Vulvodynia research update

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Clinical research and vulvodynia

Types of research
- Qualitative vs Quantitative
- Prospective vs retrospective
- Trial designs
  - Systematic review ✓ ✓ ✓
  - Randomised controlled trial ✓ ✓ ✓
  - Case series ✓
  - Case report ✓

How is clinical research conducted in the UK?

Implications of clinical research
- Adoption by medical colleges and be incorporated into guidelines
- Can influence national practice and policy eg NICE
UK GUIDELINES ON VULVODYNIA

Guidelines for the management of vulvodynia


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www.bssvd.org
REVIEW OF VULVODYNIA TREATMENT SUCCESS RATES IN PUBLISHED STUDIES

Medical treatments – 13-67%
Surgical treatments – 64-94%
Behavioural treatments - 35-83%  
Landry T, J Clin Pain 2008

PROBLEMS WITH STUDIES!
Variable inclusion criteria – different doctors make different diagnoses
Variable follow-up rates – the longer the better
No control arm – placebo effect. Does the treatment really work?
Outcome data – endpoints that look at the patient and function are important
Treatments are empirically based
PLACEBO RESPONSE IS IMPORTANT!

Topical lignocaine for provoked pain?


Foster DC et al, Obstet Gynecol. 2010 Sep;116(3) Oral desipramine and topical lidocaine for vulvodynia: a randomised controlled trial.
SKIN CHANGES IN VULVODYNIA

Thought to be an inflammatory condition – now discounted

No evidence of HPV, infection, precancer

Increased local blood flow

Increase density of nerve fibres and pain producing neurotransmitters e.g. CGRG, Substance P
DOES RECURRENT VULVOVAGINAL THRUSH DEVELOP INTO VULVODYNIA?

Background

Reports of vulvovaginal thrush are common in women with vulvodynia. Many women have had anti-thrush treatments prior to a diagnosis of vulvodynia. 30% of women have candida albicans (‘thrush’) in the vagina.
DOES RECURRENT VULVOVAGINAL THRUSH DEVELOP INTO VULVODYNIA?

Repeated Vulvovaginal Fungal Infections Cause Persistent Pain in a Mouse Model of Vulvodynia
Melissa A. Farmer, et al.
Sci Transl Med 3, 101ra91 (2011)
DOES RECURRENT VULVOVAGINAL THRUSH DEVELOP INTO VULVODYNIA?

RESULTS

Repeated or prolonged attacks of candida can produce sustained allodynia response in mice.

No evidence of histopathological evidence on inflammation on vulval biopsy of mice, but proliferation of nerve fibres and increase hypersensitivity.

Allodynia response is variable - genetic reasons?
DOES RECURRENT VULVOVAGINAL THRUSH DEVELOP INTO VULVODYNIA?

Possibly, but does not explain why other inflammatory conditions of the vulval cause pain!
Early diagnosis is important before establishment of the pain pathways.
DO ENOXAPARIN INJECTIONS HELP IN THE TREATMENT OF LOCALISED PROVOKED VULVODYNIA?

Enoxaparin – a standard treatment for prevention and treatment of blood clots in the leg/chest. Given as a subcutaneous (fat) injection

**Background**

In this group, previous studies have shown an increase in nerve endings in vestibular skin, increase in mast cells, and in heparinase activity.

Mast cells – heparin sulphate is a protector of the cell. Heparinase weakens the cells and possibly allows Nerve growth.

Enoxaparin – blocks heparinase in the laboratory.
DO ENOXAPARIN INJECTIONS HELP IN THE TREATMENT OF LOCALISED PROVOKED VULVODYNIA?

Enoxaparin treatment for vulvodynia – a randomised controlled trial
Farajun Y et al Obstetrics and Gynaecology 565-572,120(3), 2012

Methods
40 women with severe localised provoked vulvodynia
Randomised double blinded placebo controlled trial (40mg drug/saline) for 90 days
Required two biopsies before and after treatment!

Results
224 suitable, 40 randomised
**Fig. 4.** Percentage of women with localized provoked vulvodynia who experienced a reduction of more than 20% in their Q-tip sensitivity score between beginning of treatment and end of treatment or end of study.

RESULTS
Treatment arm showed a greater reduction in vestibular sensitivity at the end of treatment and three months later (29.6% vs 11.2%) 7 treatment patients and 3 placebo patients had painless sex at the end of the study
Reduction in the number of nerve fibres in the treatment group in those women who had a improvement in sensitivity at site by the side of the original biopsy

DO ENOXAPARIN INJECTIONS HELP IN THE TREATMENT OF LOCALISED PROVOKED VULVODYNIA?

Possibly. Perhaps a subgroup of patients? Not suitable for all patients (bruising, administration)
SUMMARY

Still many gaps in our understanding of vulvodynia

In the UK pathways are still unclear and good research will decide on the best model

See www.vulvalpainsociety.org for more information and take part in online research projects

Contact us with your research questions at vulvalpainsociety@gmail.com
Thank you