Complete Summary

GUIDELINE TITLE

Lower urinary tract symptoms suggestive of benign prostatic hyperplasia.

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Lower urinary tract symptoms suggestive of benign prostatic hyperplasia. Singapore: Singapore Ministry of Health; 2005 Jan. 49 p. [56 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISCLAIMER

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Benign prostatic hyperplasia (BPH) Lower urinary tract symptoms (LUTS)

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Urology

INTENDED USERS

Health Care Providers Physicians

GUIDELINE OBJECTIVE(S)

- To define the most cost-effective evaluation and treatment of benign prostatic hyperplasia (BPH) based on current medical evidence
- To assist family physicians in the evaluation and treatment of BPH and to specify clinical situations when referral to an urologist is recommended.

TARGET POPULATION

Male patients in Singapore with lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. History of symptoms
- 2. Digital rectal examination (DRE)
- 3. Abdominal examination
- 4. Urine labstix tests for haematuria, pyuria and glycosuria
- 5. Serum prostate specific antigen (PSA) test
- 6. Ultrasound of the kidneys, bladder and prostate
- 7. Urogram (not recommended)
- 8. Transabdominal ultrasound
- 9. Voiding diary
- 10. Quantification of symptoms using the International Prostatic Symptom Score (I-PSS)
- 11. Quantification of symptoms using the Quality Of Life (QOL) index
- 12. Uroflowmetry
- 13. Transrectal Ultrasound (TRUS) with biopsy
- 14. Urodynamic Studies (UDS)
- 15. Flexible cystoscopy

Treatment/Management

- 1. Watchful waiting
- 2. Pharmacotherapy
 - Alpha-adrenergic blockers (prazosin, terazosin, alfuzosin)
 - 5alpha-reductase inhibitors (finasteride, dutasteride)
- 3. Transurethral resection of the prostate (TURP)
- 4. Referral to a urologist
- 5. Prostatic stenting

- 6. Transurethral needle ablation (TUNA)
- 7. Transurethral microwave thermotherapy (TUMT) (not routinely recommended)
- 8. Laser prostatectomy
 - Interstitial laser coagulation (not routinely recommended)
 - Holmium laser resection (not recommended)
- 9. Plasma-kinetic vaporization

MAJOR OUTCOMES CONSIDERED

- Peak urinary flow rate
- Obstruction rates for both kidneys and bladder
- Rates of acute and chronic retention of urine
- Incontinence rates
- Retrograde ejaculation rates
- Effectiveness, safety and adverse effects of interventions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials

Level Ib: Evidence obtained from at least one randomised controlled trial

Level IIa: Evidence obtained from at least one well-designed controlled study without randomisation

Level IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

These guidelines were developed by a workgroup of urologists and general practitioners from both public and private hospitals, Singapore Ministry of Health, the College of Family Physicians, and the Singapore Urological Association.

These guidelines provide recommendations that were adapted from the recommendations of the International Consultations on Urological Diseases. They were modified for local needs based on local clinical research, availability of resources in Singapore and expert judgment.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

GPP (good practice points): Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations that follow summarize the content of the guideline. Please refer to the original guideline document for more detailed recommendations. Each recommendation is rated based on the level of the evidence and the grades of recommendation. Definitions of the grades of the recommendations (A, B, C, Good Practice Points [GPP]) and level of the evidence (Level I-Level IV) are presented at the end of the "Major Recommendations" field.

Guidelines for Family Physicians

Identification and Evaluation

GPP - When a patient is above 50 years of age and presents with lower urinary tract symptoms, history-taking should include these three basic questions:

- Do you get up more than once at night to pass urine?
- Do you have to wait a long time to initiate urination and do you have a weak stream?
- Are you bothered by your urination pattern?

Other important signs and symptoms include:

- Blood in the urine (haematuria)
- Uncontrolled leakage of urine (incontinence). (GPP)

GPP - Conduct a clinical examination including:

- Digital rectal examination (DRE) to assess size and exclude cancer of the prostate (when the prostate is hard and/or irregular).
- Abdominal examination to exclude palpable bladder. (GPP)
- **C** Conduct a urine labstix test to detect haematuria, pyuria, and glycosuria. **(Grade C, Level IV)**
- **C** Offer the option of serum prostate specific antigen (PSA) test. **(Grade C, Level IV)**

B - Ultrasound examination of the urinary system may be considered. The purposes are to estimate residual urine and to detect hydronephrosis of the kidneys. **(Grade B, Level III)**

Management

- **B** In a patient with benign prostatic hyperplasia (BPH) without significant obstruction and without bothersome symptoms (Stage I): watchful waiting is an acceptable option. (**Grade B, Level III**)
- **GPP** Family physicians who are confident of evaluation of lower urinary tract symptoms (LUTS)/BPH can initiate treatment with medical therapy if the patient is bothered by his symptoms, has no significant residual urine, and cancer of the prostate has been excluded. **(GPP)**
- **A** Alpha-adrenergic blockers are recommended as first-line medical therapy for patients with bothersome symptoms. They have been shown to be effective in improving symptoms. (**Grade A, Level Ia**)
- A 5alpha-reductase inhibitors can be considered an acceptable first-line treatment for patients with large glands. (Grade A, Level Ia)
- **A** 5alpha-reductase inhibitors should be taken for at least 3 to 6 months to be effective. **(Grade A, Level Ia)**
- **A** In the event that PSA is more than 2.0 micrograms/L, a urological assessment is recommended. (**Grade A, Level Ib**)

Indications for Referral to a Urologist

- **C** Consider referring the patient to a urologist when he presents with or has:
- Retention of urine
- Palpable bladder and/or high residual urine
- Incontinence
- Haematuria
- Proven urinary tract infection (UTI)
- Persistent bothersome symptoms
- Bladder stones
- Hard and/or irregular prostate
- PSA > 4 micrograms/L (> 2 micrograms/L if on 5alpha-reductase inhibitors)
 (Grade C, Level IV)

Guidelines for Urologists

Recommended Evaluation

GPP - Conduct a clinical examination including:

• Digital rectal examination to assess size and exclude cancer of the prostate (when the prostate is hard and/or irregular)

- Abdominal examination to exclude palpable bladder (GPP)
- **C** Conduct a urine labstix test to detect haematuria, pyuria, and glycosuria. **(Grade C, Level IV)**
- C Offer the option of serum PSA test. (Grade C, Level IV)
- **C** Consider a voiding diary (frequency-volume chart) when nocturia is the dominant symptom. (**Grade C, Level IV**)
- **B** Detect possible hydronephrosis with ultrasound of kidneys. This is more sensitive than measuring serum creatinine levels to detect back pressure effect of obstruction. (**Grade B, Level III**)
- **B** Ascertain the post-void residual urine with transabdominal ultrasound examination. (**Grade B, Level III**)
- **B** Assess the size and the degree of intravesical prostatic protrusion (IPP) with transabdominal ultrasound scan. This information helps to predict the natural history of the disease. (**Grade B, Level III**)
- **B** Assess severity and degree of bother of the patient's symptoms using the International Prostatic Symptom Score (I-PSS) and the Quality Of Life (QOL) index. (**Grade B, Level III**)
- **B** Use uroflowmetry to determine the degree of urine flow impairment. (**Grade B, Level III**)

Optional Evaluation

These investigations may be indicated for selected patients.

- **B** Transrectal Ultrasound (TRUS) with biopsy is recommended for patients with:
- Suspicious digital rectal examination findings
- Elevated PSA (Grade B, Level III)
- **C** Urodynamic Studies (UDS) are recommended:
- When it is not certain whether outlet obstruction or neuropathic bladder is the cause of voiding dysfunction
- For patients with bothersome symptoms but no clinical or ultrasound evidence of obstruction (no IPP)
- For patients with previous surgery (Grade C, Level IV)
- **C** Flexible cystoscopy is recommended for patients with:
- Previous lower urinary tract surgery
- Obstruction suspected to be due to non-BPH causes (significant residual urine with small volume prostate and low IPP)

• Hematuria (Grade C, Level IV)

Management

The guidelines recognize the different philosophies of treatment held by practitioners. The following is a possible framework for selecting treatment. Patient's age, general medical conditions, and preferences should be taken into consideration.

Significant obstruction is defined by persistently high residual urine (more than 100 mL) and low flow rate of less than 10 mL/s. This is generally associated with prostate volume more than 40 gm and significant IPP (more than 1 cm).

- **B** In a patient with BPH without significant obstruction and without bothersome symptoms (Stage I), watchful waiting is an acceptable option. (**Grade B, Level III**)
- **B** In a patient with BPH with significant obstruction with or without bothersome symptoms (Stage III), surgery can be considered, if the patient is fit. **(Grade B, Level III)**
- **B** In a patient with BPH without significant obstruction but who has bothersome symptoms (Stage II), after discussing with the patient, medical treatment with alpha-adrenergic blockers may be used for symptomatic relief, and 5alpha-reductase inhibitors for a gland of more than 40 gm. (**Grade B, Level III**)
- ${\bf C}$ The following conditions indicate complicated BPH (Stage IV) and are definite indications for surgery:
- Repeated acute retention of urine
- Chronic retention of urine
- Bladder stones
- Recurrent urinary infections
- Recurrent or persistent gross hematuria (Grade C, Level IV)
- **B** Prostatic stenting is indicated in elderly and frail patients at high risk for surgery. (**Grade B, Level III**)
- **A** Transurethral microwave thermotherapy (TUMT) is not routinely recommended as a less invasive treatment of BPH. (**Grade A, Level Ib**)
- **A** Interstitial laser coagulation is not routinely recommended for treatment of BPH. (**Grade A, Level Ib**)

Definitions:

Grades of Recommendations

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Level III: Evidence obtained from well-designed nonexperimental descriptive studies, such as comparative studies, correlation studies, and case studies

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and cost-effective evaluation, management and treatment of patients with lower urinary tract symptoms and benign prostatic hyperplasia
- Reduction in patient symptoms

POTENTIAL HARMS

- Transurethral resection of the prostate (TURP): Potential side effects include retrograde ejaculation, impotence, secondary hemorrhage, bladder neck stenosis, urethral strictures, recurrent adenoma.
- Alpha-adrenergic blockers (prazosin, terazosin, alfuzosin): Side effects include dizziness and orthostatic hypotension; use with caution in patients on antihypertensive medication and those with coronary artery disease or cerebrovascular accidents.
- *5alpha-reductase inhibitors (finasteride, dutasteride)*: Side effects include diminished libido, reduced ejaculation, and impotence; may mask cancer development.
- Transurethral needle ablation (TUNA): Main side effects are retention of urine requiring catheterization for up to a month occasionally and urinary tract infection
- *Stents*: Problems of stent migration and possible stone formation in the longterm.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are not intended to serve as a standard of medical care.
 Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.
- The contents of this publication are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not ensure a successful outcome in every case. These guidelines should neither be construed as including all proper methods of care, nor exclude other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient, in the light of the clinical data presented by the patient and the diagnostic and treatment options available.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The following clinical audit parameters, based on the recommendations in these guidelines, are proposed:

For family physicians: Percentages of family physicians who self-report that they conduct the follow tests for all patients with lower urinary tract symptoms (LUTS):

- Digital rectal examination (DRE)
- Abdominal examination
- Urine labstix tests

<u>For urologists</u>: Percentage of patients who have complicated benign prostatic hyperplasia (BPH) with definite indications for surgery*:

- Repeated acute retention of urine
- Chronic retention of urine
- Bladder stones
- Recurrent urinary infection
- Recurrent or persistent hematuria
- Obstructive uropathy who are offered surgery.

The initial audit would establish a baseline and subsequent audits would allow a study of trends.

The audit would require case record reviews so only a sample of cases may be audited.

* one or more indications

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Chart Documentation/Checklists/Forms Foreign Language Translations Patient Resources Staff Training/Competency Material

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Lower urinary tract symptoms suggestive of benign prostatic hyperplasia. Singapore: Singapore Ministry of Health; 2005 Jan. 49 p. [56 references]

ADAPTATION

These guidelines provide recommendations that were adapted from the recommendations of the International Consultations on Urological Diseases:

Chatelain CH, Denis L, Foo KT, et al. 5th International consultation on BPH -- Recommendations of the International Scientific Committee: Evaluation and treatment of lower urinary tract symptoms (LUTS) in older men 2001.

DATE RELEASED

2005 Jan

GUIDELINE DEVELOPER(S)

Singapore Ministry of Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Singapore Ministry of Health (MOH)

GUIDELINE COMMITTEE

Workgroup on Lower Urinary Tract

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Dr Foo Keong Tatt (Chairman) Senior Consultant, Dept of Urology, Singapore General Hospital; A/Prof Chia Sing Joo, Head & Senior Consultant, Dept of General Surgery, Tan Tock Seng Hospital; Dr Enoch Gan, Consultant Urologist, Raffles Hospital; Dr Ng Foo Cheong, Chief & Senior Consultant, Dept of Urology, Changi General Hospital; Dr Damian Png, Consultant Urologist, MD Specialist Healthcare; Dr Michael Wong, Senior Consultant, Dept of Urology, Singapore General Hospital; Dr David Consigliere, Chief, Dept of Urology, National University Hospital; Dr Lim Kok Bin, Associate consultant, Dept of Urology, Singapore General Hospital; Dr Jonathan Pang Sze Kang, Everhealth Family Clinic & Surgery; Dr Tan Kok Leong, Director, SingHealth Polyclinic (Outram)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Singapore Ministry of Health Web site.

Print copies: Available from the Singapore Ministry of Health, College of Medicine Building, Mezzanine Floor 16 College Rd, Singapore 169854.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Audit criteria, a continuing medical education (CME) self-assessment, and International Prostate Symptom Score (I-PSS) and Quality of Life Due to Urinary Symptoms (QOL) checklists (in English, Chinese, and Malay) are available in the original guideline document.
- The full text guideline and summary card are available for PDA download in ISilo and MSReader formats from the Singapore Ministry of Health Web site.

PATIENT RESOURCES

The following is available:

 Patient education brochure on Lower urinary tract symptoms suggestive of benign prostatic hyperplasia. Singapore: Singapore Ministry of Health; 2006 Feb. 5 p.

Electronic copies: Available in Portable Document Format (PDF) from the Singapore Ministry of Health Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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