

# Drug interventions for sexual problems: integrating sex therapy and pharmacotherapy

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# Disclosures

- Within the past three years, Dr Dean has acted as a consultant to, or lecturer for the following companies on subjects unrelated to this clinical area:
  - Emotional Brain, Pfizer, Plethora, Repros Therapeutics

# Why do we need integrated care?

Physiological response

≠

Sexual pleasure  
Sexual satisfaction

# Ideology (noun)

1. A system of ideas and ideals, especially one which forms the basis of economic or political theory and policy.

e.g. "the ideology of feminism"

*Synonyms:* beliefs, ideas, ideals, principles, doctrine, creed, credo, teaching, dogma, theory, thesis, tenets, canon(s); conviction(s), persuasion, opinions, position, ethics, morals  
the set of beliefs characteristic of a social group or individual.

2. (*archaic*) The science of ideas; the study of their origin and nature.

## In men...

- Approved...
  - None
  
- Unapproved...
  - Testosterone
  - Flibanserin

## In women...

- Approved...
  - Testosterone (Intrinsa<sup>®</sup>, EU only)
  
- Unapproved...
  - Testosterone, etc., etc.
  - Flibanserin
  - T + PDE5-inhibitor
  - T + 5HT1a antagonist

# Drugs for sexual desire

# Integrated care for problems with sexual desire

- Case reports
- Expert opinion

## In men...

- Approved...
  - PDE<sub>5</sub>-inhibitors
  - Alprostadil
  
- Unapproved...
  - Papaverine
  - Bi-mix, Tri-mix

## In women...

- Approved...
  - None
  
- Unapproved...
  - Alprostadil (topical)
  - T + PDE5-inhibitor
  - T + 5HT<sub>1a</sub> antagonist

# Drugs for sexual arousal

# Integrated care for problems with sexual arousal

- *Aim:* Pilot study to compare integrative treatment protocol (ITP) with sildenafil and cognitive-behavior sex therapy (CBST) and sildenafil alone for men with psychogenic ED
- *Outcome measures:* Change from baseline on IIEF erectile function and sexual satisfaction domains
- *Method:* 53 heterosexual couples were randomized to receive either sildenafil alone or an ITP with sildenafil and CBST for the first 4 weeks. In the last 4 weeks, couples in the sildenafil group added CBST sessions to their regimen; patients in the ITP group continued the combined therapy



# Results

- After the first 4 weeks of sildenafil and ITP, 48% of men met criteria for success on erectile function and 65.5% for satisfaction, compared to men on sildenafil alone with 29% and 37.5% success rates, respectively
- After the last 4 weeks, integration of CBST with sildenafil resulted in a 58% success rate for erectile function which was comparable to the 66% rate for the initial drug/ITP group
- Satisfaction rates for men were 45% and 75%, respectively

# Conclusions

- CBST was shown to have a positive influence when used throughout the entire 8 weeks of the ITP or added to the sildenafil in the last 4 weeks.
- Although patients in both treatment regimens had significant improvements in the IIEF domain scores confirming efficacy of sildenafil, those in the CBST and drug regimen achieved higher rates of clinical success within the first 4 weeks of therapy

## In men...

- Approved...
  - None
  
- Unapproved...
  - Yohimbine
  - Cyproheptadine
  - Apomorphine
  - Oxytocin

## In women...

- Approved...
  - None
  
- Unapproved...
  - None

# Drugs for orgasmic disorder (DE and anorgasmia)

# Integrated care for problems with orgasmic disorder

- Case reports
- Expert opinion

- Denial and isolation
- Anger
- Bargaining
- Depression
- Acceptance

## In men...

- Approved...
  - Dapoxetine (some markets)
  
- Unapproved...
  - PSD-502
  - Topical anaesthetics
  - SSRIs
  - Clomipramine

# Drugs for PE

# Integrated care for problems with premature ejaculation

- Case reports
- Expert opinion

# Men don't "do" therapy...



- Historical and cultural factors
- Male developmental factors
- Male relationship factors
- Men and the medical model
- Therapy for men?



## In men...

- Approved...
  - Gabapentin
  - Pregabalin
  - Amitriptyline
  - NSAIDs
- Unapproved...
  - Alpha-blockers
- Physical treatments...
  - Thermotherapy
  - Botox
  - Nerve block

## In women...

- Approved...
  - Gabapentin
  - Pregabalin
  - Amitriptyline
  - NSAIDs
- Physical treatments...
  - Electro-analgesia
  - Nerve block
  - Botox
  - Vestibulectomy

# Drugs for sexual pain

# Integrated care for problems with sexual pain I

- *Objective:* To standardize and evaluate a combined physical and psychosexual therapy for women with provoked vestibulodynia
- *Methods:* 24 patients underwent the treatment program. Sessions with a psychosexual counselor included issues on sexual functioning, psychological adjustments, and stress elimination. Exercises for mucosal desensitization and reestablishment of pelvic floor function were supervised by a midwife
- *Outcome measure:* A questionnaire was used for evaluation at a minimum of 6 months after the treatment

# Results

- The mean number of appointments to the counselor was 12 (4-24) and 15 (9-26) to the midwife during a mean period of 53 weeks (19-92)
- 19 women (79%) considered themselves to be cured or having greatly improved. Intercourse frequency was increased ( $p = 0.001$ ) and coital pain was reduced ( $p = 0.02$ ) after completing the treatment
- Improvements in sexual functioning and coping strategies for psychological impairment and stress were reported

# Conclusions

Women with provoked vestibulodynia benefit from a multidisciplinary treatment model, which included desensitization of the vestibular mucosa, rehabilitation of the pelvic floor, and psychosexual adjustments

# Integrated care for problems with sexual pain II

- *Aims:* The aims of this secondary analysis of a prospective study were to:
  - Assess changes over a 2-year period in pain, depressive symptoms, and sexual outcomes in women with PVD
  - Examine changes based on treatment(s) type
- *Methods:* Participants completed questionnaire packages at end of treatment and follow-up 2 years later
- *Outcome measures:* Visual analogue scale of genital pain, Global Measure of Sexual Satisfaction, Female Sexual Function Index, Beck Depression Inventory, Dyadic Adjustment Scale, and sexual intercourse attempts over the past month

# Results

- 239 women completed the study
- There was significant improvement over 2 years on pain ratings, sexual satisfaction and function, and depressive symptoms
- The most commonly received treatments were physical therapy, sex/psychotherapy, and medical treatment, although 41.0% did not undergo any treatment
- Women receiving no treatment also improved significantly on pain ratings
- No single treatment type predicted better outcome for any variable except depressive symptoms, in which women who had surgery were more likely to improve

# Opportunities for greater physician-therapist collaboration

- Cardiorespiratory health
- Endocrine health
- Neurologic health
- Mental health
- Gastrointestinal health
- Genitourinary health
- Musculoskeletal health
- Neoplasia

# Co-existing health issues are frequently relevant to sexuality

- Chronic medical conditions are frequently associated with sexual difficulties and problems, which are often underreported and underdiagnosed
- Patients may feel that sexual problems in the context of disease are not important enough to be mentioned to their physicians, and physicians may feel uncomfortable and sometimes incompetent
- Diagnostic criteria of DSM and ICD are focused on the phenomenology of the sexual response without any specificity regarding diseases



# An assessment process...

- Based on the experience of a liaison-consultation sexological division of the university hospital of Basel, the authors analysed the sexological diagnostic workup performed with the following groups of female patients:
  - Women with benign gynecologic conditions
  - Women with incontinence
  - Oncological patients (mammary carcinoma, genital carcinoma)
  - Neurological patients (multiple sclerosis, spine injury, Parkinson's)
  - Patients with metabolic and endocrine disorders (diabetes, metabolic syndrome, polycystic ovarian syndrome)
  - Patients with mental health disorders (depression, anxiety disorder, schizophrenia)
- The authors extracted commonly-used steps in the workup to construct a tool to help the physician to evaluate patients' sexual problems, and plan for referral or therapy

# Conclusion

Sexual problems are frequent in many clinical conditions, but are not yet a routine part of diagnostic workup and therapeutic planning

# Cardiorespiratory health

- Exercise tolerance-limiting heart disease
  - Angina, heart failure, arrhythmia
- Thrombosis
- Lymphoedema
- Exercise tolerance-limiting respiratory disease
  - Asthma, COPD

# Endocrine health

- Diabetes
- Obesity
- Metabolic syndrome
- Hypogonadism
- Hyperprolactinaemia
- Hypothyroidism
- Hyperthyroidism

# Neurologic health

- Head injury
- Spinal cord injury
- Stroke
- Epilepsy
- Neurodegenerative disorders
  - Parkinson's disease
  - Dementia
- Coital headache

# Mental health

- Cognitive impairment
- Psychosis
- Anxiety
- Depression
- Substance misuse

# Gastrointestinal health

- Inflammatory bowel disease
  - Chronic diarrhoea
  - Stoma
- Oesophageal reflux

# Genitourinary health

- STI
  - Ulcerative, no-ulcerative, HIV
- Other GU infection
- Overactive bladder
- Stress incontinence
- Prolapse
- Menstrual disturbance



# Musculoskeletal health

- Arthritic pain
- Arthritic movement limitation
- Back pain
  - Disc prolapse and radiculopathy
  - Non-specific

# Neoplasia

- Pelvic and genital cancers
- Breast cancer
- Lung cancer
- GI and GU cancers with stoma
- Skin cancers
- Head and neck cancers

# Conclusions

- Robust evidence of additional benefit from integrated therapy-medical care is lacking
- There are several possible reasons for this
  - Problems with methodology and outcome measures
  - Problems with recruitment and retention
  - Problems with resources and collaboration
  - Men lack enthusiasm for therapy interventions
  - All effects of integrative care may not be understood
- Despite this, a bio-psycho-socio-relational approach is endorsed by most authorities

# This may take a little longer...



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