DOI: 10.7860/JCDR/2023/65320.18619

Original Article

Physiotherapy Section

Effect of Ice Pack on Pain and Activities of Daily Living after Episiotomy: A Randomised Controlled Trial

RAKSHA RAJU SUVARNA[1], PURUSOTHAM CHIPPALA[2]

ABSTRACT

Introduction: Episiotomy is a common surgical procedure used during childbirth. Approximately 52% of women who have vaginal births undergo episiotomy, with 93.3% of primiparous women and 30.2% of multiparous women being affected. Perineal pain is a prevalent issue among mothers and can negatively impact their daily functioning and early experiences of motherhood. The use of an ice pack on the perineum is a simple, non pharmacological treatment for pain relief that may have an impact on postpartum recovery. However, no study has been conducted to determine the effect of an ice pack on postnatal mothers' compliance with Activities of Daily Living (ADL) following episiotomy.

Aim: To evaluate the effect of an ice pack on pain and ADL after episiotomy.

Materials and Methods: This trial is an experimental, parallel, and assessor-blinded allocation with a computer-generated randomisation sequence. A randomised controlled trial conducted in the Department of Obstetrics and Gynaecology at Justice KS Hegde Charitable Hospital in Deralakatte, Mangaluru, India. The study duration was one year, from March 2022 to March 2023. A total of 64 postnatal mothers (32 in each group) were included. This trial is an experimental, parallel, and assessor-blinded allocation with a computer-generated randomisation sequence. The inclusion criteria were primiparous women aged between 18-35 years, who underwent episiotomy within 6 to 24 hours postpartum, delivered a live baby, complained of pain at the incision site, had a full-term labour, and had no other complications during pregnancy or labour. The participants were also required to be literate. Age, Numerical Pain Rating Scale (NPRS), and Barthel Index (BI) were compared between the groups using the independent sample t-test. The paired t-test was used for within group (pre to post-test) comparison of NPRS and Barthel index. A p-value of <0.05 was considered significant.

Results: There was a significant difference in pain experienced by the groups, as assessed by NPRS ($p<0.001$). However, there was no difference in ADL between the groups ($p>0.05$). No side effects or harms were reported. Ice pack application, once daily for two days, was found to be safe and feasible for post-episiotomy patients.

Conclusion: The current randomised controlled trial concludes that the application of an ice pack once daily for two days is significantly effective in reducing pain after episiotomy. However, it does not improve ADL in patients with post-episiotomy.

Keywords: Barthel index, Cryotherapy, Episiotomy, Pain measurements

INTRODUCTION

Episiotomy is a common surgical procedure used during childbirth, which is an essential part of most women's labour management. It aims to widen the vaginal opening and prevent perineal tears [1]. It has been noted that almost half of the women (52.0%) who had normal deliveries underwent an episiotomy, with 93.3% of primiparous women and 30.2% of multiparous women opting for the procedure [2]. However, suturing at the perineum may cause more pain for new postnatal mothers, making it difficult for them to adjust to their new circumstances during the postpartum phase and impacting their daily living activities [2]. Episiotomy pain can cause discomfort and interfere with women's ability to nurse and fulfill their maternal obligations. It greatly affects daily tasks such as moving or sitting comfortably, feeding and caring for the baby, and causes discomfort during urination or bowel movements [2]. Non pharmacological treatments for episiotomy pain have been studied worldwide. Ice packs are easily accessible and inexpensive pain-relieving treatments, and their use on the perineal region is being extensively investigated [3]. Cold treatment administered immediately after an injury reduces inflammation, secondary hypoxia, cellular debris formation, oedema, haematoma growth, and metabolism. Additionally, it accelerates the healing process and enhances endorphin release [3].

Ice packs reduce blood flow and metabolic demands in the affected region, thereby decreasing oedema and nerve stimulation, resulting in reduced discomfort [3]. According to the Cochrane database, the use of ice packs on the perineal region is considered safe and has no side effects. However, due to the lack of rigorous standards, the effectiveness of cryotherapy on the perineal region remains debatable [3]. The primary outcome, NPRS, is an 11-point scale (0-10) used to measure the subjective intensity of pain [4]. The secondary outcome, the BI scale, measures ADL with a score ranging from 0 to 100, where 80-100 indicates independence and less than 20 indicates total dependence [5]. In the present trial, it is hypothesised that there will be a significant effect of ice packs on pain and ADL after episiotomy.

However, no study has been conducted to determine the effect of an ice pack on postnatal mothers' compliance with ADL after episiotomy. Therefore, the present study aimed to evaluate the effect of ice packs compared to routine treatment on pain and ADL in post-episiotomy women.

MATERIALS AND METHODS

This trial is an experimental, parallel, and assessor-blinded randomised controlled trial conducted in the Department of OBG at Justice KS Hegde Charitable Hospital, Deralakatte, Mangaluru, India. The study was conducted over a duration of one year, from March 2022 to March 2023. Ethical approval was obtained from the Institutional Ethics Committee (IEC) of NITTE Institute of Physiotherapy, Mangaluru, Karnataka, India, with reference number NIPT/IEC/Min//24/2021-2022, dated 12-02-2022. After approval from the IEC, the trial was

registered prospectively in the Clinical Trial Registry of India with the registration number CTRI/2022/06/043448.

Inclusion criteria: A total of 64 primiparous women who underwent episiotomy between 6 and 24 hours postpartum, aged 18-35 years, delivered a live baby, experienced pain at the site of incision, completed full-term labour, and had no other complications during pregnancy or labour were included in the study [6].

Exclusion criteria: Two women and/or infants with respiratory or cardiac-related issues, mothers under sedation, mothers with postnatal complications, musculoskeletal complications during pregnancy, and catheterisation were excluded from the study as they did not meet the criteria [7].

Sample size calculation: The sample size of the study was 64 (32 in each group). Sample size calculation was based on the Standard Deviation (SD) of NPRS, which was 2.7 in the experimental group and 3 in the control group [2]. With a mean difference of 2, effect size of 0.7017, alpha error of 5%, power of 80% for a 2-sided hypothesis test, the sample size required per group was 32, totaling 64. This calculation was performed using nMaster software version 2.0.

Study Procedure

Before participation, all participants were given information about the trial process. The information included the purpose of the study, intervention procedures, and the potential therapeutic and adverse effects of the assigned interventions. The researcher and research guide prepared an English, Kannada, and Malayalam version of the informed consent to provide the necessary information. Participants were informed that they could withdraw from the trial at any point if they chose not to continue.

Randomisation and allocation: Random numbers ranging from one to 64 were generated using the website www.random.org. These numbers were divided into two groups, consisting of 32 participants each. The random number generation was performed by an independent researcher not involved in the study. Each random number was concealed in a Small Opaque Envelope (SNOSE), and participants were equally allocated to the two groups in a 1:1 ratio.

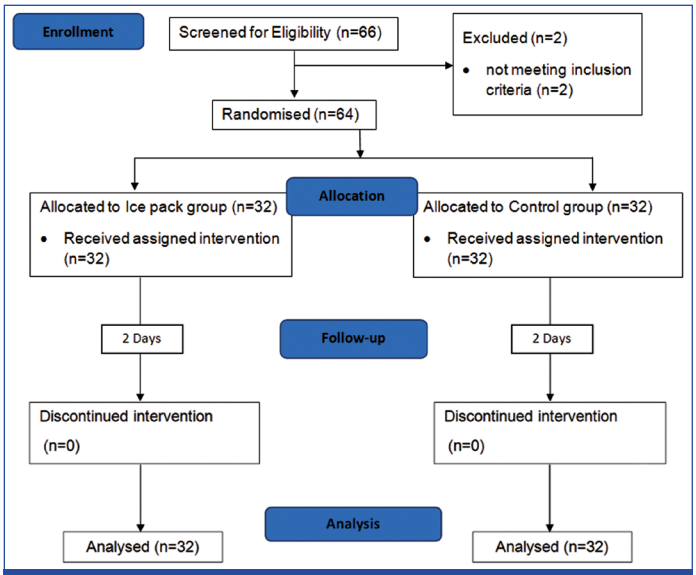
Blinding: Outcome measures were conducted by a graduate physiotherapist who was blinded to the random allocation of participants and their individual assigned interventions throughout the study period. Assessor blinding was maintained by instructing the assessor not to inquire about the type of intervention from the participants. Participants were also instructed not to disclose the intervention they had received.

Interventions: Participants were screened based on inclusion and exclusion criteria, and a consent form was provided. They were then randomly assigned to one of the two groups and received a 10 minute treatment each [8]. The materials used included a bed, a well-ventilated room, an ice pack (155×110×32 mm in size), surgical sterile gloves, cotton gauze, paper, pencil, and outcome measure forms.

Experimental group: In the experimental group, the patient was taken to the examination room to maintain their privacy. The patient received the same education as the control group for 10 minutes, provided by the therapist. Afterward, an ice pack was applied to the perineal region [9]. The ice pack was covered with a single layer of cotton gauze to prevent direct contact with the participant's skin. The patient was positioned comfortably in the dorsal recumbent position during the 10 minute ice pack therapy session, which was conducted once per day for two days [10].

Control group: In the control group, participants received education on bed mobility, breastfeeding techniques, infant positioning, and sitting postures. The therapist also guided the mother through breathing exercises, including diaphragmatic breathing, thoracic expansion exercises, ankle toe movements, and heel slides. The treatment duration was 10 minutes, given once for two days.

Outcomes: The primary outcome, which measures pain levels, was assessed using the NPRS. The secondary outcome, measuring ADL, was evaluated using the BI scale. The assessments were conducted by an assessor who was blinded to the group allocation method for two days. [Table/Fig-1] shows the flowchart of participants.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flowchart of participants.

STATISTICAL ANALYSIS

The data collected was summarised using descriptive statistics (frequency, percentage, mean, and SD). The independent samples t-test was used to compare age, NPRS, and BI between the groups. The paired t-test was used for the within-group (pre to post-test) comparison of NPRS and BI. A p-value <0.05 was considered significant. The data was analysed using the Statistical Package for Social Sciences (SPSS), version 26.0 (SPSS Inc.; Chicago, IL).

RESULTS

The present study was conducted among 64 post-episiotomy women. The age of the women ranged from 19 to 34 years with a mean of 24.7±3.8. The experimental group included 32 participants, while the control group consisted of 32 participants. All the women included in the present study had full-term normal deliveries, underwent right mediolateral episiotomy, were primiparous, literate (>10th standard), 6 to 24 hours postpartum, and delivered live babies. None of the women had catheterisation, musculoskeletal complications during pregnancy, complications during delivery, or reported any side effects [Table/Fig-2,3].

Parameter	Range	Mean±SD
Age (in years)	19 to 34	24.7±3.8

[Table/Fig-2]: Descriptive statistics for age.

Parameters		Frequency (n)	Percentage (%)
Groups	Experimental	32	50
	Control	32	50
Gender (female)		64	100
Term of delivery (FTND)		64	100
Type of delivery (RMLE)		64	100
Primipara (Yes)		64	100
Episiotomy (Yes)		64	100
6 to 24 hours postpartum (Yes)		64	100
Delivered live baby (Yes)		64	100
Complications (No)		64	100

[Table/Fig-3]: Study groups and characteristics of women.
FTND: Full term normal delivery; RMLE: Right mediolateral episiotomy (N=64)

The age of the women in the experimental group was 24.8±3.3 years, and for the control group, it was 24.7±4.2 years. The age differences between the groups were compared using an independent sample t-test (t=0.098). There was no difference in the mean age between the experimental and control groups (p>0.05). The NPRS scores were compared between the groups using an independent sample t-test. On day one, there was a significant difference (p<0.05) in the NPRS scores between the experimental and control groups for both activity and rest during the post-test. Additionally, both the pretest and post-test NPRS scores for activity and rest showed a difference between the experimental and control groups on day two [Table/Fig-4].

NPRS (0-10)		Experimental n=32 Mean±SD	Control n=32 Mean±SD	t-value	p-value
Day 1 (Activity)	Pretest	8.4±0.9	8.3±0.7	0.15	0.878
	Post-test	6.5±1.3	8.3±0.7	-7.10	<0.001*
Day 1 (Rest)	Pretest	4.3± 1.4	4.4±1.2	-0.29	0.774
	Post-test	2.7±1.2	4.4±1.2	-5.60	<0.001*
Day 2 (Activity)	Pretest	6.0±1.0	7.3±0.7	-5.81	<0.001*
	Post-test	4.4±1.4	7.3±0.7	-10.29	<0.001*
Day 2 (Rest)	Pretest	2.5±1.2	3.5±1.0	-3.79	<0.001*
	Post-test	0.8±1.0	3.5±1.0	-10.47	<0.001*

[Table/Fig-4]: Comparison of Numerical Pain Rating Scale (NPRS) between the groups.
t=Independent sample t-test; *Significant (<0.05); NPRS: Numerical pain rating scale

An independent sample t-test was used to compare the BI between the groups. There was no significant difference (p>0.05) in BI between the experimental and control groups during the pretest as well as the post-test day one and day two [Table/Fig-5].

Barthel index (0-100)		Experimental Mean±SD	Control Mean±SD	"t"	p-value
Day 1	Pretest	55.6±2.5	55.0±0.0	1.44	0.156
	Post-test	55.6±2.5	55.0±0.0	1.44	0.156
Day 2	Pretest	96.1±9.2	97.2±11.1	-0.43	0.669
	Post-test	96.1±9.2	97.2±11.1	-0.43	0.669

[Table/Fig-5]: Comparison of Barthel Index between the groups.
t=Independent sample t-test

The pre- and post-test comparison of NPRS scores was done using the paired t-test. There was a significant difference (p<0.05) in the NPRS scores from pre to post-test for both activity and rest at day one and two. However, the mean BI remained constant from the pretest to the post-test for day one and two, indicating no difference in BI between the pre and post-tests. The paired t-test was used to compare NPRS scores within the groups. There was a significant difference (p<0.05) in the NPRS scores from the pretest to the post-test for both activity and rest at day one and two within the experimental group. The mean NPRS scores from the pretest to the post-test (both activity and rest) for day one and two remained constant. Hence, there was no difference in NPRS scores within the control group. The mean BI from the pretest to the post-test for day one and two remained constant for both the experimental and control groups. Therefore, there was no difference in BI within the groups.

DISCUSSION

Episiotomy, a common delivery procedure, often leads to perineal pain in the early postpartum period, which can impact maternal well-being [1]. The present study assessed the impact of ice pack application on pain and daily activities following episiotomy. The results showed a significant improvement in pain (measured using the NPRS scale) (p<0.001), but no significant differences were observed in ADL (p>0.05). No side effects were reported, indicating that ice packs are safe and feasible for managing post-episiotomy pain. According to the study conducted by El-Saidy TMK et al., [1], the level of perineal pain was measured using the short-form McGill pain questionnaire and NPRS for both groups. Postvaginal episiotomy women who had just given birth were assessed for episiotomy pain during the first two hours following delivery as a baseline, as well as on the 1st, 3rd, and 7th days after delivery. NPRS was used as the primary outcome measure for pain in the current study, specifically on day one and day two. [1].

In a study by Beleza ACS et al., it was found that a single 20 minutes cryotherapy session within 24 hours after delivery effectively reduced perineal discomfort [2]. In contrast, the current study involved daily ice pack application for two days, which significantly lowered NPRS pain scores. This highlights the varied impacts of interventions based on their duration. The comprehensive evaluation conducted in the current study over two days provides clarity regarding the sustained pain reduction achieved through ice pack therapy. Additionally, the use of blinded evaluators in the current study enhances validity, unlike Beleza ACS et al., which lacked assessor blinding, potentially introducing bias [2]. These variations emphasise the significance of effective pain management in postpartum care. A study by Navvabi S et al., suggests that cold pack application may reduce local cellular damage by preventing haemorrhage and oedema, as well as decreasing the metabolic demands of injured tissues [11]. When pain is relieved, the reflex arc is broken, and the motor impulses that trigger muscle spasms cease. As a result, it is hypothesised that reduced pain leads to skeletal muscle relaxation. Cold can induce analgesia by decreasing neuronal conduction and receptor activation, or through competitive inhibition within the central nervous system, or a combination of both mechanisms [11].

The current study has several merits. Firstly, there were no dropouts, making it reliable. Secondly, it was convenient due to its short duration and easy administration-a once-a-day intervention for two days with no reported adverse events during the treatment. Additionally, the ice pack used in the study was readily available in the department, making it feasible for patients to self-administer in the future. It was a non invasive procedure requiring limited skills. However, a study conducted by Shehta MS et al., mentioned the high implementation costs associated with the study due to the unavailability of cold packs in hospitals during their research [12].

Limitation(s)

The current study does have some limitations. Patient follow-up was not possible, and the use of the ice pack was restricted to a maximum of two days. Furthermore, the study did not observe any improvements in group ADL as a result of using the ice pack. Although the trial group experienced immediate pain relief compared to the control group, the evaluation one hour later was not performed. Also, the treatment could have been better if it had lasted for more than three to four days.

CONCLUSION(S)

The current randomised controlled trial concludes that applying an ice pack once daily for two days is significantly effective in reducing pain. However, it does not improve ADL in patients with post-episiotomy. The findings of the present study highlight the potential benefits of incorporating ice pack therapy into postpartum care. This provides a more effective method for pain control and supports women's recovery following episiotomies.

Acknowledgement

The authors would like to express their gratitude to the women who participated in the study, Ms. Neha Shetty, the Physiotherapy OBG faculty, and the entire medical staff of the Department of Obstetrics and Gynaecology, including the Head of Department (HOD), for their

support. The authors would also like to thank Dr. Neevan D'Souza and Dr. Sanal T S for assisting in data analysis.

REFERENCES

[1] El-Saidy TMK, Aboushady RMN, SolimanHFA. Effect of applying crushed ice gel pads on episiotomy pain and wound healing among postpartum primiparous women. IJND. 2018;8(07):19-29.
[2] Beleza ACS, Ferreira CHJ, Driusso P, Dos Santos CB, Nakano AMS. Effect of cryotherapy on relief of perineal pain after vaginal childbirth with episiotomy: A randomized and controlled clinical trial. Physiotherapy. 2017;103(4):453-58.
[3] East CE, Dorward EDF, Whale RE, Liu J. Local cooling for relieving pain from perineal trauma sustained during childbirth. Cochrane Database Syst Rev. 2020;10(10):CD006304.
[4] Rabello DR, Umarani J, Agarwal A. Effectiveness of labour supportive measures on selected maternal physiological parameters, labour pain, and maternal satisfaction a review. Journal of Population Therapeutics and Clinical Pharmacology. 2023;30(15):259-70.
[5] Duffy L, Gajree S, Langhorne P, Stott DJ, Quinn TJ. Reliability (inter-rater agreement) of the Barthel Index for assessment of stroke survivors: Systematic review and meta-analysis. Stroke. 2013;44(2):462-68. Doi: 10.1161/STROKEAHA.112.678615.
[6] Francisco AA, De Oliveira SMJV, Steen M, Nobre MRC, De Souza EV. Ice pack induced perineal analgesia after spontaneous vaginal birth: Randomized controlled trial. Women Birth. 2018;31(5):334-40.
[7] Morais Í, Lemos A, Katz L, de Melo LFR, Maciel MM, de Amorim MMR. Perineal pain management with cryotherapy after vaginal delivery: A randomized clinical trial. J BJGO. 2016;38(7):325-32.
[8] Lua YY, Sub ML, Gauc ML, Lind KC, Aue HK. The efficacy of cold-gel packing for relieving episiotomy pain - a quasi-randomised control trial. Contemp Nurse. 2015;50(1):26-35. Doi:10.1080/10376178.2015.1010257.
[9] Francisco AA, de Oliveira SM, Leventhal LC, de Bosco CS. Cryotherapy after childbirth: The length of application and changes in perineal temperature. Rev Esc Enferm USP. 2013;47(3):555-61. Doi: 10.1590/s0080-623420130000300005.
[10] Leventhal LC, de Oliveira SMJV, Nobre MRC, da Silva FMB. Perineal analgesia with an ice pack after spontaneous vaginal birth: A randomized controlled trial. J JMWH 2011;56(2):141-46. Doi: 10.1111/j.1542-2011.2010. 00018.x.
[11] Navvabi S, Abedian Z, Steen-Greaves M. Effectiveness of cooling gel pads and ice packs on perineal pain. Br J Midwifery. 2017;17(11):724-29.
[12] Shehta MS, Fahmy NM, Ramadan SA, AbdAlmeniem SO. Effect of cold-gel packing on episiotomy pain among postnatal mothers. Egyptian Journal of Health Care. 2017;8(3):86-102.

PARTICULARS OF CONTRIBUTORS:
1. Postgraduate, Department of Physiotherapy, Nitte Institute of Physiotherapy, NITTE (Deemed to be University), Mangaluru, Karnataka, India.
2. Professor, Department of Physiotherapy, Nitte Institute of Physiotherapy, NITTE (Deemed to be University), Mangaluru, Karnataka, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Purusotham Chippala,
Nityananda Nagar, Deralakatte, Mangaluru-575018, Karnataka, India.
E-mail: chippala_puru@nitte.edu.in

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: May 15, 2023
- Manual Googling: Aug 22, 2023
- iThenticate Software: Sep 05, 2023 (10%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **May 09, 2023**
Date of Peer Review: **Aug 05, 2023**
Date of Acceptance: **Sep 07, 2023**
Date of Publishing: **Oct 01, 2023**