatment choice in BPH
Seftel et al. (21)	Mail-based questionnaire survey of US physicians	Urologists (n = 1087) PCPs (n = 177)	12-Item questionnaire covering treatment of patients with BPH (post-treatment assessment)	Most patients received medical therapy, with a similar distribution among urologists (59%) and PCPs (62%); α-blockers were the most common medication prescribed by urologists and PCPs.

5ARI, 5α-reductase inhibitor; BPH, benign prostatic hyperplasia; PCP, primary care physician; PV, prostate volume; AUR, acute urinary retention; TURP, transurethral resection of the prostate.

significantly higher health utility scores for BPH symptoms than those who ranked TURP first or second ($p < 0.0005$). More patients rated watchful waiting as their first choice option above α-blocker therapy (47% vs. 34% respectively).

Piercy et al. evaluated treatment preferences in 635 Canadian men with BPH who had not yet undergone any treatment, by asking the question 'Based on what you know now, what is your current treatment preference between surgical and non-surgical therapy?'; the response categories were 'definitely prefer surgery', 'probably prefer surgery', 'no preference', 'probably prefer non-surgical therapy', 'definitely prefer non-surgical therapy' and 'not sure'. Patients (59.4%) had a definite or probable preference for non-surgical therapy, with 31.5% of patients unsure and only 9.1% of patients expressing a preference for surgery (18). Patients with severe symptoms were more than twice as likely to prefer surgery than those with mild or moderate symptoms. Viewing an educational programme had only a minor impact in changing the preferences of those patients who had expressed an initial preference (for either surgery or medical treatment), with 89.7% and 89.4% of patients preferring surgical and non-surgical therapy (respectively) maintaining their preferences after viewing the programme. However, the programme reduced the percentage of patients who were unsure about their preference to 14.8%.

In a telephone survey conducted in the USA, 419 men diagnosed with BPH were questioned about preferences and attitudes towards BPH treatment (pretreatment assessment) (19). The survey included 74 questions from a number of validated symptom and quality of life scales, including the American Urological Association-Symptom Index, BPH Impact Index, Health Related Quality of Life index, and Jackson Sleep Scale. Preferences for BPH medication were not significantly influenced by the patient's symptom severity. Most men (70%) with moderate–severe BPH agreed that they were more concerned about the long-term risks of their condition than about symptoms (Figure 1). Patients (64%) with moderate–severe symptoms were willing to wait up to 3 months for symptom relief if long-term treatment was achieved, and 76% were willing to take two medications to reduce prostate size and provide symptom improvement. The most important attributes of a medication were prevention of further prostate enlargement, sustained reduction of prostate size and reduction of the risk of surgery.

The recent PROBE study evaluated healthcare-seeking behaviour and attitudes towards medical treatment in 502 patients with BPH, and the beliefs and management practices of 100 urologists from France, Germany, Italy, Spain and the UK (3). Eligible patients had consulted a physician in the past 12 months for BPH and were receiving prescription medications for their prostate problem at the time of interview. The patients received either an α-blocker or the 5ARI finasteride and were asked their treatment preference by rating attributes of a drug treatment for BPH on a scale of 1 (drug providing a 50% reduction in the risk of surgery and onset of symptom relief within 6 months) to 8 (drug providing relief from symptoms within 2 weeks but no reduction in the risk of surgery) (Figure 2). The average total score was 3.0, with more than 75% of patients preferring a drug that provides a 50% reduction in the risk of surgery than one offering faster symptom relief.

In general, reducing progression to surgery was favoured over symptom relief regardless of whether patients were receiving an α-blocker or 5ARI, although there was minor variation across countries.

Physicians

Stoevelaar et al. used a questionnaire to assess urologist preferences in a study in the Netherlands (20). Based on data from 670 BPH patients referred to one of 39 urologists, a list of 23 diagnostic criteria was developed, and the urologists were asked to rate each criterion as 'for' or 'against' the use of watchful waiting, surgery, the 5ARI finasteride or an α-blocker. Agreement on criteria between urologists was poor. In a logistic regression analysis, urologist personal preference for treatment was significantly correlated with the actual choice of treatment, with a 2.2 times greater probability of the urologist preferring surgery. For finasteride and α-blockers, these ratios were 9.4 and 1.8, respectively, in the probability of that type of therapy being prescribed. The authors concluded that 'the influence of urologist personal preferences on treatment choice in BPH is considerable'; however, this study was performed nearly 10 years ago, and the present situation may be different.

In a larger, more recent survey of US physicians, questionnaire responses were obtained from 1087 urologists and 177 PCPs on treatment preferences and perceptions of side effects for patients with LUTS or BPH (21). Most patients received medical therapy, with a similar distribution among urologists (59%) and PCPs (62%); α-blockers were the most common medication prescribed by urologists and PCPs.

Patients managed by urologists were more likely to receive an α-blocker than those managed by PCPs (56% vs. 47%), while 5ARIs were more likely to be

prescribed by a PCP than by a urologist (21% vs. 13%). Asked about side effects of α-blockers, PCPs perceived a higher incidence of erectile dysfunction (34%) and reduced libido (25%) in their patients compared with urologists (23% and 17%), while urologists perceived a higher incidence of ejaculatory dysfunction (32%) compared with PCPs (22%). Asked about side effects of 5ARIs, PCPs and urologists perceived similar rates. PCPs reported similar levels of sexual side effects with 5ARIs and α-blockers, while urologists observed a higher rate of ejaculatory dysfunction (28%) and a lower rate of reduced libido (10%) with α-blockers compared with 5ARIs (16% and 17% for ejaculatory dysfunction and reduced libido respectively) (21).

In the telephone survey in the USA (19), 100 urologists and 100 PCPs were asked about preferences and attitudes towards BPH treatment, in addition to patients answering questions about their preferences and attitudes. More urologists than PCPs rated 5ARIs as very effective in reducing prostate size (52% vs. 19%) and halting disease progression (40% vs. 21%), while more PCPs than urologists rated α-blockers as very effective in achieving these same goals (5% vs. 1% for reducing prostate size; 10% vs. 4% for halting disease progression). However, contrary to the findings of patient preferences, few physicians believed that patients are more concerned with long-term effects than symptom relief (31% of PCPs and 37% of urologists; Figure 1).

In terms of physician preferences in the recent PROBE study (3), 63% of 100 urologists reported that they prescribe drug therapy to more than 70% of their patients. Of those who chose medical treatment, α-blockers were prescribed for most of the patients. Although 58% of urologists reported prescribing α-blockers in > 70% of cases, none prescribed 5ARIs in > 70% of cases, the majority (85%) prescribing 5ARIs in ≤ 30% of cases. Prescription of α-blockers was highest in the UK (75% prescribe to > 70% of patients), while prescription of 5ARIs was highest in Italy (45% prescribe to 31–70% of patients). Factors that were considered important when choosing to prescribe drugs for BPH were prostate volume (68% of urologists) and evidence of progression (66% of urologists). Overall, 78% of urologists thought that 5ARIs would reduce the risk of BPH progression, whereas 44% thought that α-blockers could reduce the risk of progression.

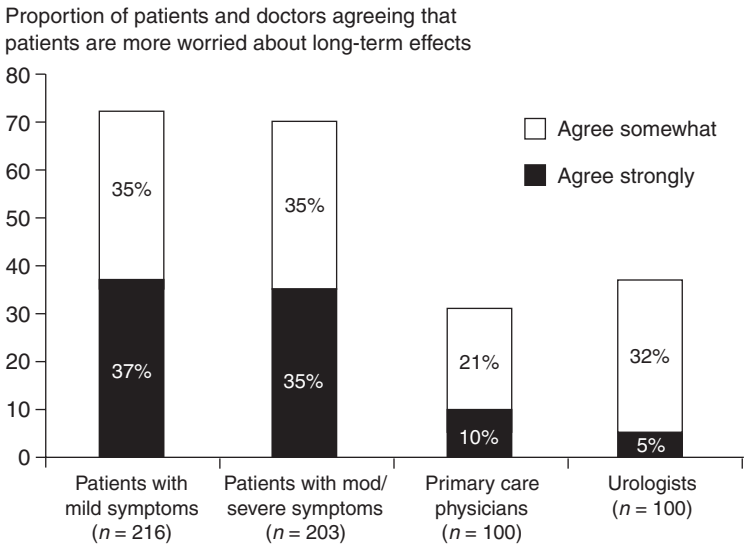

Figure 1 Most of the men in the Kaplan survey were more worried about long-term risks of benign prostatic hyperplasia than with immediate symptoms. On the other hand, most physicians believed that patients were more concerned with immediate symptom relief than with long-term effects (19). Reproduced from Ref. (19) with permission from Wiley Blackwell

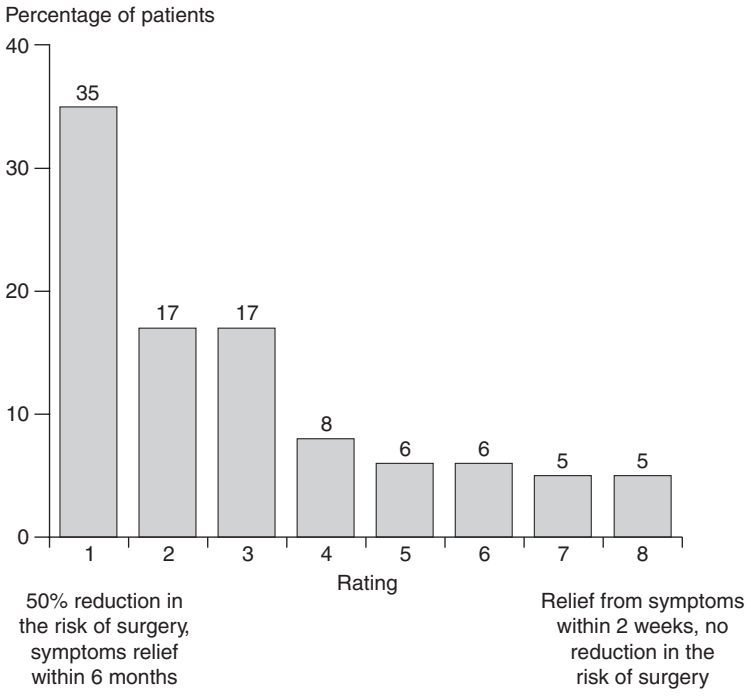

Figure 2 Patient selection of important drug attributes on a scale of 1–8, where 1 is a drug providing a 50% reduction in the risk of surgery and onset of symptom relief within 6 months, and 8 is a drug providing relief from symptoms within 2 weeks but no reduction in the risk of surgery (n = 502) (3). Reproduced from Ref. (3) with permission from Wiley Blackwell

Treatment satisfaction

A total of six studies were identified that assessed satisfaction with specific medical treatments for BPH (Table 2). Of these, two studies were patient surveys, one was a clinical trial of 5ARI therapy, two were clinical trials of α-blocker therapy and one was a clinical trial of combination therapy.

Table 2 Surveys and clinical trials evaluating patient satisfaction with treatment of their BPH

Study	Study design	Patient population	Treatment(s)	Satisfaction outcome measure	Summary of improvement in satisfaction
Surveys					
Kaplan and Olsson (22)	US telephone survey of patients 9–12 months after surgery or starting finasteride treatment	Men with symptomatic BPH. Average age 69.4 years in finasteride group, 72.7 years in TURP group. 87% of men in finasteride group and 76% in TURP group rated their pretreatment BPH symptoms as moderate or severe	TURP (n = 109) Finasteride (n = 102)	Satisfaction with treatment response (five-point scale ranging from 'excellent' to 'poor') at 3 months	87% of patients stated that finasteride improved their condition
Emberton et al. (PROBE study) (3)	Interview-based study in five European countries	Men (age range 45–80 years) with BPH receiving prescription medication	α-Blocker (n = 288) 5ARI (n = 65)	Satisfaction with treatment response (five-point scale: not at all satisfied, not very satisfied, fairly satisfied, very satisfied, or neither satisfied nor dissatisfied). Patients had to have consulted with a physician in the past 12 months for BPH or an enlarged prostate, and had to be receiving prescription medications for their prostate problem at the time of interview	80% of patients receiving finasteride reported satisfaction 68% of patients receiving an α-blocker reported satisfaction
Clinical trials – 5ARI therapy					
Desgrandchamps et al. (23)	24-Week open-label trial	Men aged ≥ 50 years with symptomatic BPH and prostate volume ≥ 30 ml. Mean IPSS score 15.3 (moderate disease severity)	Dutasteride 0.5 mg/day (n = 366)	0–100 Visual analogue scale at 12 and 24 weeks	Satisfaction increased significantly at weeks 12 and 24 with dutasteride ($p < 0.001$; values not reported)
Clinical trials – α-blocker therapy					
Cam et al. (24)	3-Month open-label trial	Men aged ≥ 50 years with LUTS and no indication for surgery. PSA < 4 ng/ml. Mean IPSS score 24 (moderate disease severity)	Doxazosin 4 mg/day (n = 178)	Self-report questionnaire of effectiveness of treatment (three-point scale: ineffective, no change in symptoms, effective), assessed at months 1 and 3	44% of patients considered doxazosin effective
Hareendran and Abraham (25)	12-Week randomised, double-blind, placebo-controlled trial	Men aged ≥ 40 years with LUTS plus IPSS ≥ 13 and Q_{max} 5–15 ml/s. Mean IPSS score 18.55 (moderate disease severity)	Placebo (n = 65) Low dose α-blocker* (n = 127) Medium-dose α-blocker* (n = 129) High-dose α-blocker* (n = 125)	TSS–BPH. Consists of 13 items; 11 have a five-point Likert-like response scale, 2 have dichotomous (yes/no) response options. Assessed at the end of the study, or at withdrawal	Overall satisfaction was significantly greater in the high-dose ($p = 0.045$) and medium-dose ($p = 0.010$) α-blocker groups vs. placebo

Table 2 (Continued)

Study	Study design	Patient population	Treatment(s)	Satisfaction outcome measure	Summary of improvement in satisfaction
Clinical trials – combination therapy					
Barkin et al. (CombAT study) (4)	4-Year randomised, double-blind, parallel-group study	Clinically diagnosed BPH in men aged ≥ 50 years, IPSS ≥ 12 units, prostate volume ≥ 30 cc, PSA 1.5–10.0 ng/ml, Q_{max} > 5 ml/s and minimum voided volume ≥ 125 ml	Dutasteride (0.5 mg/day) (n = 1623) Tamsulosin (0.4 mg/day) (n = 1611) Combination therapy (n = 1610)	PPSM questionnaire. 12-Item questionnaire of satisfaction across different aspects of urinary symptoms. Individual scores for questions 1–11 ranged from 1 to 7; response to question 12 was yes, no or not sure. Assessed at baseline then every 3 months during treatment	81% of patients reported overall satisfaction with improvement in urinary problems with combination therapy; 74% with dutasteride monotherapy; 73% with tamsulosin monotherapy

*Specific agent and doses not stated in manuscript.
5ARI, 5α-reductase inhibitor; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; NA, not applicable; PPSM, Patient Perception of Study Medication; PSA, prostate-specific antigen; Q_{max}, maximum urinary flow rate; TILC, transurethral interstitial laser coagulation; TSS–BPH, Treatment Satisfaction Scale–Benign Prostatic Hyperplasia; TUIP, transurethral incision of the prostate; TUMP, transurethral microwave thermotherapy of the prostate; TURP, transurethral resection of the prostate.

Patient surveys

In a US telephone survey, 211 men who had undergone TURP within the last 9–12 months or been receiving the 5ARI finasteride for 9–12 months were asked to rate their satisfaction with their treatment on a five-point response scale ranging from 'excellent' to 'poor' (22). In patients receiving finasteride, 54% rated their health as 'excellent' or 'very good'; no patient rated their health as 'poor'. Eighty-seven per cent of patients stated that treatment had improved their condition; 13% stated that it had remained the same; and no patients reported that it had got worse. Ninety-seven per cent of patients would recommend this 5ARI to a friend or relative with BPH. In patients who had undergone TURP, 51% categorised their health as 'excellent' or 'very good'; 16% rated it as 'fair' or 'poor'; 79% of patients considered their condition improved; 15% reported it was the same; and 5% considered their condition worsened. The percentage of patients who would recommend TURP to a friend or relative was not reported.

As part of the PROBE study, treatment satisfaction was assessed in patients receiving treatment for BPH. Patients rated their satisfaction with treatment as 'very satisfied', 'fairly satisfied', neither satisfied nor dissatisfied', 'not very satisfied' or 'not at all satisfied' (3). Of patients receiving finasteride monotherapy, 80% were 'fairly' or 'very' satisfied with treatment, compared with 68% of patients receiving an α-blocker. Satisfaction varied across countries, with 85% of Italian patients satisfied with finasteride compared with 60% of German patients. Medication was changed in 19% of patients since their original diagnosis, with a lack of symptom improvement (38%) cited as the main reason for the switch.

Clinical trials of medical treatment

As part of a French open-label trial of the 5ARI dutasteride (0.5 mg/day), satisfaction with treatment was evaluated in 366 men after 12 and 24 weeks (23). Patients rated satisfaction from 0 to 100 on a visual analogue scale (with higher scores indicating a greater level of satisfaction). Satisfaction score increased significantly from baseline (zero) at weeks 12 and 24 ($p < 0.001$). Satisfaction score was significantly correlated with an improvement in IPSS score ($p < 0.001$).

Satisfaction with the α-blocker doxazosin (4 mg/day) was evaluated in 178 men in a 3-month open-label trial in Turkey (24). Patients were asked 'What is your opinion about the efficacy of the drug you have taken to relieve your urinary symptoms?' Possible answers were: (i) ineffective (their symptoms are worse, they are not happy with this drug), (ii) no

change in symptoms (their complaints are not changed, they are unsure whether or not to use this medication) or (iii) effective (their symptoms are improved, and they wish to continue this drug). Doxazosin was considered effective by 44% of patients, ineffective by 23% of patients and there was no change in 33% of patients. After 1 year, 93% of patients in the 'ineffective' group, 59% of patients in the 'no change' group and 15% of patients in the 'effective' group underwent subsequent surgery. The probability of surgery was significantly higher in patients who considered treatment ineffective than in the other two groups ($p < 0.05$), and was also significantly higher in those who felt that their condition remained unchanged than in those who considered treatment effective ($p < 0.05$).

In a 12-week multinational randomised, double-blind trial, three doses ('low', 'medium' and 'high') of an unnamed α-blocker were compared with placebo (25). The 'Treatment Satisfaction Scale–Benign Prostatic Hyperplasia', a validated, disease-specific 13-item questionnaire, was used to assess patient's perceptions of satisfaction with efficacy, dosing and side effects on a scale of 0–100, with lower scores indicating greater satisfaction with treatment. Overall satisfaction and satisfaction with efficacy were significantly greater in the high-dose ($p = 0.045$ and $p = 0.003$ respectively) and medium-dose ($p = 0.010$ and $p = 0.005$ respectively) groups, compared with placebo (Table 3). Satisfaction with side effects was significantly worse in the high-dose group ($p = 0.001$ vs. placebo).

In the planned 2-year analysis of the randomised, double-blind 4-year CombAT study in 4844 men with moderate–severe BPH, the combination of dutasteride (0.5 mg/day) plus tamsulosin (0.4 mg/day) was compared with each drug administered alone (26). Two-year data from this study have been reported (4,15). Patient treatment satisfaction was assessed using a specifically developed instrument, the Patient Perception of Study Medication (PPSM) questionnaire, which consists of 12 questions that assess a patient's perception of improvement and satisfaction with response across a range of domains and the desire to request the medication received in the study. Results of the preliminary validation of this questionnaire have been published (27).

At month 24, the percentage of patients reporting an improvement, satisfaction or desire to request study treatment in response to the 12 PPSM questions was significantly higher with combination therapy compared with either monotherapy (Table 4; $p < 0.01$), with the exception of improvement in pain prior to urination, for which combination therapy was not significantly superior to tamsulosin ($p > 0.01$). The percentage of patients reporting overall satisfaction with treatment (PPSM Question 11) was significantly higher with combination therapy from month 3 vs. dutasteride and from month 15 vs. tamsulosin (Figure 3; $p < 0.01$).

Discussion

In the management of men with LUTS/BPH, it is important to appreciate the relative perspectives of both patient and physician as these perspectives exhibit great variability. Similarly, understanding the determinants of satisfaction with various therapeutic alternatives is as important as these factors are likely to have the greatest impact on quality of life, compliance and persistence with therapy over time, and ultimately may affect to what degree clinical outcomes are improved.

Many different methods have been used to evaluate physician behaviour, patient preferences and treatment satisfaction, making comparisons between studies difficult. Overall, surveys show substantial differences in prescribing behaviour of primary and secondary physicians. In one survey, urologists were found to be more likely than PCPs to rate 5ARIs as highly effective, with the reverse true for α-blockers (19). Seemingly in contrast to this observation, a second survey showed that patients managed by a urologist were more likely to receive an α-blocker,

Table 3 Adapted from Hareendran and Abraham (25). Treatment satisfaction scores by treatment group. Values are expressed as mean (SD). Lower scores indicate better satisfaction

	Placebo *n* = 65	Low dose α-blocker *n* = 127	Medium-dose α-blocker *n* = 129	High-dose α-blocker *n* = 125
Satisfaction with efficacy	39.11 (18.07)	36.10 (15.09)	31.61 (15.94)*	31.41 (17.91)*
Satisfaction with side effects	6.15 (18.68)	6.77 (18.03)	9.30 (21.66)	18.55 (30.19)*
Overall satisfaction	30.56 (13.59)	28.77 (11.30)	25.19 (12.28)*	26.64 (14.86)*

*$p < 0.05$ vs. placebo.

while 5ARIs were more likely to be prescribed by PCPs (21). The differing attitudes of physicians with regard to their prescribing behaviour for the medical treatment for BPH may relate to the belief among up to 10% of PCPs that α-blockers can halt disease progression (19). Although α-blockers are effective at relieving bothersome symptoms, they do not slow the progression of BPH (28–30). The time frame for the management of BPH should also be considered when interpreting these contrasting results as it may differ between PCPs and urologists. The PCP, for example, may have a period of 12 months or less in mind when writing a prescription; in which case, α-blockers work quickly and are effective at reducing symptoms in about two-thirds of patients.

When urologists were asked to rate criteria that determined the prescription of four treatment modalities, there was little agreement (20). Surveys of patient and physician preferences show that physicians may not fully appreciate their patients' views of treatment. Men with BPH are often more worried about the long-term risks of their condition than they are about immediate symptoms, but most doctors believe that patients are more concerned with symptom relief (19) (Figure 1). Improved physician–patient communication is therefore required to help determine the best treatment option for patients with BPH.

Two studies demonstrated that the priority for patients is the treatment of underlying disease rather than immediate symptom relief (16,19). In the Kaplan and Naslund study, patients were willing to wait up to 3 months for symptom relief if long-term treatment of the underlying condition was achieved, and patients in the Watson study would wait 13 months in exchange for a decrease in prostate size. The longer length of time that patients would be willing to wait in the Watson study may be a reflection of the fact that this was a discrete choice experiment in which a younger population of patients was assessed (208 men aged > 40 years; 10% over the age of 70), only 20% of whom had moderate-severe BPH symptoms, and 93% had not previously received any treatment for BPH. In contrast, the Kaplan and Naslund study used over twice as many men from a national sample (n = 419) with a diagnosed enlarged prostate, aged 50–79 years (42% over the age of 70), and 48% had moderate–severe BPH symptoms. This suggests that older patients with more severe BPH symptoms may be less willing to wait for symptom relief.

Surveys did not routinely discuss the potential side effects that result from different BPH treatments, which may be important for determining a patient's preference for one treatment over another. For example, sexual dysfunction (including erectile dysfunction) commonly occurs in parallel with BPH (31), and men may wish to avoid any medications that have side effects relating to sexual dysfunction.

In terms of patient satisfaction, the importance of immediate symptom relief remains unclear. Treatment satisfaction with dutasteride has been demonstrated to be related to symptom relief (23), and

Table 4 Adapted from Barkin et al. (4). Percentage of patients reporting an improvement, satisfaction or desire to request study treatment in response to the Patient Perception of Study Medication (PPSM) questionnaire

	Percentage of patients with any improvement/satisfaction		
PPSM question	**Combination**	**Dutasteride**	**Tamsulosin**
Q1. Improvement in control of urinary problems			
Baseline	44	41	45
Month 24	81*†	75	76
Q2. Satisfaction with control of urinary problems			
Baseline	45	41	43
Month 24	80*†	73	73
Q3. Improvement in strength of urinary stream			
Baseline	40	38	39
Month 24	77*†	67	67
Q4. Satisfaction with change in strength of urinary stream			
Baseline‡	40	37	39
Month 24	76*†	67	66
Q5. Improvement in pain prior to urination			
Baseline‡	39	37	39
Month 24	75*	67	69
Q6. Satisfaction with change in pain prior to urination			
Baseline‡	41	38	39
Month 24	71*†	64	65
Q7. Improvement in pain during urination			
Baseline‡	38	35	39
Month 24	75*†	67	69
Q8. Satisfaction with change in pain during urination			
Baseline‡	40	38	39
Month 24	71*†	63	66
Q9. Improvement in level of interference with daily activities			
Baseline‡	32	30	31
Month 24	73*†	66	66
Q10. Satisfaction with change in level of interference with daily activities			
Baseline‡	39	35	37
Month 24	76*†	70	69
Q11. Overall satisfaction with improvement in urinary problems			
Baseline‡	46	43	44
Month 24	81*†	74	73
Q12. Would you ask your Dr for the medication you received in the study?			
Yes			
Baseline‡	38	35	37
Month 24	65*†	60	60

*$p < 0.01$ for combination vs. dutasteride; †$p < 0.01$ for combination vs. tamsulosin. ‡Baseline assessment was made after 4 weeks of placebo run in.

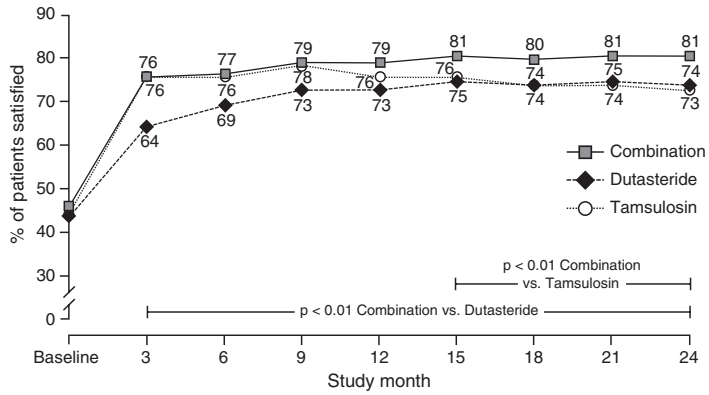

Figure 3 Proportion of subjects reporting satisfaction overall with treatment and its effect on their urinary symptoms [question 11 of the Patient Perception of Study Medication (PPSM)]. At month 24, the proportion of patients reporting any satisfaction with treatment in response to question 11 was significantly higher with combination (81%) than with dutasteride (74%) and than with tamsulosin (73%), and the onset of significance was from month 3 for combination vs. dutasteride ($p < 0.001$) and from month 15 for combination vs. tamsulosin ($p < 0.01$) (4). Reproduced from Ref. (4) with permission from Wiley Blackwell

studies of patient satisfaction with specific treatments generally show a high level of overall satisfaction (Table 2). However, some of these studies have important limitations, such as small sample sizes, open-label/non-comparative studies, and satisfaction assessed with a single question rather than a validated questionnaire. Not all studies looked at what drove satisfaction, e.g. symptom reduction. In addition, very few studies reported baseline prostate-specific antigen level or prostate volume, and this can have important implications for the type of agent that is prescribed by the physician, and thus can possibly influence whether or not the patient achieves satisfaction.

The CombAT study is the first to evaluate treatment satisfaction with combination therapy compared with each monotherapy, using a specific validated questionnaire developed to evaluate satisfaction (PPSM). In addition, sustained improvements in quality of life measures, assessed using IPSS Question 8 and the BPH Impact Index, were demonstrated for dutasteride compared with tamsulosin. This is a methodologically rigorous, long-term study, which is assessing outcomes in a large BPH patient population. The 2-year findings showed that combination therapy with a 5ARI and α-blocker provided significantly greater improvements in treatment satisfaction compared with either monotherapy.

Conclusions

The available data suggest that patients prefer therapies that affect long-term disease progression over those that provide short-term symptom relief. This preference may be underestimated by physicians, and there may be a general discord between patients' views and beliefs and those of their physician. Therefore, it is vital that physicians assess and fully understand their patients' satisfaction with BPH treatment, their preferred treatment options and expectations. There are also differences between urologist and PCP preferences, reflected in prescribing patterns. Patient satisfaction with BPH treatment is generally reported as high, although the use of non-validated questionnaires in small, open-label non-controlled studies makes interpretation of data difficult.

Results from large-scale, methodologically robust studies such as CombAT provide clearer information on patients' treatment preferences and the long-term benefits of patient-reported health outcomes. Greater treatment satisfaction is likely to be associated with greater compliance, which can lead to improved outcomes and greater treatment success.

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