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Does Combining Warm Perineal Compresses with Perineal Massage During the Second Stage of Labor Reduce Perineal Trauma? A Randomized Controlled Trial

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Condensation

Perineal tears occurred at similar rates following the application during the late second stage of labor, of warm compresses and perineal massage versus perineal massage alone.

Short title: Warm compresses for reducing perineal trauma.

AJOG at a Glance

A. Why was this study conducted?

- The efficacy of warm compresses during the second stage of labor for reducing occurrences of perineal tears is controversial.
- We aimed to determine whether adding warm compresses to perineal massage would yield a lower rate of perineal tears.

B. What are the key findings?

- Following treatment with warm compresses and perineal massage vs. perineal massage alone, the rates of spontaneous perineal tears requiring suturing were similar.
- The rates of obstetric anal sphincter injuries were similar for the two groups.

C. What does this study add to what is already known?

- The addition of warm compresses to perineal massage during the late second stage of labor did not result in a lower rate of perineal tears.

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Abstract

Background: Various interventions have been applied to reduce perineal trauma and obstetric anal sphincter injuries (OASIS). The efficacy of warm compresses during the second stage of labor for reducing the occurrence of perineal tears is controversial.

Objective: We aimed to compare rates of spontaneous perineal tears requiring suturing, between women who received warm compresses plus perineal massage vs. perineal massage alone.

Study design: Women admitted to a single tertiary university-affiliated hospital between June 2023 and January 2024 were randomized to receive warm compresses and perineal massage (n=206) or perineal message only (n=206) during the second stage of labor. Excluded were women with a history of third-degree perineal tear, nut allergy, fetal death, Crohn's disease with perineal involvement, or delivery number >5. Participant allocation was concealed until the second stage of labor. The allocated perineal management was implemented at the time of active fetal descent and when the participant felt the need to push. During active maternal pushing, gentle perineal massage with almond oil was performed in both study groups. In one group, warm compresses were applied between contractions, for a minimum of 10 minutes and a maximum of 30. The temperature of the warm compresses was kept in the range of 45-59°C. The perineum was protected during delivery with a hands-on technique. After delivery, the perineum was assessed by an intervention-blinded senior midwife and rectal examination was performed for ruling out OASIS. The primary outcome was the rate of perineal tears requiring suturing. Secondary outcomes included the rates of OASIS and episiotomies. A sub-analysis according to parity and an intention-to-treat analysis were performed.

Results: Similar proportions of women treated and not treated with warm compresses had spontaneous perineal tears requiring suturing: 43.7% vs 45.1%, p-value=0.766. The groups did

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not differ in the proportions with first-degree tears, 22.8% vs 21.4%, p-value=0.722; second-degree tears, 21.4% vs 23.8%, p-value=0.566; and OASIS rates, 0.5% in each. In a sub-analysis according to parity, the proportion with perineal tears did not differ between the two groups.

Conclusion: For women treated during the second stage of labor with warm compresses and perineal massage, compared to perineal massage alone, the rate of spontaneous perineal tears requiring suturing was similar.

Keywords: perineal massage, warm compresses, perineal tears, obstetric anal sphincter injuries (OASIS), episiotomy, vacuum delivery

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Introduction

Perineal trauma is genital tissue damage that commonly occurs during childbirth. Reported rates of perineal trauma in primiparous women vary from 35.1 to 78.3%[1] for second-degree tears and from 0.7 to 2% for obstetric anal sphincter injuries (OASIS).[2,3] The corresponding reported ranges for multiparous women are 34.8–39.6%[1] and 0.1-0.3%.[2,3 12,312,3] Long-term outcomes of OASIS include chronic pain, sexual dysfunction, and urinary or anal incontinence.[4] Among the risk factors that have been reported for perineal trauma are: a history of perineal trauma, prolonged second stage of labor, instrumental delivery, midline episiotomy, persistent occiput posterior position, nulliparity, large-for-gestational-age babies, and ethnicity.[5–7]

Various interventions including perineal massage with oil,[8] and cold or warm compresses,[9] have been used to prevent perineal trauma. In a previous meta-analysis, the incidence of severe perineal trauma was lower among women who had received perineal massage during labor than among those who had not.[10] However, controversy exists regarding the efficacy of using warm compresses during the second-stage of labor.[11] A study at the University of New Mexico randomized 1,211 women to one of three interventions in the late second stage of labor: warm compresses, perineal massage, and no perineal contact until crowning. The groups were not found to differ in genital tract trauma.[12] However, in their Cochrane meta-analysis, Magoga et al.[11] found that warm compresses during the second stage of labor, compared to a control group, increased the likelihood of an intact perineum and reduced the risk of OASIS. Yet, the rates of first- and second-degree perineal tears remained similar. The limitations noted in this meta-analysis included non-uniformity in the temperature and the duration of the use of the warm compresses.[11] A Cochrane meta-analysis of 22 trials,[9] including 15181 participants, provided moderate-quality evidence that both warm compresses and perineal massage might reduce third-

and fourth-degree tears; but the impact on other outcomes such as intact perineum was unclear.[12]According to the abovementioned Cochrane meta-analyses, further randomized controlled studies are needed for evaluating the optimal perineal protection technique.[9,11] The aim of this study was to assess the additional effect of warm compresses, in combination with perineal massage, on reducing the rate of perineal tears requiring suturing.

Materials and Methods

This randomized control trial adhered to the CONSORT guidelines (Figure 1). The trial was registered as ClinicalTrials.gov identifier: NCT05851170, and was approved by the Helsinki Committee of our medical center (approval number: NHR-0198-22).

Participants

Women admitted to the delivery rooms of Galilee Medical Center from June 2023 to January 2024 were assessed for eligibility. Inclusion criteria were ≥18 years old, a term singleton pregnancy, and vertex presentation. Excluded were women with a history of third-degree perineal tear, nut allergy, intrauterine fetal death, Crohn's disease with perineal involvement, >5 deliveries, and a contraindication for vaginal delivery.

Recruitment and randomization

The research staff recruited women who fulfilled initial eligibility criteria. After providing written informed consent, the participants were randomized at the time of their admission to the delivery room to either the warm compresses with perineal massage group or the perineal massage alone group. The randomization was done in a 1:1 ratio and managed using the National

Cancer Institute's Clinical Trials Randomization tool,[13] which follows the maximum-tolerated imbalance method. The allocation was concealed from clinical staff and participants until the second stage of labor, and access was restricted to research staff prior to disclosure.

Interventions

The perineal management allocation was implemented with active fetal descent and at the time the participant felt the need to push. For the warm compresses group, clean pads were made warm by immersion in a container of hot water from the tap, at a temperature of 45-59°C.[14] The warm compresses were held to the perineum between contractions, by the midwife's gloved hands. During contractions, the midwives performed gentle perineal message with almond oil as a lubricant, with the use of two fingers. Meanwhile, the compresses were returned to the container of hot water. The compresses and water were changed at a maximum of every 15 minutes, and as needed to maintain warmth of 45-59°C and cleanliness.[11] A thermometer was used to ensure that the water temperature remained in the desired range. Warm compresses were used for a minimum of 10 minutes, and a maximum of 30 minutes.

In the perineal massage group, midwives inserted two fingers (index and middle) into the vagina, and performed gentle lateral sweeping motions (half-circles). This technique stretched the perineum downward toward the rectum. Almond oil was used to facilitate the process.[15,16] . The findings of a recent meta-analysis that included 1,057 women support the use of perineal massage as the standard of care. A potential benefit was shown of perineal massage, in reducing the rates of second-degree perineal tears.[17] All the midwives involved in the trial were trained in the techniques and had been instructed in the abovementioned protocol several months before the trial.

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Blinding

Blinding of the midwives and the participates to the group assignment was not possible. Independent, senior midwives blinded to the allocated group independently assessed the degree of perineal trauma and whether suturing was required. A per-rectal examination was performed using the pill-rolling technique to assess the integrity of the external anal sphincter.

Outcome measures

After birth, intervention-blinded midwives performed thorough inspections of the perineum and vagina, and rectal examinations for assessing OASIS. The degree and site of perineal trauma, and whether suturing was performed, were recorded on the patients' electronic data sheets. An intact genital tract was defined as the absence of tissue trauma at any site, including the vagina, vulva, and perineum, resulting from either a spontaneous tear or an episiotomy. Our department follows a restricted approach to mediolateral episiotomies. These are performed selectively according to clinical judgment in specific circumstances, such as posterior occiput fetal position, operative vaginal delivery, and indications of fetal distress. The primary outcome was the rate of perineal tears that required suturing, which was defined as greater than a first-degree tear. This entailed any tear that was bleeding or did not fall into anatomical apposition (including first-degree tears). Women who underwent episiotomy and subsequently experienced lacerations were included in the analysis of laceration outcomes. The secondary outcomes included the rates of OASIS and episiotomies. Data were also collected on the use of epidural analgesia, induction of labor, oxytocin augmentation, the duration of the second stage of labor, delivery mode, birthweight, and postpartum urinary retention.

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Participants were asked to confirm the comfort of the warm compress temperature and were informed they could request cessation of the intervention at any time, particularly if the compresses felt excessively hot. Midwives' survey

After completion of the enrollment and before the statistical analysis, the midwives were asked to respond to four questions. First, they were asked which intervention they would use in the future for perineal protection during the second stage of labor: warm compresses or almond oil alone. Second, they were asked whether preparing the warm compresses was time consuming. Third, for validation of our study protocol application, midwives were anonymously asked whether they applied warm compresses for a minimum of 10 minutes and a maximum of 30 minutes. Lastly, they were asked whether they ensured that the temperature of the compresses was kept in the range of 45-59°C, according to the protocol.

Sample size calculation

The required sample size was calculated according to Terre-Rull et al.'s[18] which examined the efficacy of warm compresses in reducing perineal trauma. We selected that study [18]for sample size calculation due to its similar primary outcome, namely perineal tears requiring suturing, and the comparable intervention design, by which warm compresses were applied for 10 to 30 minutes. Furthermore, the control group in both studies received standard departmental care. In Terre-Rull et al.'s study, an effect size of 15% in perineal tears requiring suturing was considered significant (28.8% in the study group and 43.9% in the control group). After applying a power of 80% and alpha = 0.05, 158 women were required in each group. Considering that our episiotomy rate in the two years prior to the study period was 18.8%, and an expected dropout of 10%, 206 women were required in each group.

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Statistical analysis

Continuous variables are presented as means ± standard deviations (SD), or as medians and ranges. Qualitative variables are presented as frequencies and percentages. Continuous variables were compared between the study groups using either the independent sample *t*-test or the Mann–Whitney test, according to the sample sizes of the groups and the distribution shapes of the variables. Categorical variables were analyzed using Pearson's chi-squared test or Fisher's exact test. An intention-to-treat analysis was performed. For the primary outcome, a per-protocol analysis was also performed. A two-tailed *p*-value of <0.05 was considered statistically significant. Statistical analysis was performed by the Statistics Unit at Galilee Medical Center using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA).

Results

Characteristics of the participants

During the study period, 672 women were evaluated for eligibility. Of them, 186 did not meet the inclusion criteria and 74 declined to participate. In total, 412 were recruited to the study, 206 were randomized to each group. In the warm compresses and perineal massage compared to the perineal massage alone group, 17 (8.3%) and 11 (5.4%) women, respectively, did not receive the allocated intervention due to cesarean delivery. In the warm compresses group, deviation from protocol was reported for 13 (6.3%) due to a short duration of second-stage labor (<10 minutes) (Consort flowchart, Figure 1).

Characteristics of the women are shown in table 1. Significant differences were not found between the groups in the mean values of age, BMI, and pregnancy week; in the median values

of gravidity; and in the distributions of parity. Nor were significant differences found between the groups in the proportions with diabetes, a previous cesarean delivery, or a previous vacuum-assisted delivery. Rates of epidural analgesia, induction of labor, oxytocin use during the first and second stages of labor, and delivery mode were similar between the groups (Table 2).

Associations with the study outcomes

The proportions of women with spontaneous perineal tears were similar between those treated with warm compresses and perineal massage, and those treated with perineal massage alone: 44.7% vs. 45.6%, p=0.843 (Table 3). A sub-analysis according to the degree of perineal tears showed similar proportions in the two groups: first-degree tear, 22.8% vs. 21.4%, p=0.722; second-degree tear, 21.4% vs. 23.8%, p=0.566; and third-degree tear, 0.5% for both, p=1.000. Also similar were the rates of episiotomies: 19.4% in each group; and the rates of intact perineum: 45.1% vs. 41.7% (p=0.920). Among women with episiotomy, perineal tears requiring suturing occurred in 11/40 (27.5%) recipients of warm compresses and perineal massage, compared to 12/40 (30%) recipients of perineal massage alone (p=0.804). In a per-protocol analysis for the primary outcome, the rates of perineal tears requiring suturing were 83/173 (47.9%) in the warm compresses and perineal massage group, and 91/195 (46.7%) in the perineal massage alone group, p=0.801.

Table 3 shows the results of perineal lacerations according to parity, for the warm compresses and perineal massage group, and for the perineal massage alone group. For the respective groups, the rates of perineal lacerations (all degrees) were 51.8% and 56.6% in first deliveries, p=0.480. For the respective groups, these comprised first-degree tears in 22.7% and 20.8%, p=0.725; and second-degree tears in 28.2% and 34.9%, p=0.515. One third-degree tear occurred in each group.

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The proportions with second-degree perineal tear and episiotomies, according to parity, were also similar in the two groups.

In both groups, none of the participants who had received the allocated intervention (per-protocol) dropped out voluntarily. In the warm compresses group, 172 (97.7%) of the women reported that the temperature of compresses was acceptable.

In the warm compresses and perineal massage vs. perineal massage alone group, there were no differences in postpartum outcomes, including retained placenta: 1.5% vs. 2.4%, p=0.723; manual revision of the uterus, 4.3% vs. 6.3%, p=0.511; and urinary retention, 0% vs. 1%, p=0.244. Also similar were neonatal birthweight (grams): 3323 $\pm$ 426 vs. 3347 $\pm$ 424.0, p=0.570. None of the neonates had Apgar 5 minutes <7.

Midwives' survey (n=20)

After completion of the study, 12 (60.0%) midwives reported that they would prefer to use warm compresses as the standard of care, while the remaining 8 (40.0%) reported that they would prefer to use almond oil alone. Seventeen midwives (85.0%) reported that the intervention of warm compresses was time consuming. All the midwives reported that the women in the intervention group whose second-stage duration was longer than 10 minutes were treated with warm compresses for at least 10 minutes and less than 30 minutes. All the midwives reported that they kept the water temperature for the compresses in the range of 45-59°C.

Comment

Principal findings

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In this randomized controlled trial of 412 women, the use of warm compresses and perineal massage compared to perineal massage alone during the second stage of labor was associated with similar rates of intact perineum, perineal trauma requiring suturing, and episiotomy. Rates of perineal tears according to the intervention were also similar in a sub-analysis according to parity.

The vast majority of women (97.7%) in the warm compresses group who received the allocated intervention reported that the temperature of compresses was acceptable. Most midwives (60%) reported that they would prefer to use warm compresses for perineal protection as the standard of care. However, most (75%) also reported that preparing the warm compresses was time consuming.

Results in the context of what is known

In this randomized controlled trial, we evaluated the efficacy of warm compresses during the second stage of labor. The application of heat has been shown to result in positive therapeutic effects leading to dilatation of blood vessels and increased blood flow.[19] This can reduce the level of nociceptive stimulation and increase the clearance of inflammatory mediators.[19] During the second stage of labor, we did not find an added benefit of the use of warm compresses, compared to perineal message alone, also not for nulliparous women specifically. Similarly, in a randomized controlled trial by Dahlen et al., [14] the application of perineal warm packs in the late second stage was not found to reduce the likelihood of perineal suturing in nulliparous women. In that study, the temperature of the water for the warm compresses was equal to that used in our study (45-59°C). However, we pre-determined the control group, as uniformly receiving perineal message with almond oil. Notably, in a recently published study, among women treated with perineal massage and warm compresses, compared to a hands-on technique, the incidence of

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intact perineum was higher, and the incidences of second-degree tear, episiotomy, and OASIS were lower.[20]

Importantly, all the participants in our study received perineal massage with oil during active pushing; massage with oil is thought to increase the elasticity in the perineum.[21] The use of perineal massaging with oil has been shown to reduce occurrences of severe perineal trauma and to increase the likelihood of intact perinium.[20,22] We used almond oil as a lubricant for massaging the perineum, as this has been our standard of care for several years. However, the type of oil used during the second stage of labor for prevention of perineal tears was found to have no effect on the perineal integrity.[22]

Our rate of OASIS (0.5%) falls within the reported range of 0.1-0.6% in Israel, of all vaginal births.[23] This is considerably lower than the rates reported in the United Kingdom (3%),[24,25] and the United States (3%)[26] and is similar to rates reported in Spain (0.91%),[27] Croatia (0.34%),[28] and Finland (0.8%).[29] . Our relatively lower rate of OASIS may be related to the avoidance of midline episiotomies and the rarity of forceps deliveries; none were performed in our participants. However, underdiagnosis of OASIS cannot be ruled out.[23]

Importantly, none of our participants dropped out voluntarily in either group. Although in retrospect, 4 (2.3%) women reported that the temperature of the compresses was slightly above their tolerance level, none asked to stop the intervention. Although we did not examine pain scores during childbirth, lower pain scores at birth were previously reported among women with warm compresses than among women who received standard of care treatment.[14]

Clinical implications

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Preventing severe perineal trauma is important, to reduce blood loss and perineal pain; and also to reduce urinary, bowel, and sexual dysfunction. Based on the study results, and to facilitate perineal protection, our standard care of almond oil massage during the second stage of labor seems sufficient. This is because the warm compresses did not demonstrate added benefit, and most of the midwives reported that preparing them was time consuming.

Research implications

As all the trial's participants received perineal massage with almond oil, future studies could compare the use of perineal massage with oil vs. no perineal massage. Future studies should also focus on maternal satisfaction and attitudes regarding techniques for perineal protection.

Strengths and limitations

A strength of our study is the relatively large sample size, the strict pre-specified protocol of the use of warm compresses, the allocation concealment, and the blinding of the senior midwives who assessed the perineum. A novelty of the study is the inclusion of the midwives' survey. As the intervention is usually applied by a midwife, it was important for us to review their attitudes towards the perineal protection approach.

This study also has some limitations. The performance of the intervention and assessment of the perinium for suturing by several midwives may have affected the study's internal validity. Additionally, the relatively high episiotomy rate (19.4%), compared to other regions,[30,31] may reflect differences in institutional practices. We did not address the potential impact of episiotomies on post-delivery complications such as pain, and healing time, which could influence maternal recovery. We also did not record the length of time the warm packs were

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applied to the perineum. Furthermore, the study was underpowered to detect a difference in OASIS rates.

Conclusions

Among women treated during the second stage of labor with warm compresses and perineal massage, compared to perineal massage alone, spontaneous perineal tears and episiotomies were similar.

Acknowledgements

None

Details of Ethics Approval

This trial was approved by the Galilee Medical Center Institutional Review Board (reference number (NHR-0198-22) in March 2023. The work described was carried out following The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Written informed consent was obtained from all the women prior to their participation.

Data Sharing Statement

Reasonable requests for data that do not identify patients will be addressed by the corresponding author.

Contribution to Authorship

R.A.S, A.B, S.N.B, I,S, R.K, N.G., and L.L were involved in conceiving, planning, carrying out, analyzing, and writing the work. S.M.M was involved in conceiving, analyzing, and writing and revising the work.

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Table 1: Characteristics of the study groups

	Warm compresses and perineal massage (n=206)	Perineal massage alone (n=206)	P-value
Age, years	28.3 ± 4.7	28.5 ± 4.8	0.724
BMI, kg/m2	29.5 ± 4.8	29.8 ± 5.0	0.539
Diabetes	19 (10.6)	15 (8.3)	0.476
Gravidity	2 (1-6)	2 (1-8)	0.659
Parity			
First delivery	110 (53.4)	106 (51.5)	0.960
Second delivery	53 (25.7)	63 (30.5)	
Third delivery	32 (15.5)	27 (13.1)	
Fourth delivery	10 (4.85)	8 (3.9)	
Fifth delivery	1 (0.5)	2 (1.0)	
Previous cesarean delivery	96 (46.6)	100 (48.5)	0.693
Previous vacuum assisted delivery	39 (18.9)	30 (14.6)	0.235

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Pregnancy week	39.8 ± 1.2	39.9 ± 1.2	0.970

Continuous data are reported as either mean (standard deviation) or median (range). Categorial data are reported as number (%)

BMI- body mass index

Table 2: Obstetrical variables during labor and birth according to the study groups.

	Warm compresses and perineal massage (n=206)	Perineal massage alone (n=206)	P value
Labor			
Epidural analgesia	174 (84.5)	174 (84.5)	0.861
Induction of labor	115 (55.8)	98 (47.6)	0.091
Oxytocin use during first stage of labor	91 (44.2)	93 (45.1)	0.824
Oxytocin during second stage of labor	89 (43.2)	90 (43.7)	0.920
Second stage of labor duration (hours)	1.3 (0.2-4)	1.2 (0.3-4)	0.821
Delivery mode			
Normal vaginal delivery	174 (84.4)	173 (83.9)	0.892
Vacuum-assisted	15 (7.3)	22 (10.7)	0.301
Cesarean section	17 (8.3)	11 (5.3)	0.328
Postpartum outcomes			
Retained placenta	3 (1.5)	5 (2.4)	0.723

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Manual revision of the uterus	9 (4.3)	13 (6.3)	0.511
Urinary retention	0 (0)	2 (1)	0.244
Neonatal outcomes			
Birth weight, grams	3323.9 ± 426	3347.7 ± 424.0	0.570
Apgar 5 minutes <7	0 (0)	0 (0)	1.000

Continuous data is reported as either mean (standard deviation) or median (range). Categorial data is reported as number (%)

Table 3: Perineal lacerations according to the study groups.

	Warm compresses and perineal massage (n=206)	Perineal massage alone (n=206)	P value
Total spontaneous perineal tears rates	92 (44.7)	94 (45.6)	0.843
First-degree/Total participants	47/206 (22.8)	44/206 (21.4)	0.722
First degree/Spontaneous perineal tears	47/92 (51.1)	44/94 (46.8)	
Second-degree/Total participants	44/206 (21.4)	49/206 (23.8)	0.566
First degree/Spontaneous perineal tears	44/92 (47.8)	49/94 (52.1)	
Third-degree/Total participants	1/206 (0.5)	1/206 (0.5)	1.000
First degree/Spontaneous perineal tears	1/92 (1.1)	1/94 (1.1)	

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Fourth-degree/Total participants	0/206 (0)	0/206 (0)	1.000
First degree/Spontaneous perineal tears	0/92 (0)	0/94 (0)	
Episiotomy/Total participants	40 (19.4)	40 (19.4)	1.000
Intact perineum/Total participants	85 (45.1)	84 (41.7)	0.920
PERINEAL LACERATION ACCORDING TO PARITY			
Perineal laceration (all degrees)			
First delivery	57/110 (51.8)	60/106 (56.6)	0.480
Second delivery	23/53 (43.4)	22/63 (34.9)	0.350
Third – fifth delivery	12/43 (27.9)	12/37 (32.4)	0.659
First degree			
First delivery	25/110 (22.7)	22/106 (20.8)	0.725
Second delivery	14/53 (26.4)	14/63 (22.2)	0.599
Third – fifth delivery	8/43 (18.6)	8/37 (21.6)	0.736
Second degree			
First delivery	31/110 (28.2)	37/106 (34.9)	0.287
Second delivery	9/53 (17.0)	8/63 (12.7)	0.515
Third – fifth delivery	4/43 (9.3)	4/37 (10.8)	0.822
Episiotomies			
First delivery	36/110 (32.7)	33/106 (31.1)	0.884
Second delivery	2/53 (3.8)	7/63 (11.1)	0.301
Third – fifth delivery	2/43 (4.7)	0/37 (0)	0.495

The data are reported as number (%)

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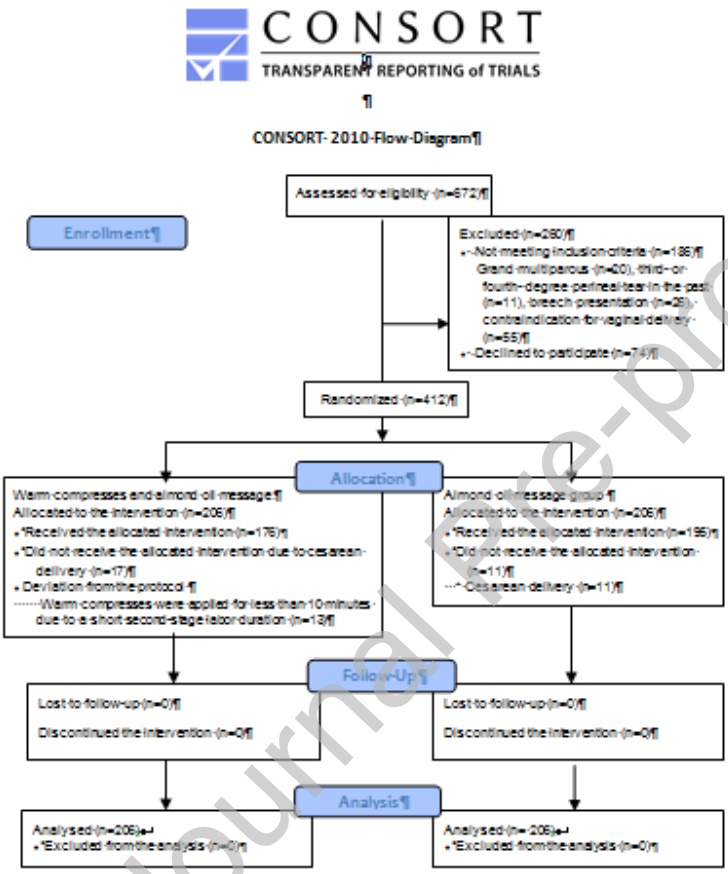
Figure legends

Figure 1. Consort flowchart of the study population



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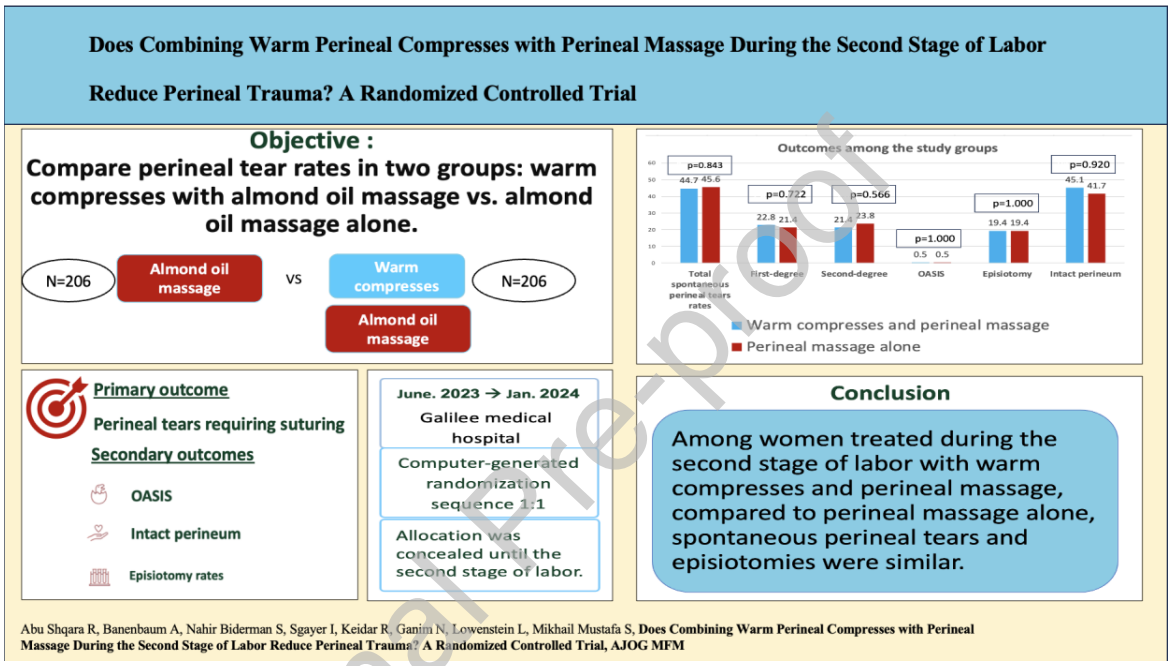
Graphical abstract



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