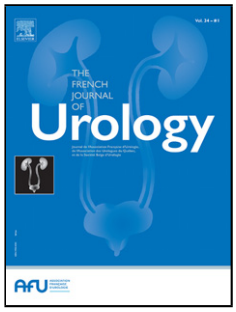
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Pre-therapeutical assessment of lower urinary tract symptoms in adult men: Systematic Review and clinical practice guidelines

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PRE-THERAPEUTICAL ASSESSMENT OF LOWER URINARY TRACT SYMPTOMS IN ADULT MEN: SYSTEMATIC REVIEW AND CLINICAL PRACTICE GUIDELINES

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PRE-THERAPEUTICAL ASSESSMENT OF LOWER URINARY TRACT SYMPTOMS IN ADULT MEN: SYSTEMATIC REVIEW AND CLINICAL PRACTICE GUIDELINES

Introduction. The aim was to propose initial and pre-therapeutical assessment of lower urinary tract symptoms in adult men through a systematic review and clinical practice guidelines

Methods. These guidelines were based on a systematic review performed between January 2011 and November 2021 in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses criteria. The protocol was registered in the International Prospective Register of Systematic Reviews database (CRD42022336418). The recommendations and the methodology of elaboration were prospectively validated by the French Health Authority (Haute Autorité de Santé - HAS).

Results. In total, 1662 publications were screened for eligibility and 311 met the inclusion criteria, 167 studies were retained among them 17 guidelines from French, European or International institutions. Perform on initial evaluation: identification of cardiovascular risk factors, metabolic syndrome, current medication, urinary and sexual symptoms (by structured interview or validated self-questionnaires), physical examination (lumbar fossa, pelvis, prostate, genitalia), urinalysis (dipstick or microscopy), abdominal ultrasound of the urinary tract (kidneys, bladder, prostate), post-void

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residual urine measurement (by ultrasound or automated measurement; under physiological conditions). Micturition flowmetry is recommended (except for general practitioners). Update and complete initial assessment before medication, interventional or surgical treatment if too old or incomplete. Perform a preoperative assessment (bleeding risk, infectious risk, geriatric risk). Urodynamic assessment, endorectal ultrasound and cystoscopy should not be systematically performed (only if additional information is needed). Perform urodynamics and urethrocystoscopy in case of failed interventional or surgical treatment. Following the initial workup, it is recommended to refer the patient to a urologist in case of: macroscopic hematuria, recurrent urinary tract infection or persistent perineal and/or suprapubic pain, persistent microscopic hematuria or leukocyturia in absence of urinary tract infection, predominant storage-phase symptoms, abnormal examination of the genitals or suspected prostate cancer, urinary retention, urinary tract stones, ureterohydronephrosis or morphological abnormalities of the prostate or the urinary tract.

Conclusion. These guidelines aimed to define the recommended investigation for LUTS in adult men at diagnosis, before medical treatment and before surgical and interventional treatments, in order to better personalize management and avoid unnecessary and/or invasive examinations.

Key words: guidelines; benign prostate hyperplasia; benign prostatic obstruction; lower urinary tract symptoms; pre-therapeutical assessment

BILANS PRE-THERAPEUTIQUES DES TROUBLES MICTIONNELS DE L'HOMME ADULTE : MODALITES ET ACTEURS

Introduction. L'objectif était de définir des recommandations pour l'évaluation initiale et pré-thérapeutique des symptômes du bas appareil urinaire (SBAU) chez l'homme adulte en lien avec une hypertrophie bénigne de prostate (HBP).

Méthode. Revue systématique de la littérature entre janvier 2011 et novembre 2021 enregistré dans le Registre prospectif international des revues systématiques (CRD42022336418). Les recommandations et la méthodologie d'élaboration ont été validées prospectivement par la Haute Autorité de Santé (HAS).

Résultats. Au total, 1662 publications ont été examinées pour éligibilité et 311 répondaient aux critères d'inclusion, 167 études ont été retenues parmi lesquelles 17 recommandations émanant d'institutions françaises, européennes ou internationales. Bilan initial : recherche de facteurs des risque cardiovasculaire, du syndrome métabolique, médication, des

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symptômes urinaires et sexuels (par interrogatoire structuré ou auto-questionnaires validés), examen physique (fosse lombaire, pelvis, prostate, organes génitaux externes -OGE-), analyse d'urine (BU ou ECBU), échographie abdominale des voies urinaires (reins, vessie, prostate), mesure du résidu post-mictionnelles (par échographie ou mesure automatisée dans des conditions physiologiques). La débitmétrie est recommandée (sauf pour les médecins généralistes). Mettre à jour et compléter l'évaluation initiale avant un traitement médicamenteux, interventionnel ou chirurgical s'il est trop ancien ou incomplet. Compléter le bilan préopératoire avec une évaluation du risque hémorragique, infectieux et gériatrique (après 75 ans). Un bilan urodynamique, une échographie endorectale et une cystoscopie ne doivent pas être systématiquement réalisés (uniquement si des informations complémentaires sont nécessaires). Effectuer un bilan urodynamique et une urétrocystoscopie en cas d'échec du traitement interventionnel ou chirurgical. Il est recommandé d'adresser le patient en consultation d'urologie en cas d' hématurie macroscopique ou microscopique ou leucocyturie persistantes, infection urinaire récidivante, douleurs périnéales et/ou sus-pubiennes persistantes, SBAU prédominants de la phase de remplissage, anomalie de l'examen des OGE, suspicion de cancer de prostate, globe vésical, calculs de l'appareil urinaire, urétéro-hydronéphrose, anomalies morphologiques de la prostate ou de l'appareil urinaire.

Conclusion. Cette recommandation de bonne pratique a pour objectifs de lister les éléments des bilans pré-thérapeutiques et de définir la place de chacun à différentes étapes de la prise en charge (au diagnostic, avant initiation d'un traitement médical, avant réalisation d'un traitement chirurgical ou interventionnel) afin d'optimiser l'évaluation pré-thérapeutique, de mieux personnaliser la prise en charge et d'éviter les examens « inutiles » et/ou invasifs.

Mots clefs: recommandations; hypertrophie bénigne de la prostate; obstruction sous-vésical; symptômes du bas appareil urinaire; bilan initial, bilan pré-thérapeutique

Introduction

Lower urinary tract symptoms (LUTS) are among the most frequently reported disorders in adult men [1]. The etiologies of male LUTS are very diverse. They may be related to prostatic pathologies, but also to bladder, urethral, neurological, endocrine or infectious pathologies, and even to sleep disorders [2]. These different diseases can lead to bladder outlet obstruction (BOO) and/or to bladder dysfunction and/or to nocturia. In addition, benign prostatic hyperplasia (BPH) exists in varying degrees in most men after 50 years old and it is responsible for LUTS or complications in a small proportion of them [2]. In most cases, BPH coexists with other bladder or general diseases which may also lead to urinary symptoms, but may also require non-urological, management [2]. The multiplicity of these etiologies means that the diagnostic

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approach needs to be optimized and should not be limited to a simple prostatic evaluation, which could lead to inappropriate, ineffective or even harmful treatments. For these reasons: precise questioning, good clinical examination and various complementary tests are essential.

In France, current practices are based on the 2014 AFU guidelines [3] which need to be updated. In this context, the CTMH-AFU (Comité des Troubles Mictionnels de l'Homme de l'Association Française d'Urologie) and the CPP-AFU (Comité des Pratiques Professionnelles de l'AFU) were asked to analyze the literature and to draw-up clinical practice guidelines on the pretherapeutic management strategy for LUTS.

These guidelines aimed to define the recommended investigation for LUTS in adult men at diagnosis, before medical treatment and before surgical and interventional treatments, in order to better personalize management and avoid unnecessary and/or invasive examinations.

Methods

Evidence acquisition

These guidelines were based on a systematic review performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria. The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42022336418). The recommendations and the methodology of elaboration were prospectively validated by the French Health Authority (Haute Autorité de Santé - HAS).

Literature search

A systematic literature search was performed in PubMed/Medline® to identify reports published in French or English between January 2011 and November 2021 (see full report on the Urofrance website) on pre-therapeutical assessment of LUTS in adult men. The full search strategy is in Supplementary Table 1. The study focused on the PICOS[1] criteria: 1) population (P): patients with LUTS; 2) intervention (I) : physical exploration, biological tests, imaging and complementary explorations ; 3) compared intervention (C): other tests ; 4) outcome (O): diagnostic performances [Sensitivity, Specificity, Negative Predictive Value, Positive Predictive Value] or correlation of the test results with symptoms or independent predictive value of the test in multivariate analysis; 5) study design (S): meta-analysis, randomized controlled trial, prospective non-randomized study, or retrospective study. The literature data were completed by literature monitoring (up to July 2022) and by consultation of the websites of international organizations (EAU, AUA, etc.), by a search of

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systematic reviews on La Cochrane library, and by suggestions from the working group members, particularly concerning studies not indexed in Medline® at the time of the bibliographic search.

Study selection

The inclusion and exclusion criteria were defined before the literature selection.

Studies were included if they evaluated the pre-therapeutical assessment of LUTS in adult men. Publications deemed ineligible were: i) health economic studies because they depend largely on the country healthcare system; ii) studies on the impact of tests on clinical decision-making or practice surveys; iii) pharmacological studies; iv) studies evaluating urinary disorders associated with central neurological pathologies (stroke, spinal cord injury, multiple sclerosis, Parkinson's disease, etc.) or urethral strictures; v) animal or *in vitro* studies, vi) case reports, general reviews, editorials, letters or comments. The studies were selected by the methodologist (DK) on the basis of these criteria, after reading the abstract. The selection was independently validated by the steering committee (SL, JG, SD, BP and GR) and subsequently by the whole working group. The full text of the selected relevant reports was read. After an initial round of data extraction by the steering committee, articles selection was confirmed by two other authors (GR and DK) and disagreements were solved after the working group discussion.

Project methodology

This project was carried out by the CTMH/AFU with a multidisciplinary task force composed of urologists, general practitioners, radiologists, geriatricians, biologists, infectious diseases specialists, physiotherapists, nurses and patients' representatives.

The recommendations were defined following the Clinical Practice Recommendation method based on the systematic review and the experts' judgment. The methodological quality of the selected studies was analyzed using dedicated grids. The levels of evidence (LoE) of each study and their conclusions were assessed after taking into account the consistency of their results.

These conclusions and the working group members' arguments were used to define the recommendations: i) the formulated recommendation is the clinical attitude unanimously recognized as the reference by the experts: ii) if a clinical attitude was judged acceptable on the basis of literature data and expert opinion, but was not unanimously recognized as the reference, it is indicated that it can be discussed/proposed; iii) in the absence of expert consensus, no recommendation is formulated.

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The classification of conclusions by LoE (LoE1 being the highest; LoE4 the lowest) and the recommendations grading (grade A is the highest; grade C the lowest; Expert Agreement [EA] in the absence of data) are based on the grid proposed by the HAS [4].

In January 2023, the document was reviewed using the Appraisal of Guidelines for Research and Evaluation II [5] instrument [5] by 46 independent experts from all the medical and surgical specialties involved in LUTS management (23 urologists, 5 physiotherapists, 3 infectiologists, 3 physical medicine and rehabilitation specialists, 2 neuro-urologists, 2 radiologists, 2 geriatricians, 2 general practitioners, 2 nurse practitioners and 2 patient representatives. Their comments were incorporated into the final version of the guideline in March 2023.

The full document, including project rationale, methodology, detailed study analysis, conclusions, recommendations and review process, can be consulted on urofrance since 2024 (https://www.urofrance.org/recommandation/bilan-pre-therapeutique-des-troubles-mictionnels-de-lhomme-adulte-modalites-et-acteurs/?date=&themes=&search=).

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Results and guidelines

The study selection is outlined in the PRISMA flow diagram (Figure 1). In total, 1662 publications were screened for eligibility and 311 met the inclusion criteria. After full-text reading, bibliographic monitoring and working group suggestions, 167 studies were retained among them 17 guidelines from French, European or International institutions [6]22].

1. What is the initial assessment for LUTS in adult men?

1.1. Conclusions based on data analysis

1.1.1. Risk factors

Four systematic reviews or meta-analyses [23]26] and 8 original studies were identified [27]34]. Studies were heterogeneous and generally of low LoE, with no established causal link. The risk factors for LUTS linked to prostate enlargement were not well established, and LoE were heterogenous. The main risk factors associated with the occurrence of LUTS and prostate enlargement were body mass index (BMI) (LoE4), metabolic syndrome (LoE3) and cardiovascular history (LoE4). Other risk factors associated with LUTS with or without BPH were sleep disorders (LoE4), hypo-testosteronemia (LoE4), aging (LoE4), diabetes (LoE4) and anxiety (LoE4).

1.1.2. Urinary symptom self-questionnaires (IPSS scores, etc.) / sexuality self-questionnaires

Two systematic reviews or meta-analyses [35] [36] and 21 original studies were identified [37-57]. Several questionnaires have been developed to assess LUTS in men. Nevertheless, the LoE, the methodological quality of the assessments and the lack of external validation limited the possibility of recommending most of them in daily practice. The IPSS had good psychometric properties (reliability, internal and external validity). Today, it is the most widely used questionnaire for the initial assessment and follow-up of male LUTS (LoE4). Multicenter studies on larger cohorts and comparison with the reference questionnaire (IPSS) are still needed in order to validate most of ther other tests. The VPSS is a simplified visual questionnaire that correlates well with the IPSS total score, and is well accepted and understood by patients, particularly those with reading or comprehension difficulties (LoE4).

1.1.3. Frequency-volume chart

Two systematic reviews or meta-analyses [58] [59] and 1 original study were identified [60]. Frequency-volume chart is the only means of analyzing the frequency, volume and distribution of micturition over the course of the day. It can be used to differentiate nocturnal pollakiuria from nocturnal polyuria, and to identify a reduction in functional bladder capacity (LoE4).

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1.1.4. Physical examination

Three original studies were identified [61-63]. Despite the fact that few new studies have been carried-out in the last 10 years, all recommendations recognize the usefulness of urogenital examinations, including the digital rectal examination (DRE). It is accepted that DRE enables a rough assessment of prostate volume and the search for cancer; its diagnostic performance depends on physisians' expereience.

1.1.5. Abdominal bladder ultrasound

One systematic review or meta-analysis [64] and 10 original studies were identified [65-74]. It is accepted that ultrasound of the urinary tract, when performed under the right conditions, enables the : assessment of prostate volume, bladder and upper urinary tract morphology, as well as post-void residual (PVR). The conditions under which the PVR urine is measured, in particular bladder repletion and optimal physiological voiding conditions, influence its results. As a reminder, a PVR urine is considered significant when it exceeds one-third of the pre-voiding bladder volume. The link between detrusor thickness, bladder mass and BOO has not been clearly established, making it impossible to conclude if these parameters are relevant (LoE4).

1.1.6. Prostate ultrasound

Twelve original studies were identified [62] [75-85]. Ultrasound tends to underestimate prostate volume because of the assumption that the prostate is an ellipsoid (mathematical formulae) (LoE4). The endorectal route is more accurate than the abdominal route for determining prostate volume (LoE4). However, a high level of accuracy for prostate volume evaluation is not required to manage LUTS and does not justify routine use of the trans-rectal route. The abdominal approach should be preferred. No direct link between prostate volume and symptom severity or BOO has been established (LoE4). The specific measurement of the transition zone is not required (LoE4).

1.1.7. MRI / Spectroscopy / CT scan

Two original studies were identified [86] [87]. Studies on spectroscopy, MRI and CT in the assessment of male LUTS are few in number and of low LoE. If MRI is performed as part of the early diagnosis of prostate cancer, it can be used to estimate prostate volume, but should not be used for this purpose alone (LoE4).

1.1.8. Automated measurement of post-void residual urine volume

One systematic review [36] and 3 original studies were identified [88-90]. Automated PVR urine measurements are sufficiently reliable to be preferred to catheterization whenever possible (LoE4).

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1.1.9. Free uroflowmetry

Eight original studies were identified [74] [91-97]. Uroflowmetry is an examination that is only available for specialists. It is a reliable, non-invasive, reproducible test when performed in conditions close to those of daily life (moderate need to urinate, suitable environment). Uroflowmetry can characterize voiding phase disorders, but cannot identify the cause (LoE4). Combining uroflowmetry with PVR urine measurement, clinical data and ultrasound improves diagnostic accuracy (LoE4).

1.1.10. Urethrovesical fibroscopy

One original study was identified [98]. Urethrocystoscopy for LUTS does not allow the diagnosis of BOO of prostatic origin (LoE4). There is no association between endoscopic and urodynamic findings (LoE4). Indications for urethrocystoscopy are essentially the search for differential diagnoses (bladder tumor, stenosis, etc.).

1.1.11. Urodynamic assessment

Two systematic reviews [99] [100] and 14 original studies were identified [101-114]. Urodynamic assessment, including a pressure-flow study, is efficient in diagnosing BOO and detrusor contractility disorders (LoE4). The penile cuff test is a non-invasive examination that has been proposed for estimating bladder contractility and BOO: its results are heterogeneous (LoE4). No other non-invasive methods have been validated for diagnosing BOO or detrusor hypoactivity (LoE4).

1.1.12. Creatininemia

Six original studies were identified [115-120]. Decreased Qmax was associated with chronic renal failure in patients with LUTS (LoE4). There was no significant association between symptom severity and creatinine levels (LoE4).

1.1.13. PSA

Two original studies were identified [121] [122]. Total PSA is an indirect but unaccurate estimation of prostate volume (LoE4). PSA is of no interest in the LUTS management unless they are considered to be related to prostate cancer. PSA prescriptions should comply with current recommendations for the early diagnosis or follow-up of prostate cancer [123].

1.1.14. Urinalysis (dipstick and microscopy)

No original studies were identified. There are no studies to support the use of urinalysis (dipstick and micoscopy) to characterize LUTS. According to existing recommendations, these tests are useful for differential diagnosis [7] [10] [11] [17] [21].

1.2. Recommendations

The initial assessment of male LUTS (storage phase, voiding phase or post-voiding phase) is the responsibility of the primary care physician (mainly a general practitioner). Clinical interview, physical examination and other complementary

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tests (biology, imaging) are recommended (Table 1). Referral to a specialist in urinary disorders (urologist in particular) is recommended for second-line treatment, or according to the results of the initial assessment (Table 2 and Figure 2).

1.2.1. Clinical interview and physical examination

- It is recommended to look for metabolic syndrome, cardiovascular risk factors (grade C), as well as other medical histories likely to lead to LUTS, such as diabetes (grade C), sleep disorders (grade C), anxiety (grade C), or medications inducing LUTS (Expert Agreement).
- It is recommended to assess: LUTS (storage phase, voiding phase or post-voiding phase), urinary quality of life and sexual function either by using validated self-questionnaires or a structured questioning (Expert Agreement). The International Prostate Symptom Score (IPSS) questionnaire has good psychometric properties (reliability, internal and external validity). The use of simplified questionnaires such as the Visual Prostate Score (VPSS) can be proposed as a complement or alternative to the IPSS, particularly in cases of comprehension difficulty (grade C).
- A physical examination of the abdomen, pelvic floor, lumbar fossa, external genitalia and rectal examination (by an experienced practitioner) is recommended (Expert Agreement). The digital rectal examination estimates prostate volume, and helps detecting malignant pathology (Expert Agreement). The digital rectal exam does not replace an imaging test to assess prostate volume (Expert Agreement).
- If storage phase symptoms predominate, it is recommended that a frequency-volume chart (grade C) should be carried-out over a 72-hour period (Expert Agreement).

1.2.2. Biological tests

- **It is recommended to perform a urinalysis (dipstick and/or microscopy), in particular to identify hematuria, leukocyturia or glycosuria (Expert Agreement).**
- **Assessment of renal function is recommended in cases of risk factors for renal failure, acute or chronic urinary retention, or morphological abnormalities of the upper urinary tract (Expert Agreement). It is recommended that renal function tests should not be repeated in patients under regular medical monitoring (Grade C).**
- **In accordance with current recommendations and as part of a shared medical decision, and after informing the patient of the consequences of this assay, it is recommended to offer a total prostate-specific antigen (PSA) assay to any patient consulting for LUTS, and in particular in cases of clinical suspicion of prostate cancer (Grade C).**

1.2.3. Imaging

- **It is recommended that post-void residual urine should be assessed using a non-invasive method (abdominal ultrasound or automated measuring device) (Grade C). The conditions under which PVR urine is measured, in particular bladder repletion and emptying conditions (voiding in toilets, and repeated if necessary), should be**

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as physiological as possible. PVR urine is considered significant when it exceeds one-third of the pre-micturition bladder volume (Expert Agreement).

- **Ultrasound of the entire urinary tract by a qualified practitioner is recommended to assess: prostatic volume, prostate shape, bladder and upper urinary tract evaluation, as well as post-void residual urine (Expert Agreement). Endorectal prostate ultrasound is not recommended as a first-line procedure, given its invasive nature (Expert Agreement). It should be reserved for pre-therapeutic situations where a precise estimate of prostate volume is required (Grade C). CT scan or MRI are not recommended (Expert Agreement).**

1.2.4. Following the initial workup, it is recommended to refer the patient to a urologist (Expert agreement) in case of:

- **macroscopic hematuria, recurrent urinary tract infection or persistent perineal and/or suprapubic pain**
- **persistent microscopic hematuria or leukocyturia in absence of urinary tract infection**
- **predominant storage-phase symptoms**
- **abnormal examination of the genitals or suspected prostate cancer**
- **urinary retention, urinary tract stones, ureterohydronephrosis or morphological abnormalities of the prostate or the urinary tract**

1.2.5. Complementary assessments

When the patient is referred to a urologist, , the latter should discuss the need for further specialized tests such as uroflowmetry, urethrocystoscopy and urodynamic testing (Table 3):

- **Spontaneous uroflowmetry is not mandatory in general practice, but if the professional is equipped with a flowmeter (urologist), it is recommended (Expert Agreement). Uroflowmetry coupled with non-invasive measurement of post-micturition residual urine should be performed in conditions close to those of daily life (moderate need to urinate and suitable environment) (Expert Agreement).**
- **Uretrocystoscopy should not be performed to support the diagnosis of bladder outlet obstruction of prostatic origin. It should be reserved for the search for a differential diagnosis (Grade C).**
- **Urodynamic assessment should not be systematically performed (Expert Agreement). Urodynamic testing is recommended whenever it is necessary to clarify the mechanism of the LUTS (Expert Agreement). When a urodynamic assessment is performed, it should include an evaluation of the voiding phase to help diagnose bladder outlet obstruction and estimate detrusor contractility (pressure/flow study) (Expert Agreement).**
- **It is recommended that non-invasive tests should not be offered as an alternative to pressure-flow urodynamic tests (Grade C).**

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Depending on the results of the initial work-up, monitoring of the patient or initiation of medical treatment may be indicated.

2. What assessment should be made prior to medical management of LUTS in adult men?

2.1. Conclusions based on data analysis

2.1.1. Risk factors

Three original studies were identified [124-126]. The data in the literature are discordant, making it impossible to conclude whether obesity or metabolic syndrome is associated with clinical response to drug treatment (LoE4).

2.1.2. Urinary symptom self-questionnaires (IPSS scores, etc.) / sexuality self-questionnaires

Three original studies were identified [127-129]. The type of LUTS (storage phase or voiding phase) or the initial severity of symptoms do not affect the efficacy of drug treatment (LoE4).

2.1.3. Frequency–volume chart

No additional studies compared to Q1.

2.1.4. Physical examination: rectal examination

No additional studies compared to Q1.

2.1.5. Ultrasound

Eight original studies were identified [130-137]. Grade 3 Prostatic Protrusion Index (PPI) >10mm) or unfavorable ultrasound parameters (detrusor thickness, estimated bladder weight) are associated with a poorer response to drug treatment (LoE4).

2.1.6. MRI

No additional studies compared to Q1.

2.1.7. Measurement of post-void residual urine volume

No additional studies compared to Q1.

2.1.8. Spontaneous uroflowmetry

No additional studies compared to Q1.

2.1.9. Urethrovesical fibroscopy

No additional studies compared to Q1.

2.1.10. Urodynamic assessment

No additional studies compared to Q1.

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2.1.11. Creatininemia

No additional studies compared to Q1.

2.1.12. PSA

No additional studies compared to Q1.

2.1.13. Urine dipstick and CBEU

No additional studies compared to Q1.

2.1.14. Urine dipstick and CBEU

No additional studies compared to Q1.

2.2. Recommendations

The assessment prior to medical treatment of LUTS in adult men is the responsibility of the primary care healthcare professional (general practitioner). Referral to the urologist or another specialist in urinary disorders (neuro-urologist, specialist in physical and rehabilitation medicine) is recommended as a second-line treatment, depending on the results of this assessment (Table 2 and Figure 2). As part of the work-up prior to medical treatment of LUTS in adult men, it is recommended to update and complete the initial work-up if it is too old or incomplete (interview, clinical examination and other complementary tests) (Expert Agreement) (Table 1).

2.2.1. Clinical interview and physical examination

It is recommended to ensure that there are no contraindications or drug interactions, particularly in the elderly men (Expert agreement). It is recommended that urinary symptoms (storage, voiding and post-voiding phases), urinary quality of life and sexual function should be assessed using validated self-questionnaires or structured questioning (Expert Agreement).

2.2.2. Paraclinical examinations

The intensity of LUTS or morphological features such as the Prostatic Protrusion Index (PPI), detrusor thickness or estimated bladder weight on ultrasound should not be considered when ruling out the initiation of medical treatment in the first instance (Grade C). Invasive examinations (cystoscopy, urodynamic assessment, endorectal ultrasound) are not recommended to be routinely carried-out (Expert Agreement).

Following this assessment, it is recommended to refer patient to a urologist in the event of complications (urinary retention, urinary tract stones, ureterohydronephrosis or morphological abnormalities of the prostate and urinary tract) (Expert Agreement).

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2.2.3. *Complementary assessments*

When the patient is referred to a urologist, the latter should discuss the need for further specialist investigations such as uroflowmetry, urethrocystoscopy and urodynamic testing (Table 1, Table 3):

- **Spontaneous uroflowmetry is not mandatory in general practice, but it is recommended for** specialists in urinary disorders **(urologist** and other specialist in voiding disorders such as neuro-urologists, specialists in physical and rehabilitation medicine**) (Expert Agreement). Uroflowmetry coupled with non-invasive measurement of post-void residual urine volume should be carried-out in conditions close to those of daily life (moderate need to urinate and suitable environment) (Expert Agreement). If medical treatment fails, spontaneous uroflowmetry coupled with non-invasive measurement of post-micturition residual is recommended (Expert Agreement).**
- **It is not recommended to perform urethrocystoscopy to support the diagnosis of BOO of prostatic origin. It should be reserved for the search for a differential diagnosis (Grade C).**
- **It is recommended not to carry-out systematically a urodynamic assessment (Expert Agreement). This assessment is recommended whenever it is necessary to clarify the mechanism at the origin of the LUTS (Expert Agreement). When a urodynamic assessment is carried-out, it should include an evaluation of the voiding phase to help diagnose BOO and estimate detrusor contractility (pressure/flow study) (Expert Agreement).**
- **It is recommended that non-invasive tests should not be offered as an alternative to pressure-flow urodynamic tests (Grade C).**

Depending on the results of the initial assessment, or if medical treatment fails, surgical or interventional treatment may be indicated. It is recommended that patients should be referred to a urologist if medical treatment is ineffective (Expert Agreement) or if significant PVR urine persists after a medical treatment has been initiated (Expert Agreement).

3. What assessment should be made prior to surgical or interventional management of LUTS in adult men?

3.1. Conclusions based on data analysis

3.1.1. Risk factors or severity

One original study was identified [138]. Taking anticoagulants or a 5-alpha reductase inhibitor may influence the risk of post-operative haemorrhage (LoE4).

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3.1.2. Urinary symptom self-questionnaires (IPSS scores, etc.) / sexuality self-questionnaires and assessment scores

Three original studies were identified [139-141]. Measuring the severity of symptoms using validated questionnaires contributes to the therapeutic decision. The IPSS is accepted as a standard tool for assessing LUTS associated with BPH. However, the IPSS does not include specific questions assessing urinary incontinence and provides a limited assessment of the clinical syndrome of overactive bladder. The Urinary Symptoms Profile [142] score is a self-questionnaire developed and validated by the AFU. It comprises 13 items covering stress urinary incontinence, overactive bladder and obstructive symptoms. The use of validated self-questionnaires is useful for pre- and post-operative patient assessment (LoE4). The absence of frailty, confirmed by a geriatric assessment of patients aged over 75 with a bladder catheter prior to surgery, is predictive of post-operative success (LoE4).

3.1.3. Frequency–volume chart

No additional studies compared to Q1.

3.1.4. Physical examination: rectal examination

No additional studies compared to Q1.

3.1.5. Abdominal ultrasound of the urinary tract

Two original studies were identified [143] [144]. Assessment of prostate volume by suprapubic ultrasound is just as effective as endorectal ultrasound in determining the volume of the transitional zone (LoE4).

3.1.6. Prostate ultrasound

Four original studies were identified [145-148]. Morphological parameters of the prostate (index of prostatic protrusion, median lobe, shape, angulation of the urethra), determined by imaging or endoscopy, have an impact on the ease of execution and functional results of interventional treatment (LoE4).

3.1.7. MRI / CT scan

Four original studies were identified [149-152]. Morphological parameters of the prostate (index of prostatic protrusion, median lobe, shape, angulation of the urethra), determined by imaging or endoscopy, have an impact on the ease of execution and functional results of interventional treatment (LoE4).

3.1.8. Measurement of post-micturition residual

One original study was identified [153]. A post-void residual urine volume of more than 1 litre is correlated with the presence of renal failure but is not predictive of the surgical outcomes (LoE4).

3.1.9. Spontaneous flowmetry

No additional studies compared to Q1.

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3.1.10. Urethrovesical fibroscopy

One original study was identified [154]. Morphological parameters of the prostate (index of prostatic protrusion, median lobe, shape, angulation of the urethra), determined by imaging or endoscopy, have an impact on the ease of execution and functional results of interventional treatment (LoE4).

3.1.11. Urodynamic assessment

Three meta-analyses [155-157] and 7 original studies were identified [158-164]. BOO (when confirmed by urodynamic assessment) is associated with better surgical outcomes (LoE4). Detrusor hypocontractility is associated with poorer surgical outcomes (LoE4). Detrusor hyperactivity does not change surgical outcomes (LoE4). Routine pre-operative urodynamic testing does not improve surgical outcomes (LoE4).

3.1.12. Creatininemia

No additional studies compared to Q1.

3.1.13. PSA

Two original studies were identified [165] [166]. Total PSA is an indirect but an unaccurate evaluation of prostate volume (LoE4). PSA is of no interest in the management of LUTS unless they are considered to be related to prostate cancer. PSA test must comply with current recommendations for the early diagnosis or follow-up of prostate cancer [123]

3.1.14. Urine dipstick and CBEU

No additional studies compared to Q1.

3.1.15. Prostatic protrusion index (PPI)

Five original studies were identified [167-171]. Morphological parameters of the prostate (PPI, median lobe, shape, angulation of the urethra), determined by imaging or endoscopy, have an impact on the ease of execution and functional results of interventional treatment (LoE4).

3.2. Recommendations

The assessment before surgical or interventional treatment of adult male LUTS is the responsibility of the urologist or another specialist in voiding disorders who has access to all the necessary diagnostic methods (Table 3). As part of the assessment prior to surgical or interventional management, it is recommended to update and complete the initial work-up if it is too old or incomplete (interview, clinical examination and other complementary tests) (Expert Agreement).

3.2.1. Clinical interview and physical examination

It is recommended to check for the use of anticoagulants, platelet anti-aggregates and any other therapy that modifies hemostasis (Expert Agreement). It is recommended that urinary symptoms, quality of life (Grade C) and sexual function should be assessed using validated self-questionnaires (Expert Agreement). It is recommended that

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a geriatric assessment should be carried-out in patients aged over 75 with frailty criteria (e.g. FRIED criteria), particularly in cases of chronic urine retention (grade C).

3.2.2. Biological tests

Assessment of renal function is recommended (Expert Agreement). According to current recommendations, as part of a shared medical decision and after informing the patient of the consequences of this test, it is recommended that a total prostate specific antigen (PSA) test should be proposed if it is likely to modify the subsequent management. Total PSA testing is also recommended if there is clinical suspicion of prostate cancer (Expert Agreement).

3.2.3. Imaging

It is recommended that the volume and shape of the prostate (prostatic protrusion index, median lobe) should be assessed by abdominal ultrasound performed by a qualified practitioner (Grade C). It is recommended that endorectal ultrasound or MRI should not be systematically performed. They are only recommended if they may change the subsequent interventional management (Expert Agreement).

3.2.4. *Additional specialist examinations*

It is recommended that uroflowmetry coupled with PVR measurement should be carried-out (Experts Agreement) in conditions close to those of daily life (moderate need to urinate and suitable environment) (Experts Agreement). A urodynamic assessment is recommended: if there is any doubt on the origin of the LUTS, if there is any doubt about the existence of BOO or if detrusor hypocontractility is suspected (Grade C). When a urodynamic assessment is carried-out, it should include an evaluation of the voiding phase to help diagnose BOO and estimate detrusor contractility (pressure/flow study) (Expert Agreement).

Urethrocystoscopy is recommended if it is necessary to rule out a differential diagnosis or if it is likely to influence the choice of treatment (Grade C). Urethrocystoscopy to support the diagnosis of BOO of prostatic origin is not recommended.

Before any repeated minimally invasive or surgical procedure, it is recommended that the cause of the failure of the first interventional or minimally invasive treatment should be investigated (Expert Agreement). Cystoscopy and urodynamic assessments are recommended if a previous interventional or surgical treatment failed (Experts Agreement).

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Conflicts of interest

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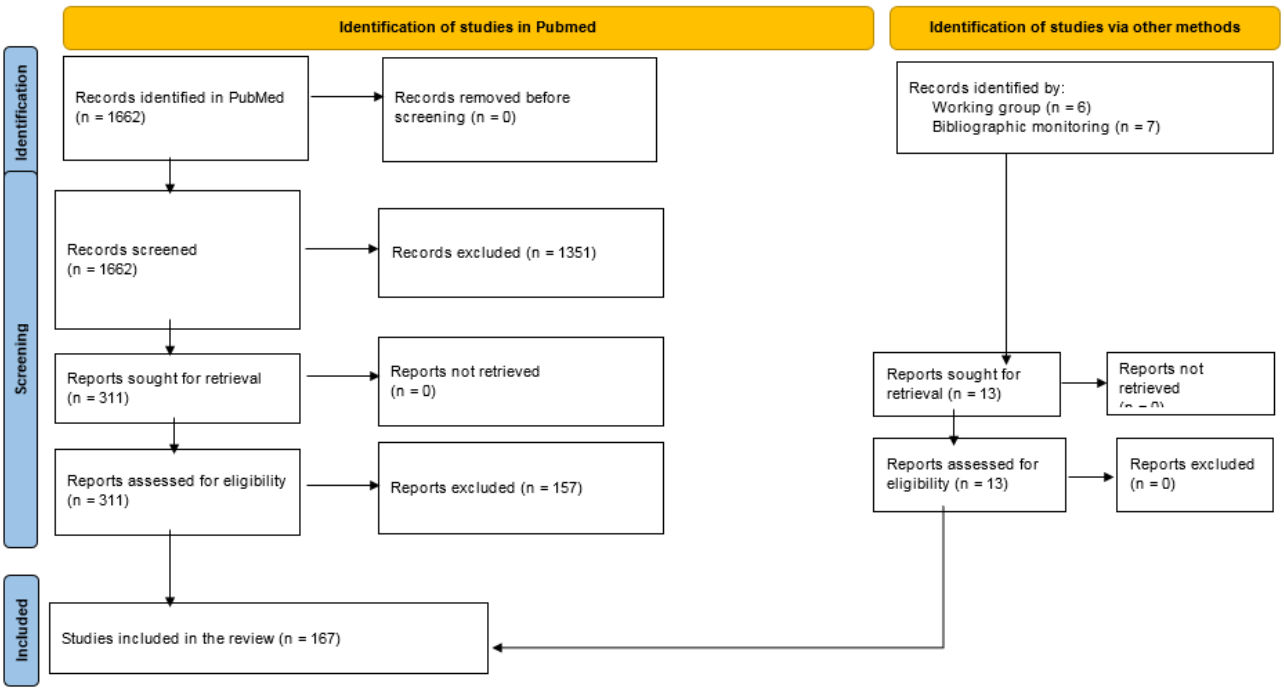
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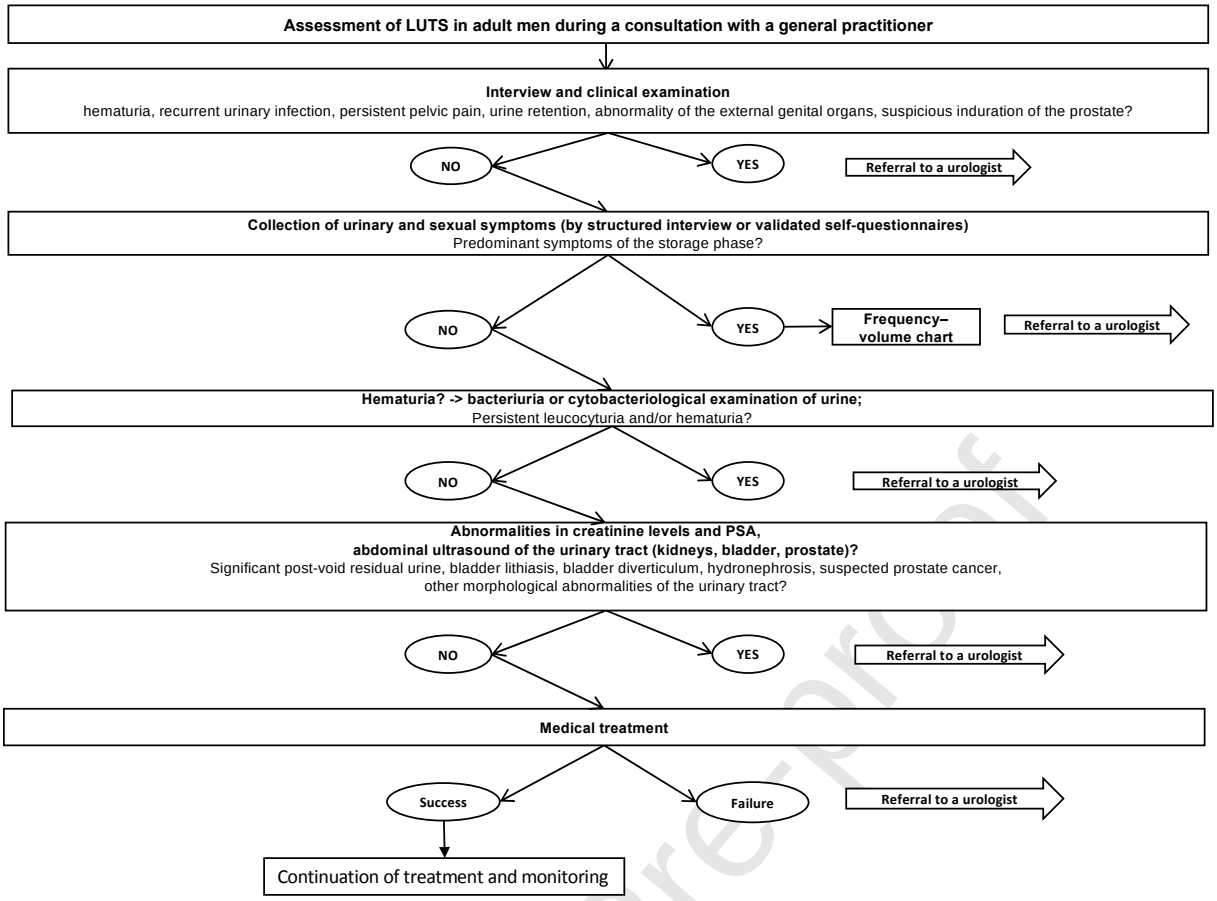
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Figure 2 Assessment of LUTS in adult men to be carried out during a consultation with a general practitioner.



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Table 1. Initial work-up and pre-medical treatment of LUTS in adult men to be carried out during a consultation with a general practitioner

Examinations	Initial assessment	Assessment before medical treatment
Identification of cardiovascular risk factors, metabolic syndrome, current medication	R	O (depending on last assessment anteriority)
Collection of urinary and sexual symptoms (by structured interview or validated self-questionnaires)	R	R
Physical examination (lumbar fossa, pelvis, prostate, genitalia)	R	R
Bladder diary (if predominant storage phase LUTS)	O	O
Urinalysis (dipstick or microscopy) (microscopic hematuria, leukocyturia, glycosuria)	R	O (depending on last assessment anteriority)
Creatinine levels	O	O (depending on last assessment anteriority)
PSA (early diagnosis of prostate cancer, in accordance with current guidelines and as part of a shared medical decision)	O	O
Abdominal ultrasound of the urinary tract (kidneys, bladder, prostate)	R	O (depending on last assessment anteriority)
Endorectal ultrasound of the prostate	NR	NR
Measurement of post-void residual urine (by ultrasound or automated measurement; under physiological conditions)	R	O (depending on last assessment anteriority)
Prostate MRI, Uro-CT	NR	NR

***MRI**: magnetic resonance imaging; **NR**: not recommended; **O**: optional; **R**: recommended; **LUTS**: lower urinary tract symptoms; **Uro-CT**: abdominal and pelvis computed tomography with urography.*

Table 2. Reasons requiring referral to a urologist

Examinations	Designs
Interview and clinical examination	Hematuria, recurrent urinary tract infections, persistent pelvic pain, urine retention, genitalia abnormalities, suspicious induration of the prostate.
Urinary symptoms	Predominant symptoms of the storage phase (to be determined by a bladder diary)
Ultrasound of the urinary tract	Significant post-void residual urine, bladder lithiasis, bladder diverticulum, hydronephrosis, other morphological abnormalities of the urinary tract.
Urinalysis	Persistent leukocyturia and/or hematuria
PSA	Suspicious elevation

Table 3. Assessment of LUTS in adult men to be carried out during a urology consultation

Examinations	Initial assessment	Assessment before medical treatment	Assessment prior to surgical or interventional treatment
Collection of cardiovascular risk factors, metabolic syndrome, usual treatments	R	O (depending on last assessment anteriority)	O (depending on last assessment anteriority)
Collection of urinary and sexual symptoms	R (self-questionnaires or structured interviews)	R (self-questionnaires or structured interviews)	R (self-questionnaires)
Physical examination (lumbar fossa, pelvis, prostate, genitalia)	R	R	R

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Bladder diary (if predominant storage phase LUTS)	O	O	O
Urinalysis (dipstick or microscopy) (microscopic hematuria, leukocyturia, glycosuria)	R	O (depending on last assessment anteriority)	R (ECBU required)
Creatinine levels	O	O (depending on last assessment anteriority)	O (depending on last assessment anteriority)
PSA (as part of the early diagnosis of prostate cancer, in accordance with current recommendations and as part of a shared medical decision)	O	O	O
Abdominal ultrasound of the urinary tract (kidneys, bladder, prostate)	R	O (depending on last assessment anteriority)	O (depending on last assessment anteriority)
Endorectal ultrasound of the prostate gland	NR	NR	O (if precise measurement of prostate volume is likely to change the indication)
Micturition flowmetry with measurement of post-void residual urine (by ultrasound or automated measurement; under physiological conditions)	R	R	R
Urodynamic assessment (if there is any doubt about the cause of the symptoms)	O	O	O
Cystoscopy (to rule out a differential diagnosis)	O	O	O (if likely to modify the indication)
Preoperative assessment (bleeding risk, infectious risk, geriatric risk)	NA	NA	R
Prostate MRI, Uro-CT	NR	NR	O (if likely to modify management or in doubt about the origin of symptoms)

NA: *not applicable;* ***NR:*** *not recommended;* ***O:*** *optional;* ***PSA****: prostate specific antigen;* ***R:*** *recommended;* ***LUTS****: lower urinary tract symptoms;* ***Uro-CT****: abdominal and pelvis computed tomography with urography*

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