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SYSTEMATIC REVIEW OF LASER THERAPY FOR GENITOURINARY SYNDROME OF MENOPAUSE (GSM)

Hypothesis / aims of study

Genitourinary syndrome of menopause (GSM) is characterized by symptoms such as vaginal dryness, dyspareunia, pain, urinary incontinence, and urinary tract infections. GSM replaces the prior term vulvovaginal atrophy as agreed upon by the joint terminology conference sponsored by the North American Menopause Society (NAMS) and the International Society for the Study of Women's Sexual Health (ISSWSH)[1]. This is a common condition which can significantly affect quality of life and sexual function. Several therapeutic options are available to alleviate these symptoms including hormonal and non-hormonal products. Most recently laser therapy has gained interest as a non-hormonal therapeutic option for GSM. We aimed to do a systematic review on laser therapy as a treatment modality for symptoms of GSM.

The following questions were used to inform the rapid appraisal:a). What will happen if we do not offer this treatment modality? (Prognosis) b). Is there evidence to show this intervention helps? (Treatment Benefit) c). Are there harms reported as a result of the intervention? (Treatment Harm)

Study design, materials and methods

Six electronic databases and the world-wide-web without language restrictions were searched from inception until March 2016. Relevant publications and websites included Cochrane, PUBMED(Medline), EMBASE, CINAHL plus, OneSearch and Google Scholar databases. The manual search included journals and abstracts of international conferences, including oral podium presentations and oral poster presentations. The following keywords were used when searching for the relevant articles: Genitourinary syndrome, vulvovaginal atrophy, atrophic vaginitis, postmenopausal symptoms, laser therapy and fractional laser treatment. The evidence was reviewed for study design, selection and number of participants and clinical outcomes assessed. The subjective outcomes specific to the study objectives included follow-up time, subjective cure rates using questionnaires, success rates and complication rates. Data was extracted from included studies and assessed for validity independently by two reviewers. One of the reviewers then entered data into an excel database. A third reviewer then checked the collated data quality. Study validity was formally assessed using a published checklist for this review[2]. A consensus approach was used to resolve differences between the reviewers.

Results

Table 1. Results of search for "Genitourinary syndrome of menopause, Vulvovaginal atrophy AND Laser therapy" (search undertaken on 1st March 2016)

Type	Term used	Number of articles
All articles	(no filter)	165
RCT	"random allocation" [MeSH]	Nil
Cohort	"cohort studies" [MeSH]	3
Case-control	"Case-Control Studies"[Mesh]	2
Case Reports	Case Reports [Publication Type]	0

165 articles met the inclusion criteria for at least one of the three objectives.Out of the 165 articles identified in the search, no randomised controlled trials (RCT) were found. As a result, we included five well-designed multi-centric case-control/cohort studies that met our inclusion criteria and the subjective outcomes comparing laser therapy with hormonal treatment for the symptoms of GSM. Three cohort and one case-control studies were published as full manuscripts and one case-control study was a conference abstract. As the conference abstract lacked quality and the design was unclear, it was excluded from the analysis. The total number of women included in the 4 studies was 224. Due to lack of Level 1 evidence (RCTs) and because the subjective cure rates were assessed using different types of questionnaires, it was not possible to compare the studies. For the purpose of systematic review, subjective cure rate or overall cure rates following laser therapy for GSM were calculated.

The studies reviewed made use of questionnaires to determine subjective cure rates including visual analogue scales. Only one study used Erbium laser therapy whereas the other three studies used CO_2 laser. In this analysis, all recruited patients experienced significant improvement in the different domains of the questionnaires used. Median followup time was 12 weeks.Table 2 illustrates the methodology used for assessment.

Table 2. Subjective cure rate (1-6 months)

Study or subgroup	**Level of evidence**	**Outcome assessment**	**Outcome measures**	**Treatment success (number)**
Gambacciani et al 2015	II-B	Questionnaires (6 months)	VAS, VHIS, ICIQ-SF	VEL (49) P<0.01
Salvatore et al 2014	II-B	Questionnaires (12 weeks)	VAS, VHIS, SF-12	CO_2 laser (50) P<0.001
Salvatore et al 2015	II-B	Questionnaires (12 weeks)	FSFI, SF-12	CO_2 laser (77) P<0.001
Perino et al 2014	II-B	Questionnaires (30 days)	VHIS, VAS	CO_2 laser (48) P<0.0001

VEL – Vaginal Erbium Laser
VAS- Visual Analogue Scale
VHIS- Vaginal Health Index Score
ICIQ-SF – International Consultation on Incontinence Questionnaire –Short Form
SF-12 – Sexual Function 12
FSFI – Female Sexual Function Index
No adverse events were reported in any of the studies. In no case was it necessary to stop the procedure because of patient pain or intolerance.

Interpretation of results

The collated evidence to date from the studies (level of evidence II-B) to date suggest that the laser therapy appears to be effective in the treatment of GSM. The lack of RCTs made it difficult to meta-analyse the studies based on the PRISMA statement[3]. Hence it was difficult to give weight to the above selected studies. Of the 4 studies, one was based upon Erbium and the other 3 were based upon CO_2 laser therapy. All studies report observed results upto a maximum of 6 months with no further followup. Therefore assumptions cannot yet be made regarding the durability of this treatment nor the long term effects, either positive or negative.

Concluding message

The evidence reviewed shows that laser therapy can be used successfully and safely for the treatment of GSM symptoms However, there does not appear to be sufficient research, especially of high quality, on the long term efficacy and other effects. Higher quality of evidence in the form of randomised controlled trials comparing laser treatment versus placebo or hormonal treatment and well designed case-control studies is required to further investigate the potential benefits, harms and efficacy of laser therapy in the treatment of GSM symptoms.

References

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Disclosures

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