

## ERECTILE DYSFUNCTION (ED): CLINICAL GUIDELINES

### Initial Assessment

- Include: BP, urinalysis, fasting glucose or HbA1C and cholesterol, smoking status.
- Consider full profile including LFTs, U&Es and initial testosterone-if abnormal then repeat including sex hormone binding globulin (SHBG), FSH, LH and prolactin) especially in patients under 50 years of age or where loss of libido appears to be a primary problem.

### History \* (See notes)

- Explain possible causes of ED and treat any co-morbidity.
- Consider withdrawal of any drugs possibly causing ED

**Examination** external genitalia, secondary sexual characteristics, lower limb pulses, gross sensation, possibly PR

### Treatment (see cautions and contra-indications below)

Discuss modifying lifestyle, if appropriate  
Explain the government guidelines regarding prescribing and methods of obtaining drugs. Available at:

<http://www.nhs.uk/Conditions/Erectile-dysfunction/Pages/Treatment.aspx>

Wirral guidelines continue to recommend that if treatment is successful, patients should be prescribed up to 4 doses per month, although this may change if national guidance is updated. SLS regulations no longer apply to **generic sildenafil** so GPs may prescribe more if they judge this to be clinically appropriate.

#### Phosphodiesterase type 5 (PDE5) inhibitors

All patients should be offered a trial of 4 doses of a PDE5 inhibitor unless contra-indicated. Onset of action may be delayed if taken with food. Sildenafil and vardenafil have a similar, short duration of action. Tadalafil is longer-acting.

- **1st choice:Sildenafil** 50mg approx 1 hour before sexual activity. Adjust subsequent doses according to response if necessary to 25-100mg. Max 1 dose in 24 hours.
  - **2nd choice:Vardenafil** 10mg (elderly 5mg) 25-60 minutes before sexual activity. Adjust subsequent doses to between 5mg and 20mg if necessary. Max 1 dose in 24 hours.
  - **3rd choice:Tadalafil** 10mg at least 30 minutes before sexual activity. Adjust subsequent doses up to max of 20mg if necessary. Max 1 dose in 24 hours.
- Please refer to BNF for more information.**

### Treatment Failure

- Check the patient used the drug appropriately
- Increase the dose of the same drug, if tolerated, or try an alternative PDE5 inhibitor
- British Society of Sexual Medicine Guidelines: trial of a minimum of 8 doses of max tolerated dose of any given PDE5 before considered a treatment failure
- Referral to ED clinic at Arrowse Park Hospital NHS Trust for other treatment options (see page 2 for these)

PDE5 inhibitors are effective in approximately 80% of patients. Patients who fail to respond or cannot be prescribed a PDE5 inhibitor can still be managed in primary care, particularly by GPs with a special interest, but management is easier with the facilities in a specialist ED clinic.

### \*History

#### Physical Causes

- History of occlusive arterial disease
- Diabetes
- Hypertension
- Dyslipidaemia
- FH of CVD
- Smoking
- Alcoholism and drug abuse
- Pelvic surgery, trauma
- Spinal injury,
- Radiotherapy
- Neurological disease, stroke
- Obesity-(10% weight loss significantly improves ED.)

#### Psychological Causes

- Libido and relationship factors
- Stress and anxiety
- Depression

#### Potential Drug Causes

- Antihypertensives, particularly  $\beta$  blockers and thiazide diuretics. Less risk with ACE inhibitors, calcium channel blockers-caution with amlodipine and sildenafil
- Unless there is an obvious temporal relationship between commencing drugs and onset of erectile dysfunction, withdrawal of drugs rarely helps.
- Antidepressants, particularly SSRIs and tricyclics
- LHRH analogues eg goserelin
- Fibrates eg gemfibrozil
- Anticonvulsants eg phenytoin, carbamazepine
- H2 antagonists eg cimetidine
- Anti-Parkinson's drugs eg levodopa

### Contraindications with PDE5 inhibitors

- Concomitant treatment with nicorandil or nitrates (potentially serious hypotension and possibly myocardial infarction )
- Recent MI (within the last 90 days, 6 months for vardenafil)
- Recent CVA (within the last 6 months)
- Unstable angina or uncontrolled arrhythmias
- Hypotension - blood pressure < 90/50 mmHg
- Uncontrolled hypertension
- Severe hepatic impairment
- Retinitis pigmentosa

#### Cautions

- Caution in cardiovascular disease
- Hypotensive effect with alpha blockers, establish treatment before starting PDE5 inhibitors

#### Drug interactions (see BNF or SPC for more information)

- Erythromycin, itraconazole, ketoconazole, cimetidine, possibly clarithromycin – reduce dose of sildenafil or tadalafil
- Grapefruit juice-avoid concomitant vardenafil or sildenafil
- Use with extreme caution if taking antivirals
- Rifampicin, barbiturates and phenytoin may possibly reduce serum levels of sildenafil and tadalafil
- No need to avoid PDE5 inhibitors in patients taking other antihypertensives but tadalafil is contra-indicated with  $\alpha$  blockers and avoid  $\alpha$  blockers for 4 hours after sildenafil and for 6 hours after vardenafil

## Erectile dysfunction clinic

- Reassess patient and reconsider psychosexual referral and hormonal profile.
- Most antidepressants have sexual side effects. If patient requires antidepressants consider use of trazodone.

### Other Treatment Options (initiated by secondary care only)

- Patients with a principally psychosexual disorder can be referred for psychosexual counselling to Dr Helen Wilkins, Specialist Sexual Health Services, St Catherine's hospital (Tel: 0151 514 6464) or to Relate (Tel: 0300 100 1234)
- Patients with ejaculatory disorders, hormonal problems, pain or other pathology precluding intercourse should be referred to the appropriate specialist.
- If erectile problems are principally curvature due to Peyronies disease and this curvature is not precluding intercourse, the patient can be reassured. If curvature is not progressing there is probably no need to review the patient.
- If the patient has progressive curvature or pain as a result of Peyronies disease and this is precluding to intercourse, the patient should be referred to the ED clinic if they wish to undergo treatment.
- If it is a rigidity issue and not just curvature causing the problem, a trial of PDE5 or a vacuum pump is appropriate

**Alprostadil** (intracavernosal or transurethral). Refer to dose instructions in the BNF. The first dose must be given by medically trained personnel:

- **MUSE® urethral stick** Max 2 doses in 24 hours and 7 doses in 7 days.
  - **Caverject® Dual Chamber** Max 1 dose in 24 hours and 3 doses per week: 10 micrograms, 20 micrograms.
  - **Caverject vials** 5 micrograms, 10 micrograms, 20 micrograms, 40 micrograms
- Invicorp®** injection (aviptadil 25 micrograms, phentolamine 2mg) Max 1 dose in 24 hours and 3 doses per week

#### Vacuum Pumps:

- **Genesis Accord Erection Assistance System** (Genesis medical Ltd)
- **SomaErect Response II** (iMEDicare Ltd)
- **Osbon Erecaid Vacuum Therapy System** (Mediplus Ltd)

Battery operated versions of the above systems available for manual dexterity issues

### Prescribing for ED

Drug therapies and vacuum devices are currently only available on the NHS for certain patients under the prescribing system "Schedule 11". The prescription should be marked "SLS" (selected list scheme). The exception is generic sildenafil which is now exempt from the SLS requirement.

These patients fall into two main groups:

1. Men who are suffering from any of the following:
  - Diabetes
  - Multiple sclerosis
  - Parkinson's disease
  - Poliomyelitis
  - Prostate cancer
  - Severe pelvic injury
  - Single gene neurological disease
  - Spina bifida
  - Spinal cord injury
  - Receiving dialysis or have had kidney transplant
  - Undergone a prostatectomy or radical pelvic surgery
2. Men who were already being treated for ED on the NHS on 14<sup>th</sup> September 1998

Additionally for other men who are suffering from extreme distress as a result of ED, government guidelines state that they can receive treatment on the NHS in exceptional circumstances. **Assessing the degree of distress can be left to the GPs discretion without the need for specialist assessment.**

Patients being prescribed drugs under Schedule 11 would pay the normal prescription charge unless they are exempt from doing so. Patients who do not fit into any of the above categories can be prescribed treatment for their ED on private prescription.

The DOH has recommended that 4 doses per month of PDE5 inhibitors are prescribed for financial reasons and this is now under review. There is no clinical reason why patients may not obtain larger quantities than this on private prescription alone.

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