Chapter 2: Methodology

Introduction

The original benign prostatic hyperplasia clinical practice guideline published in 1994 by the Agency for Health Care Policy and Research (AHCPR; now known as the Agency for Healthcare Research and Quality or AHRQ), was developed using an explicit approach as outlined by David M. Eddy [11]. In this approach, specific outcomes data (results of outcome measures extracted from a variety of studies) are combined and analyzed. Patient preferences with regard to these outcomes are assessed and overlayed to determine treatment recommendations. Thus, the process creates practice recommendations using a methodology that systematically considers relevant factors for selecting among alternative interventions.

The original Benign Prostatic Hyperplasia (BPH) Guideline Panel, comprising urologists, internists, a family physician, a radiologist and a registered nurse (Appendix 2-A), was appointed by the AHCPR under the auspices of the United States Department of Health and Human Services. This group conducted a literature search, and extracted data from relevant studies published as early as 1937 through the year 1991 that evaluated the diagnosis and treatment of BPH. From these data, the sensitivity, specificity and utility of various diagnostic tests were explicitly described and used to define diagnostic recommendations and options. In addition, the net value of all treatment modalities was determined using the treatment preferences of individual patients with varying symptoms of BPH as a key factor in the analysis.

The American Urological Association (AUA) Benign Prostatic Hyperplasia Guideline Update Panel (hereafter the Panel; Appendix 2-B), which included many of the original panel members, followed the same basic methodology in developing this updated guideline, including:

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- a structured evidence review leading to assessments of the benefits and harms of alternative therapies;
- consideration of patient preferences; and
- use of a multidisciplinary expert panel and consultants to resolve discrepancies and to create clinically relevant practice policy recommendations to assist patients and physicians in a shared decision-making process.

For this update, a number of previously extracted randomized, controlled trials (RCTs) that met the Panel's extraction criteria were carried forward, reextracted, and included in the meta-analysis. The literature published on diagnosis was not revisited. (The rationale for this decision is detailed in Chapter 1.) Patient preferences were not reassessed because there was no reason to believe that important changes had occurred. Nevertheless, several significant process modifications were necessary. A different analytical method (which included Bayesian meta-analysis) was used due to the large number of subsequently published RCTs. When published data were not presented in a form compatible with the analytical approach, unpublished data were sought from the investigators of record. Economic analyses were not performed.

As in the 1994 AHCPR guideline, the principal objective of the literature analysis was to provide estimates of treatment outcomes of importance to patients. These outcomes were presented in a series of tables that enabled the Panel to formulate practice recommendations. The resultant recommendations would allow physicians and patients to make informed decisions about available therapies for BPH. Unfortunately, the published data did not always permit clear-cut estimates of outcomes. Similarly, the differences among outcomes were not always consistent, making the development of recommendations difficult. In these cases, that is, when the treatment of choice was not clear-cut, the outcomes tables were to be used as a source of

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information on which patients might base informed decisions while incorporating personal preferences.

Defining the topics, the literature search and data extraction

Defining the Topics

The Panel defined the topics to be addressed, such as the disease entity, which included the syndrome of lower urinary tract symptoms (LUTS), with or without enlargement of the prostate, and the Index Patient, a male greater than 50 years old with classic LUTS but with no other severe or confounding medical morbidities or other known causes of voiding dysfunction; revised the list of alternative interventions; and expanded the patient outcomes of interest. Establishing a list of appropriate treatment outcome measure(s) was a challenge since these measures differed from study to study. Treatment outcome measures were categorized as follows:

- measures of symptom severity and frequency (direct measures), such as the AUA Symptom Index/International Prostate Symptom Score (AUA/IPSS; Appendix 1-A)[26], the Boyarsky symptom index[102], the Madsen-Iversen symptom index[103]; various subsets and reworkings of these scoring systems; and other study-specific scores;
- measures of patient quality of life, such as the Disease Specific Quality of Life (QoL) Question from the IPSS, the BPH Impact Index (Appendix 1-B)[26] and other custom measures;
- measures of physiologic function (indirect outcome measures), such as peak urinary flow rate, average urinary flow rate and postvoid residual urine levels; and
- adverse events, such as side effects of drugs and complications associated with minimally invasive and invasive therapies.

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While indirect measures have the advantage of being objective and consistent, they do not measure outcomes of importance to patients. Patient concerns include symptoms such as urgency and frequency while peak urinary flow rate or residual urine levels indirectly relate to the outcomes that bother patients. Despite this insight, the Panel decided to include peak flow rate, an indirect measure, in the outcomes tables.

The 1994 AHCPR guideline panel deemed the symptom score to be the outcome most important to patients. Unfortunately, over the years, studies evaluating BPH treatment efficacy outcomes have used a variety of symptom scores, their subsets and adaptations. The Panel decided that the AUA/IPSS, the Boyarsky and Madsen-Iversen symptom indices and modifications of these would be used in the analysis. Because partial scores, such as the irritability or bothersomeness subscores, did not correlate well with full scores, they could not be combined with full scores and were not used in the analysis. To permit a meta-analytic combination, all scores were linearly adjusted to a 0- to 35-point scale corresponding to the AUA/IPSS. The options considered by the Panel, the reasons for this decision and an example of a score adjustment are detailed in Appendix 2-C.

Similarly, the Panel chose to analyze results of the two most frequently employed quality-of-life measures used in the published clinical trials: the BPH Impact Index, which is scored from 0 to 13, and the Disease Specific QoL Question, which is scored on a 6-point scale. These scores were deemed sufficiently different so that no attempt was made to adjust them to a single scale.

The efficacy outcome measures described are all represented by numbers on a scale that should change as a result of treatment; for example, urinary flow rate is expected to increase while the symptom and QoL Question scores are expected to decrease. In published studies, these changes are reported as follows: the final value, the absolute change from the baseline

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measurement and/or the percentage change from baseline. In the present literature review, very few investigators reported outcomes as the percentage change from baseline and even fewer reported measures of variance needed for meta-analysis. After exhaustive discussion, the Panel deemed the absolute change of a measure from baseline to be the best method of presentation of outcomes for this guideline given the data available. (See Appendix 2-C for more details about this decision.)

The Literature Search

A comprehensive data extraction form was devised to capture as much pertinent information as possible about each study (Appendix 2-D-a). The Panel chairpersons and staff developed suitable search terms and criteria. Reference sources included: the MEDLINE® database from 1991 to early 2000 using the search terms "benign prostatic hyperplasia" and "human subjects"; Panel members; and a few selected unpublished industry-generated studies. A total of 3413 references was identified (Appendix 2-D-b). From a review of study titles and abstracts, the Panel chairpersons identified a total of 365 references that was relevant for retrieval and data extraction (Appendix 2-D-b). Study results were requested from study authors when additional data were needed to permit meta-analysis or when the Panel members knew that the authors had important data about additional outcomes or follow-up times not previously published. Subsequent to the Panel's initial review of the data, in order to ensure that the guideline was current, additional literature searches identified new technologies and key studies for Panel scrutiny.

Data Extraction

Data extractors recruited from the residency program at the University of Texas Southwestern Medical Center in Dallas were trained to use the extraction form and then were

supervised by a Panel chairperson. While no formal quality measures were used, the extraction process included assessing study flaws. All articles were independently extracted by two extractors who then met and resolved differences. Failing a resolution, the Panel chairpersons or staff made the final decision. For unpublished data, the Panel served as extractors.

After reviewing the completed extraction forms, the Panel rejected 114 articles that contained no relevant data, duplicated data, lacked outcomes data, did not provide information that fit the extraction form or were superceded by a later article from the same investigators (Appendix 2-D-c). The remaining 251 articles were used as the source of data to update the clinical practice guideline (Appendices 2-D-d and 2-D-e). The studies that were actually used in the meta-analysis are listed by treatment modality in the comprehensive version of the outcomes tables (see Chapter 3). All data were entered into a Microsoft Access® (1997 to 2000) database (Microsoft Corporation, Redmond, Washington).

Figure 2-D-i categorizes by year of publication the number of articles reviewed and the number accepted for data extraction. Figure 2-D-ii classifies the articles by source. Approximately 77% of the included articles were published in the *Journal of Urology,* the *British Journal of Urology, Urology, European Urology*, the *Scandinavian Journal of Urology and Nephrology* or the *Journal of Endourology*.

Evidence combination

The data resulting from the article-selection and data-extraction process were combined to generate the comparative estimates for alternative interventions displayed in the outcomes tables (see Chapter 3). A variety of methods can be used to combine outcomes evidence from the literature. The choice of methods is based on the nature and quality of the evidence. In this case, the published evidence from the data-extraction process was a mixture of results from RCTs and

results from uncontrolled studies. Because data were generated from different study designs, they could not be combined directly. In addition, the RCTs employed different outcome measures and did not compare treatments to a standard control.

The original guideline panel treated all studies as single-arm clinical series. When published RCTs were treated as a clinical series, each arm of the study was considered as an independent study. The present analysis found a greater number of RCTs on literature review, making it possible to analyze them as such. Not all outcomes comparisons were possible using RCT data, however. In some cases, only clinical series data were available, or RCT data were reported in an unusable form. Furthermore, RCTs included different control groups. Creating outcomes tables that present comparable outcomes required development of an appropriate means of comparison. This approach combined a Bayesian meta-analysis of RCTs (pairwise analysis of differences between treatment and control) as such, along with Bayesian meta-analysis of the clinical series and the separate arms of RCTs (single-arm analysis). Where formal meta-analysis was not possible due to lack of data on the variances of study outcomes, single-arm weighted averages (SAWA) of all relevant study arms were used. The basic features of this analytical approach are outlined below and are detailed in Appendix 2-C:

1. Outcomes were presented in two manners. The primary efficacy outcomes (AUA/IPSS, peak urinary flow rate, BPH Impact Index score and the Disease Specific QoL Question score) were presented as estimated changes from pretreatment values. Adverse events (side effects of medical interventions and adverse outcomes of invasive therapies) were presented as estimated probabilities of occurrence.

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2. Placebo, sham procedure and transurethral resection of the prostate (TURP) were considered standard controls. Virtually all RCTs compared treatment to one of these controls.
3. All RCTs that compared the same treatment to the same control were meta-analyzed for each outcome. When an RCT was designed such that multiple treatments were compared to the same control, each treatment outcome was analyzed with the control in the appropriate meta-analysis. Three-way analyses were not performed.
4. In addition to the use of pairwise comparisons in meta-analyses of RCTs, either a single-arm meta-analysis (SAMA) or a SAWA was computed that combined all arms that dealt with a particular treatment regardless of study type. This combination was performed for each outcome.
5. Efficacy outcomes provided in the outcomes tables were calculated per the process described below. As mentioned earlier, the efficacy measures used in this meta-analysis were those reported as estimates of changes in symptom and QoL Question scores or in flow rates from baseline to endpoint. Weighted averages of all similar control arms were used to estimate changes for each of the three controls (placebo, sham and TURP). Single-arm weighted averages also were used to estimate changes for treatments or time points where RCT data were not available. Where RCT data were available, results of both analyses of controls and meta-analyses of treatments versus controls were added together to estimate changes in scores and flow rates from baseline for treatments:

   Consider a given RCT: If the change in symptom score from baseline to last measurement in control patients is -1 and in treated patients is -5, then the difference between groups in treatment effect is -4.

Meta-analysis creates parallel difference measures. To estimate the change from baseline for treatments, the weighted average of changes from baseline in symptom score in the control group was added to the estimated difference in scores between control and treatment groups:

> For example, if the weighted average of the control group outcomes yielded a change in a symptom score of -2 and an analysis of treatment group outcomes found a difference from the control group of -4, then the final estimate of change from baseline in symptom score in treated patients is -6.

It is worth noting that an estimate of change in control groups developed using this method may differ from results reported for any given RCT because the control arm weighted average includes RCTs of many different treatments.

6. Analysis of adverse events was based on the overall frequency of occurrence for each event, unlike those for the efficacy measures, which were based on differences from baseline. Several statistical analytic procedures were used, including analysis of RCTs in a pairwise fashion. However, the adverse event outcomes tables presented in Chapter 3 of this document reflect only a single-arm Bayesian meta-analysis because:
   a. Compared with RCTs, clinical series usually provide data on larger populations and present occurrences of rarer complications than reported in RCTs.
   b. Confidence intervals cannot be calculated for the RCT-based estimates of probabilities. While analysis of RCTs allows for computation of confidence intervals for the difference in outcomes between the treatment and the control groups, calculating confidence intervals for the incidence of a complication is not possible.

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c. It can be argued that results based on clinical series may be more generalizable to the Index Patient than those based on RCTs. Results based on a clinical series, though, may be biased because participants are not chosen randomly.

Meta-analysis results for RCTs also were generated for adverse events and are presented in the full outcomes tables (see Chapter 3).

7. Differences in outcomes among alpha-adrenergic blockers were evaluated. Bayesian subtraction of the posterior distributions estimated differences between alpha blockers with regard to efficacy outcomes and selected adverse events.
8. Patient preferences were assessed for the original set of guidelines but were not analyzed by the current Panel. Updated recommendations were generated and approved.
9. Head-to-head comparisons of treatments are generally not available for these treatments. An attempt was made to create such comparisons for the alpha blockers using Bayesian techniques on the RCTs that had a comparable placebo control. The results of these comparisons are presented in Chapter 3. This analysis is not a totally satisfactory substitute for actual comparative trials, but it is all that is available at this time.
10. After completion of the data analysis, but prior to completion of this guideline, one key study evaluating long-term outcomes with medical therapy and several others evaluating the efficacy and safety of newly developed treatment modalities were identified by the Panel as warranting review. The Panel agreed that although the data analysis could not be reopened, this new information should be considered for inclusion in the guideline. Thus, several studies cited in Chapter 1 support recommendations made by Panel consensus but are not included in the analysis presented in Chapter 3 or in the appendices.

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Developing recommendations

Generally, recommendations are based strictly on evidence as synthesized in the outcomes tables and tempered by the panel's expert opinion. When evidence is not available, the panel's expert opinion may be used exclusively. In the development of the present guideline, the Panel also directly reviewed evidence to support recommendations for the few interventions whose outcomes data became available after the meta-analysis was completed.

As in the original clinical practice guideline, the Panel members graded their recommendations according to three levels of flexibility as determined by strength of evidence and the expected amount of variation in patient preferences. In reference to diagnostic tests, the Panel utilized the terms "recommended," "optional" and "not recommended" to indicate desirability of specific diagnostic interventions. A test was categorized as optional for the following reasons: 1) if there was clear evidence of its benefit for certain patients but the data were insufficient to demonstrate the test's value in confirming the diagnosis of BPH and in predicting the results of treatment for routine patients; or 2) if the definitions of normal and abnormal test values were uncertain. The evidence is thus insufficient to mandate use of the test prior to a decision to treat. If a test was not recommended, the Panel believed either that there was insufficient evidence to indicate clinical value or that in routine cases the test was associated with potential harms that exceeded its potential benefits[11].

With regard to treatment policies, the three levels of flexibility are defined as follows[11]:

1. **Standard:** A policy is considered a standard if the health and economic outcomes of the alternate interventions are sufficiently well known to permit meaningful decisions and if there is virtual unanimity about which intervention is preferred.

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2. **Guideline:** A policy is considered a guideline if the health and economic outcomes of the interventions are sufficiently well known to permit meaningful decisions and if an appreciable but not unanimous majority agrees upon the preferred intervention.
3. **Option:** A policy is considered an option if the following criteria apply: a) the health and economic outcomes of the interventions are not sufficiently well known to permit meaningful decisions; b) preferences among the outcomes are not known; c) patients' preferences are divided among the alternative interventions; or d) patients are indifferent about the alternative interventions.

Obviously, guidelines have significantly more flexibility in use than do standards while options are the most flexible. As noted in the definitions, options can exist due to insufficient evidence or because patient preferences are divided or unknown. In the latter case particularly, it is important to consider the preferences of individual patients in selecting among alternative interventions.

Of note, United States Food and Drug Administration (FDA) approval alone was not sufficient to justify a positive recommendation in this guideline. First, FDA approval may be requested by a manufacturer for a non-BPH indication because a specific BPH indication may be more complicated and expensive to attain. Second, FDA approval may precede the publication of key pivotal studies precluding Panel analysis. Third, FDA approval once given does not imply that the intervention is still currently recommended or even available (e.g., balloon dilation). Finally, the FDA may have approved a treatment that the Panel believes is not appropriate given the other available treatment options.

A draft document written and reviewed by the Panel underwent peer review by 58 urologists and other health care professionals. The resulting comments were assembled in a database,

sorted, and distributed to the Panel members, who approved the final revisions. The final document was reviewed by the Panel and was approved by the AUA Practice Guidelines Committee and the AUA Board of Directors.

Details of the original methodology and information about the original panel members are contained in the 1994 AHCPR guideline. The following section and the Appendix 2 detail the process and problems encountered.

Limitations

The methodology used in this analysis had several limitations, and procedures devised to handle these drawbacks were not completely successful:

1. A variety of symptom scores is used in the literature. The major symptom scores were linearly adjusted to a common scale to allow pooling, but this adjustment may have introduced some inaccuracies.
2. Efficacy outcomes were measured at varying time points after treatment, and study durations varied. The Panel elected to group efficacy outcome measures by the following time periods: 3 to 9 months, 10 to 16 months and long term (greater than 16 months). For the 3- to 9-month time period, the outcome reported closest to the time point of 6 months was used. Thus, if outcomes were reported at 3 months and at 6 months, the six-month data point was used. For the 10- to 16-month reported time period, 12-month data were used preferentially. For the long-term period, either 24-month data or data gathered at a time closest to 24 months were included in the analysis. Twenty-four months was selected as the long-term measure because studies were rarely conducted for a longer duration. For adverse events, the overall study occurrence rate was used; when overall data were not available, the longest term data were used.

3. Complications were not reported consistently. Various terms were used to describe the same complication, and complications were grouped differently. For example, some authors reported nausea and vomiting separately from diarrhea while others combined these complications as gastrointestinal problems. The Panel created standard categories for complications (Appendices 2Ea and 2Eb) and assigned the reported outcomes to these groups. However, this approach can be misleading in that it may overestimate the number of patients reporting a specific complication. For example, if two complications from one article are combined, it is unclear if separate patients were reported to have the two complications or if some patients reported both. Moreover, for longer term studies, overall complication rates could be large simply due to the time period allowed for reporting.
4. In many cases, data required for analyses were not available in published articles. In particular, many articles did not report changes in symptom scores or did not report a measure of the variability of observed changes (e.g., variance, standard deviation, standard error or confidence interval). Since a measure of variability was necessary for the meta-analysis, authors of RCTs that reported efficacy data using an acceptable measure were contacted and asked to either provide variability data or to provide raw data from which this information could be computed. Where no such data were available, articles were not included in the RCT meta-analyses.
5. Methods of combining data were not uniform. Outcomes for the control arms (placebo, sham and electrocautery TURP) included relevant control data from RCTs regardless of the treatment being studied and were analyzed using single-arm techniques. (For example, placebo arms from alpha-blocker studies and finasteride studies were

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combined.) Adverse events were combined using a single-arm Bayesian meta-analysis. For the efficacy measures, SAMA was not possible due to a lack of variance data for changes in most studies. Instead, the results for the control arms were computed using weighted (by study size) averages. Similarly, when single-arm analysis was needed for an efficacy outcome for an active treatment, weighted averages were used. Weighted average computation does not allow for calculation of confidence intervals. Because results of meta-analyses for RCTs (where confidence intervals were computed) for efficacy outcomes were added to the control outcome, no confidence intervals were possible for the resultant efficacy outcome estimates.

6. The method used to create head-to-head comparisons and estimates of outcomes had the potential to yield anomalous results, particularly when the outcomes from one control group varied significantly from the outcomes reported in the other studies for the same control group. Then, when the results of the meta-analysis of change from baseline in scores in the control group were added to estimated differences in scores between control and treatment groups, unexpected findings sometimes were obtained:

   > For example, the meta-analysis might reveal an average symptom score change of -4 for the control group but a particular RCT might have reported an average reduction of -10 for controls and -11 for treated patients. The difference between treatment and control in the RCT is -1, which if added to the -4 results in an estimated reduction of -5, less than half of the reduction of -11 reported in the RCT.

   It is not possible in these instances to know whether discrepancies are due to placebo effects or to genuine differences in outcomes. In particular, when TURP is used as a

control, anomalous results may occur due to differences in the quality of the TURP procedure across studies. Unlike other controls, which have no therapeutic benefit, TURP is an active treatment. If the control in a study was TURP, quality differences can yield study results like the above illustration. In that case, the efficacy of the study treatment will be underestimated by the methods used in this guideline.

Reading the outcomes tables

The outcomes tables have been prepared in several ways. The set of comprehensive tables (Appendix 3) shows the results of all analyses undertaken and provides several different estimates for many of the outcomes. The Simplified Outcomes Tables in Appendix 1-C represent a condensation of the comprehensive outcomes tables; only one estimate is given for each outcome. Where available, 95% confidence intervals (2.5 percentiles and 97.5 percentiles of the posterior distributions) are given.

Estimates in the Chapter 3 tables reflect the following:

1. For efficacy outcomes of control interventions (placebo, sham and TURP), estimates of changes in scores/rates were based on weighted averages of all similar control arms.
2. For efficacy outcomes of medical therapies, estimates of changes in scores/rates were based on SAWAs if no data from RCTs comparing treatment to control were available. When RCT-based data comparing treatment to control existed, estimates reflect the difference between active treatment and control computed from the RCTs added to the estimated change from baseline for the control group. The Panel reviewed the 1998 report by Sech and associates[104] that provided evidence that the placebo effect was likely an example of regression to the mean and an artifact of the selection criteria of the studies. The decision to add the control data back in was taken based on the assumption that

patients actually offered treatment under the current algorithm would more closely match the study populations than the more general population studied by Sech and colleagues[104].

3. For efficacy outcomes of invasive therapies, estimates of changes in scores/rates were based on SAWAs if no data from RCTs comparing treatment to TURP were available. When RCT-based data comparing treatment to TURP existed, estimates reflect the difference between active treatment and TURP, computed from the results of the RCTs added to the estimated change from baseline for the TURP group.
4. For efficacy outcomes of minimally invasive therapies, estimates of changes in scores/rates were based on SAMA if no data from RCTs comparing treatment to either TURP or sham were available. If RCT-based data comparing treatment to sham existed, the estimates reflect the difference between active treatment and sham computed from the RCTs added to the estimated change from baseline for the sham group. If RCT data comparing the treatment to TURP were available and no RCT data comparing the treatment to sham were found, then estimates reflect the difference between active treatment and TURP computed from the RCTs added to the estimated change from baseline for the TURP group.
5. For adverse events (complications and side effects), estimates of probabilities of occurrence are results of SAMA.

Additional facts about the tables include:

- All efficacy data are estimates of changes from baseline in the respective measures at each of the three time points: 3 to 9 months, 10 to 16 months and greater than 16 months.

- When efficacy outcomes, except for peak urinary flow rate, increase in negativity, greater improvement is implied. For peak urinary flow rate, a greater positive estimate implies greater improvement.
- Adverse event outcomes data are presented as estimates of overall probabilities of occurrence rather than estimates at any specific time point.
- For efficacy outcomes data, estimates based on the single-arm analysis are marked with asterisks. Estimates from RCTs have no asterisks.
- Individual tables generated for the phytotherapeutic interventions are shown in Appendices 3-A-h and 3-A-i.

Appendix 2-A: Agency for Health Care Policy and Research Benign Prostatic Hyperplasia Guideline Panel (1994)

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Appendix 2-B: American Urological Association Benign Prostatic Hyperplasia Guideline Update Panel (2003)

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Appendix 2-B: American Urological Association Benign Prostatic Hyperplasia Guideline Update Panel (2003)

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Appendix 2-C: Methodologic Appendix

The studies of benign prostatic hyperplasia (BPH) treatment present data in a number of different ways. This variation created significant problems for the Panel as it attempted to combine the data into a consistent representation that would support patient and physician decision making. This Appendix will discuss the methodolgic problems and the approaches that were used to resolve them.

Efficacy Outcome Analysis

The first problem was the question of which of the many symptom scores for BPH should be included in this analysis. Over time, authors have used a wide variety of symptom score measures, and many are unique to specific institutions or even specific studies. Moreover, some authors have adapted standardized instruments. The database created for this guideline includes more than 150 different names of symptom score and quality of life instruments. The Panel desired to utilize as much good data as possible without providing so many conflicting outcome measures that users would become confused. Although the Panel considered the American Urological Association (AUA) Symptom Index/International Prostate Symptom Score (IPSS) to be the gold standard of symptom scores only a minority of studies used these scores. The Panel reviewed the results of comparability of scores as reported by the Measurement Committee of the AUA [Barry, Fowler, O'Leary, et. al 1992] and decided that the standardized scores compared in that article were sufficiently similar to be used. The Panel also decided that the Disease Specific Quality of Life Question of the IPSS questionnaire could be used as a separate measure as could the BPH Impact Index.

All of these measures share the property of being a numeric measure with a bounded range. The measure changes with improvement in the patient's condition. On most of these measures, a decrease in value represents an improvement, but the Boyarsky score usually has an increase representing improvement. In all cases, the treatment results can be evaluated in three ways:

The final value of the score at some time point after treatment.

The absolute change in the value of the score from before treatment to some time after treatment. For example, if the patient started with a score of 20 and had a score of 10 after treatment, the absolute change would be 10 points.

The relative or percentage change in the score. The example in #2 above would represent a 50% reduction in score.

If all patients started with the same score, the choice of measure would not matter, but patients enter treatment with widely varying treatment scores. Also, the mix of patients who start treatment is not uniform across studies. In this circumstance, the selection of the outcome measure is important and depends upon the impact of the treatment. If the treatment provides a roughly constant final score regardless of starting score, then the first measure must be used in meta-analysis. Similarly if absolute change is roughly constant regardless of starting score, then absolute change must be used. If relative change is the constant measure then that should be chosen. Unfortunately, it is not clear from the nature of the treatment which situation should be expected.

The Panel debated extensively about which outcome measure to use, and was roughly evenly split between viewing the absolute versus relative changeof the score as the appropriate measure.

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Appendix 2-C: Methodologic Appendix

Ultimately, absolute change was chosen primarily because studies rarely report the required information to allow meta-analysis of relative change. Meta-analysis of relative change would require some measure of variance of the relative change, and only one study provided such data. More studies reported variance data for absolute changes, and correspondence with authors increased the numbers to an analyzable level for many treatments. However, even after requesting data from authors, variance data were not available for most studies, including virtually all case series. As a result it was not possible to meta-analyze the totality of studies for the efficacy measures. Meta-analysis was used for those randomized controlled trials (RCTs) where variance data were available. Hierarchical Bayesian meta-analysis was used assuming equal variance between the study groups and was performed using the FAST*PRO v. 1.7 software (Eddy and Hasselblad, 1992). Hierarchical analysis was used regardless of the homogeneity of the studies due to the variability of the patient populations and treatments used (treatment dosages or surgical techniques varied between studies somewhat). However, for the single-arm analysis, the joint analysis used weighted averages created with weights corresponding to study-arm size. Thus, studies were weighted so each patient studied contributed equally, and no attempt at hierarchical analysis was made.

The Panel extensively debated which symptom scores to use. There was universal agreement that the full AUA Symptom Index or IPSS was appropriate. It was also agreed that minor variant versions could be linearly rescaled and used. There was less agreement about using other scores or about how to handle them. Ultimately, the Panel agreed to use full (or nearly full) versions of the Madsen-Iverson and Boyarsky symptom indices because the Measurement Committee's results showed comparability. Subset scales (e.g. bothersomeness or irritability subscores) were not included. Also debated was the method of transforming scales to a common measure. Linear transformation was chosen as being simplest and least likely to cause problems at the extreme ranges of the scale. The linear transform used was $y = (x-L)*35/(H-L)$ where x is the original score, y the rescaled score, H the worst possible score on the original scale, and L the best possible score on the original scale.

The Panel also debated how to handle the various lengths of follow-up that different studies used. While ideally studies should follow all patients the same length of time, this does not always occur. So, if a study reports a mean follow-up of 1 year, some patients will have been followed for shorter or longer time periods. The Panel decided that studies that report mean follow-up could be used if the minimum follow-up was at least 3 months (90 days). Studies with no minimum follow-up or with a minimum follow-up of less than 3 months were excluded from any analysis of efficacy outcomes, although they were still available for analysis of adverse events.

Presentation of Data

One of the aims of the guideline process is to provide outcomes tables, sometimes called balance sheets, that provide estimates of all treatment effects in a way that allows easy comparison among treatments. Ideally, these tables show outcome estimates in consistent and comparable forms. The complexity and variety of analyses for this topic made generating such tables difficult. Ultimately, two different formats were devised: one for the efficacy outcomes

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and one for adverse events. This was necessary because efficacy outcomes were all measured as absolute changes in continuous (actually discrete but treated as continuous) measures. Adverse events were analyzed as rates and are discussed in the section on adverse event analysis below.

Difficulties arose in the presentation of the efficacy outcomes for several reasons:

RCT data were not available for all treatments for all outcomes at all time points.

RCTs used different controls (placebo, sham, and transurethral resection of the prostate (TURP) , which meant differences between treatment and control did not always mean the same thing.

Difference data are difficult to interpret for the typical patient.

As a result the Panel determined that displaying the overall effect of a treatment would be desirable. Where no RCT data were available, single arm weighted average data from all acceptable studies were used in the outcomes table. When RCT data were available, the single-arm weighted average for the control was added to the meta-analyzed RCT difference data to yield an estimate of the overall effect. If data were available from studies that used different controls, sham controlled data were used preferentially. The major disadvantages to this approach are:

Data from studies of different quality are displayed together in the same table.

Confidence intervals cannot be computed because weighted averages are used.

The efficacy of the control may vary substantially from study to study. As a result, the efficacy of the treatment may look significantly different from the base study results when the average value for the control is added back. This is particularly true for TURP controls whose efficacy may depend on the skill of the surgeon.

Dosage Selection for Alpha Blockers

Alpha blockers were evaluated differently in studies. Some studies put all patients on specific doses of alpha blockers, while others, in fact most, titrated up to an effective dose or down to eliminate bothersome side effects. As a result, patients in different studies, or even within a single study, received varying doses. The comparability of the studies is thus compromised to some extent. Ultimately, the Panel determined that the best approach was to combine all studies using the same drug provided that dosages were available in the United States. Separate analyses were performed for the two different dosages of tamsulosin (0.4 mg and 0.8 mg), but all studies using either dosage were combined into a single estimate that is reported here. In the separate analyses, there generally was slightly greater symptom improvement with the higher dose of tamsulosin but also the side effect rates were slightly higher with the increased dose. Several doses of alfuzosin have been used in studies over the years. While analyses of earlier studies with 3 and 5 mg doses were performed, only studies using the newer 10 mg dose are reported here. Earlier studies were excluded because the lower dose tablet will not be available in the United States.

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Appendix 2-C: Methodologic Appendix

Comparison of Alpha Blockers

Randomized controlled trials comparing the alpha blockers directly to each other have not been performed. However, there are trials comparing each of the alpha blockers to placebo. From these trials, it is possible to estimate the difference of each alpha blocker from placebo. Meta-analyses were used to summarize the estimates from all the relevant trials. The meta-analyses can show whether each alpha blocker is significantly different from placebo, and because meta-analyses were done using Bayesian techniques, it is possible to use their results to compare the alpha blockers to each other. Each meta-analysis produces a posterior distribution for the difference between the active treatment and placebo. These distributions can be subtracted to yield the distribution for the difference between two active treatments. From that distribution, the two alpha blockers can be considered statistically significantly different at p=.05 if the 95% CI does not include 0. This technique was used to compare alpha blockers for the efficacy outcomes and selected adverse events (asthenia, GI symptoms, nasal congestion, symptomatic postural hypotension, and syncope). This technique is accurate to the extent that the results of the meta-analyses are accurate and the patient populations studied are similar across the alpha blockers. These are essentially the assumptions made throughout this guideline.

Adverse Events Analysis

The analysis of adverse events presented several difficulties:

- There was no uniformity in adverse event reporting. Studies used a variety of terms for the similar events and have widely varying thresholds for event reporting.
- Adverse events happened at various times after the treatment. Studies followed patients for varying lengths of time, and thus adverse event reports may be inconsistent.
- Assessment of adverse events can vary significantly. For example, some studies waited for patients to report events while others solicited events.
- While RCTs exist for many treatments, they do not exist for all treatments. Also, the controls used in RCTs varied (placebo, sham, and TURP). Finally, many of the RCTs were quite short, included relatively few subjects, and may not have detected all occurrences of some events.
- Adverse events may be counted by occurrence or by number of patients experiencing the event (some perhaps multiple times). Papers varied in the method used to count events, and some papers did not make it clear which method was used.

The Panel debated how to handle these problems and finally determined that the author's description of the event would be used even given the considerable variation among papers. In addition, adverse events were grouped into classes, a method that may have resulted in some double counting. The Panel also decided not to try to analyze events by time of occurrence but rather evaluated overall event rates for each study.

Analysis of adverse events was performed in multiple ways. First, single-arm hierarchical Bayesian meta-analysis was performed using all study arms that had been accepted by the Panel. Meta-analysis of RCTs with the same treatments and controls was performed using hierarchical Bayesian meta-analysis for two-armed studies. This yields an estimate of the adverse event

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frequency. For studies with multiple arms, each treatment and the control were treated as separate studies. This meta-analysis of RCTs yielded a difference in event rate between the treatment and the control. Two different methods were tried to create an estimate of the event rate from this difference. One method added this difference to the median estimate for the control in a manner similar to that used for the efficacy outcomes. The disadvantage of this method is that no confidence intervals can be computed. The second method used Bayesian techniques to add the posterior distribution for the controls to the posterior for the difference. This method does yield confidence intervals but has several different problems. First, the FAST*PRO software approximates the posterior distribution of the sum with a normal distribution which can result in confidence intervals that exceed the [0,1] range for rates. Second, the addition of the posteriors is dependent on independence of the distributions, which is quite unlikely. Ultimately, the Panel chose to use the single-arm meta-analysis results as the primary outcome estimates. This decision was reached for three reasons:

- The desire to have confidence intervals around the estimates.
- The lack of RCT data for some treatments/outcomes and the lack of overall study size where RCT data were available.
- The analytical problems posed by adding the two posterior distributions.

The results of all three analyses are presented in Table 3-g of Appendix 3 for purposes of comparison.

Panel Process

After the initial article selection, data extraction, and data entry, evidence tables were created showing all the data that had been extracted. The Panel then reviewed the tables for consistency and to determine which studies would be accepted into the analysis. Studies were rejected primarily because the treatments listed were not part of the analysis plan, the patients did not meet the criteria for the target patient group, or the data were either fatally flawed or not part of the analysis plan (e.g. if the study did not report any of the efficacy outcomes that were being analyzed, it was rejected for that phase).

Because only a few studies provided all the necessary data for analyzing changes in the efficacy arguments, the Panel took the unusual step of contacting study authors for additional data. Study authors were requested to either provide additional analyses that included the necessary data or to provide the raw data for analysis by the Panel staff. The data provided were added to the Panel's database of extracted information and used in the meta-analyses.

Following the meta-analysis, the Panel met to discuss the data, generate the outcomes tables and recommendations, and begin the process of writing this document as described in Chapter 2.

References

Eddy DM, Hasselblad V. FAST*PRO: Software for Meta-Analysis by the Confidence Profile Method. San Diego: Academic Press, 1992.

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____

Cover Sheets

1. **Journal:(Vol:Pg)** _____ **Year:** _____

   Article: _____

   Authors: _____

   Institution: _____

   Country: _____

2. **Extractor 1:** _____ **Date:** _____

   Extractor 2: _____ **Date:** _____

   Reconciled: **Date:** _____

(Check one)

3. ____ **Reviewed and extraction completed. Data are important** and should be included in evidence tables. (go to #5)

   ____ **Reviewed but extraction not done** because (see #4, circle one or more).

(Check all that apply)

4. ____ Data updated in more recent report (this may not require exclusion, see #5, choice P).
   ____ Data are absent (i.e. Review Article)
   ____ Data are present but cannot be interpreted to complete categories of extraction work sheet.
   ____ Data not relevant to project

5. **Extracted Data was:**
   (Enter one from below) _____

   N New data never before published.
   U Updated report on previously published data but longer f/u, more complete or newly analyzed.
   P These data were updated in a more recent report but included in evidence table because these older data are unique or at least different from that recently published.
   O Other: _____

6. **Study Design: (Check One)**

   ____ Controlled trial
   ____ Case-control study
   ____ Cohort Study
   ____ Case Series/Report
   ____ Review/policy
   ____ Meta-analysis
   ____ Data base or surveillance
   ____ Letter: Ref. _____
   ____ Opinion or testimony
   ____ Other: spec. _____

   Study Features: (check all that apply)

   ____ Prospective
   ____ Retrospective
   ____ Provider blinded
   ____ Patient blinded
   ____ Outcome evaluator blinded
   ____ Randomized
   ____ Placebo
   ____ Sham
   ____ Multicenter
   ____ Single Center
   ____ Cross Over

7. **Study Dates:** **Year** _____ through **Year** _____
   (leave blank if not specified)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: ____

Cover Sheets

8. Study Inclusion Criteria:

	>		<		>=		<=
Age (years):		or		or		and	
Peak Flow Rate (ml/sec):		or		or		and	
Residual urine volume (ml):		or		or		and	
PSA (ng/ml):		or		or		and	
Biopsy required if PSA above:		ng/ml					
	>		<		>=		<=
Prostate Size (cc):		or		or		and	
Prostatic Urethra (cm):		or		or		and	
Symptom Score (points):		or		or		and	
of total points: ____							
P_{det} @Q_{max} (cm H_20):		or		or		and	

Other Inclusion Criteria: _____

_____

9. Number of groups: (including Group 0) ____

10. Definition of Groups:

Divide the article into groups. There should be one group for each group of patients for whom outcomes are reported. In some cases, data are reported in a hierarchical manner. Use hierarchical numbering in those cases. Group 0 always contains data that applies to the article as a whole. Groups may be subdivided if data are present that apply to the whole group and other data that apply only to the subgroup. For example, group 1 (patients treated with TURP) may be subdivided if symptom scores are reported for a subgroup with large prostate volumes and a subgroup with small prostate volumes, but complications are only given for the group as a whole. The two subgroups (1.1 and 1.2) would contain the symptom score results, but the sheet for group 1 would contain the complication results. Only create subgroups if there are data available at each level. If, in the above example, complications and all other relevant data had also been subdivided, then you would just create two groups (1 and 2) and no subgroups. Fill out one definition form and one outcomes form for each group or subgroup you use (including group 0 if needed). List below the definition of each group and its number. Use the back if more than 10 groups or subgroups are used. You may also diagram the group structure on the next page for clarity, but it is not required.

0.	Relevant data pertaining to the total study which cannot be accurately extracted for a particular sub-group.

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Appendix 2-D: Data Retrieval, Review and Extraction

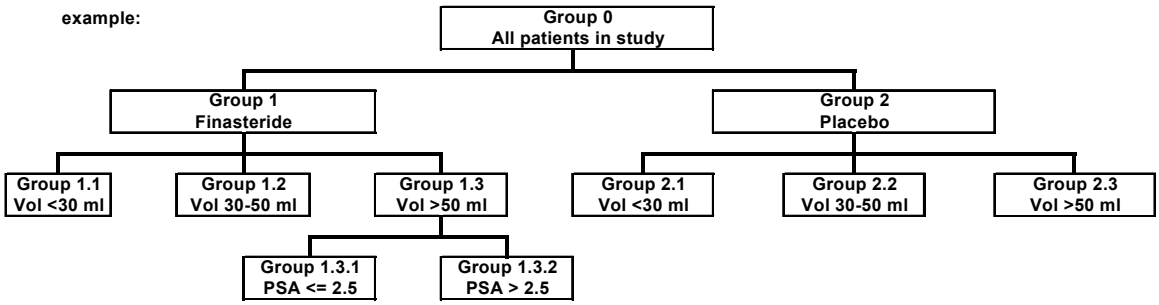
Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number:

Cover Sheets

11. Group Structure Diagram - Optional

example:



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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: ____

Cover Sheets

12. **Comments:**
(Please describe any biases, challenges to validity, or other difficulties with the article. In addition, indicate any data which do not fit on the form and may be of interest to the panel.)

13. **Please either circle relevant citations in the reference list or list the citation numbers here.** _____

14. **Total time completing the extraction:** _____ **minutes**

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Definition

1. Population description:

Original number of patients entered/enrolled: _____

Number of patients used to calculate baseline data: _____ **y**

	Mean	Median	Min	Max	SE	SD
Age (Years):						
___Sitting___Standing ___Supine ___Not specified Systolic:						
Diastolic:						
___Sitting___Standing ___Supine ___Not specified Systolic:						
Diastolic:						
Peak Flow Rate (ml/sec):						
Residual urine volume (ml):						
PSA (ng/ml):						
Prostate Size (cc):						
Prostatic Urethra (cm):						
Duration of Symptoms (months):						
Symptom Score (points):						
of total points: _____						
P_{det} @Q_{max} (cm H_20):						

% **x**

Patients in retention: _____ _____

2. Treatment Description: _____

a. ____ Watchful Waiting

b. ____ Medical Treatment

Drug Class: ____ Alpha Blocker ____ Hormonal _____ Placebo
____ Phytotherapeutic ____ Combination

Drug Name: _____

Drug #2 Name: _____

Placebo Lead in: ____ Duration of placebo Lead in (days): _____

Wash out: ____ Duration of wash out (weeks): _____

____ Fixed Dose ____ Titration to response

Final / Maximum Dosage: _____ mg _____ times per day

If Combo, drug #2 dosage: _____ mg _____ times per day

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Definition

c. ____ **Balloon Dilation**
Brand of balloon: _____
Size in French: _____ FR
Duration of dilation: _____ minutes
Maximal Pressure: _____ Atm

d. ____ **Stent**
Brand of Stent: _____
____ Temporary ____ Permanent

e. Heat Treatment:
Name of Machine: _____
____ **Hyperthermia**
____ **Thermotherapy**
Number of Treatments: ____ Single Treatment
_____ times per week for _____ weeks
= _____ total treatments
Duration of each treatment: _____ Minutes

f. Needle Ablation of Tissue
Brand name of Device: _____
____ **by Radiofrequency (TUNA)**
____ **by Interstitial Laser**

	Mean	Median	Min	Max	
Number of Lesions:					(Lesions = planes x 2)

g. ____ **HIFU (High Intensity Focused Ultrasound)**

h. ____ **Laser Coagulation of Tissue**
Brand name of Device: _____
Duration of Treatment: _____ seconds per application
Power: _____ watts

	Mean	Median	Min	Max	
Number of Applications:					
Total Energy:					joules

i. ____ **TUIP**
Number of Incisions: _____
Location: _____ o'clock _____ o'clock _____ o'clock

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Definition

2. Treatment Description (con't.)

j. Transurethral Resection of Tissue

____ by Electrocautery (TURP) Brand name of Device: _____

____ by Laser energy (Holmium)

	Mean	Median	Min	Max	SE	SD
Resected Weight:						

k. Transurethral Vaporization of Tissue

____ by Electrocautery (TVP) Brand name of Device: _____

____ by Laser

Duration of Treatment: _____ seconds

Power: _____ watts

	Mean	Median	Min	Max	
Total Energy:					joules

l. Open Surgery

____ Suprapubic

____ Retropubic

____ Not Specified / Mixed

	Mean	Median	Min	Max	SE	SD
Weight:						

3. For ALL devices and surgery

Anesthesia requirements:

	%	x	
General:			
Spinal:			
IV Sedation:			Describe/Define Oral
Oral:			_____
Local only:			

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Definition

4. **Number of Follow-up Time Points:** _____

5. **Definition of Follow-up Time Points**

Example: 3 Time points

Time Point	Definition
1	Followed up to 6 months
2	at 12 months follow-up
3	at 24 months follow-up

Time Point	Definition

6. **Comments about this group**

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes - Short Term

1. Number of patients entered/randomized to this group:	y = _____ (Patients who received this treatment)									
2. Immediate Peri-Procedural Events		%	x							
a. Operative Mortality (<30 days):										
b. Catheter Issues:		%	x							
Patients with catheter placed after procedure:										
		Mean	Median	Min	Max	SE	SD		%CI	
Days with catheter:										
		%	x							
Patients with post procedure retention requiring secondary/unplanned catheterization										
		Mean	Median	Min	Max	SE	SD		%CI	
Days with catheter:										
		Mean	Median	Min	Max	SE	SD		%CI	
c. Blood Loss and Replacement Blood Loss (ml):										
		%	x							
Patients receiving transfusions:										
		Mean	Median	Min	Max	SE	SD		%CI	
Number of transfusions:										
		Mean	Median	Min	Max	SE	SD		%CI	
Hematocrit: Baseline:										
Post-op:										
		Mean	Median	Min	Max	SE	SD		%CI	
Hemoglobin: Baseline:										
Postop:										
		%	x							
Patients needing Secondary Interv. for Bleeding:										
d. Surgical Complications										
List by name:		%	x							
_____:										
_____:										
_____:										
_____:										
_____:										
_____:										
_____:										
		Mean	Median	Min	Max	SE	SD		%CI	
3. Hospitalization Hospital Days (Planned):										
Hospital Days (Readmission):										
		%	x							
Day Surgery / outpatient surgery:										

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes at Follow-up: Time Point _____ of _____

1. Number of Patients

Original number of patients randomized/entered in this group: _____

Number of patients who were available or who completed this follow-up time point (y): _____

Withdrawals during this interval:	%	x	
Side effects:			
Worsening symptoms / lack of improvement:			
Other BPH treatment:			(including surgery or retreatment)
Lost to follow-up:			
Withdrew consent:			
Other:			
Overall:			

Definition of this follow-up time point

	Mean	Median	Min	Max
Months from baseline to this follow-up:				

2. Symptom Score

Name of instrument: _____

Range of points: from _____ to _____

Number of patients: (y) _____
(denominator for this outcome measure only)

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes at Follow-up: Time Point _____ of _____

3. Other Score(bother,impact,QOL,etc.) Name of instrument: _____

Range of points: from _____ to _____

Number of patients: y = _____
(denominator for this outcome measure only)

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

4. Other Score(bother,impact,QOL,etc.) Name of instrument: _____

Range of points: from _____ to _____

Number of patients: y = _____
(denominator for this outcome measure only)

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

5. Other Score(bother,impact,QOL,etc.) Name of instrument: _____

Range of points: from _____ to _____

Number of patients: y = _____
(denominator for this outcome measure only)

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes at Follow-up: Time Point _____ of _____

6. Other Score(bother,impact,QOL,etc.) Name of instrument: _____

Range of points: from _____ to _____

Number of patients: (denominator for this outcome measure only) y = _____

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y				
				Points			%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

7. Other Score(bother,impact,QOL,etc.) Name of instrument: _____

Range of points: from _____ to _____

Number of patients: (denominator for this outcome measure only) y = _____

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y				
				Points			%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

8. Peak Flow Rate (ml/sec)

Number of patients: (denominator for this outcome measure only) y = _____

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in rate (number):								
Change in rate (percentage):								

	%	x	y				
				ml/sec			%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes at Follow-up: Time Point _____ of _____

9. Detrusor Pressure at Peak Flow Rate (cm H_20)

	y	Mean	Median	Min	Max	SE	SD		%CI
Number of patients:		Baseline:							
(denominator for this outcome measure only)		at Follow-up:							
		Change in rate (number):							
		Change in rate (percentage):							

	%	x	y		cm H_20		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

10. Residual urine (ml)

	y	Mean	Median	Min	Max	SE	SD		%CI
Number of patients:		Baseline:							
(denominator for this outcome measure only)		at Follow-up:							
		Change in score (number of points):							
		Change in score (percentage):							

	%	x	y		ml		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

11. PSA (ng/ml) Method: _____

	y	Mean	Median	Min	Max	SE	SD		%CI
Number of patients:		Baseline:							
(denominator for this outcome measure only)		at Follow-up:							
		Change in PSA (number):							
		Change in PSA (percentage):							

12. Prostate Size (cc)

Method of assessment: ____ DRE ____ TRUS ____ MRI

Other: _____

	y	Mean	Median	Min	Max	SE	SD		%CI
Number of patients:		Baseline:							
(denominator for this outcome measure only)		at Follow-up:							
		Change in Size (number):							
		Change in Size (percentage):							

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes at Follow-up: Time Point _____ of _____

13. Blood Pressure Outcomes

Number of patients: y = _____
(denominator for this outcome measure only)

____ Sitting ____ Standing ____Supine ___not specified

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in value (number)								
Change in value(percentage)								

____ Sitting ____ Standing ____Supine ___not specified

	Mean	Median	Min	Max	SE	SD		%CI
Baseline:								
at Follow-up:								
Change in value (number)								
Change in value(percentage)								

14. Outcomes Assessed at this Follow-up Time Point

a. Sexual Function: Assessment of Potency: ____ Interview ____ Questionnaire

____ Test: _____

List:

	%	x	y
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			

b. Urinary Function:

	%	x	y
Patients experiencing unspecified incontinence:			
Patients experiencing stress incontinence:			
Patients experiencing urge incontinence:			
Patients experiencing total incontinence:			

c. Stricture

	%	x	y	
Patients experiencing urethral stricture:				
Patients experiencing urethral stricture req. dilation:				(may be repeat dilation)
Patients experiencing urethral stricture req. surgery:				

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcomes at Follow-up: Time Point _____ of _____

14. Outcomes Assessed at this Follow-up Time Point (con't.)

d. Bladder Neck Contracture

	%	x	y	
Patients experiencing BNC:				
Patients experiencing BNC req. dilation:				(may be repeat dilation)
Patients experiencing BNC req. surgery:				

e. Retreatment

	%	x	y	
Patients who required/requested any retreatment:				(during period of follow-up)
Patients who required/requested surgical retreatment:				(during period of follow-up)

f. Other Long Term or Persistent Complications or Side Effects

List:	%	x	y
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			

15.

Comments about these outcomes

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcome: Entire Study Duration

1. Number of Patients

Original number of patients randomized/entered in this group: _____

Number of patients available or who completed the study _____ **y**

Withdrawals during the study:	**%**	**x**	
Side effects:			
Worsening symptoms / lack of improvement:			
Other BPH treatment:			(including surgery or retreatment)
Lost to follow-up:			
Withdrew consent:			
Other:			
Overall:			

2. Other outcomes reported for the entire duration of the study:

a. Sexual Function: Assessment of Potency: ____ Interview ____ Questionnaire

____ Test: _____

List:	**%**	**x**	**y**
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			

b. Urinary Function:	**%**	**x**	**y**
Patients experiencing unspecified incontinence:			
Patients experiencing stress incontinence:			
Patients experiencing urge incontinence:			
Patients experiencing total incontinence:			

c. Stricture	**%**	**x**	**y**	
Patients experiencing urethral stricture:				
Patients experiencing urethral stricture req. dilation:				(may be repeat dilation)
Patients experiencing urethral stricture req. surgery:				

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-a: Benign Prostatic Hyperplasia Data Extraction Form

Reference Number: _____ **Group:** _____

Group Outcome: Entire Study Duration

d. Bladder Neck Contracture

	%	x	y	
Patients experiencing BNC:				
Patients experiencing BNC req. dilation:				(may be repeat dilation)
Patients experiencing BNC req. surgery:				

e. Other Long Term or Persistent Complications or Side Effects

List:

	%	x	y
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			
_____:			

Comments about these outcomes:

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-b: Summary of data retrieval, review and extraction

Sources of References for Review

Original AHCPR Guideline	138
August 1996 MEDLINE	1,347
February 1998 MEDLINE	630
August 1998 MEDLINE	752
January 1999 MEDLINE	235
July 1999 MEDLINE	277
Studies/Data provided by authors/industry	13
References provided by Dr. McConnell, 1998	21
Total references selected	**3,413**

References Selected or Rejected

		% Total	% Selected
Rejected on the basis of title or abstract	3,048	89.3	
Selected for data extraction	365	10.7	
Extracted and accepted	251	7.4	68.8
Selected for extraction but rejected	114	3.3	31.2
Total	**365**		
Distinct patient groups extracted and included in the evidence tables	723		

References Recommended for Inclusion in Databases by Study Type

Controlled trial	137
Case series/Report	90
Cohort study	11
Database or surveillance	1
Meta-analysis	3
Other	9
Total	**251**

References Recommended for Exclusion From Database by Study Type

Controlled trial	37
Case series/Report	25
Case series – Open-label extension	2
Cohort study	8
Controlled trial – Secondary analysis	1
Meta-analysis	1
Review/Policy	3
Other (undefined, unknown)	37
Total	**114**

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-c: Reasons for reference rejection

Reference Rejections*	
Duplicate	16
Data were updated	12
Data were absent	19
Data did not fit extraction form	46
Data were not relevant	5
No reason given	28
Total	**126**

*References may have been rejected for >1 reason

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-d: References extracted and used in data analysis (by first author)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-d: References extracted and used in data analysis (by first author)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-d: References extracted and used in data analysis (by first author)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-d: References extracted and used in data analysis (by first author)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-d: References extracted and used in data analysis (by first author)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-d: References extracted and used in data analysis (by first author)

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Appendix 2-D: Data Retrieval, Review and Extraction

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Appendix 2-D: Data Retrieval, Review and Extraction

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-e: References extracted and used in data analysis (by Procite number)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-e: References extracted and used in data analysis (by Procite number)

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Appendix 2-D: Data Retrieval, Review and Extraction

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-e: References extracted and used in data analysis (by Procite number)

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Table 2-D-e: References extracted and used in data analysis (by Procite number)

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Appendix 2-D: Data Retrieval, Review and Extraction

Table 2-D-e: References extracted and used in data analysis (by Procite number)

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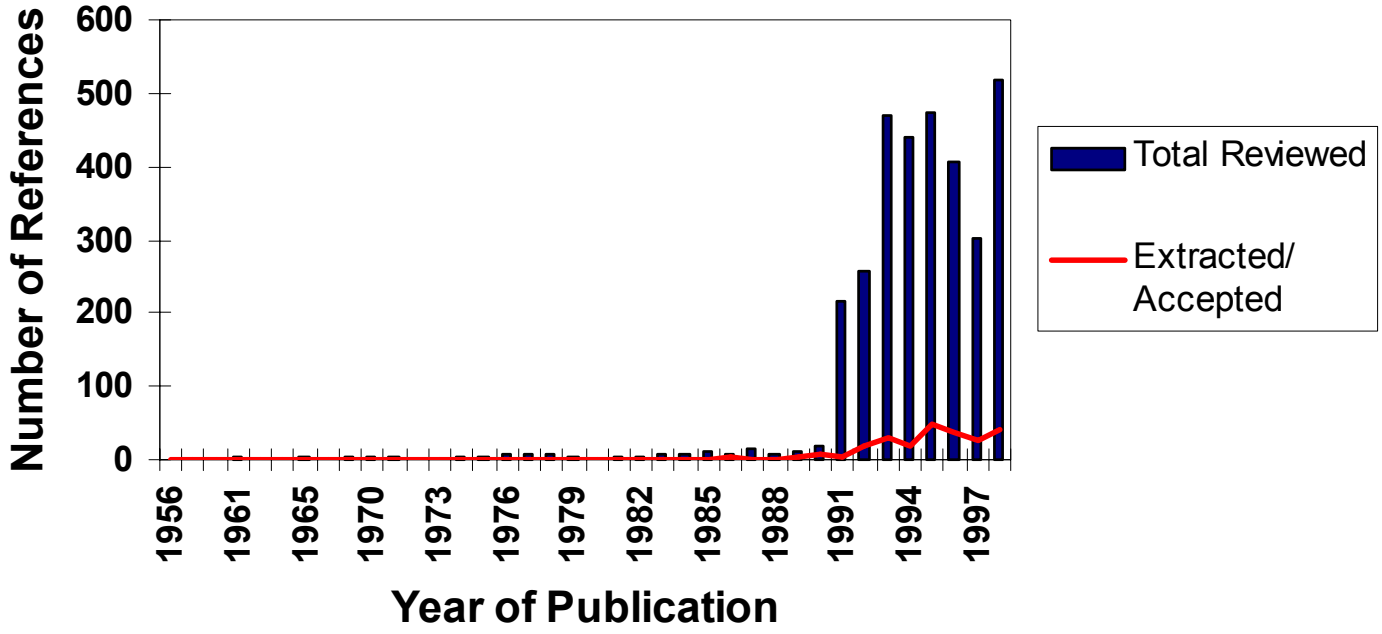
Appendix 2-D: Data Retrieval, Review and Extraction

Figure 2-D-i: References reviewed and extracted by year of publication



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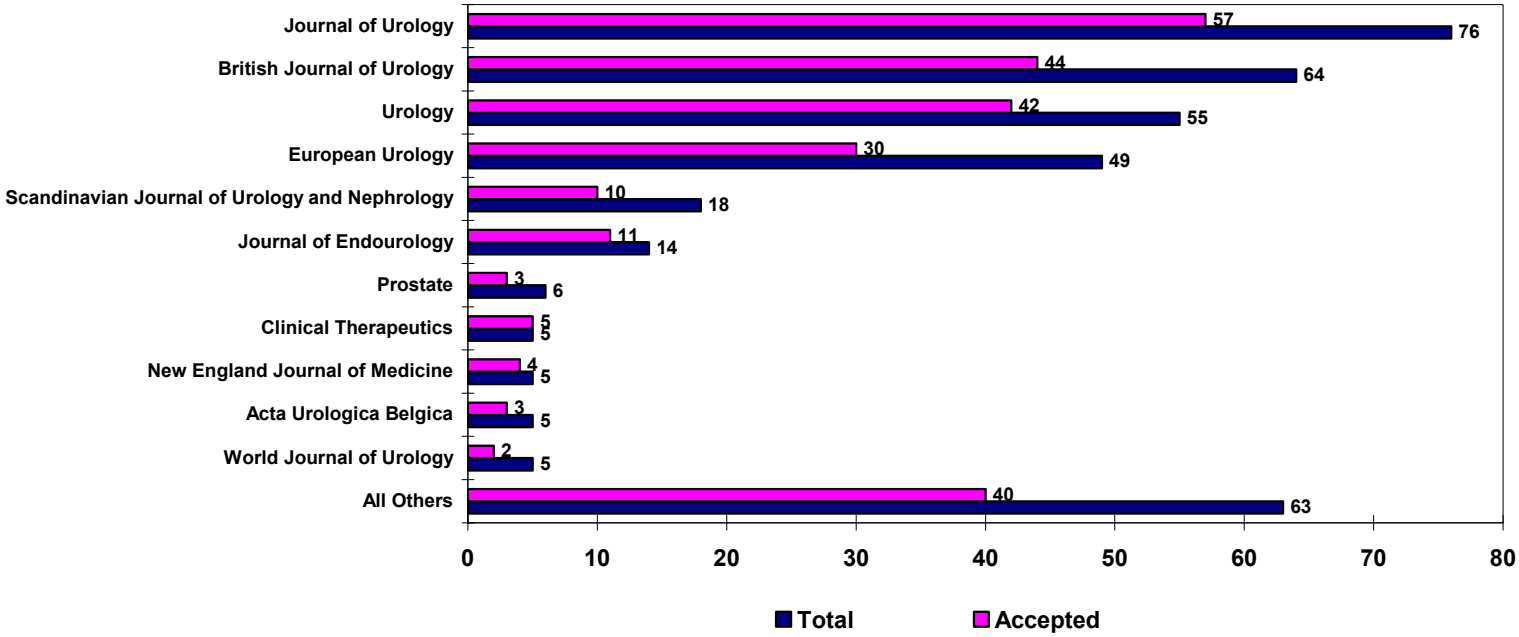
Appendix 2-D: Data Retrieval, Review and Extraction

Figure 2-D-ii: References reviewed and extracted by journal source



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Appendix 2-E: Categories of Adverse Events

Table 2-E-a: Medical therapy: reported adverse events

Acute Urinary Retention (AUR)

Acute Retention
Acute Urinary Retention
Urinary Retention
Urinary Retention (>1 week)

Asthenia

Asthenia
Asthenia/Fatigue
Drowsiness
Fatigue
Important Fatigue
Malaise
Muscle Weakness
Somnolence

Breast

Breast Enlargement
Breast Pain
Breast Tenderness

Cardiovascular

Angina Pectoris
Cardiac Arrhythmia
Cardiovascular
Cardiovascular System
Deep Vein Thrombosis
EKG Abnormalities
Hypertension
Hypertension Aggravated
Palpitation
Second-Degree A-V Block
Tachycardia
Tachycardia/Palpitation
Weight Gain
Weight Increase (>6 pounds)

Cardiovascular-Peripheral Edema

Edema
Oedema Peripheral
Peripheral Edema

Cardiovascular-Serious

Myocardial infarction

Death

Operative Mortality (<30 days)Dizziness

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Appendix 2-E: Categories of Adverse Events

Table 2-E-a: Medical therapy: reported adverse events

Dizziness
- Dizziness/Nervousness
- Dizziness/Vertigo
- Light-Headedness
- Vertigo
- Vertigo/Dizziness

Gastrointestinal (GI) Systems
- Abdominal Pain
- Constipation
- Diarrhea
- Digestive
- Digestive System
- Dry Mouth
- Dyspepsia
- Epigastric Pain
- Flatulence
- Gamma-Glutamyltranspeptidase
- Gastric Irritation
- Gastritis
- GI
- GI Disorders
- GI Upset
- Hepatic Enzymes Increased
- Nausea
- Stomach Discomfort
- Vomiting

Headache
- Headache
- Headache/Slurred Speech

Hypotension-Asymptomatic
- Asymptomatic Diastolic Postural Hypotension
- Asymptomatic Hypotension
- Asymptomatic Orthostatic Hypotension
- Asymptomatic Postural Hypotension
- Asymptomatic Postural Hypotension-Diurnal
- Asymptomatic Postural Hypotension-Nocturnal
- Asymptomatic Systolic Postural Hypotension
- Hypotension
- Orthostatic Hypotension
- Postural Hypotension

Hypotension-Symptomatic
- Dropouts Due to Vasodilation-Related Events
- Hypotension
- Symptomatic Hypotension

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Appendix 2-E: Categories of Adverse Events

Table 2-E-a: Medical therapy: reported adverse events

Hypotension-Symptomatic-Postural

Orthostatic Disorder
Postural Dizziness
Postural Hypotension
Postural Symptoms
Symptomatic Postural Hypotension
Symptomatic Postural Hypotension-Diurnal
Symptomatic Postural Hypotension-Nocturnal

Hypotension-Symptomatic-Syncope

Postural Syncope
Syncope

Respiratory-Nasal Congestion

Coughing
Flu Syndrome
Influenza-Like Symptoms
Nasal Congestion
Rhinitis
Sinusitis
Upper Respiratory Tract Infection
URI

Sexual-Ejaculation

Abnormal Ejaculation
Decreased Ejaculate
Ejaculation Disorder
Ejaculation Failure
Hematospermia
Loss of Ejaculation

Sexual-Erectile Problems

Any Sexual Adverse Event
Erectile Dysfunction
Impotence
Orgasm Dysfunction
Sexual
Sexual Dysfunction
Withdrawal Secondary to Sexual Adverse Events
Withdrawal Secondary to Adverse Events

Sexual-Libido

Decreased Libido
Libido
Libido Decreased

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Appendix 2-E: Categories of Adverse Events

Table 2-E-b: Invasive therapy: reported adverse events

Aborted Procedure/Device Failure

Equipment Malfunction/Aborted Procedure
Pain Requiring Stopping Treatment
Treatment Interruption and Withdrawal

Acute Urinary Retention (AUR)

Secondary/Unplanned Catheterization
Urinary Retention
Urinary Retention (>1 week)
Urinary Retention Subsequent to PostRx Catheterization Period

Bladder Neck Contracture (BNC)/Stricture

BNC
BNC Requiring Dilation
BNC Requiring Surgery
Meatal Stenosis
Meatal Stricture
Stricture
Urethral Stricture
Urethral Stricture Requiring Dilation
Urethral Stricture Requiring Surgery

Cardiovascular

Arrhythmia
Cardiovascular Disease
Hypertension

Cardiovascular-Serious

Cerebrovascular Accident
Myocardial Infarction

Cardiovascular-Thromboembolic

Deep Vein Thrombosis
Pulmonary Embolism (PE)
Thrombophlebitis

Death

Death
Death by PE (≤90 days)
Operative Mortality (<30 days)

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Appendix 2-E: Categories of Adverse Events

Table 2-E-b: Invasive therapy: reported adverse events

Hematuria-Significant

Bleeding-Important
Bleeding-Significant
Clot Retention
Conversion to Transurethral Resection of the Prostate (TURP) Secondary to Bleeding
Delayed Hemorrhage
Excessive Bleeding
Hematuria – (>1 month, Excessive or Recrudescent)
Hematuria – Gross
Hematuria – Prolonged
Hematuria – Prolonged Gross
Hematuria-Significant (requiring re-admission)
Hemorrhage-Significant
Re-Admission for Bleeding

Incontinence

Incontinence
Incontinence-Total Urinary
Stress Incontinence
Total Incontinence
Unspecified Incontinence
Urge Incontinence
Urinary Leakage
Urinary Urge Incontinence-Transient

Infection / Urinary Track Infection (UTI)

Epididymitis
Epididymitis/Orchitis
Prostatitis
Prostatitis-Acute
Pyelonephritis
Scrotal Abscess
Sepsis
Septicemia
Urethritis
Urosepsis
UTI-Recurrent
UTI-Simple
UTI or Culture Confirmed Bacteriuria

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Appendix 2-E: Categories of Adverse Events

Table 2-E-b: Invasive therapy: reported adverse events

Intraoperative

Bladder Perforation
Blood Pressure Changes During the Procedure
Capsular Perforation
Capsular Perforation Requiring Surgery
Catheter Misplacement
Catheter Replacement
Rectal Injury
Urethral False Passage
Urethral Injury

Post-Procedure-Irritative

Dysuria
Dysuria (>1 month or Excessive)
Dysuria – Mild (<72 hrs)
Dysuria – Persistent
Dysuria – Severe
Dysuria – Sterile
Dysuria (>7 days)

Post Procedure-Irritative (continued)

Dysuria (<6 weeks)
Irritative Symptoms
Irritative Symptoms-Severe
Irritative Voiding Symptoms
Irritative Voiding Symptoms-Significant
Passage Urinary Debris
Persistence Urgency Frequency
Storage Symptoms
Urgency

Secondary Procedure

Conversion to TURP
Crossover to TURP
Crossovers-Required TURP
Withdrawn and Retreated

Sexual-Ejaculation

Abnormal Semen Analysis
Anejaculation
Decreased Ejaculate
Ejaculatory Disorder
Hematospermia
Loss of Ejaculation
Retrograde Ejaculation

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Appendix 2-E: Categories of Adverse Events

Table 2-E-b: Invasive therapy: reported adverse events

Sexual - Erectile Problems

Change in Sexual Function
Decreased Sexual Activity
Decreased Potency
Decreased Sexual Performance
Erectile Dysfunction
Impotence
Impotence-Transient
Sexual Deterioration
Sexual Dysfunction

Stent-Complications

Bridging Effect
Obstruction Due to Prostatic Urothelial Hyperplasia
Incrustation
Migration
Migration + AUR
Migration + Incontinence
Migration/Repositioning
Misplacement/Mis-Sizing
Misplacement/Repositioning
Removal
Stent Migration

Transfusion

Transfusion

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