Complete Summary

GUIDELINE TITLE

AUA guideline on the pharmacologic management of premature ejaculation.

BIBLIOGRAPHIC SOURCE(S)

Erectile Dysfunction Guideline Update Panel. AUA guideline on the pharmacologic management of premature ejaculation. Linthicum (MD): American Urological Association, Inc.; 2004. 19 p. [30 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.
- May 12, 2006, Paxil (paroxetine) and Paxil CR: Changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information related to adult patients, particularly those who are younger adults.

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SCOPE

DISEASE/CONDITION(S)

Premature ejaculation

GUIDELINE CATEGORY

Diagnosis
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide appropriate recommendations for the diagnosis and treatment of premature ejaculation and concomitant erectile dysfunction

TARGET POPULATION

Male patients experiencing premature ejaculation with or without concomitant erectile dysfunction

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Detailed sexual history
2. Assessment of concomitant erectile dysfunction

Treatment

1. Patient education regarding treatment risks and benefits
2. Oral medications
    - Nonselective serotonin reuptake inhibitor
        - Clomipramine (Anafranil®)
    - Selective serotonin reuptake inhibitors
        - Fluoxetine (Prozac®, Sarafem®)
        - Paroxetine (Paxil®)

- Sertraline (Zoloft®)

3. Topical anesthetic agents
    - Lidocaine/prilocaine cream (EMLA® cream)
4. Other pharmacologic therapies (discussed but not specifically recommended)
    - Intracorporal injection of a vasoactive agent (alprostadil)
    - Administration of sildenafil citrate
    - Adrenergic blockade

MAJOR OUTCOMES CONSIDERED

- Efficacy of pharmacologic treatment
- Treatment-associated side effects and adverse event rates
- Patient and partner satisfaction with treatment outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Using the MEDLINE® database with Medical Subject Headings (MeSH) related to ejaculatory dysfunction, initial literature searches were performed limiting papers to reports of human studies published in English-language journals between 1966 and January 2001. Only a small number of articles provided outcomes data on premature ejaculation (PE). Additional studies were identified from references cited in these articles and from recommendations of individual Panel members. The MEDLINE search was last updated in October 2002. Even after the final literature search was completed, however, the Panel continued to scrutinize key references that were identified up until the peer review process.

NUMBER OF SOURCE DOCUMENTS

51

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

From a review of abstracts, the Panel chairs selected articles with potentially usable information. Selected papers were reviewed in detail, and relevant data on efficacy and adverse events were extracted and listed in evidence tables (see Appendix 1 in the original guideline document). Only papers with outcomes data that were relevant to premature ejaculation (PE), involving pharmacologic treatments generally available in the United States, were included in the evidence tables. If the study was seriously flawed, the article was not considered. Summary tables of adverse event rates and effects of various treatments on latency were created to supplement the data captured in the evidence tables (see Appendices 2 and 3 in the original guideline document). The full Panel reviewed the evidence and summary tables at successive meetings.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Panel´s recommendations were developed either solely by consensus or by consensus combined with a review of the available, though limited, evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After this guideline was written, it was reviewed and approved by each member of the Panel and submitted for peer review by 57 physicians. Based on the results of peer assessment, revisions were made and the guideline was forwarded to the Panel again, to the Practice Guidelines Committee, and to the Board of Directors of the American Urological Association (AUA), all of which rendered approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse: The recommendations without the associated supporting text have been excerpted from the guideline. For full context, please refer to the original guideline document.

Recommendation 1:

The diagnosis of premature ejaculation (PE) is based on sexual history alone. A detailed sexual history should be obtained from all patients with ejaculatory complaints. (Based on Panel consensus.)

Recommendation 2:

In patients with concomitant PE and erectile dysfunction (ED), the ED should be treated first. (Based on Panel consensus.)

Recommendation 3:

The risks and benefits of all treatment options should be discussed with the patient prior to any intervention. Patient and partner satisfaction is the primary target outcome for the treatment of PE. (Based on Panel consensus.)

Recommendation 4:

Premature ejaculation can be treated effectively with several serotonin reuptake inhibitors (SRIs) or with topical anesthetics. The optimal treatment choice should be based on both physician judgment and patient preference. (Based on Panel consensus and review of data.)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. The majority of the recommendations contained in the guideline are based on a consensus of expert opinion following review of the literature. In some cases, expert consensus is supplemented with a focused review of the limited data.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis and pharmacologic management of premature ejaculation and concomitant erectile dysfunction
- Decreased medication-associated side effects and adverse events
- Improved treatment outcomes and patient satisfaction

POTENTIAL HARMS

Serotonin Reuptake Inhibitors (SRIs)

Although the adverse effects of the serotonin reuptake inhibitors (SRIs) have been well described in the management of clinical depression, the following facts should be considered when weighing the risks of prescribing these agents for the patient with premature ejaculation (PE):

- First, men being treated for PE often are different from those being treated for depression, and the adverse effects of these medications have not been well assessed in settings other than depression. However, from evidence gathered to date, it appears that the adverse event profiles of the SRIs reported in the treatment of PE are similar to those reported in patients being treated for depression. The type and rate of occurrence of side effects appear to be acceptable to most patients and typically include nausea, dry mouth, drowsiness, and reduced libido (see Appendices 1 and 2). Isolated cases of more serious complications, such as mania and withdrawal symptoms, and potential drug interactions also have been associated with the use of SRIs. Pharmacodynamic drug interactions resulting in a "serotonergic syndrome," characterized in mild cases by headache, nausea, sweating, and dizziness and in severe cases by hyperthermia, rigidity, delirium, and coma, have been reported rarely with concomitant use of monoamine oxidase inhibitors, lithium, sumatriptan and tryptophan. Pharmacokinetic interactions resulting in alterations in drug blood levels have been reported with the concomitant administration of agents that, like the SRIs, also are metabolized by the cytochrome P450 isoenzyme system or are bound to plasma proteins. Clinically significant pharmacokinetic interactions may rarely occur with the use of anticonvulsants, benzodiazepines, cimetidine, tricyclic antidepressants, antipsychotic agents, tolbutamide, antiarrhythmics, and warfarin especially in the elderly patient.
- Second, doses that are effective in the treatment of PE usually are lower than those recommended in the treatment of depression, suggesting that the frequency and severity of adverse events also could be less.
- Third, because two drug administration regimens, continuous daily dosing and situational dosing, are employed in the treatment of PE, adverse event profiles may differ among patients depending on the regimen prescribed.

CONTRAINDICATIONS

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Topical anesthetics are contraindicated in patients who are either allergic themselves or have partners who are allergic to any component of the product.

QUALIFYING STATEMENTS

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- This guideline will address only pharmacologic therapies, as other therapies are not routinely prescribed by the target audience.

- This guideline does not preempt physician judgment in individual cases. Variations in patient subpopulations, physician experience, and available resources necessarily will influence choice of clinical strategy. Adherence to the recommendations presented in this document cannot assure a successful treatment outcome.
- Three major limitations were encountered in the evaluation of the evidence that precluded the ability to combine outcomes data and to perform study outcomes comparisons:
    - The lack of standardization in studying premature ejaculation (PE). Clinical trials employ a variety of definitions, entry criteria, physiological measurements, and psychometric instruments for evaluation.
    - The lack of agreement in quantifying the amount of stimulation that patients experienced. Time to ejaculation is a function of many factors, not the least of which is the nature of the stimulation. The same stimulus may be excessive for one man but elicit little excitement in another. Furthermore, the lack of a consistent stimulus (partner variables, nature of sexual activity, presence or absence of foreplay, preference for single or multiple stimuli) precludes a rigorous experimental design.
    - The lack of consistency and accuracy in measurements of time to ejaculation and other outcomes. The most common outcome parameter, time to ejaculation, is either recorded at the time or documented later by recall. These measurements lack accuracy but generally are useful when applied consistently within a single study. Application across multiple studies in a meta-analysis is problematic because any methodological differences will compromise the ability to make a valid comparison. Other common outcome measures concern patient and partner satisfaction. A variety of assessment tools are used, and there is no assurance of comparability between studies.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society

SOURCE(S) OF FUNDING

American Urological Association, Inc. (AUA)

GUIDELINE COMMITTEE

Erectile Dysfunction Guideline Update Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Drogo K. Montague, MD, Cochair; Jonathan Jarow, MD, Cochair; Gregory A. Broderick, MD; Roger R. Dmochowski, MD; Jeremy P.W. Heaton, MD; Tom F. Lue, MD; Ajay Nehra, MD; Ira D. Sharlip, MD

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Urological Association, Inc. (AUA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Pharmacologic treatment of premature ejaculation appendices. 2004.

Electronic copies: Available in Portable Document Format (PDF) from the American Urological Association, Inc. (AUA) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 10, 2004. The information was verified by the guideline developer on August 4, 2004. This summary was updated by ECRI on May 31, 2006 following the U.S. Food and Drug Administration advisory on Paxil (paroxetine hydrochloride). This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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