INFORMATION BRIEF (RAPID REVIEW)

Laser Therapy for Genitourinary Syndrome of Menopause

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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TITLE: LASER THERAPY FOR GENITOURINARY SYNDROME OF MENOPAUSE

PURPOSE

To provide scientific evidence on the effectiveness, safety and cost-effectiveness of laser therapy for genitourinary syndrome of menopause following a request from the Director of Medical Practice Division, Ministry of Health, Malaysia.

BACKGROUND

Menopause is a distinct stage in a woman's life where her ovaries cease the production of oestrogen, leading to the cessation of her menstrual cycle. Additionally, it signifies the conclusion of her reproductive capability.[1] Menopause is defined retrospectively as the time of the final menstrual period, followed by 12 months of amenorrhea. Post-menopause describes the period following the final menses. The major consequences of menopause are related primarily to estrogen deficiency.[2] Genitourinary syndrome of menopause, previously known as vulvovaginal atrophy, atrophic vaginitis, or urogenital atrophy, is a chronic, progressive vulvovaginal, sexual, and lower urinary tract condition characterized by a host of symptoms secondary to a clinical state of hypoestrogenism after onset of menopause.[3,4] The syndrome or its features manifest in some manner in approximately 15% of premenopausal women and 40-54% of postmenopausal women.[3,4] Vaginal dryness is the most prevalent and bothersome symptom, affecting up to 93% of women, with 68% experiencing moderate to severe intensity.[3,4] Women with genitourinary syndrome of menopause frequently complain about irritation, burning or itching of the vulva/vagina, with 63.3% of affected women reporting these symptoms. Sexually active women commonly express concerns about reduced lubrication and dyspareunia, with reported prevalence rates of 90% and 80%, respectively. Additional complaints include decreased libido and arousal, as well as vaginal bleeding or spotting during or after intercourse. Urinary symptoms are less frequent but still present, with dysuria reported by 29% of women, along with urgency, urge incontinence, recurrent urinary tract infections, stress incontinence, and voiding issues being among the most common manifestations.[3,4] Previous research suggested that the prevalence of urinary incontinence among Malaysian women have varied between 9.9 to 44.1%.[5,6]

In Malaysia, the average age of menopause is around 50.7 years.[7] A significant portion of women in Malaysia who are currently experiencing menopause will spend 25 years or more living with an oestrogen deficiency. Previous research has indicated that Malaysian women tend to underestimate the challenges associated with menopause and often neglect to seek appropriate treatment for related issues.[7] Symptoms associated with the genitourinary syndrome of menopause, such as bladder incontinence, vaginal dryness, and sexual health concerns, are rarely discussed among Malaysian women. This leads to many women silently enduring these symptoms, considering them an inevitable aspect of aging. As a result, their self-confidence and relationships with their partners are negatively impacted.[7] Management of symptoms associated with estrogen deficiency includes both hormonal and non-hormonal

approaches.[8] Hormonal treatment, involving the administration of estrogen and dehydroepiandrosterone (DHEA), as well as non-hormonal interventions such as lifestyle modifications and moisturisers, are commonly employed.[8] Nevertheless, women who have conditions that make hormonal therapy unsuitable are exploring non-hormonal alternatives like light amplification by stimulated emission of radiation (LASER) technology.[8]

For several years, LASER technology has been employed as a minimally invasive approach for various diseases and symptoms in the field of gynaecology. The introduction of LASERs began in the 1960s, and among the earliest types were the carbon dioxide (CO2) LASER, along with the erbium:yttrium-aluminum-garnet (Er:YAG) LASER and the neodymium-doped:yttrium-aluminum-garnet (Nd:YAG) LASER.[8] There are two main categories of lasers utilized for vaginal therapy: ablative fractional CO2 and non-ablative Er:YAG.[8,9] The ablative fractional CO2 laser operates at a wavelength of 10,600 nm, while the non-ablative Er:YAG laser operates at a wavelength of 2,940 nm.[9] Both types of lasers have the common objective of remodeling collagen in the subepithelial connective tissue.[9] This is accomplished by precisely raising the temperature of the tissue, which leads to the activation of vasodilation and subsequent tissue remodeling.[9] The effects of these changes in morphology have been observed through histological examination of vaginal mucosal samples taken from post-menopausal individuals who underwent laser treatment.[9] The examination revealed thickening of the epithelial layer, lengthening of papillae, and increased storage of glycogen as well as heightened fibroblast activity, which have become the foundation for the use of lasers for these purposes.[9]

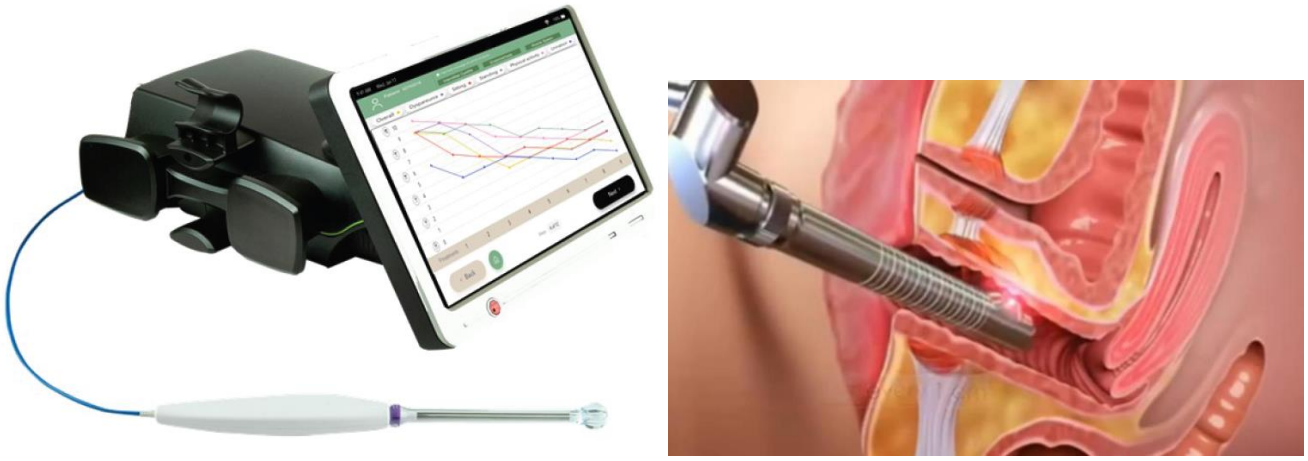

Figure 1: Laser therapy device and procedures

Vaginal and vulvar LASER procedures involve the use of a handpiece, and the treating operator manually triggers each impulse, determining the number of impulses required. This treatment is completed quickly, typically lasting just a few minutes. The LASER emits small impulses that pass through a small window, directly affecting the mucosal tissue.[8] The procedures for both types of lasers are mostly similar.[9] The patient is positioned in dorsal lithotomy and the vulva can be prepared by applying topical anesthetics like lidocaine.[9] Once the topical anesthetic is removed using gauze or swabs, a vaginal probe is inserted into the vaginal apex, and the treatment is delivered at specific intervals as the probe is gradually withdrawn (Figure 1).[9] There is no established scientific methodology regarding the treatment sequence.[9] Typically for both lasers, a treatment consists of three sessions of five to 10

minutes at intervals of four to six weeks.[9] With ablative fractional CO2 laser, the initial treatment is the most superficial with subsequent treatments advancing the depth of ablation to limit the risk of burns.[9] For Er:YAG laser, the sequential treatments are generally at the same depth, with repeated passes when there is also a goal of treating vaginal laxity.[9] After the initial series of treatments, "booster" treatments are offered to patients approximately every 12 to 18 months after the last treatment.[9]

Laser therapy is claimed to induce the denaturation of collagen and subsequent neocollagenesis, which is followed by the thickening and strengthening of the anterior vaginal wall, and could determinate a greater support of the bladder and urethra and is, consequently, an improvement of the continence.[8] It is claimed to effectively treat vaginal symptoms associated genitourinary syndrome of menopause including vaginal dryness, atrophy, pain and incontinence.[8]

EVIDENCE SUMMARY

A total of 40 titles were retrieved from the scientific databases via OVID, PubMed and general search engines [Google Scholar], using the search term; *laser therapy, genitourinary syndrome of menopause, urinary incontinence* and *post-menopausal symptoms.* The last search was conducted on 5th May 2023. Seven articles were found to be relevant and included in this review which comprised of four systematic reviews with meta-analyses and three systematic reviews.

EFFICACY/ EFFECTIVENESS

Mortensen O E et al. (2022) conducted a systematic review which included 114 papers, of which 15 were randomised controlled trials (RCTs). A total of 36 studies (including six RCTs) examined the impact of LASER as a treatment for genitourinary syndrome of menopause. In addition, 34 studies (including four RCTs) investigated its effect on vulvovaginal atrophy, while 30 studies (including two RCTs) focused on urinary incontinence. Furthermore, ten studies (including three RCTs) specifically explored the effectiveness of vulvar treatment for lichen sclerosus. The review reported half of the included RCTs, irrespective of indication, did not find a significant difference in improvement in women treated with vaginal CO2 or Er:YAG LASER compared with their respective controls. However, most non-comparative studies reported significant improvement after exposure to vaginal or vulvar LASER across all indications. Included studies generally had a short follow-up period and only a single RCT followed their participants for more than 6 months post treatment.[8]

Wang Y et al. (2021) conducted a systematic review and meta-analysis to evaluate the safety and efficacy of laser treatment for stress urinary incontinence. The review included 16 published clinical research studies, involving 899 patients with stress urinary incontinence. The analysis showed that after laser treatment, the change in the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI-SF) score at one, two, and six months was −5.49 (95% CI: −6.74 to −4.24; I^2=91%, P<0.01), −4.97 (95% CI: −6.24 to −3.71), and −5.48 (95% CI: −6.15 to −4.81), respectively. Significant reduction in median ICIQ-SF scores

between baseline and post-intervention reflects the efficacy of laser treatment. The improvement in 1-hour pad weight test results at one, three, and 12 months post treatment was −5.59 (95% CI: −6.93 to −4.25), −4.96 (95% CI: −6.73 to −3.20), and −5.82 (95% CI: −6.77 to −4.87), respectively. The PISQ-12 score improved from baseline to post-intervention for SUI was 5.39 (95% CI: 1.20–9.58; I^2=96%, P<0.01).[10]

Sarmento ACA et al. (2021) conducted a systematic review to verify whether the physical methods of laser can be recommended as safe and effective options for the treatment of genitourinary syndrome of menopause. The review included 49 studies, 37 were on the CO2 laser, 10 on the Erbium laser, and two on radiofrequency. The analysis reported that the CO2 laser seems to be an efficacious therapy for the management of all symptoms of genitourinary syndrome of menopause up to 12 months after treatment, irrespective of the number of sessions of laser therapy. The Vaginal Health Index (VHI) score was significantly improved. There was an improvement in elasticity, volume of fluid, pH, epithelial integrity, and vaginal moisture. The Visual Analog Scale (VAS) scores were significant for sensitivity, itching, stinging, vaginal dryness, dyspareunia, and dysuria. Application of the Er:YAG laser is associated with an improvement in vulvovaginal atrophy, and such treatment induced a significant decrease in VAS, an increase of VHI, and a significant improvement in urinary incontinence.[11]

Another systematic review with meta-analysis which was conducted by Mounir DM et al. (2021) reported that prospective observational studies were the predominant evidence currently available for laser treatments of the genitourinary syndrome of menopause.[9] These studies are limited by observational design and a small number of women treated with short term follow up.[9] A meta-analysis of 14 studies involving 542 participants showed the improvement of quality of life, reduction of genitourinary syndrome of menopause symptoms and positive structural changes in the vaginal mucosa.[9] However, the body of evidence was assessed as “low” or “very low”.[9] A systematic review of 17 observational studies by Song et al (2018), looking at both laser types, found that genitourinary syndrome of menopause symptoms and urinary incontinence decreased with vaginal laser therapy.[12] For stress incontinence, a systematic review on this topic, evaluating thirteen studies which were mainly case series, case control studies evaluated 818 female subjects who underwent vaginal laser surgery (Er:YAG and fractional CO2) for stress urinary incontinence.[13] The authors concluded that although it could be useful as a minimally invasive technique for stress urinary incontinence, shown by improvement of symptoms on questionnaires such as the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF), there were methodological limitations on the available studies.[13]

A recent systematic review with meta-analysis was conducted by Li F et al. (2021) which has included three randomised studies, 16 prospective studies, and 7 retrospective studies representing data from 2678 participants. The authors reported that most studies included were low quality, with high risk of bias, and no double-blind or placebo-controlled randomized trials yet available. Pooled data from three randomised controlled trials show no difference between vaginal laser and topical hormonal treatments for change in vaginal symptoms (−0.14, 95% CI: −1.07 to 0.80) or sexual function scores (2.22, 95% CI: −0.56 to 5.00). No difference among vaginal laser, topical hormone, and lubricant was demonstrated in sexual function (p=0.577). As in previous review, non-randomised data support energy-based

treatments in improving vaginal symptoms, sexual function, and clinician-reported outcomes.[14]

Li B et al. (2020) conducted a systematic review with Bayesian network meta-analysis which included 29 randomised controlled trials (RCTs) evaluating five different treatment regimens (laser therapy, vaginal oestrogen, ospemifene, vaginal dehydroepiandrosterone and moisturization/lubrication) for genitourinary syndrome of menopause, involving 8311 patients. The review reported that laser therapy had excellent effect on vaginal dryness, dyspareunia, urinary incontinence, proportion of parabasal cells, pH and vaginal health index (VHI). Vaginal oestrogen also had significant effects on these aspects, although its effect was inferior to that of laser therapy.[15]

Another systematic review was conducted by Mackova K et al. (2020) which has included 31 studies recruiting 1530 adult women, to review the available evidence on laser therapy for pelvic organ prolapse and urinary incontinence. The review reported that all studies on vaginal and/or urethral laser application for pelvic organ prolapse and urinary incontinence showed significant improvement either on urinary incontinence, pelvic organ prolapse or both; however, the heterogeneity of laser settings, application and outcome measures was huge.[16]

SAFETY

In terms of safety, Mortensen O E et al. (2022) reported that adverse events were mild and transient and 99 studies including 51 094 patients provided information of no serious adverse events.[8] Wang Y et al. (2021) stated that the adverse effects were reported in six of the 16 trials and affected only a small number of patients. Most adverse events were mild or moderate and required no medical intervention or resolved in a few days.[10] None of the studies included in the systematic reviews by Sarmento A C A et al. (2021) and Li F et al. (2021) presented significant adverse effects.[11,14] Based on the findings of network analysis by Li B et al. (2020), using laser therapy conferred the lowest risk of developing adverse events, with an Odd Ratio (OR) of 0.36 (95 %CI 0.15 to 0.83). The risk of developing adverse events for laser therapy was significantly lower than that of vaginal estrogen [-2.4 (95 %CI -5.8 to -1.1)].[15] In another systematic review by Mackova K et al. (2020), no major adverse events were reported, mild pain and burning sensation were the most commonly described adverse events.[16]

The US Food and Drug Administration (USFDA) has cleared a fractional CO2 laser for the indications of “incision, excision, ablation, vaporization, and coagulation of body soft tissues in medical specialties, including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery”. In addition, Er: YAG laser has also been cleared by the FDA for “incision, excision, ablation, vaporization of soft tissue for general dermatology, and dermatologic and general surgical procedures for coagulation and hemostasis”. However, the specific indication for the treatment of vulvovaginal atrophy and the genitourinary syndrome of menopause symptoms are not listed.[9,17]

On July 30, 2018, the USFDA released an FDA Safety Communication warning against the use of energy-based devices for vaginal “rejuvenation” or vaginal cosmetic procedures following acknowledgment of numerous manufacturers who marketed devices for laser therapy for uses not approved by the USFDA. The USFDA stated that it “has not cleared or approved for marketing any energy-based devices to treat the symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function” including procedures for vaginal laxity, vaginal atrophy, dryness, or itching, pain during sexual intercourse, pain during urination or decreased sexual sensation.” It is stated by USFDA that “the safety and effectiveness of energy-based devices for treatment of these conditions has not been established” and warned that “the treatment of these symptoms or conditions by applying energy-based therapies to the vagina may lead to serious adverse events, including vaginal burns, scarring, dyspareunia, and recurring/chronic pain.”[9,17] It is particularly justified to express concern and caution when these procedures are carried out by individuals who lack the necessary qualifications, such as aestheticians, and who may also be promoting lasers for the purpose of "rejuvenation" among women.[9,17]

In 2019, a cross-sectional analysis of the FDA database, Manufacturer and User Facility Device Experience (MAUDE), for events related to laser and energy-based devices for vaginal rejuvenation was performed by Ahluwalia et al. (2019) which analysed 45 distinct events describing 46 patients. The most common indications for the vaginal laser therapy were unspecified and the most reported complications and adverse effects was pain followed by numbness or burning sensation and scarring.[18]

The position of leading medical bodies with regards to the use of laser therapy are described below. In the past, the American College of Obstetricians and Gynecologists (ACOG) released a significant statement in 2007 regarding female genital cosmetic surgery (FGCS), including the use of vaginal lasers. The position paper emphasised that procedures like vaginal rejuvenation and other forms of FGCS are not recognized as established surgical practices. This is primarily due to the lack of substantial evidence supporting their safety and effectiveness. Furthermore, these procedures carry potential risks and complications, such as infection, dyspareunia (painful sexual intercourse), scarring, and changes in sensation.[19] ACOG in its 2016 Position Statement on Laser Treatment of Vulvovaginal Atrophy and USFDA Clearance, reviewed the lack of sham-controlled or long-term data on vaginal lasers and stated that its members should be “cognizant of the evidence regarding innovative practices” and should be wary “of adopting new or innovative approaches on the basis of promotions or marketing.” ACOG reaffirmed this position following the FDA warning in 2018.[9,20,21] In 2018 an International Continence Society/International Society for the Study of Vulvovaginal disease (ICS/ISSVD) best practice consensus document regarding the use of laser for vulvar and vaginal treatments highlighted the results of 24 studies for this technique for the genitourinary syndrome of menopause and vaginal atrophy. As a result of inconsistent clinical outcomes observed across these studies, the International Continence Society/International Society for the Study of Vulvovaginal Disease (ICS/ISSVD) has categorized this technique with a grade of recommendation C. They highlight the importance of conducting additional prospective randomised controlled trials that include a placebo or sham control group in order to accurately ascertain any differences.[9,18]

The International Urogynecological Association (IUGA) published a committee opinion in 2018 regarding the use of laser therapy for the GSM. The committee opinion emphasised the

need for new clinical trials involving low dose local hormones and moisturizer are warranted. The committee stated, “Although the review of the literature shows it may be used to treat genitourinary syndrome of menopause, there appears to be insufficient evidence of its long-term efficacy and side effects. Evidence from robustly conducted RCTs with long-term follow-up comparing laser with placebo or hormonal treatment are lacking”.[22] Moreover, the published guidelines from the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) neither endorse nor make any mention of vaginal laser treatments as a recommended approach for stress urinary incontinence or overactive bladder.[22,23] In Malaysia, recent Clinical Practice Guidelines (CPG) on Management of Menopause in Malaysia 2022 has a statement saying “Non-ablative laser therapy has been shown to improve vulvovaginal symptoms on a short-term basis but may need to be repeated at regular intervals”.[7] However, its recommendation highlights that women with symptoms related to genitourinary syndrome of the menopause are advised for topical vaginal oestrogen therapies as they are highly efficacious and carry minimal side effects.[7]

COST/COST-EFFECTIVENESS (If any)

There was no retrievable evidence from the medical databases on the cost/cost-effectiveness of laser therapy for urinary incontinence and post-menopausal symptoms. The single treatment of vaginal rejuvenation therapy price is ranged around [redacted][25]

CONCLUSION

Based on the review conducted, there is evidence suggesting that laser therapy holds potential for improving symptoms in the treatment of genitourinary syndrome of menopause. It was found to be well-tolerated, with no serious short-term adverse events reported. However, despite these findings, there appears to be limited evidence on its long-term effectiveness and safety, suggesting more robust studies with long term follow-up are warranted.

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