

Effect of Therapeutic Ultrasound on Episiotomy: a Clinical Trial: Pilot Study

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Abstract: Therapeutic ultrasound has been employed therapeutically for decades and it is currently used by physiotherapists to treat a wide variety of soft tissue injuries and wound healing. It is thought that using low intensity ultrasound ($\leq 3 \text{ W/cm}^2$) can be used to stimulate normal physiological responses to injury to aid repair. Proper aseptic precautions were taken while giving ultrasound. Women were divided into two groups, treatment and placebo. Treatment was given only after 24 hours of delivery for 3 consecutive days. The duration of the treatment was 4 minutes. Women belonging to both the groups were requested not to take any type of sit bath and ointment for 3 days of the treatment which was discussed with the respective gynecologists. VAS score was noted and pretreatment and post treatment healing was observed using REEDA scale. A condom was filled with degassed water and tied up. Sterile lube gel was applied on the condom side facing the episiotomy and ultrasonic gel was applied on transducer head of ultrasound and other side of condom. Statistical analysis was done using paired 't' test and unpaired 't' test. Reduction in pain was achieved in both the groups after treatment but was appreciably more significant in the therapeutic ultrasound group.

Keywords: Episiotomy, perineal pain, therapeutic ultrasound, wound healing

I. Introduction

Episiotomy was developed in Ireland in 1742 for difficult child birth, but had not been in use until the early to mid-1900s. Today it is estimated that episiotomy is utilized in 80-90% of 1st time births and 50% of sub-sequent births. Episiotomy is a minor surgical procedure in which an incision is made to enlarge the vaginal opening just prior to the birth of baby [16]. Perineum is a very sensitive area, in which there are muscles involved in sitting, walking, bending down, squatting, urination and defecation. Any incision in this area can cause pain and discomfort. This discomfort can interfere with resting, sleeping, eating, and babysitting [12, 19]. Studies have proved that episiotomy has mental, social and physical effects on women [6, 14]. The perineal pain resulting from episiotomy is a stressful factor in mothers, which interferes with their ability of nursing and doing their duties as a mother [9, 14]. Episiotomy in India is done in more than 90 percent of deliveries and in a recent study it was shown to be done in 88.31% of the primiparous women. Since the perineum in primiparous mothers is less elastic, they need episiotomy more than multiparous mothers [3]. Studies also show that women do not want to take care of episiotomy with oral analgesia [4].

Therapeutic Ultrasound has been employed therapeutically for decades and it is currently used by physiotherapists to treat a wide variety of soft tissue injuries and wound healing [6, 4, 18]. It is thought that using low intensity ultrasound ($\leq 3 \text{ W/cm}^2$) can be used to stimulate normal physiological responses to injury to aid repair [18]. Other ultrasound regimens, delivered in a water bath, have been used with the primary aim of debriding wounds [13]. It produces a number of biophysical effects that are relevant to wound healing. These include alterations in cellular protein synthesis and release, blood flow and vascular permeability, angiogenesis and collagen content and alignment. Tissues present impedance to passage of sound waves [17]. Grant et.al did a much larger study comparing Pulsed Electromagnetic Energy, Ultrasound and placebo of both, involving 414 women. In this study neither treatment had a statistically significant effect compared with placebo treatment. He failed to demonstrate any objective benefit as far as pain and healing were concerned [21]. To investigate this further, we conducted a clinical trial to compare the effect of pulsed ultrasound treatment with placebo ultrasound on acute perineal pain due to episiotomy.

II. Aim and Objectives

Aim of Study

To assess the effects of therapeutic ultrasound on episiotomy.

Objectives

To determine the effects of therapeutic ultrasound on episiotomy for pain relief.

Need of Study

The use of therapeutic ultrasound as an element of physiotherapy practice is well established, but the nature of that practice has changed significantly over the last 25 years. The predominant use of therapeutic ultrasound is in relation to tissue repair and soft tissue lesion management, where the evidence would support its application in the inflammatory, proliferative and remodeling phases.⁴ There is not enough evidence to evaluate the use of ultrasound in treating perineal pain after childbirth [16].

III. Materials and Methodology

Material

Ultrasonic gel, sterile lubric gel, gloves, degassed water, condoms, cotton, normal saline, gauze, couch, pillows and Ultrasound machine –Frequency-1MHz, Intensity-0.7W/cm² [21, 25].

Methodology

- Type of study: Clinical trial.
- Duration of study: 2 months
- Sample size: 20
- Place of study: Bhausaheb Sardesai General Hospital, Talegaon Dabhade
- Inclusive criteria:
 - Women with episiotomy (any type)
 - Primes and multigravidas both examined by gynecologists for infection and post-operative complications of episiotomy.
- Exclusive criteria: Women having vascular problems, pre assessed by obstetrics and gynecologist.

IV. Procedure

Informed consent was taken from the patient prior to the treatment. Chit method was used for random selection. It was single blinded study, whether the treatment was therapeutic or placebo, was not known to the patient. Proper aseptic precautions were taken while giving ultrasound. Treatment was given only after 24 hours of delivery for 3 consecutive days. The duration of the treatment was 4 minutes [25]. VAS was explained to the patient and was noted pretreatment and post treatment. Healing was observed using REEDA scale.¹ For placebo treatment, the intensity was not set at all and only the time was set, similar to therapeutic treatment i.e. 4 minutes. A condom was filled with degassed water. Sterile lubric gel was applied on the condom side facing the episiotomy and ultrasonic gel was applied on transducer head of ultrasound and other side of condom [25]. Patient was made to lie comfortably in side lying position with the upper leg flexed slightly in order to place the condom over the episiotomy. The head was moved on the condom applied with the ultrasonic gel in a circular manner as given in the literature [25]. Post treatment, the VAS was noted again. Healing was observed every day prior the treatment using REEDA scale. This procedure was carried out similarly for 3 consecutive days [2, 21].

V. Observation and Result

The mean age of the experimental group was 22.7 years while the mean age of the control group was 22.6 years. Statistical analysis was performed by using paired 't' test and unpaired 't' test

1. Pain score before intervention:

Assessment of the perineal pain 24 hours after episiotomy repair and before intervention were provided among both groups. The mean score was 8.3 in experimental and 8.4 in control group. Results of the present study showed that nearly (90%) in experimental group had strong perineal pain as compared to 100% in control group. Around (10%) women in experimental group had moderate perineal pain. There wasn't significant difference between two groups ($t=-0.153$ at $p=0.880$) Fig 2. Table 1.

Assessment of the perineal pain 48 hours after episiotomy repair and before intervention were provided among both groups. The mean score was 6.50 in experimental and 7.30 in control group. Results of the present study showed that nearly (40%) in experimental group had strong perineal pain as compared to (90%) in control group. Around (60%) women in experimental group and (10%) in control group had moderate perineal pain. There wasn't significant differences between two groups ($t=-2.14$ at $p=0.046$) Fig 2. Table 1.

Assessment of the perineal pain 72 hours after episiotomy repair and before intervention were provided among both groups. The mean score was 5.10 in experimental and 7.20 in control group. Results of the present study showed that nearly (10%) in experimental group had strong perineal pain as compared to (80%) in control group. Around (80%) women in experimental group and (20%) in control group had moderate perineal pain and (10%) women in experimental group had mild pain. There wasn't significant differences between two groups ($t=-4.90$ at $p=0.000$) Fig 2. Table 1.

2. Pain score after intervention

As regards to perineal pain scores 24hours, 48hours, and 72 hours after episiotomy, the mean level of pain scores was (4.80) and (3.80) in experimental group and it was (4.90) and (5.0) in control group 24 hours and 48hours after episiotomy ($p = 0.400$ & $p = 0.044$). In addition, a no significant difference between the pain scores was shown. 72 hours after episiotomy the mean level of pain scores was (2.0) in experimental group and it was, (5.10) in control group ($p=0.00$). It showed a statistically significant difference between the pain score Fig 2. Table 2.

3. Wound healing

Healing was assessed with help of REEDA SCALE pretreatment for three consecutive days. Among therapeutic group, on the first day, 100% women were having mild redness, 80% were having mild edema and 20% were having moderate edema. On the second day, only 10% women were having mild redness 40% were having mild edema. On third day, 100% women were having mild approximation. Whereas among the Placebo group, 100% women were having mild redness and 90% were having mild edema. On second day, 50% women were having mild edema. And on the third day, only 30% women were having mild edema and only 30% were having mild approximation [13].Fig 3.Table 3, 4 & 5.

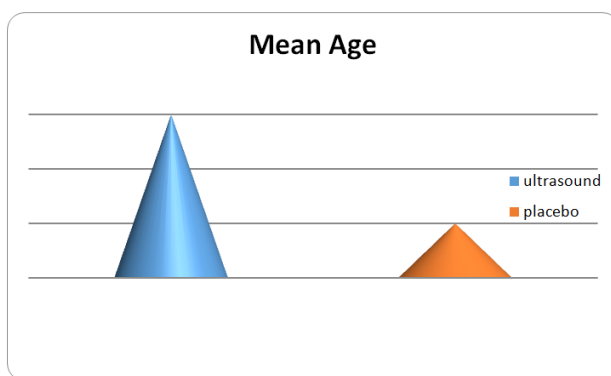


Fig 1: Mean Age

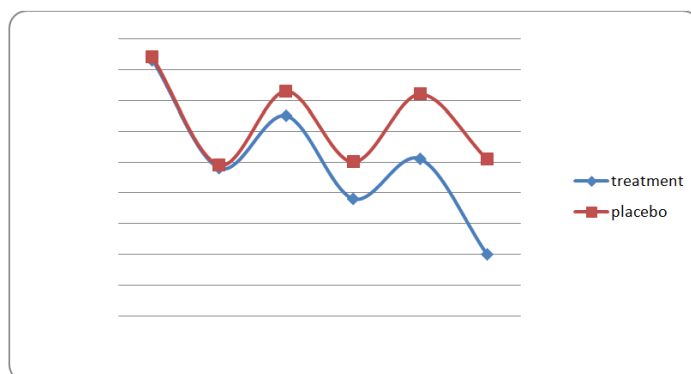


Fig. 2: Showing comparison of mean scores of VAS Of three days

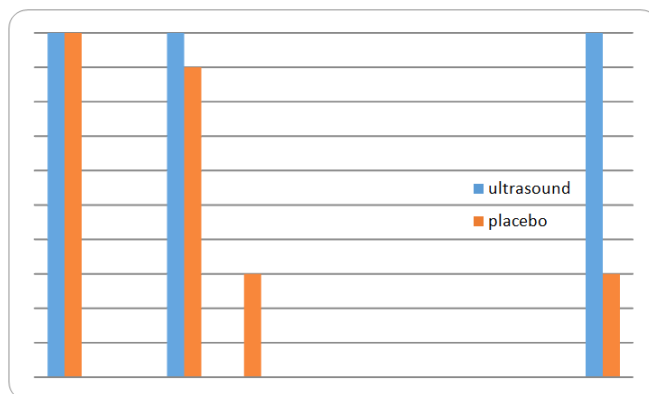


Fig 3: Showing comparison of healing

Table 1. Mean Perineal Pain Scores on Day 1, 2 and 3 Postpartum among Both Groups before Treatment

Variables	Experimental (N = 10)		Control (N = 10)		t	p	CI
	X	SD	X	SD			
DAY1	8.30	1.77	8.40	1.07	-0.153	0.880	95%
DAY2	6.50	0.972	7.30	0.675	-2.14	0.046	95%
DAY3	5.10	1.10	7.20	0.789	-4.90	0.000	95%

Table 2. Mean Perineal Pain Scores on Day 1, 2 and 3 Postpartum among Both Groups after Treatment

Variables	Experimental (N = 10)		Control (N = 10)		t	p	CI
	X	SD	X	SD			
DAY1	4.80	0.632	4.90	1.29	-0.221	0.828	95%
DAY2	3.80	1.32	5.00	1.15	-2.17	0.044	95%
DAY3	2.00	0.816	5.10	1.10	-7.15	0.000	95%

Table 3: Mean REEDA Scales Scores among two Study Groups at day 1 after Episiotomy

Variables	Experimental (N = 10)	Control (N = 10)
READNES	100% (mild)	100% (mild)
EDEMA	100% (mild)	90% (mild)
ECCHYMOSIS	0	0
DISCHARGE	0	0
APPROXIMATION	0	0

Table 4: Mean REEDA Scales Scores among two Study Groups at day 2 after Episiotomy

Variables	Experimental (N = 10)	Control (N = 10)
READNES	10% (mild)	0
EDEMA	40% (mild)	50% (mild)
ECCHYMOSIS	0	0
DISCHARGE	0	0
APPROXIMATION	0	0

Table 5: Mean REEDA Scales Scores among two Study Groups at day 3 after Episiotomy

Variables	Experimental (N = 10)	Control (N = 10)
READNES	0	0
EDEMA	0	30% (mild)
ECCHYMOSIS	0	0
DISCHARGE	0	0
APPROXIMATION	100%	30% (mild)

VI. Discussion

The aim of the present study was to evaluate the effect of therapeutic ultrasound on episiotomy pain and wound healing of postpartum women. Results of the current study supported the following investigated hypothesis that women who received ultrasound will experience lower level of post-partum perineal pain and better wound healing progress than those who did not receive the treatment.

1. Demographic characteristics of the sample

As regards to the demographic characteristics of the study sample, it was found that the mean age in the experimental and control groups was (22.7 and 22.6 years) respectively.

2. Perineal pain scores

As regards to the level of perineal pain scores, the present study showed statistically significant reduction in the level of perineal pain on 3rd day postpartum between the two groups ($p < 0.000$) and ($p < 0.000$) respectively. El Hag and coworkers reported that anti-inflammatory effect of ultrasound may be due to increased protein synthesis, increased mast cell production which leads to decrease swelling and these changes would be likely to lead to increased vascular permeability [23]. On the contrary, immediate pain reduction seen in both the groups was significant ($p < 0.001$). Massage and cooling effect of gel may be one of the reasons for pain reduction. Healing was assessed with the help of REEDA SCALE pretreatment for three consecutive days. Among therapeutic group, on the first day, 100% women were having mild redness, 80% were having mild edema and 20% were having moderate edema. On the second day, only 10% women were having mild redness 40% were having mild edema. On third day, 100% women were having mild approximation. Whereas among the

Placebo group, 100% women were having mild redness and 90% were having mild edema. On second day, 50% women were having mild edema. And on the third day, only 30% women were having mild edema and only 30% were having mild approximation [13]. Dyson and associates reported that ultrasound facilitated a greater increase in growth of tissue in experimentally wounded rabbit ears. It may be due to the acoustic streaming which may have been part of the mechanism that facilitate repair [24].

VII. Conclusion

It was found that the group receiving therapeutic Ultrasound showed better carry over effect during and after treatment as compared to the group receiving Placebo Ultrasound. Therefore ultrasound can be incorporated to reduce perineal pain and to enhance healing.

Limitation

- Short duration

Scope Of The Study

- To see long term effect
- Comparison of ultrasound with other therapeutic modalities

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