Treatment of erectile dysfunction in primary care

NHS West Essex Clinical Commissioning Group

Erectile Dysfunction (ED): Persistent inability to attain and / or maintain an erection sufficient for sexual performance

1. History

Sexual History: (i.e present & previous, duration of symptoms, original precipitants, Issues of sexual orientation and gender identity)
Risk factors for metabolic syndrome: smoker - alcohol consumption - BMI ≥ 30 - ≤ 150 mins physical activity/week,
Full medical history (i.e. high risk medical factors i.e. diabetes/hypertension)
Full medication/recreational drug history
Psychosexual History: if possible differentiate between physical and psychological causes.

2. Physical Examination

Cardiovascular Risk Assessment: BP, weight, HR, waist circumference
Genitourinary examination: it is necessary to detect, for example, Peyronie's disease, gonadal anomalies, and retractile foreskin). **Attention to any endocrine** (including testicular size and secondary sexual characteristics), neurological or vascular causes as appropriate, especially if indicated by the history
Digital rectal examination: if suspected prostate problems

3. Investigations

For all patients:
Fasting glucose, HbA1c, serum lipids
Total Testosterone (TT) **(between 8-11am)**: **if ≤ 12nmol/l** check: LH/FSH/prolactin/TSH
In selected patients:
PSA: if clinically indicated. It should be measured before commencing testosterone therapy

→ Men with a psychogenic underlying cause of ED → **Referral for psychological assessment & counselling**

→ Graded Cardiovascular (Appendix 1)

- → Severe → **Refer to cardiology**: Men who have severe cardiovascular disease that would make sexual activity unsafe, or contraindicates PDE-5 inhibitor
- → Intermediate → **Specialised evaluation:** e.g ECG & exercise test for angina, Patient to be placed in high or low risk category, depending upon outcome of testing
- → Low → **Manage ED in primary care** → **Patients should receive lifestyle advice**: Smoking cessation, weight loss, and increase physical activity, reduce alcohol consumption, reduction of stress. If men cycle for >3hrs per week, give cycling advice

→ If patient had diabetes, managed accordingly before starting treatment for ED
Men with diabetes should be asked about ED at their annual check

→ **Refer to endocrinology**:
- Men who have hypogonadism (characterized by abnormal testosterone, follicle-stimulating hormone, luteinizing hormone, or prolactin levels).
- Patients with complex endocrine disorders

→ **Refer to urology:**
- Young men who have always had difficulty in obtaining or maintaining an erection
- Men with a history of trauma (for example to the genital area, pelvis, or spine)
- If an abnormality of the penis or testicles is found on examination
- Men who do not respond to the maximum dose of at least two phosphodiesterase-5 (PDE-5) inhibitors

Pharmacotherapy
Consider phosphodiesterase type-5 (PDE-5) inhibitors (if there are no contraindications):
1st Line: Sildenafil (generic): 50 mg initially, increased to 100mg or decreased to 25 mg as required maximum once daily. Maximum NHS prescription 4 doses/ month
2ND Line: Tadalafil 10mg as required, increased to 20mg if required

Sexual stimulation is required to facilitate erection

Once daily Tadalafil (2.5mg and 5mg tablets) is not recommended for management of erectile dysfunction in West Essex CCG
Tadalafil for penile rehabilitation is NOT NORMALLY RECOMMENDED for Primary Care prescribing

A patient should receive eight doses of a PDE-5 inhibitor at a maximum dose with sexual stimulation before being classified as a non-responder.

Patient counselling and self-care advice

Counsel patients that erectile dysfunction usually responds well to a combination of lifestyle changes and drug treatment. Advise, where applicable, that he should: Lose weight (important), stop smoking, reduce alcohol consumption, and increase exercise.

- Patient should be educated on taking PDE5-inhibitors:
  - Delay in onset of action (1 – 2 hours)
  - Erotic/sexual stimulation required
  - Warn of possible side-effects including headache, flushing (common), visual disturbance, and priapism (very rar
  - Avoid heavy meals and excessive amounts of alcohol prior to taking sildenafil as they can delay the onset of action
- Not stop prescribed medicine unless specifically advised to.
- Advise patients not to take unlicensed herbal remedies for erectile dysfunction as they may contain prescription-only medicines which may be contraindicated or interact with prescribed medication.
- Advice and support is also available from the Sexual Dysfunction Association www.sda.uk.net
- Where possible, involve the man's partner in follow-up appointments (bearing in mind the sensitive nature of the condition) and ask about the effectiveness of treatment. If treatment has not been satisfactorily effective:
  - Counsel about the appropriate use of phosphodiesterase-5 (PDE-5) inhibitors
  - Reconsider comorbidities and treat where possible. In particular, consider the possibility of hypogonadism (which makes PDE-5 inhibitors ineffective)
  - Consider increasing to the maximum dose, or switching to an alternative PDE-5 inhibitor. If this fails, consider referral.

Cycling Advice

Nearly every cyclist who has erectile dysfunction as a result of cycling will have experienced prior symptoms of **pain, numbness or tingling** due to pressure on the perineum affecting the underlying blood vessels and nerves:

- If cycling >3hours/week, advise patients to try period of time without cycling
- Ride in the correct position i.e. changing position frequently during ride and sitting more upright rather than leaning forward over handlebars to reduce pressure on the perineum·
- Use a properly fitted seat, level or angled slightly downwards – never tilt saddle upwards. Use a seat with a cut out to reduce pressure on the perineum·Wear padded cycle shorts

Examples of drugs causing ED

- **Diuretics: Thiazides (for example Bendroflumethiazide), spironolactone**
- **Antihypertensives**: Methyldopa, clonidine, beta-blockers (for example propranolol), verapamil
- **Fibrates**: Clofibrate, gemfibrozil
- **Antipsychotics**: phenothiazines (for example chlorpromazine), butyrophenones (for example haloperidol)
- **Antidepressants:** Tricyclics (e.g. amitriptyline), monoamine oxidase inhibitors (e.g. phenelzine), selective serotonin reuptake inhibitors (e.g. fluoxetine), lithium
- **Hormones and hormone modifying drugs**: Oestrogens, progesterone, corticosteroids, cyproterone acetate, 5-alpha reductase inhibitors (e.g. finasteride)
- **Cytotoxics**: cyclophosphamide, methotrexate
- **Recreational drugs**: alcohol, tobacco, cannabis
- **Histamine antagonists**: cimetidine, ranitidine
- **Anti-arrythmics & anticonvulsants:** Disopyramide, carbamazepine

NHS guidance for prescribing PDE-5 inhibitors on the NHS

Prescribing of drugs for erectile dysfunction (ED) is restricted nationally under the Selected List Scheme on the grounds of cost to the National Health Service.

On August 1st, 2014 an amendment to regulations removed the prescribing restrictions for generic sildenafil as a consequence of Viagra® losing its patent and generic preparations of sildenafil being available much more cheaply.

Prescribing restrictions have only been removed for **generic sildenafil**, they remain applicable for the following in patent and branded ED treatments:

- Alprostadil (Caverject®, MUSE®, Viridal®, Vitaros®)
- Avanafil (Spedra®)
- Tadalafil (Cialis®)
- Vardenafil (Levitra®)
- Viagra®

Only the following groups of patients are eligible to receive branded ED treatments on the NHS, as defined by the Selected List Scheme:

- Men who have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis
- Men who have renal failure treated by transplant or dialysis
- Men who have had radical pelvic surgery; prostatectomy and/or have been treated for prostate cancer (surgery and other treatment)
- Men who have had severe pelvic injury, single-gene neurological disease, spinal cord injury, spina bifida
- Men who were not included in the above categories but were receiving Caverject®, MUSE®, Viagra®, or Viridal® for NHS treatment of impotence on 14 September 1998

Prescriptions for in-patent and branded ED treatments for patients who meet the aforementioned criteria should be endorsed "SLS"

The changes in regulations allow patients who have been prescribed sildenafil privately because they did not meet the SLS eligibility criteria; to have generic sildenafil prescribed on the NHS by a GP.

Quantities to Be Prescribed: The Department of Health's original guidance on frequency of use advises that one treatment per week will be appropriate for most patients and the CCG recommends that prescribers follow that guidance. However, the guidance also states that if GPs, in exercising their clinical judgement, consider that more than one treatment per week is appropriate, then that amount may be prescribed on the NHS.

Patients suffering from severe distress due to erectile dysfunction: can now also be prescribed generic sildenafil from their own GP, rather than attend a specialist service.

When prescribing these products please consider that these drugs do have a street value and quantities should be agreed after a discussion with the patient assessing realistic needs.

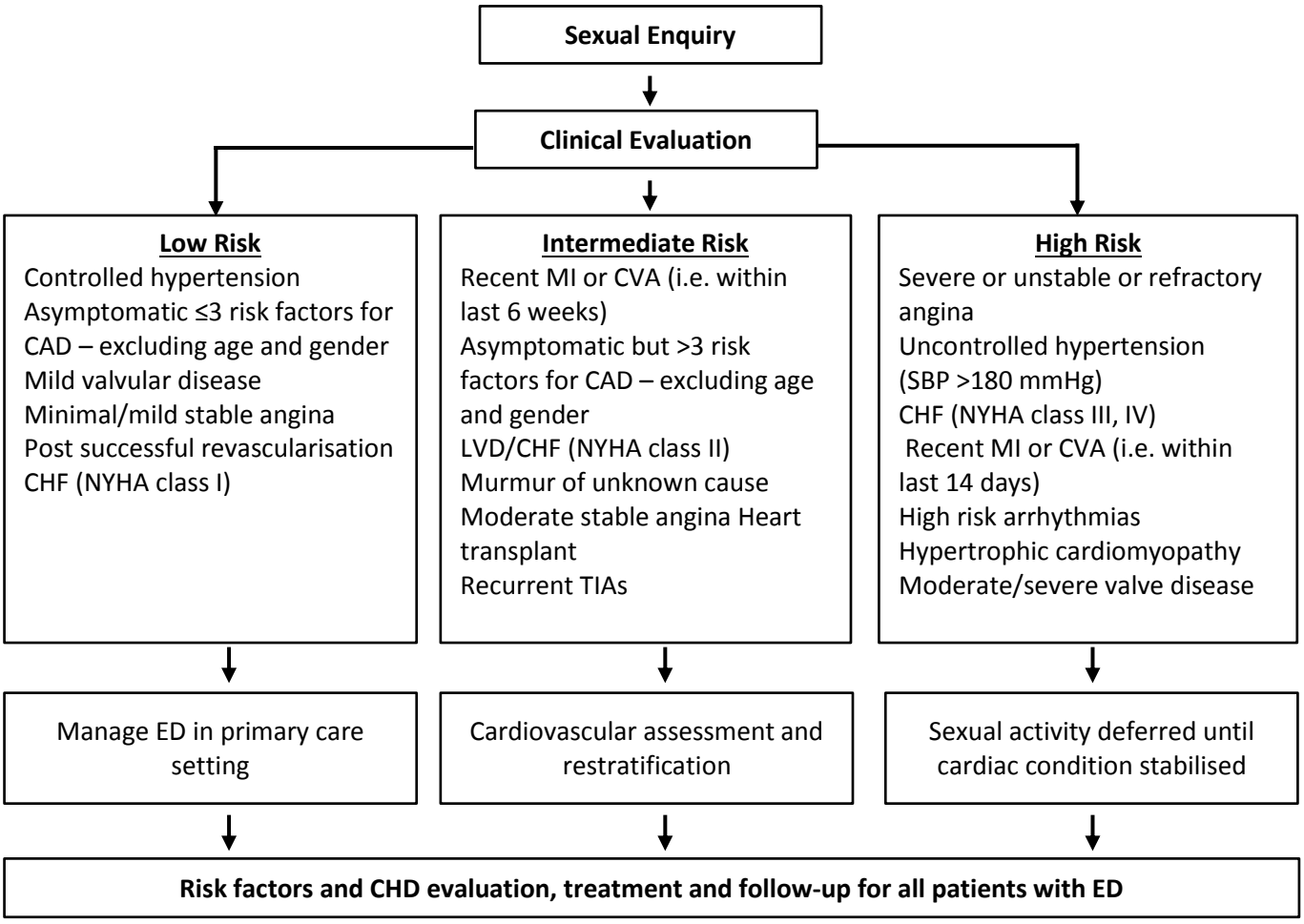
Patients who cannot tolerate generic sildenafil

Patients who cannot tolerate generic sildenafil and do not fall within the category of patients eligible to have an alternative branded ED treatment will not be able to have an alternative branded ED treatment prescribed on the NHS by a GP.

For patients unable to tolerate a particular manufacturer's generic preparation it may be appropriate to prescribe another manufacturer's generic preparation

Patients who cannot tolerate generic sildenafil and who are as a result experiencing serious distress will continue to be able to access in patent branded ED treatments through NHS specialist services, where clinically appropriate, as the statutory restrictions apply only to prescribing by General Medical Practitioners.

Appendix 1: Management algorithm according to graded cardiovascular risk



References

1. British Society for Sexual Medicine: Guidelines on the management of erectile dysfunction, July 2009, updated September 2013
2. NICE clinical knowledge summaries: Erectile dysfunction, December 2014.
3. British National Formulary. London: British Medical Association and The Royal Pharmaceutical Society of Great Britain; Accessed on September 2017 via: https://www.evidence.nhs.uk/formulary/bnf/current
4. Sildenafil- Summary of product characteristics: https://www.medicines.org.uk/emc/medicine/30942
5. Tadaladil- Summary of product characteristics: https://www.medicines.org.uk/emc/medicine/11363