



DIAGNOSIS AND TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

MARCH 2003

Guidelines Department

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This document was produced in March 2003. It may be ordered (including carriage) from

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FOREWORD

Constant growth in medical knowledge and rapid advances in new health technologies mean that preventive, diagnostic and treatment strategies are constantly changing. It is difficult for healthcare professionals to assimilate all the new information that appears in the scientific literature, and review it critically and incorporate it into their everyday practice.

The French National Agency for Accreditation and Evaluation in Health (ANAES) is pursuing the work begun by the French National Agency for Evaluation in Medicine (ANDEM). Its specific mission is to promote the evaluation of health technologies and treatment strategies, in particular by producing practice guidelines.

Practice guidelines have been defined as “proposals produced according to a formal methodology which help practitioners and patients decide on the most appropriate care in a given clinical situation”. Their main aim is to provide healthcare professionals with an overview of the level of scientific evidence supporting current scientific information and with expert opinion on an area of clinical practice. By defining what is appropriate, what is not, what is no longer appropriate, and what is still unclear or controversial, they constitute an aid to decision-making.

These practice guidelines have been produced by a multidisciplinary group of healthcare professionals, using the formal method published by ANAES in the guide “Clinical Practice Guidelines – Methodology to be used in France – 1999”.

Producing and applying practice guidelines should improve the quality of care patients receive and ensure better use of the resources available. ANAES is publishing these guidelines to help healthcare professionals ensure that their care practice is based on the most validated and objective foundation possible.

Alain Coulomb
Executive Director

These guidelines were produced at the request of the *Caisse Nationale d'Assurance Maladie des Travailleurs Salariés (CNAMTS)*, the French National Health Insurance fund for salaried workers.

They were produced under the aegis of the French National Agency for Accreditation and Evaluation in Health (ANAES), in cooperation with representatives from:

- *Association Française d'Urologie*;
- *Collège National des Généralistes Enseignants*;
- *Société Française de Gériatrie et de Gérontologie*;
- the *UNAFORMEC* general practice documentation and research centre.

The report was produced using the method described in the guide “Clinical Practice Guidelines – Methodology to be used in France – 1999”, published by ANAES.

The work was coordinated by Dr. Christine Geffrier d'Acremont, project manager, under the supervision of Dr. Patrice Dosquet, head of the Guidelines Department.

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Secretarial services were provided by Laetitia Gourbail.

ANAES would like to thank the members of the Steering Committee, the Working Group, the Peer Review Group and the members of its Scientific Council, who took part in this project.

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GUIDELINES

I. INTRODUCTION

I.1. Definition

Benign prostatic hyperplasia (BPH) is a natural condition rather than a disease. Anatomically, it is defined as an enlargement of the prostate not caused by cancer, and histologically as hyperplasia of the transitional zone of the prostate. When it becomes symptomatic, it may cause voiding frequency and urgency, which are defined as storage symptoms (formerly “irritative symptoms”) and dysuria, weak stream, and postvoid dribble, which are defined as voiding symptoms (formerly “obstructive symptoms”). In these guidelines, both groups of symptoms are referred to as “lower urinary tract symptoms (LUTS)”); they used to be called “prostatism”. However, urethral compression or histological changes may occur even when the prostate volume is apparently normal, and there is no relationship between prostate size and severity of LUTS.

I.2. Subject of the guidelines

These guidelines are limited to the diagnosis and treatment of uncomplicated BPH in men aged over 50. They were produced at the request of the *Caisse d'Assurance Maladie des Travailleurs Salariés (CNAMTS)*, the French National Health Insurance fund for salaried workers, and are intended for general practitioners, geriatricians and urologists. They do not include the tests needed to confirm a diagnosis other than BPH in a patient with LUTS.

I.3. Grading of guidelines

Guidelines are graded A, B or C as follows:

- a grade A guideline is based on scientific evidence established by trials of a high level of evidence (e.g. randomised controlled trials (RCTs) of high power and free of major bias, meta-analyses of RCTs trials or decision analyses based on properly-conducted studies);
- a grade B guideline is based on presumption of a scientific foundation derived from studies of an intermediate level of evidence (e.g. RCTs of low power, well-conducted non-randomised controlled trials or cohort studies);
- a grade C guideline is based on studies of a lower level of evidence (e.g. case-control studies or case series).

In the absence of scientific evidence, the guidelines are based on agreement among professionals.

II. DIAGNOSTIC CRITERIA FOR BENIGN PROSTATIC HYPERPLASIA (BPH)

II.1. Diagnosis

BPH is the most common cause of LUTS in men aged over 50. A diagnosis of BPH should be based on clinical context, history, absence of any other cause and digital rectal examination (agreement among professionals).

Patients should be told that BPH is benign, that LUTS vary, that LUTS may change spontaneously in severity over time, and that these changes may involve either worsening or improvement (agreement among professionals).

There is no anatomical or clinical relationship between severity of LUTS and BPH volume (agreement among professionals).

II.2. Differential diagnosis

When a patient has LUTS which are probably BPH-related, a history should be taken and a clinical examination performed to check for haematuria, any history of urological disorders and any risk factors for urethral stenosis, neurological disorders, malposition, or meatal stenosis (agreement among professionals).

In patients with symptomatic BPH, any haematuria should be investigated to find a cause other than BPH, and the haematuria should only be attributed to BPH if this investigation is negative (agreement among professionals).

II.3. BPH and prostatic cancer

BPH does not increase the risk of prostatic cancer. Determination of PSA (prostate specific antigen) is irrelevant to the diagnosis, workup or monitoring of BPH.

III. INITIAL WORKUP FOR A PATIENT WITH SYMPTOMATIC BPH

This initial workup should be repeated if necessary, depending on how the LUTS develop. There is no evidence to justify routinely repeating the workup.

III.1. Evaluation of discomfort related to LUTS

The bothersomeness caused to the patient by LUTS and their repercussions on the patient's quality of life should be evaluated. A standard questionnaire seems to be the best way of evaluating bothersomeness. The International Prostate Symptom Score (I-PSS), measured by the patient, is currently the most widely used score for both initial assessment and monitoring of symptoms, whether or not treatment is given, although it is not specific to BPH-related LUTS (Table 1). The score should not be the only factor used to determine treatment (agreement among professionals).

Table 1. I-PSS (after the 3rd International Consultation on Benign Prostatic Hyperplasia (BPH), Monaco, June 26-28, 1995)

INTERNATIONAL PROSTATE SYMPTOM SCORE (I-PSS)								
	Not at all	About 1 time in 5	About 1 time in 3	About half the time	About 2 times out of 3	Almost always		
Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	<input type="text"/>	
Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	<input type="text"/>	
Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	<input type="text"/>	
Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	<input type="text"/>	
Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	<input type="text"/>	
Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	<input type="text"/>	
	Not at all	once	twice	3 times	4 times	5 times		
Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5	<input type="text"/>	
I-PSS score S : 0 – 7 = mild 8 – 19 = moderate 20 – 35 = severe						<div style="border: 1px solid black; padding: 5px; display: inline-block;"> I-PSS Score TOTAL S = </div>	<input style="border: 2px solid black;" type="text"/>	
EVALUATION OF QUALITY OF LIFE DUE TO URINARY SYMPTOMS								
	Delighted	Pleased	Mostly satisfied	Mixed – about equally satisfied and dis-satisfied	Mostly dis-satisfied	Unhappy	Terrible	
You have just described how you urinate. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6	<input type="text"/>
						<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Quality of life score L = </div>	<input style="border: 2px solid black;" type="text"/>	

III.2. Further investigations

Urine sterility should be checked using urine test strips. Urine microscopy and culture is required if there is any sign of infection or history of urinary infection (agreement among professionals).

The following are NOT proposed as routine examinations during the initial workup for symptomatic BPH (agreement among professionals):

- *Blood creatinine*. Its determination is only recommended in patients with risk factors for renal failure. Renal failure is confirmed only by calculating creatinine clearance.
- *Uroflowmetry*. This is not a first choice examination but an optional examination performed in a specialist environment.
- *Abdominal ultrasound of the urinary tract*. It may be useful for diagnosing a bladder obstruction, bladder stone or dilatation of the upper urinary tract. Suprapubic ultrasound is not a reliable method for measuring postvoid residual urine or prostate volume.

The following are NOT recommended during the initial workup for symptomatic BPH (agreement among professionals):

- *Urodynamic tests*. These tests are invasive. They can be useful if there is concomitant morbidity, particularly a neurological disorder, and to establish whether there is an indication for treatment in a specialist unit.
- *Transrectal ultrasound of the prostate*. It has no place in the diagnosis, workup or monitoring of symptomatic BPH, but may be useful if there is an indication for surgery, to help choose the best approach in relation to prostate volume.
- *Urethrocystoscopy*.
- *Intravenous urography*.

IV. MONITORING OF BPH

Monitoring of symptomatic BPH means monitoring the course of symptoms and their repercussions on quality of life. No studies have been carried out to determine a follow-up strategy for patients with uncomplicated symptomatic BPH with no worsening of symptoms, but an annual visit seems to be consistent with current practice.

As there is no relationship between the anatomical and the clinical situation, clinical or ultrasound monitoring of prostate volume has no role in the monitoring of symptomatic BPH (agreement among professionals).

Further investigations are not recommended for the monitoring of symptomatic BPH unless there are complications or unless the symptoms worsen (agreement among professionals).

V. TREATMENT OF BPH

There are no published data to support a standardised treatment strategy for uncomplicated symptomatic BPH. The patient should be given information about the current options so that the treatment decision can be made jointly with the doctor (agreement among professionals).

- *Watchful waiting* may be suggested for patients whose symptoms are only slightly bothersome, or who find the level of bothersomeness acceptable (agreement among professionals).
- *Surgery* should be proposed in cases of recurrent acute urinary retention, chronic retention with dribbling, bladder stones, symptomatic bladder diverticula, or BPH-related renal failure (agreement among professionals).
- *Medical or surgical treatment* should be proposed if there are any other complications (haematuria, urinary infection, asymptomatic diverticula) (agreement among professionals). Otherwise, there are no formal indications for such treatment. Satisfaction with the functional results of surgery is higher, the greater the severity of the initial symptoms (agreement among professionals). The patient's wishes should be a major factor when deciding on any form of treatment, irrespective of whether this is medical or surgical (agreement among professionals).

Surgical procedures

There are three types of surgical procedure for treating symptomatic BPH. Their indications depend partly on prostate volume; their complications are given in Table 2:

- Transurethral resection of the prostate (TURP)* is considered to be the gold standard, and is the most common procedure in France. It may be recommended for reducing the severity of BPH-related LUTS and increasing maximum urine flow (grade B).
- Transurethral incision of the prostate (TUIP)* may also be recommended to reduce the severity of LUTS in patients with a prostatic volume of less than 30-40 ml (grade B).
- Open prostatectomy* is an alternative to TURP in severe BPH. The decision depends on prostate volume and the surgeon's experience.

Table 2. Complications of surgical procedures

	Retrograde ejaculation %	Incontinence %	Reintervention rate %/yr
TURP	~ 75	~ 1	2
TUIP	~ 25	~ 1	25*
Open prostatectomy	~ 75	~ 1	~ 2

* at 3 yrs

Medical treatment

There are three categories of drugs which may be used for medical treatment of symptomatic BPH. There are no properly designed studies to establish the superiority of any one category. Their efficacy is moderate according to AFSSAPS (French Agency for Health Product Safety).

- (i) *Alpha-blockers* may be proposed in the treatment of BPH-related LUTS (grade B). They are significantly more effective than placebo. None of the individual alpha-blockers has been shown to be superior to any of the others. They have few side effects and treatment rarely has to be withdrawn;
- (ii) *5-alpha-reductase inhibitors* may also be proposed in the treatment of BPH-related LUTS (grade B). Their superiority to placebo has not been demonstrated in clinical trials except when prostate volume was greater than 40 ml. They cause an iatrogenic reduction in PSA;
- (iii) Phytotherapeutic drugs (*Serenoa Repens*, *Pygeum Africanum*) have not been studied in properly designed clinical trials comparing them with placebo (a single trial comparing *Serenoa Repens* to tamsulosin, an alpha-blocker, did not find any difference in efficacy against symptoms or on uroflowmetry). However, they may be recommended for the treatment of BPH-related LUTS (grade B for *Serenoa Repens*, agreement among professionals for *Pygeum Africanum*).

Other forms of treatment for BPH such as laser therapy, microwave thermal therapy, low frequency radio wave therapy (transurethral needle ablation - TUNA), and high intensity focused ultrasound (HIFU) are currently being evaluated. Their efficacy in relation to TURP has not been established. They are therefore not recommended outside trial protocols (grade C).

VI. UPDATING OF THESE GUIDELINES

These guidelines should be updated after the final results of trials currently in progress have been published, particularly the results of trials of drug combinations used to treat BPH.