

RANDOMIZED CLINICAL TRIAL

A Randomized Clinical Trial to evaluate the Effect of Therapeutic Ultrasound and Low-level Laser Therapy on Perineal Pain following Vaginal Delivery with Episiotomy

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ABSTRACT

Background and objectives: Vaginal delivery has an enormous amount of pressure on the perineum, the area between vagina and anus, which must stretch to accommodate the baby's head during its passage through the birth canal. During childbirth, the perineum may tear or the obstetrician may decide to incise to make wider opening for baby's head to pass, a procedure called as episiotomy. The area of episiotomy may be uncomfortable and painful for several days. The present study aimed to evaluate the effect of therapeutic ultrasound and low-level laser therapy (LLLT) on perineal pain following vaginal delivery with episiotomy.

Materials and methods: Sixty women, who underwent vaginal delivery with episiotomy, complaining of perineal pain were recruited and randomly allocated to two treatment groups. Physiotherapy intervention included cryo gel pad and therapeutic ultrasound in group A and cryo gel pad and low-level laser therapy in group B once daily for 3 consecutive days.

Outcomes: Measures were documented using visual analog scale (VAS) for pain and REEDA scale (redness, edema, ecchymosis, discharge, approximation) for healing on 1st day preintervention and 3rd day postintervention respectively.

Results: The study results showed that there was statistically significant improvement postintervention in both the groups with $p < 0.05$, although therapeutic ultrasound with cryo gel pad showed better reduction in pain score and healing process as compared to low-level laser therapy.

Conclusion: Therapeutic ultrasound with cryo gel pad can be used to reduce perineal pain following vaginal delivery with episiotomy.

Keywords: Cryo gel pad, Episiotomy, Low-level laser therapy, Therapeutic ultrasound.

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INTRODUCTION

Episiotomy is also called as perineotomy, which is one of the most common procedure performed on women.¹ It is surgically planned incision on perineum and the posterior vaginal wall during second stage of labor.² The worldwide episiotomy rate is about 27, and 54% are nulliparous and 6% are multiparous women.³ Episiotomy was first described by Sir Fielding Ould in his *Treatise of Midwifery* in 1742, when perineal incision was used to facilitate deliveries.⁴ Traditionally, episiotomy was believed to prevent perineal damage, urinary incontinence, anal incontinence, pelvic floor relaxation and protect the newborn from intracranial hemorrhage and intrapartum asphyxia.⁵

In normal vaginal delivery, women suffer from perineal trauma which is a significant problem that causes pain and discomfort during the postpartum period. Perineal loss of integrity may cause postpartum discomfort and may negatively influence psychological and physical function, especially pain.⁶ Episiotomies provoke a greater loss of blood and increase the incidence of dyspareunia and perineal pain after birth.^{7,8} Pain causes stress and hampers the women's ability in infant care.^{9,10} The majority of women who deliver vaginally experience some degree of pain following delivery usually related to the type and extent of the trauma.¹¹ Perineal pain interferes in daily activities of post episiotomy mothers and as well as early bonding of mother and baby. One of the greatest challenges of the physiotherapist is to provide comfort to such clients.

Various intervention are found to reduce episiotomy pain and enhance healing process, which include administration of analgesics, cleanliness, applying ice pack, topical application by dry heat (infra red therapy), sitz bath, Kegel's exercise and perineal care.¹² Therapeutic ultrasound and low-level laser therapy are

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also used to treat perineal pain following episiotomy with low evidence.^{13,14} Two controlled trials of therapeutic ultrasound for perineal trauma were reported by Mc Learn in 1984, Creates in 1987 and they suggested that reduction in pain is associated with active treatment. Also, studies are done to evaluate the individual effect of cryo gel pads, therapeutic ultrasound and low-level laser therapy (LLLT) to reduce perineal pain and discomfort, but no studies have compared the effectiveness of therapeutic ultrasound and low-level laser therapy on perineal pain after episiotomy.

Hence, the present study was designed to evaluate the effectiveness of therapeutic ultrasound and low-level laser therapy for perineal pain following vaginal delivery with episiotomy.

MATERIALS AND METHODS

Subjects and Study Design

Sixty participants from maternity wards of tertiary care centre with complaint of perineal pain following vaginal delivery with episiotomy were recruited by probability sampling design (simple random sampling with lottery method). They were randomly allocated to two groups, i.e. group A and group B using the envelope method. Inclusion criteria were: (1) age group 18 to 35 years, (2) women who complains of pain after 12 hours of normal vaginal delivery with episiotomy, (3) primiparous women and multiparous women, (4) participants who are willing to participate in the study. Exclusion criteria were: (1) postpartum hemorrhage, (2) psychiatric problems. (3) women with diabetes and pre-eclampsia and (4) febrile conditions.

Procedure

All participants were screened for their inclusion and exclusion criteria before their recruitment in the study. A written informed consent was obtained from the study participants. Participants were allocated to two groups: group A and group B using envelop method. Baseline data were collected using VAS and REEDA (redness, edema, ecchymosis, discharge, and approximation) scale prior to the intervention.

Intervention

- *Group A:* Cryo gel pad and therapeutic ultrasound: This regime consisted of application of cryo gel pad to perineal area for 10 minute and followed by therapeutic ultrasound with a 3 MHz, intensity of 0.5 w/cm² with pulse interval 1:1. Therapy duration

was 5 minutes a day for 3 days in lithotomy position using ultrasonic gel with indirect contact method using water filled glove.

- *Group B:* Cryo gel pad and low-level laser therapy: This regime consisted of application of cryo gel pad to perineal area for 10 minute and followed by low-level laser therapy with wavelength of 660 nm, energy density of 3.8 J/cm² and radiant power 15 mW for 30 seconds at perineal area once a day for 3 days in lithotomy position.

Outcome Measures

The outcome measures for pain was visual analog scale (VAS) and healing process was measured by REEDA scale.¹⁵

The REEDA scale consists of five major assessments area. Each assessment area will be given a minimum score of 0 and maximum score of 3. The total REEDA score ranged from 0 to 15. As the score increases, it will indicate higher rate of infection. If the score decreases, it shows the evidence of healing process. Visual analog scale and REEDA scores were measured on day one pre intervention and day third postintervention.

STATISTICAL ANALYSIS

Statistical analysis was done using statistical software Statistical Package for Social Sciences (SPSS) version 10. Various statistical measures, such as mean and standard deviation (SD), were used. Wilcoxon-signed rank test was used as test of significance for outcome measure of visual analogue scale within the groups. Mann-Whitney z test was used to test the significant difference in the outcome measure of visual analog scale between groups A and B. Unpaired t-test was used to find the significant difference in the outcome measure of REEDA Scale between groups A and B. Paired t-test was used to find the significant difference in the outcome measure of REEDA scale within the groups. The level of significance was set at $p < 0.05$.

Age and Body Mass Index

There was no significant difference between the mean age and body mass index (BMI) of the participants in both the

Table 1: Age and BMI distribution

	Age (years)	BMI (kg/m ²)
Group A	23.4 ± 3.92	23.2 ± 2.72
Group B	24 ± 2.06	23.1 ± 3.54
t ₅₈	0.694	0.023
p-value	0.491	0.981

groups, which shows that the participants' characteristics in both the groups were well matched (Table 1).

Visual Analog Scale Score

In the present study, preinterventional average score of VAS in group A was 7.6 ± 1.29 and in group B was 7.6 ± 1.39 on day one with p-value 0.970, which was not statistically significant difference in both the groups. The baseline VAS scores were matched in the two groups. The average score of VAS after postintervention on day 3 was 2.2 ± 1.03 in group A and was 4.6 ± 1.32 in group B with $p < 0.001$, which showed statistically significant difference. The change in VAS score from 1st to 3rd days in group A was 5.4 ± 1.41 and was 3 ± 1.07 in group B with $p < 0.001$, which showed statistically significant difference in reducing pain. Intergroup changes in the VAS score revealed statistically significant reduction in pain on day three postintervention in both the groups. The intragroup analysis for VAS score showed statistically significant difference between groups A and B on post-day 3 with $p < 0.001$ (Table 2).

Both the groups showed statistically significant reduction in pain on 3rd day postintervention with greater reduction in group A as compared to group B.

Redness, Edema, Ecchymosis, Discharge, Approximation Scale

In the present, study preinterventional average score of REEDA scale in group A was 11.8 ± 2.45 and in group B was 13 ± 2.51 on day one with p-value 0.059, which suggest that the base line scores were well matched between the groups. The average score of REEDA scale after postintervention on day three was 2.4 ± 1.04 in group

A and 6.6 ± 2.38 was in group B with p-value on day three was <0.001 which showed statistically significant difference. The t-value on day one, when compared between group A and group B was 1.923 and on day three was 8.841. The p-value on day one was 0.059, which did not show statistical significance. The change in REEDA score from 1st to 3rd days in group A was 9.4 ± 2.04 and in group B was 6.4 ± 2.13 with $p < 0.001$, which showed statistically significant difference in improvement in REEDA score. Intergroup changes in the REEDA score revealed statistically significant improvement in healing process on day 3 postintervention for both the groups. This was done using unpaired t-test. The intragroup analysis of REEDA score showed statistically significant difference within the groups A and B on post-day 3 with $p < 0.001$. This was done by using paired t-test (Table 3).

Both the groups showed statistically significant improvement on REEDA scale on 3rd day postintervention with greater improvement in group A as compared to group B.

DISCUSSION

Perineal pain is most evident after normal vaginal delivery with episiotomy, often making women suffers from pain, discomfort and dependent in their day-to-day activity. Thus, this study aimed to observe the effect of therapeutic ultrasound and low-level laser therapy on perineal pain following vaginal delivery with episiotomy. It was noticed that there was improvement in all the above parameters in both the trial groups, but the group receiving cryo gel pad and therapeutic ultrasound had statistically better improvement as compared to the group receiving cryo gel pad and low-level laser therapy. The age distribution showed no statistical difference in both

Table 2: Comparison of VAS score in two groups (inter- and intragroup)

	Group A		Group B		Mann-Whitney test (z)	p-value
	Median	Interquartile range	Median	Interquartile range		
Day 1	7.6 ± 1.29	6.9–8.5	7.6 ± 1.39	6.6–8.7	0.037	0.970
Day 3	2.2 ± 1.03	1.5–2.8	4.6 ± 1.32	3.55–5.7	5.600	$<0.001^*$
Change from days 1 to 3	5.4 ± 1.41	4.47–6.55	3 ± 1.07	2.2–3.55	5.406	$<0.001^*$
WSR (z)	4.784		4.785		—	
p-value	$<0.001^*$		$<0.001^*$			

*p < 0.05; WSR: Wilcoxon-signed rank test

Table 3: Comparison of REEDA score in two groups (inter- and intragroup)

	Group A	Group B	Unpaired t-test	DF	p-value
Day 1	11.8 ± 2.45	13 ± 2.51	1.923	58	0.059
Day 2	2.4 ± 1.04	6.6 ± 2.38	8.841	58	$<0.001^*$
Change from days 1 to 3	9.4 ± 2.04	6.4 ± 2.13	5.510	58	$<0.001^*$
Paired t-test	25.520	16.481			
DF	29	29	—		
p	$<0.001^*$	$<0.001^*$			

*p < 0.05; DF: Degree of freedom

the groups. The findings of this study are consistent with findings of a study conducted by Dimitrov and Tsenov on causes for healing complications in episiotomy on 33 puerperal women. The study highlighted that the process of episiotomy healing is not influenced by age, parity, duration of labor or the weight of neonate.¹⁶

A randomized controlled trial was done on ice-packs and cooling gel pads versus no localized treatment for relief of perineal pain in, which it was concluded that cooling treatments can alleviate pain, when compared to no localized treatment. This treatment was found to be most acceptable by the women included in the study. Localized cooling treatments have the potential to reduce levels of perineal pain over a longer period of time.¹⁷ The present study included cryotherapy as a part of intervention in both the groups as a conventional method of treatment and cryo gel pad for 15 minutes at temperature 10 to 15°C. The possible explanation for the pain relief is by numbing the superficial tissue surrounding the wound through the action on local nerve fibers and by decreasing edema and results in change of connective tissue of perineum to have more elasticity of collagen and a decrease of muscle irritability and spasm, alleviating the perineal pain. The heat activated receptors plays a significant role in inflammation related pain and pain relieved by cooling effectively.¹⁸

In a randomized placebo trial on ultrasound and pulsed electromagnetic energy treatment for perineal trauma, ultrasound was used with a frequency of 3 MHz, an intensity of 0.5 w/cm² and pulse interval 1:4 for 2 minutes to the episiotomy area using ultrasound couplant.¹⁹ In present study frequency of 3 MHz, an intensity of 0.5 w/cm² and pulse interval 1:1 for 5 minutes was used by indirect method using water filled glove than direct contact method, which was used in the other studies, which could be the possible source of infection. Hence, water gloves method would be better in clinical practice. The heating effect of ultrasound impairs conductivity of an insonated nerve and thus decreases the sensation of pain. As is evident, in the current study ultrasound has reduced pain and facilitated healing process in episiotomy. In a randomized placebo trial on ultrasound and pulsed electromagnetic energy treatment for perineal trauma, it was concluded that bruising occurred after the ultrasound treatment.¹⁴ But in present study, no bruising was found, probably because of indirect method of application used by water filled glove unlike direct method used in the above-mentioned study.

A randomized clinical trial was conducted to see the effect of LLLT for perineal pain and healing after episiotomy, where radiation was applied at three points directly on episiotomy wound, with wavelength of

660 nm, spot size of 0.04 cm, energy density of 3.8 J/cm, radiant power of 15 mw and 10 seconds per point and assessed for pain by pain score scale from 0 to 10 cm and healing process by REEDA scale.²⁰ In the present study, LLLT was used with same procedure once a day for 3 days, which showed reduction in pain and improvement in healing process both clinically and statistically. The above stated study showed reduction in pain, but improvement in healing process was not measured. The present study had shown reduction in pain and improvement in healing process. The reason for improvement in healing process may be due to exposure of larger area for 30 seconds, which could have improved blood circulation to the perineal area around episiotomy scar.

The effect of LLLT is such that it can accelerate remodeling of scar tissues and gives a more cosmetically acceptable result to postoperative scarring.¹⁹ Trelles et al (1987) reviewed the use of local irradiation with LLLT and stated that LLLT has biostimulatory effects in ulcers, granulomas, burns, septic wounds and trauma to superficial tissues, causes stimulation of local cell metabolism in damaged tissues *in vivo* and *in vitro* and also leads to increased activity of local tissue enzymes. It is said that with laser treatment there is high level excretion of 5-hydroxy indoleacetic acid (5-HIAA), which is a metabolite of serotonin (5-HT) and the pain relief is because of the effect of LLLT on the level of serotonin and acetylcholine, which lead to the analgesic effect.²⁰ This can possibly explain the cause of pain relief in the present study where LLLT was used.

Episiotomy presents a severe health problem and produce huge burden on mothers. Simply, safe physiotherapy treatment modality, such as therapeutic ultrasound, could be of great value. This provides immediate pain relief and improves healing process, improves functional performance and reduces discomfort of the patient. Therapeutic ultrasound is low cost as compared to LLLT and less time consuming treatment in subject with perineal pain following vaginal delivery with episiotomy. The present randomized clinical trial provided evidence to support the use of physical therapy regimen in the form of cryo gel pad with therapeutic ultrasound and cryo gel pad with LLLT in relieving pain, improving healing process, improving functional performance and reducing functional disability in subjects with perineal pain.

CONCLUSION

Therapeutic ultrasound with cryo gel pad can be used to reduce perineal pain following vaginal delivery with episiotomy.

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