

Erectile dysfunction practice guidelines

Canadian Urological Association Guidelines Committee

Canada

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Erectile dysfunction has undergone dramatic advances in diagnosis and therapeutics over the past decade. Increasing numbers of men are currently seeking medical help for their sexual concerns, often from primary health care providers.

The Canadian Urological Association (CUA), Guidelines Committee is charged with the responsibility of creating practice guidelines for urologic conditions with the goal

of improving physician knowledge and enhancing patient care. These Erectile Dysfunction Guidelines highlight the evolving use of a minimally invasive patient self-directed goal oriented approach to evaluation and treatment using oral agents as first-line therapy based on efficacy, side effect profile and ease of use. Second-line therapies include vacuum devices, injectable agents and intraurethral vasoactive devices. Surgical treatments are reserved for men who cannot use or fail to respond to first and second line treatments.

Key Words: erectile dysfunction, guidelines, management, sildenafil

Summary of recommendations

- Erectile Dysfunction (ED) is the preferred clinical term describing the inability to achieve and maintain a penile erection of sufficient rigidity to permit satisfactory sexual activity.
- ED remains an under diagnosed clinical condition, believed to negatively impact quality of life among 15%-52% of men aged 40-70 years.
- Diagnosis and treatment of ED is often, most effectively performed by Primary-Care Physicians (PCP), but may benefit in selected cases from specialty consultation.

- The underlying risk factors associated with ED are common to cardiovascular disease in general, and therefore may represent the initial clinical sign of generalized vascular insufficiency.
- PCP's, urologists, internists, psychiatrists, and other treating health-care professionals should be encouraged to initiate an open dialogue of sexual issues to identify men with ED who may not otherwise volunteer their sexual health concerns.
- Frequently a careful history, physical exam, serum glucose, lipids and optional testosterone testing are all that are needed to make the diagnosis of ED and initiate appropriate therapy.
- Organic (physical) causes of ED are present in the majority of men, but situational contributing factors often play a contributory role and addressing these issues may enhance treatment efficacy.
- Once reversible causes of ED are ruled out, a trial of oral medication is recommended as first-line

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therapy, based on treatment efficacy, side effect profile and minimal invasiveness.

- Specialized testing and referral are generally reserved for cases where greater insight into the etiology is desired by the patient/physician and/or oral-first-line treatment was unsuccessful or not appropriate.
- Second-line therapies although more invasive than oral agents, are generally well tolerated and effective.
- Surgery remains an important option for those men refractory to medical management, offering durable reliable relief from ED.

Background

Erectile dysfunction is a highly prevalent component of sexual dysfunction, which impacts on the quality of life of thousands of Canadian couples. Dramatic advances in our understanding of the pathophysiology of erection has led to the development of new highly effective, minimally invasive therapeutic agents. Traditionally, the selection of treatment options for ED have been under the direction of urologists. Surgical approaches (malleable and inflatable penile implants) were the only genuinely effective therapy for decades. The introduction of intra-cavernous vasoactive agents in the mid-1980's changed the balance of care with larger numbers of men seeking non-surgical options.¹⁻⁴

Primary care physicians (PCP) are rapidly acquiring the diagnostic and therapeutic skills necessary to become the dominant healthcare providers for this condition.^{4,6} Armed with effective oral agents like the PDE-5 inhibitors, and the promise of a multitude of other new oral and sublingual agents in the research pipeline, ED is becoming more a medical clinical entity. Family physicians, internists, cardiologists and others medical specialists are being approached by couples with ED requesting treatment. In many cases longstanding relationships exist between the couple and their treating physician, fostering an important therapeutic alliance which may translate into improved clinical response to the selected treatment approach. A shared-care model for the treatment of ED, in which PCP initially identify and treat patients with ED and refer those individuals who require more invasive or specialized testing and treatment, is a valid concept.⁷

This is a rapidly expanding field with many new therapeutic options available to physicians and patients. We based our suggestions for management on peer reviewed literature, the 1999 WHO Paris consensus panel, the evolving research on new

medical approaches to ED management and placed these comments and recommendations into a Canadian perspective.

Method of preparation

The CUA Guidelines Committee is mandated to create practice guidelines for Canadian Urologists based on peer literature reviews and consensus papers from experts in the field of interest, encouraging clinical excellence. The Erectile Dysfunction guidelines underwent a committee drafting process in which the World Health Organization 1999 Paris Consensus document and other recent reports from the medical literature were reviewed. The recommendations of other guidelines were placed into a Canadian practice context and this draft document was submitted to members of the Canadian Male Sexual Health Council (a sexual health council affiliated with the CUA, composed of multidisciplinary male sexual health experts from across Canada) for review and comment. The second draft report, incorporating the requested changes were reviewed by the Guidelines Committee and a final draft published in the CUA Spring 2002 newsletter for general CUA membership review. All CUA members had the opportunity to discuss concerns with the final document in the three month period prior to the June 2002 vote and acceptance of this document which is now an official guideline of the CUA.

Global management objectives

1. To help the patient and partner establish their treatment objectives.
2. To select diagnostic tests based on the patients presenting complaints and goals of therapy.
3. To utilize diagnostic tests in a cost effective and in a manner which impact choice of treatment.
4. To provide a diagnosis and understanding of the likely etiology of the erectile dysfunction to the patient and partner.
5. To offer treatment choices with comprehensive information on cost, likelihood of success and common side-effects.
6. To initiate therapy with the least invasive option which satisfies the patient and partner goals of treatment.
7. To provide patients with support so as to maximize treatment success.
8. To re-establish the couples ability to achieve and maintain sexual intimacy in as natural a manner as possible.
9. To choose approaches which are reversible whenever possible.

Management approach

Diagnosis

1. Determine that the problem is ED, not premature ejaculation, sexual dysfunction from other causes (Peyronie's, low desire state).
2. Determine the timing of onset, nature of the problem and significance to the couple.
3. Evaluate whether a potentially reversible cause to the ED exists (medication, stress, depression, hormonal, tobacco, alcohol, drugs, partner specific issues).
4. Establish a likely underlying etiology based on the history, physical exam and lab testing (optional). A commonly used schema is:
 - Vascular
 - Endocrine
 - Neurological
 - End organ (penile deformity)
 - Situational
 - Mixed

Methodology

1. History and clinical questioning (this is the most important component of the ED evaluation).
2. Physical examination (directed at neural and vascular systems essential for erections).
3. Use of formalized questionnaire instruments: International Index of Erectile Function (IIEF), Sexual Health Inventory for Men (SHIM).
4. Labs: serum glucose, hormonal screening (total Testosterone/bioavailable), lipid screening.
5. Consultation with subspecialists (endocrinology, psychology, cardiology).
6. Specialized tests:
 - a. Combined injection and stimulation test (CIS).
 - b. Nocturnal penile tumescence testing (Rigiscan).
 - c. Duplex ultrasound with vasoactive penile injection/sildenafil
 - d. Dynamic infusion cavernosography and cavernosometry (DICC)
 - e. Penile Angiogram

The history and physical are the only essential components of the routine evaluation. Use of steps 3-6 are based on the individual patient and physician goals.

Treatment options

1. Sexual counselling (this may represent a spectrum of approaches from a simple open discussion with

the PCP to sexual therapists or psychiatry expert in intimacy building and sensate focus therapy).

2. Oral therapy.
3. Vacuum Therapy (vacuum constriction device or constriction ring alone).
4. Local Therapy (intra-urethral or intracavernous agents).
5. Surgery:
 - a. Penile Implant
 - b. Peyronie's Surgical Repair
 - c. Vascular bypass procedure (generally reserved for young men following traumatic penile vascular injury)

Diagnosis

History

This is the cornerstone of the evaluation of sexual and erectile dysfunction. The history provides the diagnosis in the vast majority of cases. There exist a variety of approaches to obtain a thorough history, with the most common feature being a supportive healthcare professional allowing the couple to relate their concerns and express their goals of treatment in an unhurried manner.

Objectives of the history

- Determine specifics of ED (onset, previous similar event, severity, significance, situations).
- Sexual desire, relationship issues, stress at home, work.
- Genital pain or altered penile shape.
- Lifestyle factors: smoking, substance use/abuse.
- Co-morbid conditions: hypertension, peripheral vascular disease, diabetes, dyslipidemia, and renal disease.
- Pelvic surgery, radiation.
- Medications.
- Psychiatric illness or conditions.

Questionnaires

Use of validated questionnaires may be of significant benefit. These tools can be patient self-administered and provide much of the above information in a time efficient non-threatening manner. There exist a number of validated instruments designed to evaluate sexual and erectile function. The greatest utility of these questionnaires may be in establishing a response to therapy and determining overall satisfaction with drug use over a specified length of time (i.e. 4 weeks). The Sexual Health Inventory for Men (SHIM) is Figure 1.

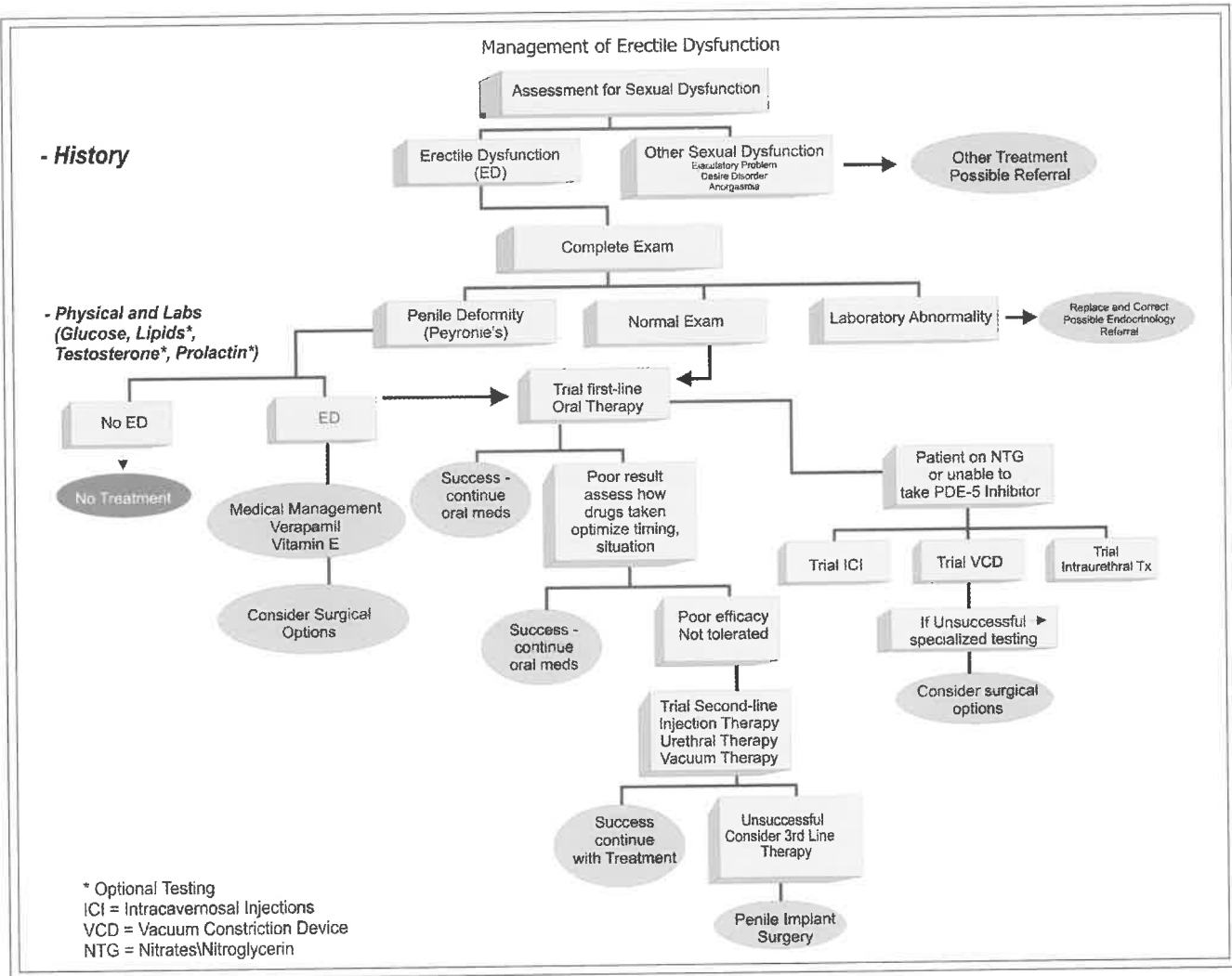


Figure 1. Management of Erectile Dysfunction

Physical exam

The physical is most useful when performed in a focused manner, concentrating on the vascular and endocrine systems. A high association exists between erectile dysfunction and peripheral vascular disease and/or occult coronary syndromes. This may be an important opportunity to unmask these conditions. Assessment should include body habitus (secondary sexual characteristics), the peripheral circulation, neurological and genitourinary systems. Identification of penile deformities is best achieved in the erect state or stretching the penis in the flaccid state to make the plaque more pronounced.

Tests

Assessment for occult diabetes may be performed with a fasting glucose or HbA1c. Although recommended by the WHO consensus panel, a lipid

screen is not a routine component of the Canadian ED assessment but is considered as a valuable addition to the evaluation and good general practice.

Hormonal profile screening remains a controversial aspect of the routine evaluation of ED. In the man with ED and hypoactive desire, testing and treatment for low levels of testosterone is appropriate. In men with normal desire and ED the need for global testing is controversial and currently undetermined. Although beyond the scope of this document, hormonal supplementation is contraindicated in men with breast or prostate cancer. Once initiated on exogenous testosterone, ongoing follow up with regular PSA and rectal exam testing is considered mandatory.

Testing for TSH, LH, prolactin, CBC, and urinalysis are considered complimentary and not felt to be essential in the evaluation of ED in most cases.

Specialized testing

Psychological/psychiatric assessment

These assessments often provide important complimentary insight into relationships and situational causes to ED. The lack of widespread availability and cost limit their use in most cases of ED treatment.

NPT testing

This is a minimally invasive means to measure and record night time erectile events (nocturnal penile tumescence). When not present little useful information is derived. Normally, measurement of 2-5 night time erections persisting with significant rigidity is recorded, allowing reassurance of a normal neurovascular axis. It's greatest utility is in medico-legal cases and pharmacological studies to assess treatment impact.

Vascular testing

A variety of vascular tests exist. Historically a PBI or penile brachial index assessment was made. This noninvasive test records penile pressure as an index of arm pressure, providing an estimate of vascular pressure into the penile circulation. The limitation was that the dorsal penile artery contributes to this index but physiologically adds little to erectile function. In most research-based centers today, availability of a duplex scan is common place. Use of the ultrasound scanner to localize and measure the size and flow through the cavernous vessels, pre- and post vasoactive injection allows a more refined assessment of the penile circulation. This test is currently performed less frequently in Canada since the advent of effective oral medications.

Another approach to evaluate the penile vascular system is the DICC (dynamic infusion cavernosometry and cavernosography). A large number of varying diagnostic protocols exist for this procedure, all aiming to define how well the penile blood-trapping mechanism (the veno-occlusive mechanism) works. In brief, dye and fluid are delivered into the penis to induce an erection. Measurement of the rise and fall of intra-penile pressure with radiologic visualization of the veins draining the penis determine if a competent or incompetent veno-occlusive mechanism exists.

The most invasive diagnostic test, reserved generally for cases of high-flow priapism or planned vascular bypass is the penile angiogram. This test allows visualization of the penile circulation and directs embolization for the unusual cases of penile injury induced high-flow priapism.

Endocrinological tests

Controversy still surrounds the ideal endocrine work up for men with ED. A morning total testosterone or bioavailable testosterone is logical in cases where sexual interest or significant reduction in ejaculate volume are aspects of the presenting complaint. Free testosterone measurement may have significant intra-assay variability which may limit it's clinical utility.

Neuro-physiological testing

This form of testing generally allows for measurement of the sacral reflex arc, an indirect measure of the perineal neural integrity. Tests to directly measure the nonadrenergic noncholinergic nervous system via biopsy or surface electrodes have proven disappointing and are not clinically useful at present.

Conclusions

1. A careful history and physical exam are the essential elements of the ED work up in most cases.
2. Basic screening tests such as serum fasting glucose and testosterone are recommended.
3. An algorithmic treatment approach using the least invasive option is suggested.
4. In some cases where greater detailed information is desired or failure of the initial oral medication is encountered, trials of more invasive second-line treatment or investigations may be appropriate.
5. Surgery should be reserved for men in whom less invasive reversible treatment has not succeeded or is contraindicated.
6. Treatment should be individualized and follow up arranged to assess efficacy of treatment. ☐

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