TD and ED:
Testosterone Deficiency (TD)
Erectile Dysfunction (ED)

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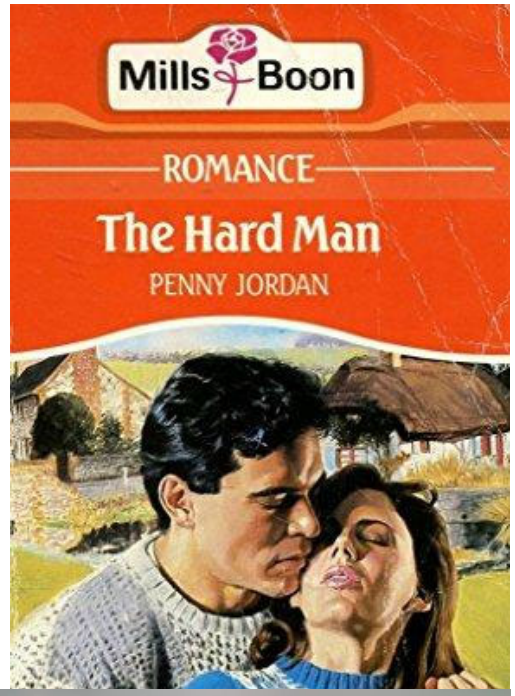
Past-President, BSSM



Testosterone Deficiency Guidelines

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Testosterone Deficiency Guidelines

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Testosterone Deficiency in Men: Diagnosis and Management

Clinical guideline [CG97] Published date: May 2010 Last updated: June 2015 Uptake of this guidance

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REVIEWS

British Society for Sexual Medicine Guidelines on Adult Testosterone Deficiency, With Statements for UK Practice

Geoff Hackett, MD,[1] Michael Kirby, MD,[2] David Edwards, MD,[3]* Thomas Hugh Jones, MD,[4] Kevan Wylie, MD,[5] Nick Ossei-Gerning, MD,[6] Janine David, MD,[7] and Asif Muneer, MD[8,†]

ABSTRACT

Background: Testosterone deficiency (TD) is an increasingly common problem with significant health implications, but its diagnosis and management can be challenging.

Aim: To review the available literature on TD and provide evidence-based statements for UK clinical practice.

Methods: Evidence was derived from Medline, EMBASE, and Cochrane searches on hypogonadism, testosterone (T) therapy, and cardiovascular safety from May 2005 to May 2015. Further searches continued until May 2017.

Outcomes: To provide a guideline on diagnosing and managing TD, with levels of evidence and grades of recommendation, based on a critical review of the literature and consensus of the British Society of Sexual Medicine panel.

Results: 25 statements are provided, relating to 5 key areas: screening, diagnosis, initiating T therapy, benefits and risks of T therapy, and follow-up. 7 statements are supported by level 1, 8 by level 2, 5 by level 3, and 5 by

Definition of TD

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- Characteristic symptoms & signs

  PLUS

- Reduced serum concentrations of testosterone
  (total or free)

Epidemiology of TD

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- Estimates for prevalence vary
- Ranges from 2-12% of men over 40 / 50
- Increases with age

Tajar A, Forti G, O'Neill TW et al. J Clin Endocrinol Metab. 2010;95:1810-8.
Araujo AB, O'Donnell AB, Brambilla DJ, et al. J Clin Endocrinol Metab. 2004;89:5920-5926.

Primary Testosterone Deficiency (TD)

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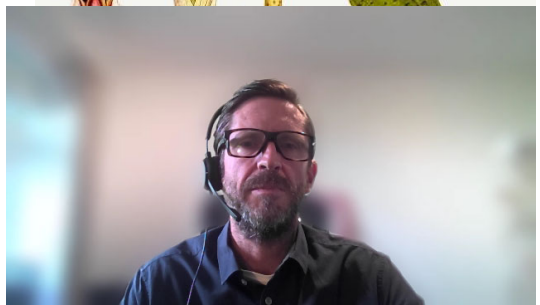
- **Testicular** problem leading to ↓ synthesis
- ↑ LH levels

- Various testicular causes
- Seen with ↑ age (but mixed picture)



Secondary Testosterone Deficiency (TD)

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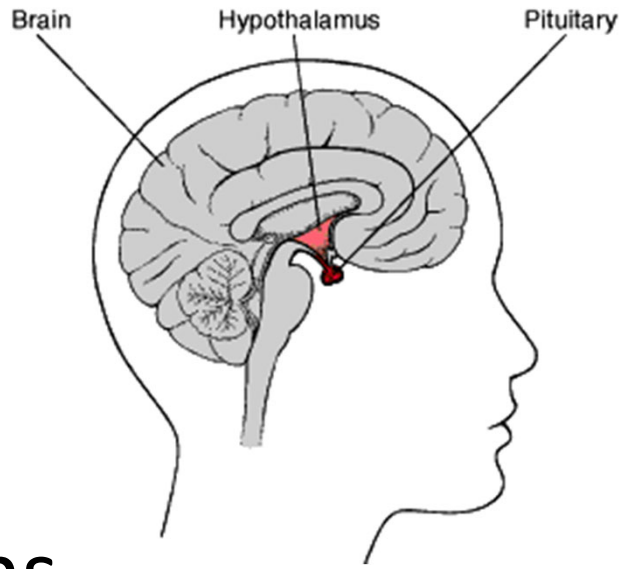
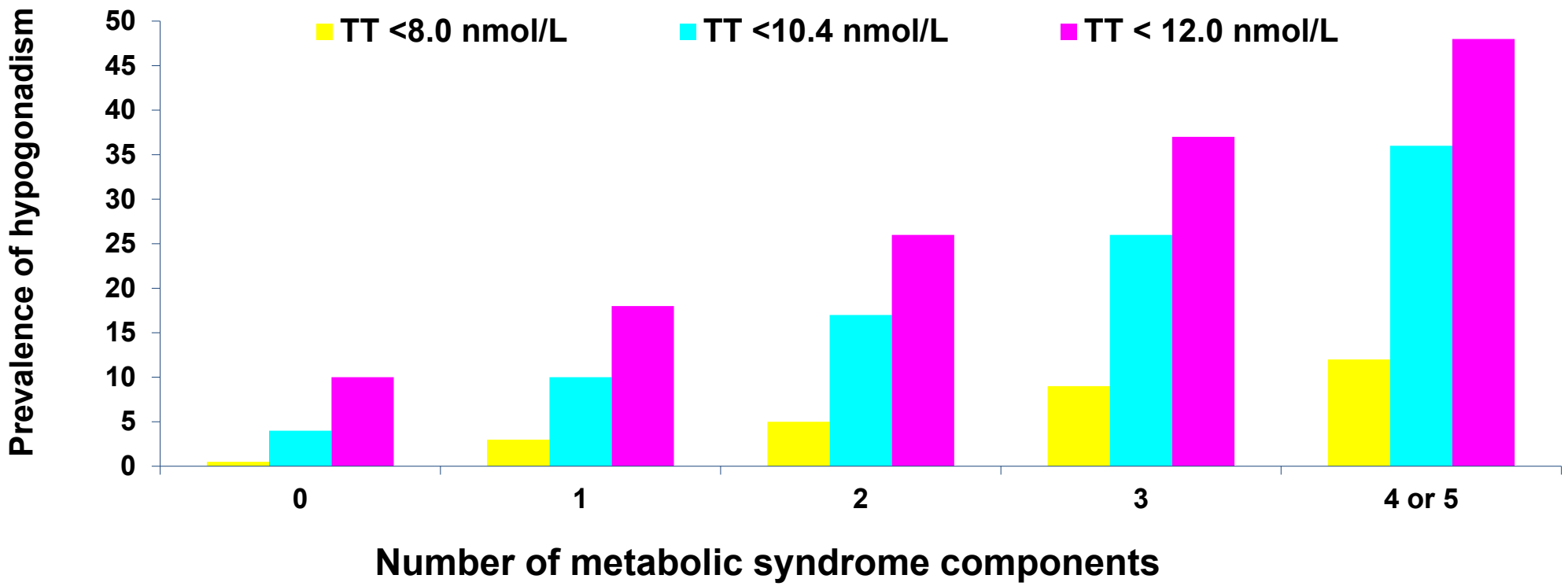
- ↓ LH to stimulate Leydig cells
- *More common* than primary



- Seen with ***obesity*** and ***type 2 DM***
- Opioids, steroids, other medications

Testosterone and metabolic syndrome



Corona G et al. Int J Androl 2009

Screening for TD

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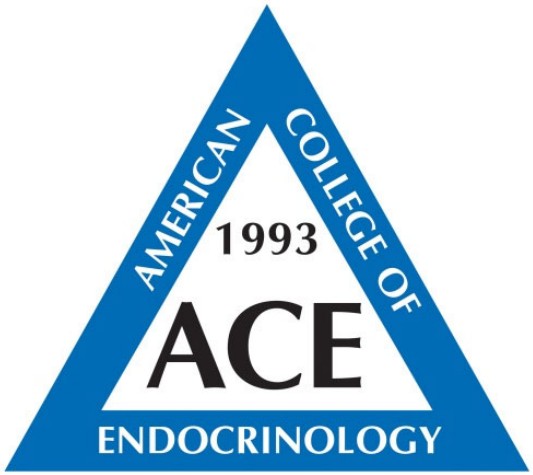
Recommendations—screening	LoE	Grade
Screen for TD in adult men with consistent and multiple signs of TD	3	C
Screen all men presenting with ED, loss of spontaneous erections, or low sexual desire	1	A
Screen for TD in all men with T2DM, BMI > 30 kg/m^2 or waist circumference > 102 cm	2	A
Screen for TD in all men on long-term opiate, antipsychotic, or anticonvulsant medication	2	B



Clinical *signs and symptoms* suggestive of TD

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- Sexual dysfunction symptoms prominent
- Also:
  - night sweats
  - sleep disturbance
  - other changes in mood

History

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- Relevant symptoms
- Current & previous drugs
- Consider use of **questionnaires**
  - Androgen Deficiency in the Ageing Male (ADAM)
  - Ageing Males' Symptoms (AMS) Scale

ADAM Questionnaire

Your answers to the following questionnaire will help to identify whether you have the features of Testosterone Deficiency Syndrome (TDS).

Please answer the questions honestly.

	YES	NO
1. Do you have a decrease in libido (sex drive)?	☐	☐
2. Do you have a lack of energy?	☐	☐
3. Do you have a decrease in strength and/or endurance?	☐	☐
4. Have you lost height?	☐	☐
5. Have you noticed a decreased "enjoyment of life"?	☐	☐
6. Are you sad and/or grumpy?	☐	☐
7. Are your erections less strong?	☐	☐
8. Have you noticed a recent deterioration in your ability to play sports?	☐	☐
9. Are you falling asleep after dinner?	☐	☐
10. Has there been a recent deterioration in your work performance?	☐	☐

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If the answer is YES to question **1 or 7**, or **at least three** of the other questions:

Further evaluate for symptoms of TD & consider testing

Google "testosterone questionnaire"

Laboratory Diagnosis of TD

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- Measure **testosterone** – fasting sample, before 11am
- Need at least 2 results, preferably 4 weeks apart
- If 1st low (or borderline), repeat & measure **LH** (+/- FSH), plus **SHBG** to calculate **free testosterone**.

  {Check **prolactin** if T very low (<5.2nmol/L) & low LH/FSH}

- Clinical symptoms more closely related to ***free testosterone*** than total

Diagnosis of TD

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www.pctag.uk/testosterone-calculator/

Google “testosterone calculator”

PCTAG
Primary Care Testosterone Advisory Group

Contact us
info@pctag.uk

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FREE & BIOAVAILABLE TESTOSTERONE CALCULATOR

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This website has been developed in part through an educational grant from Besins Healthcare (UK) Ltd. The company has no editorial control on its content.

IMPORTANT LIMITATIONS: This calculator is an educational tool and should not be solely relied upon in making any clinical decision. No responsibility whatsoever is assumed for its correctness or suitability for any given purpose. Please consult your health care provider first for any health concerns.

Additionally, the calculated free and bioavailable testosterone should not be relied upon in situations with potential massive interference by steroids binding to SHBG

Free & Bioavailable Testosterone Calculator

Albumin*: 43 **Units:** g/L

SHBG: **Units:** nmol/L

Testosterone: **Units:** nmol/L

Calculate

Free Testosterone:

Thresholds for T Therapy

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- **BEWARE LABORATORY REFERENCES RANGES**
  - Vary considerably across the country

- Use **“Action levels”** instead

Textual Investigations

SERUM FREE TESTOSTERONE:
LH, SERUM:

Coded Investigations

Serum albumin level (XE2eA)	43 g/L [35 - 52]
Serum testosterone level (XE2dr)	8.7 nmol/L [6.68 - 25.7]
Serum sex hormone binding globulin level (44CD.)	24 nmol/L [19.3 - 76.4]
Serum free testosterone level (XabD9)	200 pmol/L [163 - 473]
Serum LH level (XM0lv)	4.5 iu/L [1.7 - 8.6]
Serum prolactin level (XaELX)	120 mu/L [86 - 324]

Thresholds for T Therapy

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Remembering, WITH symptoms:

- Total T level <8 nmol/L *or* free T <180 pmol/L
  - Usually requires T Therapy
- Total T level >12 nmol/L *or* free T >225 pmol/L
  - Does not require T Therapy
- Total T 8-12 nmol/L *or* free T 180-225 pmol/L
  - Consider a ***trial*** of T Therapy for a minimum of 6 months

How to *treat* TD?

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- Lifestyle measures first
  - Weight reduction
  - Lifestyle modification
  - Optimal management of co-morbidities
- BUT:
  - **Weight loss alone** does not give the symptomatic benefit seen with **adding testosterone therapy**
- THEREFORE:
  - Guidance advises ***combination of both*** (LoE 2, Grade A)

Ng Tang Fui M, et al. Int J Obes 2017;41:420-426.
Ng Tang Fui M et al. BMC Medicine 2016;14:153.

Testosterone replacement therapy (TRT)

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- Choice usually = **gel** vs **injection**

- No justification for selecting one over another except **patient choice**

Testosterone gels

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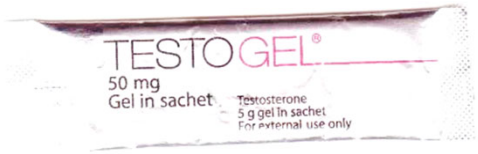
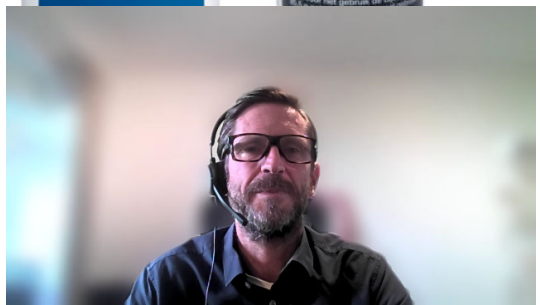
- Daily, may need titrating
- *Advantages*:
  - Fast onset
  - Levels peak at 2-4 hours then gradually ↓
- *Disadvantages*:
  - Skin irritation
  - Potential interpersonal transfer
  - Possible non-compliance long-term





Testosterone injections

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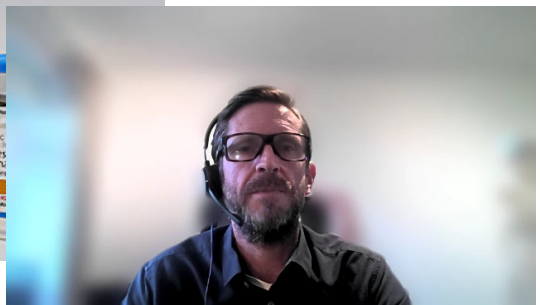
1. Short-acting:

- Usually 3-weekly

- *Advantages*:
  - Low cost prescription (*Sustanon*®)
  - Short duration allows quick withdrawal
- *Disadvantages*:
  - More injections (different cost?)
  - Fluctuation in T levels between injections



Testosterone injections

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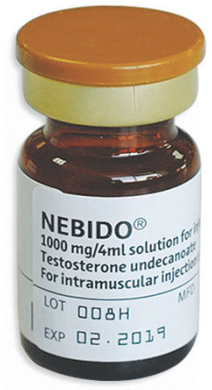
2. Long-acting:

- Every 10-14 weeks



- *Advantages*:
  - Fewer injections – ↑ compliance
  - Maintains better steady state
- *Disadvantages*:
  - Slower drug withdrawal
  - Possible painful injection site (4ml, needs to be SLOW)

Does T therapy work?

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- Good evidence cited in BSSM guidelines, improvements in:
  - Sexual desire, activity, erections
  - Waist circumference
  - BMI
  - Lean mass vs fat mass
  - Insulin resistance
  - Lipid profile
  - BP
  - Walking distances
  - Bone mineral density
  - Anaemia
  - Lower urinary tract symptoms
  - Depression scores

Hackett G et al. BSSM guidelines on adult testosterone deficiency: J Sex Med. 2017 ;14(12):150

The NEW ENGLAND JOURNAL of MEDICINE

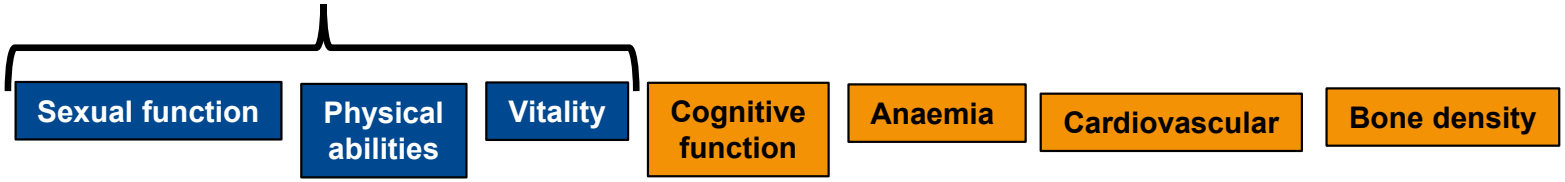
ESTABLISHED IN 1812 FEBRUARY 18, 2016 VOL. 374 NO. 7

Effects of Testosterone Treatment in Older Men

P.J. Snyder, S. Bhasin, G.R. Cunningham, A.M. Matsumoto, A.J. Stephens-Shields, J.A. Cauley, T.M. Gill, E. Barrett-Connor, R.S. Swerdloff, C. Wang, K.E. Ensrud, C.E. Lewis, J.T. Farrar, D. Cella, R.C. Rosen, M. Pahor, J.P. Crandall, M.E. Molitch, D. Cifelli, D. Dougar, L. Fluharty, S.M. Resnick, T.W. Storer, S. Anton, S. Basaria, S.J. Diem, X. Hou, E.R. Mohler III, J.K. Parsons, N.K. Wenger, B. Zeldow, J.R. Landis, and S.S. Ellenberg, for the Testosterone Trials Investigators*

Snyder P et al. *N Engl J M*

“T trial”: Coordinated, 7 overlapping trials (principally one trial)



- Aim: to show whether TRT works in older men
- Intervention: testosterone gel versus placebo gel
- Duration: 1 year (n=780)
- Prospective, randomised, placebo-controlled, double-blind

RCT evidence

- ↑ **sexual activity**, **libido**, **erections**
- ↑ self-reported **walking**, 6-min **walk distance**
- Improved measures of **mood**, & **PHQ-9**
- Improved **vitality** score
- ↓ **anaemia** (explained / unexplained): ≈1g/dL
- ↑ **bone density**
- No change in MI, stroke, CV deaths
- 7 overall deaths in placebo, 3 in T arm

Testosterone treatment to prevent or revert type 2 diabetes in men enrolled in a lifestyle programme (T4DM): a randomised, double-blind, placebo-controlled, 2-year, phase 3b trial

Gary Wittert, Karen Bracken, Kristy P Robledo*, Mathis Grossmann*, Bu B Yeap*, David J Handelsman*, Bronwyn Stuckey*, Ann Conway*, Warrick Inder*, Robert McLachlan, Carolyn Allan, David Jesudason, Mark Ng Tang Fui, Wendy Hague, Alicia Jenkins, Mark Daniel, Val Gebski, Anthony Keech*

Lancet Diabetes Endocrinol 2021; 9: 32–45

See **Comment** page 5

*Joint second authors

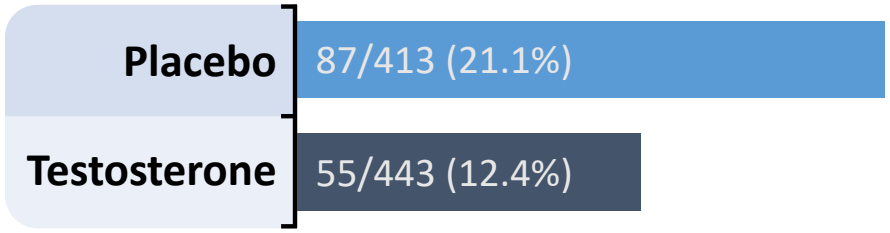
Summary

Background Men who are overweight or obese frequently have low serum testosterone concentrations, which are associated with increased risk of type 2 diabetes. We aimed to determine whether testosterone treatment prevents progression to or reverses early type 2 diabetes, beyond the effects of a community-based lifestyle programme.

Results: Primary outcomes

Primary outcome 1

Proportion with 2 hr glucose ≥11.1 mmol/L at 2 years



RR 0.59 (95% CI: 0.43, 080); p<0.001

Adjusted analyses for baseline:

Testosterone RR 0.61 (95% CI: 0.45, 0.84); p=0.002

*Risk factors RR 0.65 (95% CI: 0.50, 0.86); p=0.002

Primary outcome 2

Mean change in 2 hr glucose at 2 years (mmol/L)

Mean difference -0.75 (95% CI: 01.10, -0.40); p<0.001

Adjusted analyses for baseline:

Testosterone -0.69 (95% CI: -1.05, -0.33); p<0.001

*Risk factors -0.71 (95% CI: -1.07, -0.35); p<0.001

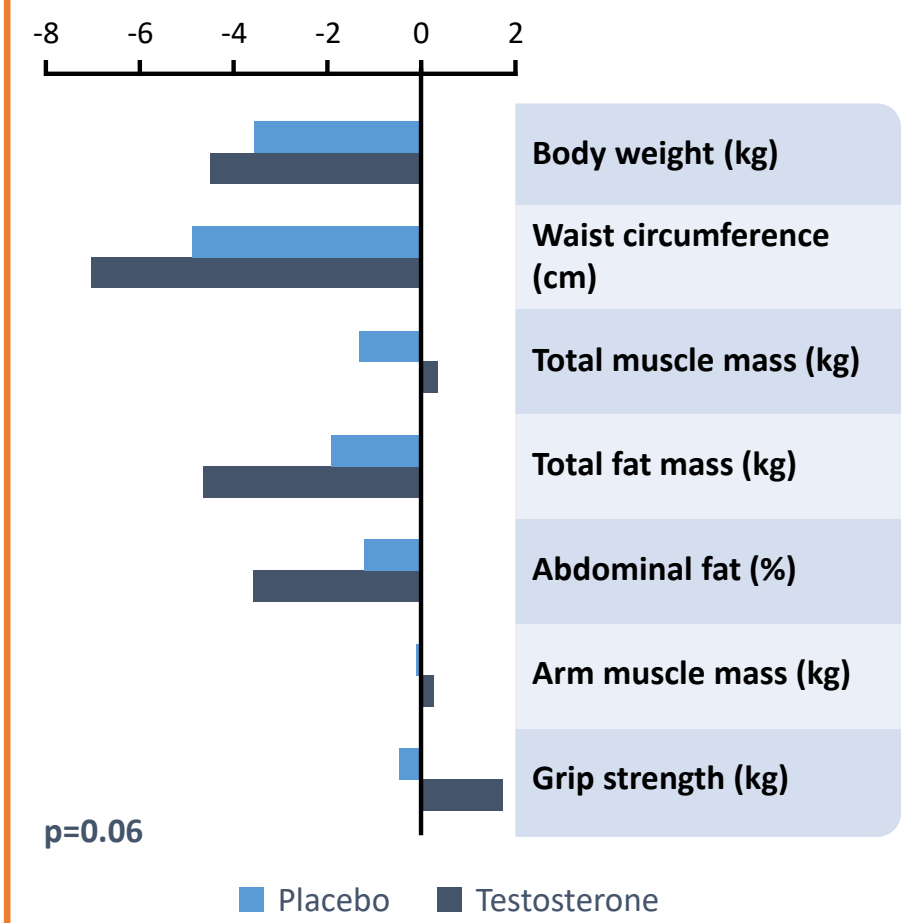
There was no relationship between baseline testosterone and the treatment effect (p=0.26)

*Centre, age group (50–59, 60–74 years), WC (95–100, 101–115, >115 cm), 2-h glucose on OGTT (7.8–9.5, 9.6–11.0, 11.1–15.0 mm
first-degree family history of T2DM (yes, no), baseline serum testosterone (≤8 (230 ng/dL), 8–11, ≥11 mmol/L (317 ng/dL)

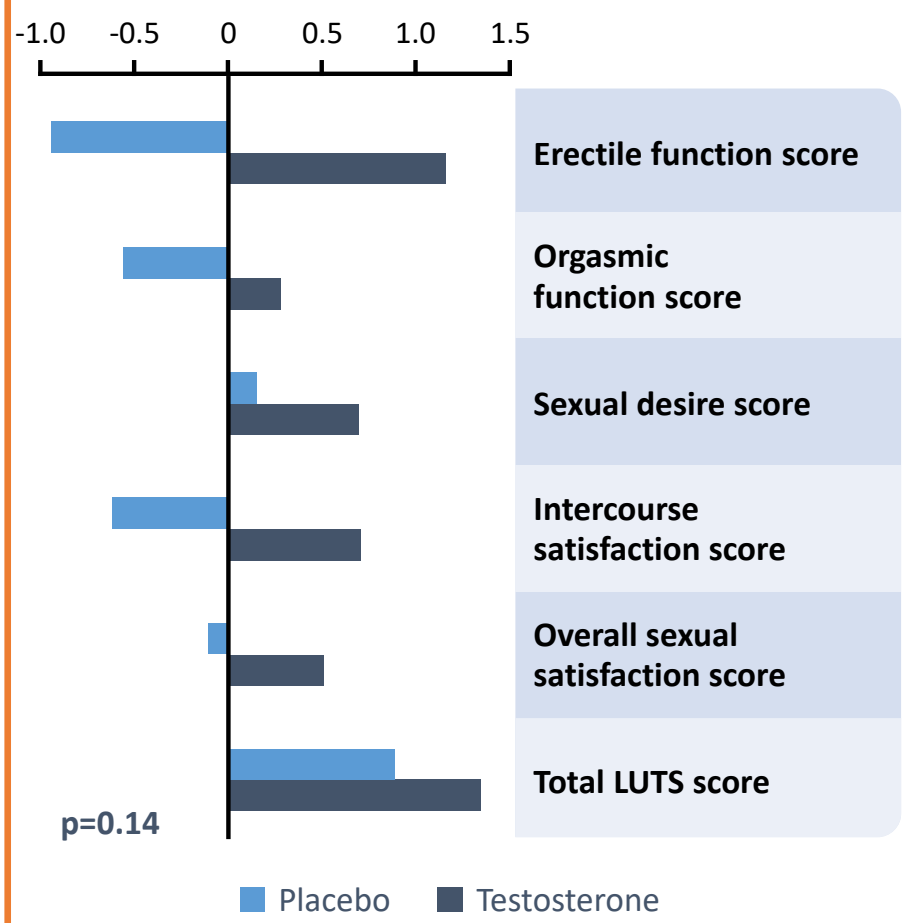
CI, confidence interval; OGTT, oral glucose tolerance test; T2DM, type 2 diabetes mellitus; WC, waist circumference.

Results: Secondary outcomes

Change from baseline in body composition

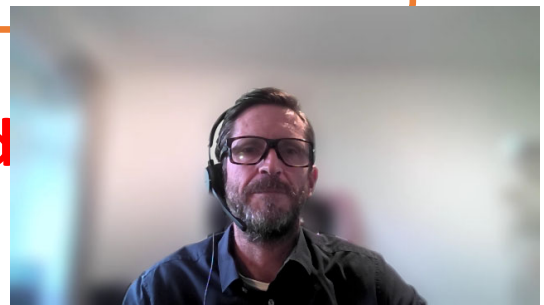


Change from baseline in sexual function



LUTS, lower urinary tract symptoms.

All p<0.001 unless otherwise stated



How long to trial treatment?

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- Different symptoms improve at different rates
  - Mental health improvements quite early
  - Sexual desire within 6 weeks, erections maybe longer
  - ↓fat mass, ↑lean mass: may take 12 months or more

- Should trial for **MINIMUM 6 MONTHS**

- Most commonly, **lifelong therapy**
  - Studies: cessation → relapse & reversal of benefits within 6 mths

Hackett G et al. BSSM guidelines on adult testosterone deficiency: J Sex Med. 2017 ;14(12):150

Adverse effects of TRT

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- Changes in mood, energy & sexual desire
- Polycythaemia
- Acne
- Gynaecomastia
- ↓ fertility

- ***Sustained supraphysiological levels should be avoided***

Follow-up and monitoring

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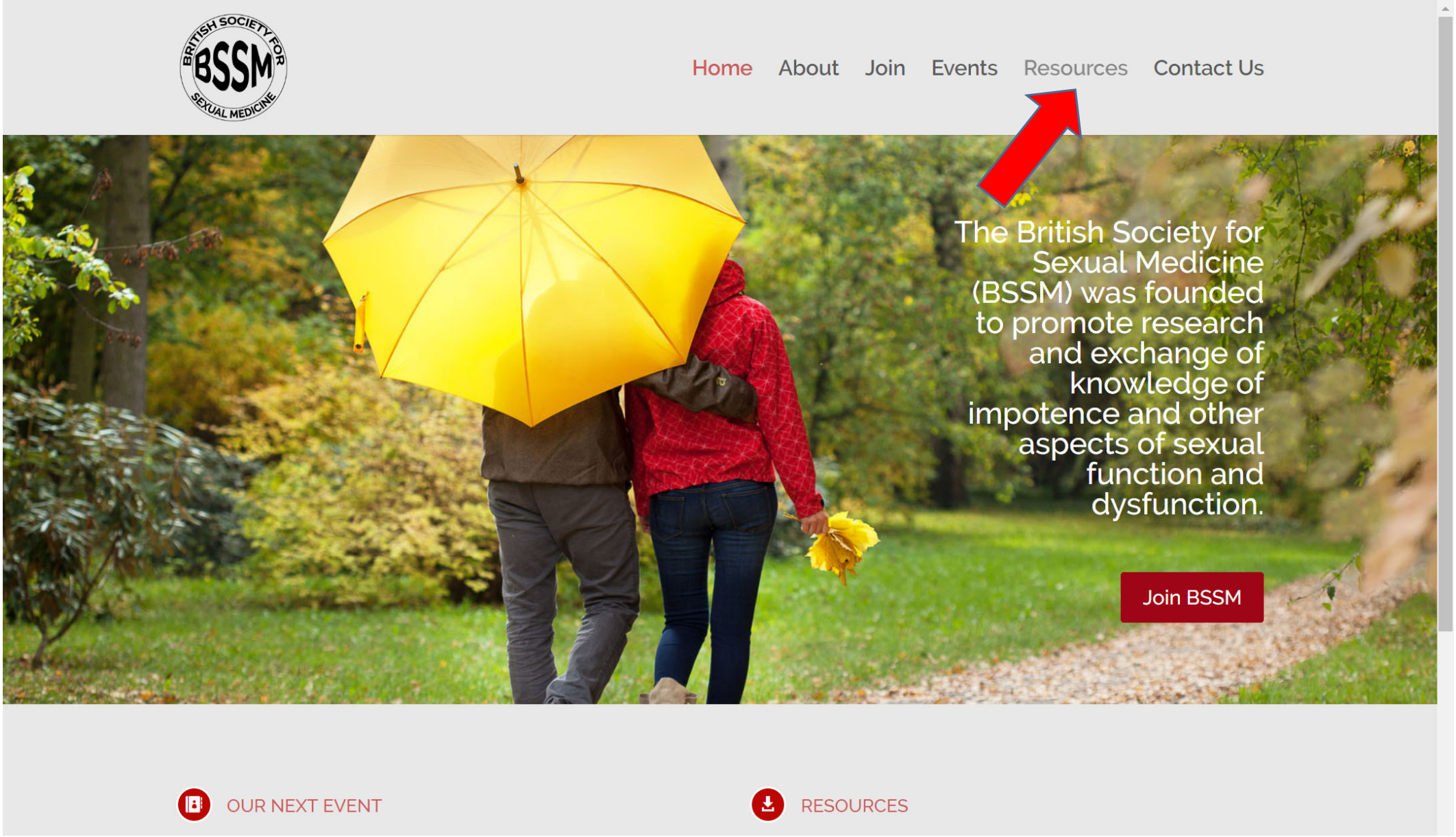
Recommendations – Follow-up	LoE	Grade
Assess the response to therapy at 3, 6 and 12 months, and every 12 months thereafter	4	C
Aim for a target level of total testosterone 15-30 nmol/l to achieve optimal response	4	C
Monitor haematocrit before treatment, at 3-6 months, 12 months and every 12 months thereafter. Decrease dosage, or switch preparation, if haematocrit >0.54. If haematocrit remains elevated, consider stopping and re-introduce at a lower dose.	4	C
Assess prostate health by PSA and DRE before commencing TRT followed by PSA at 3-6 months, 12 months and every 12 months thereafter	4	C
Assess cardiovascular risk before TRT is initiated and monitor cardiovascular risk factors throughout therapy	1b	A

Hackett G et al. BSSM guidelines on adult testosterone deficiency: J Sex Med. 2017 ;14(12):150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The British Society for Sexual Medicine (BSSM) was founded to promote research and exchange of knowledge of impotence and other aspects of sexual function and dysfunction.
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RESOURCES

bssm.org.uk

Latest resources

A practical guide on the assessment and management of testosterone deficiency in adult men

2018

Guidelines on Adult Testosterone Deficiency, with Statements for UK Practice

A video presentation of these guidelines can be viewed here.

2017

Guidelines on the management of Erectile Dysfunction

2013

Treatment Algorithm for Premature Ejaculation

2013

Management of sexual problems in men: the role of Androgens

2010

A practical guide on the assessment and management of testosterone deficiency in adult men

Based on the 2017 British Society for Sexual Medicine (BSSM) guidelines on adult testosterone deficiency, with statements for UK practice[1]

Why does it occur?

Testosterone deficiency (TD), also known as hypogonadism, may result from:[2–4]

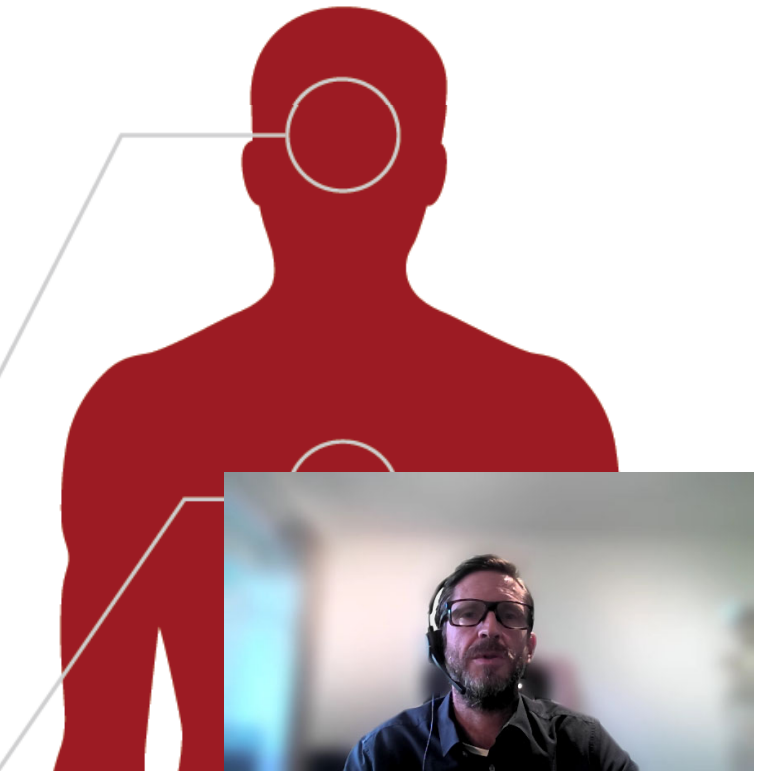
- Problems with the testes [primary (hypergonadotropic) TD]
- Problems with the hypothalamus and pituitary gland [secondary (hypogonadotropic) TD]
- Problems with the hypothalamus/pituitary and testes (combined primary and secondary TD)
- Impaired action/suppression of testosterone

How is it diagnosed?

- The diagnosis of symptomatic TD requires the presence of characteristic signs and symptoms,[2,5–8] PLUS reduced serum concentrations of total testosterone (TT) or free testosterone (FT)[5]

Psychological

- Changes in mood (e.g. anger, irritability, sadness, depression)
- Decreased well-being/poor self-rated health
- Diminished cognitive function (including impaired concentration,



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testosterone deficiency in the male

Testosterone deficiency in adult men

Based on the British Society for Sexual Medicine Guidelines on adult testosterone deficiency, with statements for UK practice1

Testosterone is the most important androgen in men. It regulates a number of vital processes in the body and is responsible for the development and maintenance of secondary male characteristics.2

When testosterone levels fall, patients can experience adverse physical and psychological effects, and a subsequent reduction in quality of life.3

Testosterone deficiency (TD) is defined as a clinical AND bioche
associated with advancing age and comorbidities, characterise
serum testosterone PLUS relevant signs and symptoms.3,4

Contributors:

- Professor Mike Kirby and Dr Jonny Coxon (May 2018)

Conclusions

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- TD is a **well-established and significant medical condition**, encompassing somatic, sexual and psychological effects
- Associated with **increased CV & all-cause mortality**

- TRT is **evidence-based and effective** in TD
- Sustained normalisation of serum T levels is probably associated with reduced mortality

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Erectile Dysfunction: Diagnosis and Management

Clinical guideline [CG97] Published date: May 2010 Last updated: June 2015 Uptake of this guidance

Erectile Dysfunction Guidelines

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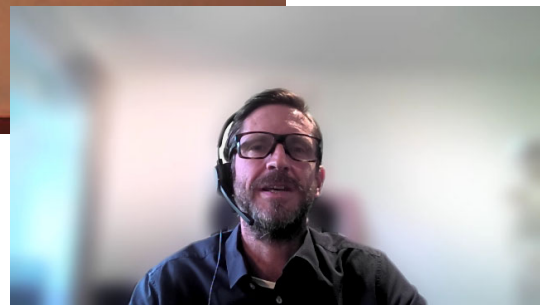
- Dearth of ED guidance in UK
- No formal NICE guidance
  - Remember diabetes guidance



Erectile Dysfunction Guidelines

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British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction in Men—2017

Geoff Hackett, MD,[1] Mike Kirby, MD,[2] Kevan Wylie, MD,[3] Adrian Heald, MD,[4] Nick Ossei-Gerning, MD,[5] David Edwards, MD,[6] and Asif Muneer, MD, FRCS(Urol)[7]

ABSTRACT

Background: This is an update of the 2008 British Society for Sexual Medicine (BSSM) guidelines.

Aim: To provide up-to-date guidance for U.K. (and international) health care professionals managing male sexual dysfunction.

Methods: Source information was obtained from peer-reviewed articles, meetings, and presentations. A search of Embase, MEDLINE, and Cochrane Reviews was performed, covering the search terms "hypogonadism," "eugonadal or hypogonadism or hypogonadal or gonadal," and "low or lower testosterone," starting from 2009 with a cut-off date of September 2017.

Outcomes: We offer evidence-based statements and recommendations for clinicians.

Results: Expert guidance for health care professionals managing male sexual dysfunction is included.

Clinical Translation: Current U.K. management has been largely influenced by non-evidence guidance from National Health Service departments, largely based on providing access to care limited by resources. The 2008 BSSM guidelines to date have been widely quoted in U.K. policy decision making.

Conclusions: There is now overwhelming evidence that erectile dysfunction is strongly associated with cardiovascular disease, such that newly presenting patients should be thoroughly evaluated for cardiovascular and endocrine risk factors, which should be managed accordingly. Measurement of fasting serum glucose, lipid profile, and morning total testosterone should be considered mandatory in all newly presenting patients. Patients attending their primary care physician with chronic cardiovascular disease should be asked about erectile problems. There can no longer be an excuse for avoiding discussions about sexual activity due to embarrassment.

Hackett G, Kirby M, Wylie K, et al. British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction in Men—2017. J Sex Med 2018;XX:XXX–XXX.

Epidemiology of ED

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How big is the problem?

- Estimates of prevalence vary
- **20-50%** of men over 40

Risk factors (ED)

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- Neuronal, **vascular**, hormonal & metabolic factors
- Major risk factors are similar to CVD
  - Sedentary lifestyle, obesity, smoking, dyslipidaemia, metabolic syndrome
- Sentinel marker for future CV events, occurring 3-5 years beforehand
- ED is itself an **established risk factor for CVD**
  - Risk equivalent to current moderate level of smoking
  - Added to **QRISK3**: 25% increased risk

History taking in ED

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- Predisposing, precipitating, maintaining factors
- Previous erectile function
- Any previous investigations
- Treatments tried, response achieved

History taking in ED

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- Description of erections
  - Rigidity
  - Spontaneous erections?
  - Masturbatory, partner-related
- Ejaculatory timing/control
- Desire / Partner issues?
- Sexual aversion / pain

History taking in ED

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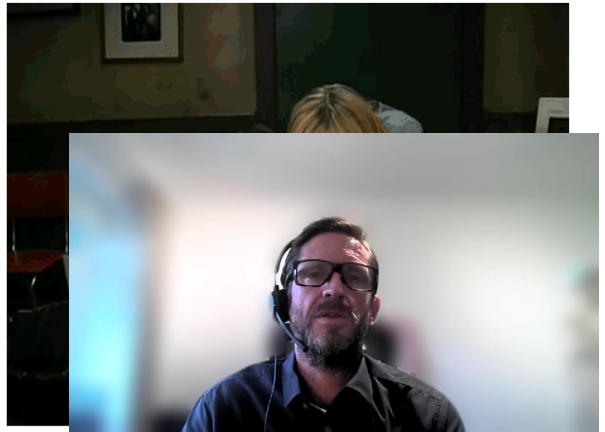
- PMH
  - especially HT, CVD, LUTS
- Meds
- Smoking, alcohol
- Recreational drugs



History taking in ED

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Questionnaire: IIEF-5 (=SHIM)

Sexual Health Inventory For Men (SHIM)

Instructions

Each question has 5 possible responses. Circle the number that best describes your own situation.
Select only 1 answer for each question.

Over the past 6 months:

1. How do you rate your confidence that you could keep an erection?

1	2	3	4	5
Very low	Low	Moderate	High	Very high

2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?

1	2	3	4	5
Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always

3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

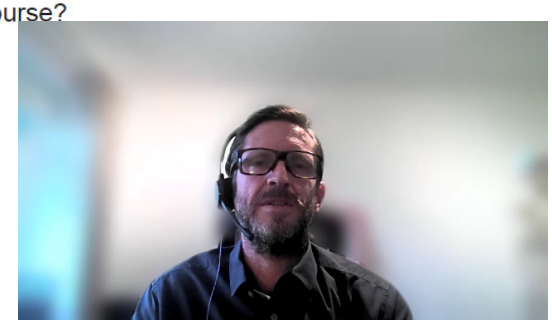
1	2	3	4	5
Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always

4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

1	2	3	4	5
Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult

5. When you attempted sexual intercourse, how often was it satisfactory for you?

1	2	3	4	5
Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always



Investigations for ED

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- Lipids
- HbA1c / glucose
- **Testosterone**
- TFTs?
- PSA?
  - Only if clinically indicated / discussed, and before TRT

Treatment of ED

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There are things to try other than just medication!

Lifestyle advice for ED

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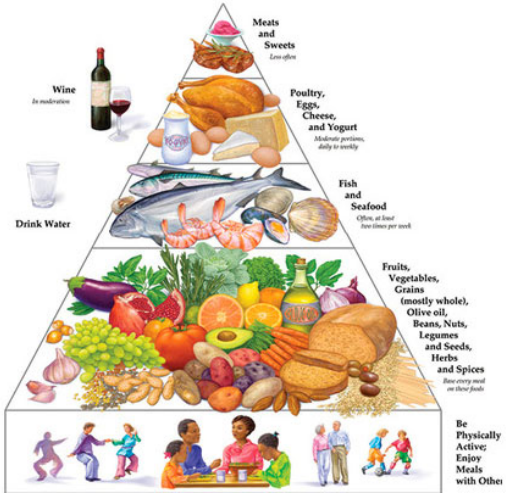
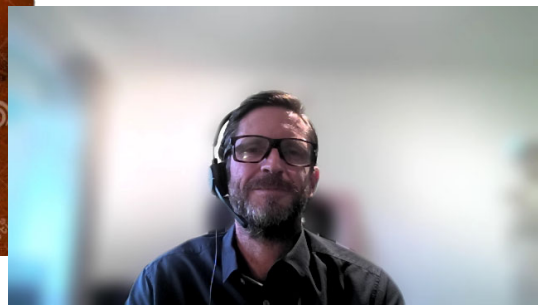
- Should accompany ANY specific treatment
  → moderate improvement in ED & CV risk markers
- Exercise
- Mediterranean diet
- Smoking cessation
- Alcohol: ***J-shaped curve***





Reversible causes of ED

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- **Testosterone deficiency**
  - Treating low T can restore PDE5i response
  - Minimum 6-month trial
- Hyperthyroidism/hypothyroidism
- Hyperprolactinaemia
  - Test in men with reduced sexual desire

Medication as causes of ED

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- Diuretics
- B-blockers (except nebivolol)
- **Antidepressants**
  - Better: escitalopram, nortriptyline, mirtazapine, trazodone
- Sedatives, antipsychotics, opiates
- Hormonal therapies
  - GnRH agonists, finasteride, cyproterone, etc
  - Corticosteroids

Partner sexual problems

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- Assess with, or ask about, the partner:
  - Aversion
  - Desire
  - Arousal
  - Pain

- Relationship therapy?

Counselling / psychosexual therapy

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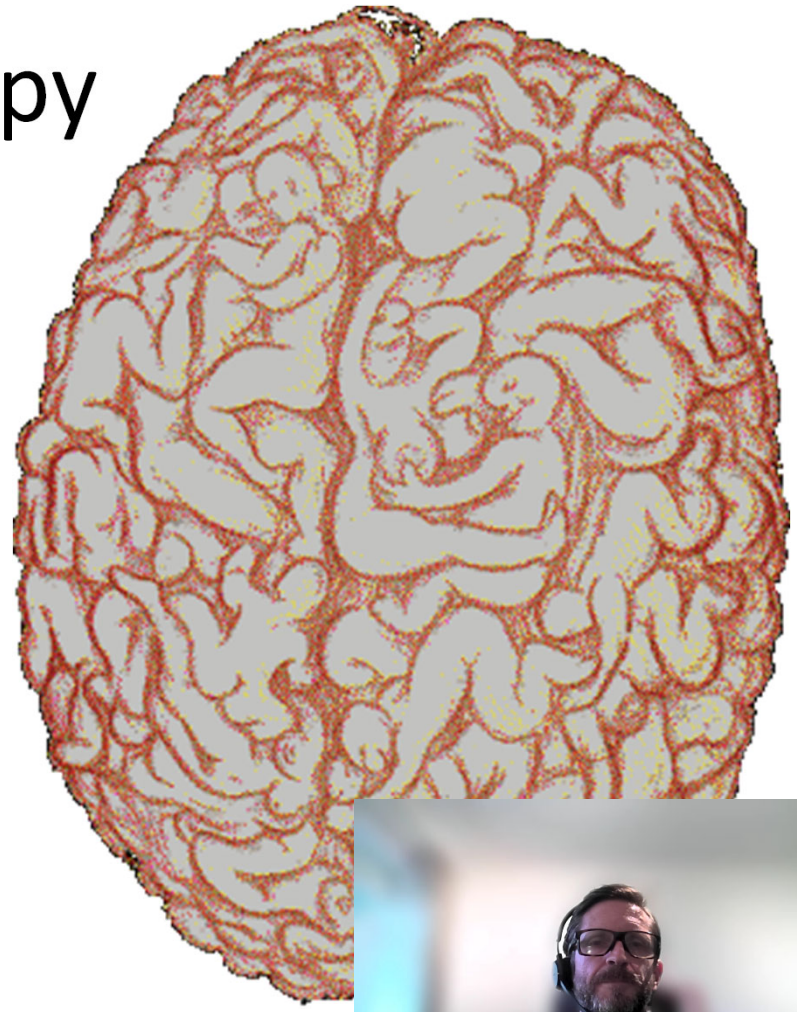
- Sex education, behavioural / relationship advice
- Formal psychosexual therapy
  - More psychogenic ED
  - +/- medication



PDE5 Inhibitors (PDE5Is)

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- **Still require sexual stimulation**
- Onset & peak of action
  - 60 mins onset, 2 hrs peak: tadalafil
  - 30 mins onset, 60 mins peak: others
- Duration
  - 36 hours: tadalafil
  - 4-6 hours: others
- Interaction with food
  - Greatest for sildenafil, least (minimal) for tadalafil
- No significant interactions with alcohol

Side effects of PDE5Is

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- Headache
- Flushing 
- Dyspepsia 
- Back pain 
- Myalgia 
- Nasal congestion 
- Dizziness
- Abnormal vision 

Safety of PDE5Is

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- ***Huge*** numbers over 20 years
- No evidence of ↑ MI
  - Emerging evidence of cardioprotective effect, e.g. in diabetes
- Safe for all but most severe cardiovascular disease
  - Walk 20 mins on flat?
  - Briskly up 2 flights of stairs?
- Legitimate concern re nitrates etc
  - Nitrates often 3rd line treatment, no prognostic benefit
  - Stop and switch?
- Caution with a-blockers (tadalafil for LU

Non-responders to PDE5Is

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- Approx 25% overall
  - More with diabetes (50%), & after prostatectomy
- Recommend 8 ***correct*** uses, maximally tolerated dose
- Measures to try:
  - Re-counsel in use
  - Find and treat TD & other co-morbidities
  - Try a different PDE5I (approx 10% success only)
  - Switch -> ***Daily dosing*** (may be 50% success)
  - ***Combine*** daily tadalafil with on-demand PDE5I

Tadalafil (Cialis) 5 mg once daily: Has a licence for treating the "*signs & symptoms of BPH*"

Comparative study of tamsulosin versus tadalafil in benign prostatic hyperplasia patients with lower urinary tract symptoms. A prospective randomized study

How to cite this article: Ahmad MS, Dar YA, Khawaja AR, Para SA, Malik SA, Wani MS, *et al*. Comparative study of tamsulosin versus tadalafil in benign prostatic hyperplasia patients with lower urinary tract symptoms. A prospective randomized study. Urol Ann 2022;14:236-40.

Table 1: Baseline parameters of patients in Group I and Group II

Patient parameters	Group I (tamsulosin 0.4 mg)			Group II (tadalafil 5 mg)			*P*
	Mean	SD	Range	Mean	SD	Range	
Age (years)	60.40	8.74	42-78	62.66	8.89	42-80	0.202
Prostate size (g)	35.32	9.79	16-50	32.20	9.26	18-48	0.284
PVRU (ml)	64.76	45.84	15-200	78.5	55.02	0-220	0.152
Qmax (ml/s)	11.44	4.49	2.9-22.1	12.46	4.54	3.9-23.1	0.248
IPSS score	16.84	4.88	4-25	15.62	4.78	3-21	0.186
SHIM score	15.5	5.12	8-25	15.8	4.89	7-25	0.395

PVRU: Postvoidal Residual Urine, IPSS: International Prostate Symptom Score, SHIM: Sexual Health Inventory for Men, SD: Standard deviation

Table 3: Parameters of patients in group I and group II AT 6 months

Patient parameters	Group I (tamsulosin 0.4mg)			Group II (tadalafil 5mg)			*P*
	Mean	Sd	Range	Mean	Sd	Range	
PVR (ml)	17.52	6.94	0-52	20.22	7.82	0-60	0.739
Q MAX (ml/s)	20.88	3.38	12.5-24.6	18.92	3.44	13.2-25.5	0.102
Ipss score	9.62	3.84	3-13	10.6	3.54	3-15	0.3
Shim score	16.3	5.31	8-22	22.1	4.93	14-25	<0.0

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World Journal of Urology (2022) 40:1799–1803
https://doi.org/10.1007/s00345-022-04005-3

ORIGINAL ARTICLE

Is tadalafil associated with decreased risk of major adverse cardiac events or venous thromboembolism in men with lower urinary tract symptoms?

Sankalp Goberdhan[1] · Ruben Blachman-Braun[2] · Sirpi Nackeeran[2] · Thomas A. Masterson 3rd[2] · Ranjith Ramasamy[2]

Received: 11 January 2022 / Accepted: 28 March 2022 / Published online: 25 April 2022

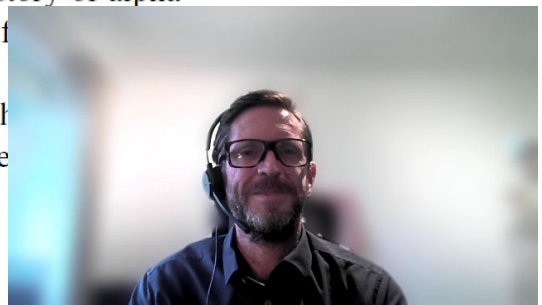
Abstract

Purpose To evaluate the association of tadalafil, a phosphodiesterase-5 inhibitor (PDE5I), with major adverse cardiac events (MACE) or venous thromboembolism (VTE) in men with lower urinary tract symptoms (LUTS).

Methods Data was obtained from the TriNetX Research Network, ICD-10 codes were used to identify men with LUTS, MACE, and VTE. In addition, demographic characteristics and use of tadalafil or alpha-blocker was evaluated. Then, unbalanced and balanced association analyses was performed to assess the relation between tadalafil and/or alpha-blocker use with MACE/VTE.

Results After participant selection, analysis included 821,592 men that did not use an alpha blocker or tadalafil, 5,004 men that used tadalafil but no alpha blocker, 327,482 men that used an alpha blocker but no tadalafil, and 6,603 men that used both an alpha blocker and tadalafil. On balanced analysis, tadalafil was independently associated with a decreased risk of MACE/VTE within a 3-year time period (OR = 0.59, 95%CI 0.49–0.70, $p < 0.0001$). Among men with a history of alpha blocker use, tadalafil use was also independently associated with a decreased risk of MACE or VTE, both bef controlling for potentially confounding variables (OR = 0.57, 95%CI: 0.50–0.66; $p < 0.0001$).

Conclusions In our study, tadalafil was associated with a decreased risk of MACE/VTE in men with LUTS with a history of alpha blocker use. It is time to perform further long-term prospective randomized studies to furthe cardiovascular effects of PDE5Is as combination treatment with alpha blockers in the management of LUTS.



Conclusions In our study, tadalafil was associated with a decreased risk of MACE/VTE in men with LUTS with and without a history of alpha blocker use. It is time to perform further long-term prospective randomized studies to further analyze the cardiovascular effects of PDE5Is as combination treatment with alpha blockers in the management of LUTS.

Vacuum Erection Devices

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- Also considered **1st line** in the guidance
- Do better with initial 1:1 instruction
- Used with constriction ring
- Highly effective, regardless of aetiology
- Can be combined with medication

Intraurethral alprostadil

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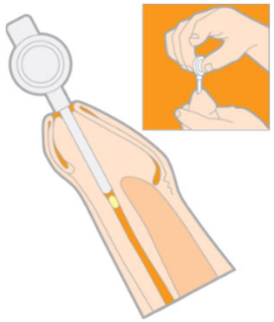
- Cream (Vitaros®)
  - Some local side effects

- Pellet (MUSE™)
  - In practice, only higher doses (500 & 1000mcg) effective
  - Can get penile pain



- Both = less invasive but **less effective** than injections

Intracavernosal injections

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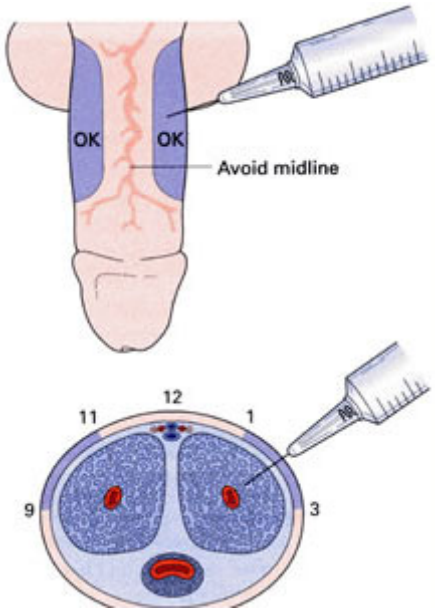
- **Most effective** ED pharmacotherapy



- *Caverject® / Viridal®* (alprostadil)
  - 70-80% success rate
  - *Compliance* issue – need good counselling
  - Penile *pain* quite common

- *Invicorp™* (aviptadil & phentolamine)
  - Sexual stimulation more of a role (more “natural”)
  - As effective as alprostadil, *less pain*

Low Intensity Extra-corporal Shock Wave Therapy (LI-ESWT)

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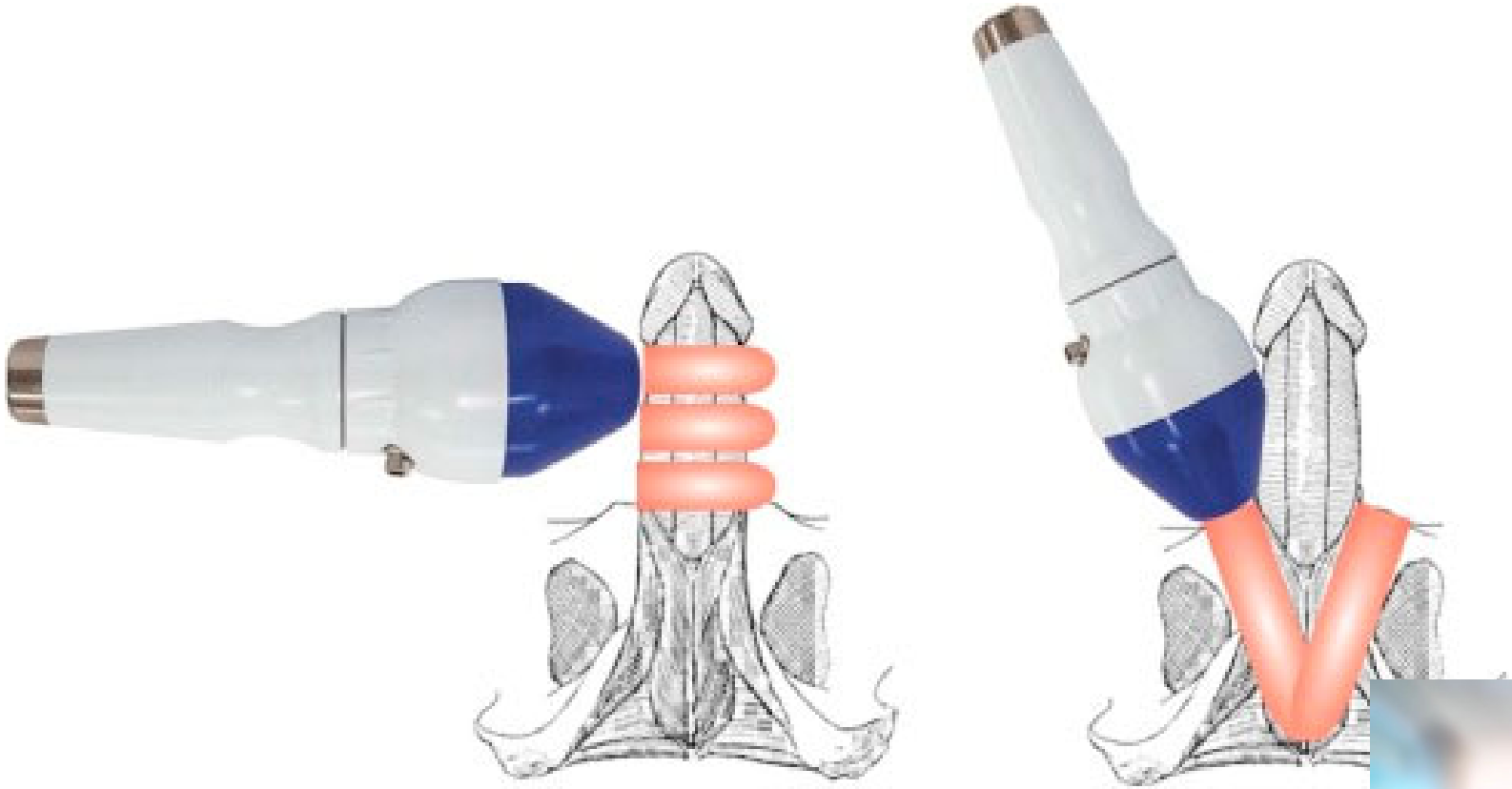
- Works through neovascularisation
- Seems can salvage PDE5i failures



Penile prosthesis

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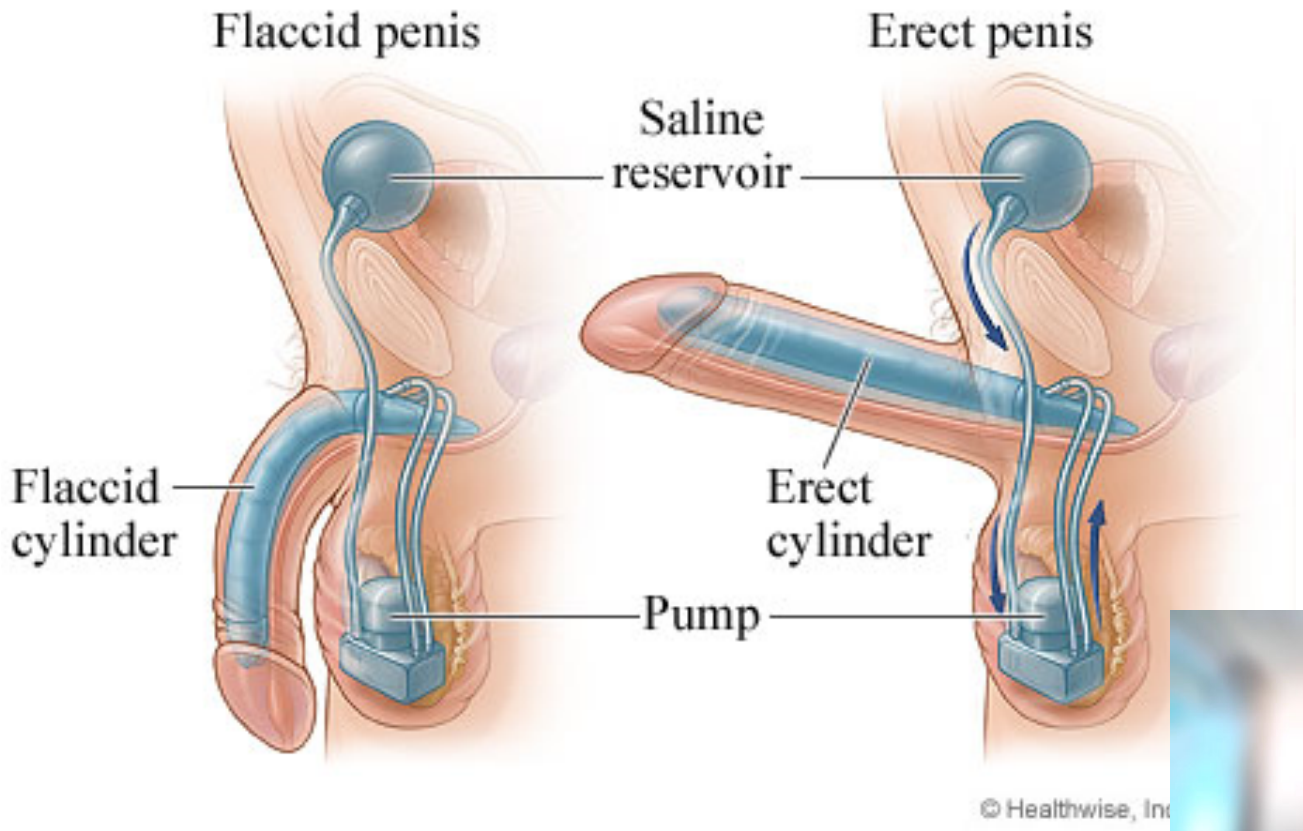
- 3rd line therapy
- Should be offered to all seeking treatment where 1st and 2nd line therapies failed



Frequency of ED treatment

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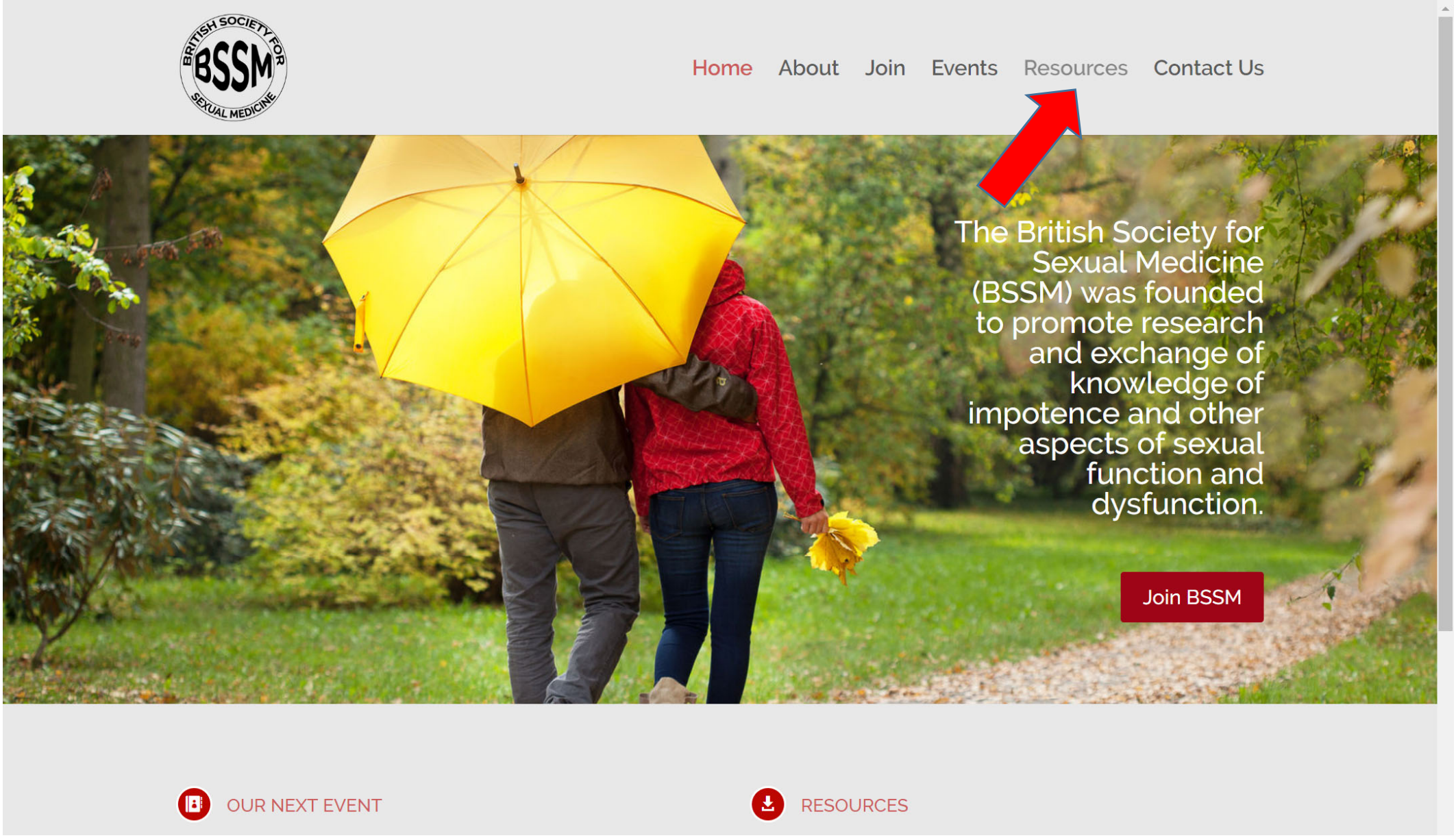
- *Health Service Circular 148,* ***1999***
  - Advises 1 Rx/week appropriate for most patients
  - *"If the Dr, in exercising their clinical judgement, considers >1 treatment/week is appropriate, they should prescribe that amount on the NHS"*
  - Reference for 1/week was a 1990 survey, all-comers
  - Frequency for 'non-ED couples' = 2x/week
  - In trials, patients given significantly more medication
  - Was written **before tadalafil 5mg daily**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The British Society for Sexual Medicine (BSSM) was founded to promote research and exchange of knowledge of impotence and other aspects of sexual function and dysfunction.
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Latest resources

A Practical Guide – On The Assessment and Management of Testosterone Deficiency in Adult Men

2018

British Society for Sexual Medicine Guidelines on Adult Testosterone Deficiency, With Statements for UK Practice

2018

A Practical Guide – On Managing Erectile Dysfunction

2018

British Society for Sexual Medicine Guidelines on the Management of Erectil Dysfunction in Men

A practical guide on managing erectile dysfunction

Based on the 2017 British Society for Sexual Medicine (BSSM) guidelines on the management of erectile dysfunction in men[1]

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What is erectile dysfunction (ED)?

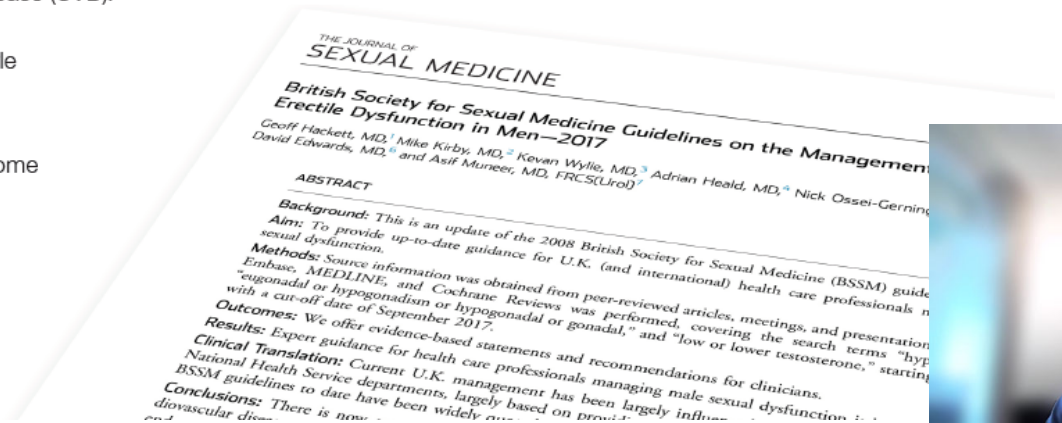
- ED is the persistent inability to attain and/or maintain an erection sufficient for satisfactory sexual performance
- ED is caused by various vascular, neuronal, hormonal and metabolic factors, mediated by endothelial and smooth-muscle dysfunction
- Although most causes of ED are physical, some are due to psychosexual issues; nevertheless, all patients with ED should have a history, examination and investigations performed, even if a psychological cause is suspected
- ED is a cardiovascular (CV) risk factor, posing a risk equivalent to that of current, moderate smoking
- ED is also an important marker for future CV events, with symptoms occurring some 3–5 years before an event[2,3]
- The physical and psychosocial effects of ED can significantly affect the quality of life of patients and their partners[4]

Who is at risk?

- The risk factors for ED are similar to those for cardiovascular disease (CVD):[2,3]
  - Older age
  - Sedentary lifestyle
  - Obesity
  - Dyslipidaemia
  - Metabolic syndrome
  - Diabetes
  - Smoking

What are the other benefits of case-finding ED in practice?

- Increasing awareness regarding the availability of safe and effective oral drugs for ED,[5–7] has led to more men seeking help for this condition, which facilitates the early detection of:
  - Diabetes (ED may be the first symptom in up to 20% of men)[8,9]
  - Dyslipidaemia (may not require treatment according to primary prevention guidelines, but may be a major reversible component in ED)[9]
  - Occult cardiac disease (in an otherwise asymptomatic man, ED may be a marker for underlying coronary artery disease)[9]
  - Testosterone deficiency (TD; a reversible cause of ED that may not require specific ED treatment, and which also has other long-term health implications)[10]
  - Associated lower urinary tract symptoms (LUTS)/benign prostatic hyperplasia (BPH) (ED and LUTS severity are closely related, and treatments for one condition may beneficially or adversely affect the other)[8,11]


THE JOURNAL OF SEXUAL MEDICINE

British Society for Sexual Medicine Guidelines on the Management
Erectile Dysfunction in Men—2017

Geoff Hackett, MD,[1] Mike Kirby, MD,[2] Kevan Wylie, MD,[3] Adrian Heald, MD,[4] Nick Ossei-Gerning
David Edwards, MD,[5] and Asif Muneer, MD, FRCS(Urol)[7]

ABSTRACT

Background: This is an update of the 2008 British Society for Sexual Medicine (BSSM) guide
Aim: To provide up-to-date guidance for U.K. (and international) health care professionals
sexual dysfunction.
Methods: Source information was obtained from peer-reviewed articles, meetings, and presentation
Embase, MEDLINE, and Cochrane Reviews was performed, covering the search terms "hyp
"eugonadal or hypogonadism or hypogonadal or gonadal," and "low or lower testosterone," startin
with a cut-off date of September 2017.
Outcomes: We offer evidence-based statements and recommendations for clinicians.
Results: Expert guidance for health care professionals managing male sexual dysfunction
Clinical Translation: Current U.K. management has been largely influenced
National Health Service departments, largely based on
BSSM guidelines to date have been widely
Conclusions: There is now
diovascular

Conclusions

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- Overwhelming evidence that ED is **strongly linked to CVD**
- **Baseline investigations** mandatory
- **Very effective medications**, variable access to them
- Possible **cardioprotective effects** of PDE5Is: trials underway

- **Generic PDE5Is**, without restricting frequency of use, can lead to radical changes in ED management

Thank you