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The Effect of Designed Protocol of Care on the Outcomes of Postpartum Perineal Trauma: a Randomized Controlled Trial (RCT)

By

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Dissertation proposal

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Introduction

Worldwide, more than 85% of women giving a normal birth experience perineal trauma spontaneous perineal tear, episiotomy or both. The incidence of spontaneous tears decreases in subsequent births, from 90.4% of first-birth women to 68.8% for multipara giving normal birth. Perineal trauma is defined as any injury to the perineum during childbirth which occurs spontaneously or intentionally through a surgical incision (episiotomy). Anterior perineal trauma includes injury to the labia, anterior vaginal wall, urethra and clitoris, and is usually associated with less mild morbidity rate while posterior perineal trauma includes injury to the posterior vaginal wall, perineal muscles and anal sphincter. During birth, the majority of the perineum traumas are on the posterior vaginal wall extending to the anus (Sotunsa, Ari, Leslie, & Ari, 2019).

Spontaneous perineal trauma (tears) during normal birth is classified into four degrees. In the first degree, only the skin of the perineum is injured, the muscles are intact. The second degree of perineal trauma involves tearing of the muscles of the perineum without affecting the anal sphincter. The third degree of injury involves tearing of the anal sphincter. While, in the fourth degree of perineum tear, there is a complex rupture of the anal sphincter which includes the external and the internal anal sphincter and the anal epithelium (East, Dorward, Whale, & Liu, 2020).

Perineal trauma may lead to short and long-term physical, physiological, social and psychological complications. In the immediate postpartum period the complications include pain, swelling, redness in the area of the surgical wound, dehiscence, hematoma, trauma of the urethra and the anal sphincter. Long-term complications include chronic infections, dyspareunia, anorectal dysfunction, faecal incontinence, urinary incontinence or retention.

Also, 23% – 43% of women continue to experience pain and discomfort in 10 – 12

postpartum days and 7% – 10% of women have long-term pain 3 – 18 months after birth, 23% of women experience surface dyspareunia in the 3rd month, 3% - 10% report of faecal incontinence, and 24% report of urinary problems (Ibrahim, Elgzar, & Hassan, 2017 & Vasileva, Strashilov, &Yordanov, 2019).

Moreover, social and psychological complications associated with perineal trauma affect the woman's ability to care for her new baby and cope with the daily tasks of motherhood and they have a significant impact on daily activities as walking, defecation, urination, self-care, breastfeeding, interfere with the women's sleep, rest, and appetite. These difficulties can cooperate towards negative, painful delivery experiences and may cause mental disorders as postpartum depression. They also change the mother's attitude towards her neonate and affect her sexual function (Mohamed, &El-Nagger, 2017).

In addition, delayed healing of postpartum perineal sutures is a significant health problem that can cause morbidity such as pathologic complication like hematoma, inflammation or even infection. So, acceleration of perineal wound healing during the puerperium is desirable to avoid postpartum women from the dangers of infection or physiological complaints, particular observations and treatments are needed to ensure that the area heals quickly and easily (Magoga et al, 2019).

Several pharmacological and non-pharmacological treatments have been investigated for healing of perineal trauma after vaginal delivery. Traditionally, oral analgesics (non steroidal anti inflammatory agents), local anesthetics (cold and warm sitz baths, lidocaine gel 2%) are used in postpartum care to alleviate perineal trauma. Currently several non-pharmacological therapies are of great importance for the treatment of perineal trauma since they do not cause systemic side effects, such as drowsiness, irritability and changes in the

composition of breast milk (Webb et al, 2019).

Non pharmacological interventions include early cold therapy (ice gel pad or ice pack) application, later performance of pelvic floor exercises (Kegel exercises) and application of perineal warm compresses or warm sitz bath. These interventions should be started immediately after delivery at early postpartum period by applying cold therapy to perineal trauma such as ice gel pad as it helps to reduce inflammation, the production of cellular debris, edema, hematoma development, spasticity, muscle spindle activity, and nerve transmissions, it also increases the release of endorphins and stimulates the repair process. The application of ice gel pad should be continued till 24 hours after delivery to decrease perineal pain (Filipinni et al, 2019).

Derya, Ergul, Senol, & Aslan, (2017) in their study about the effect of cold application to the perineum on pain relief after vaginal birth reported that the application of cold gel pad to the perineum relieved perineal pain, increased postpartum comfort and decreased the pain felt by the women during the recovery and daily activities especially urination, infant care and breastfeeding. This is consistent with the study that was conducted by El-Saidy, Abo Shady, & Soliman, (2018) to test the effect of applying crushed ice gel pads on episiotomy pain and wound healing among postpartum primiparous women and reported that women who applied the crushed ice gel pad on episiotomy during early postpartum period experienced a lower level of episiotomy pain, had good episiotomy wound healing and had better ability to perform daily living activities during the posttest than the control group.

Another non pharmacological intervention that should be started from 6 to 12 hours after birth when the patient feels ready is pelvic floor exercises (Kegel exercises). Many researchers have emphasized the potency of these exercises during the time of postpartum.

Advantages of these exercises are that they promote the healing of any tears or episiotomies by increasing blood and oxygen flow to the tissue, facilitate flexibility of the tissue, reduce edema, relieve the pressure on the incision and the surrounding tissue and might help with pain or tenderness due to scarring. They also help to regain bladder control and strengthen pelvic floor muscles. These exercises should be performed till one week postpartum (Mohammed, Mahmoud, & Abd Elhafeez, 2018; Farrag, Eswi, &Badran, 2016).

Khusniyati, &Purwati, (2018) in their study reported that Kegel exercises are recommended from six hours postpartum and till one week to help accelerate wound healing, this is confirmed by other study that was conducted to examine the effect of postnatal Kegel exercises on episiotomy pain and wound healing and revealed that practicing postnatal pelvic floor exercises (Kegel exercises) had a significant effect in decreasing perineal pain, accelerating healing of the incision and decreaseing postpartum pain associated with movement ,defecation and urination (Farrag, Eswi, & Badran, 2016). In addition, after 48 hours of birth and till one week warm compresses for perineal trauma should be done as it helps in producing vasodilatation, improving circulation to perineal area, improving tissue repair and wound healing, and decreasing incidence of wound infection (Khosla, & Pratibha, 2017).

Un fortunately, there is no available guidelines for management of postpartum perineal trauma even the guidelines developed by Royal College of Obstetricians and Gynecologists (RCOG, 2015) focused only on the management of third and fourth degree perineal tear. Moreover, the Cochrane systematic reviews reported that interventions for the management of postpartum perineal trauma are of low quality evidence and the reported findings are still conflicting and recommend that further randomized controlled trials are needed to support these interventions (RCOG, 2015& East, Dorward, Whale, &Liu, 2020).

In addition, most of the studies have been conducted to test only one intervention or compare between two interventions for treatment of perineal trauma but no study tested the impact of a designed protocol of care which starts from immediate postpartum and continues throughout the first week where a combination of therapies is implemented for treating the immediate and sustained perineal trauma. Therefore, the aim of this study is to test the impact of a designed protocol of care that combines several interventions such as perineal ice-gel pad application, performance of pelvic floor exercises (Kegel exercises) and perineal warm compresses application on the immediate and later outcomes of postpartum perineal trauma.

Significance of the study

From clinical experience, it was observed that many postpartum women with perineal trauma experience several short and long-term physical, physiological, social and psychological postpartum complications such as severe pain, delayed healing of the wound, infection and dyspareunia which may affect the women resumption of function at postpartum period and their future choice of the mode of childbirth. At the same time, there is a lack of statistical documentation on the magnitude of this problem. As well as, there are considerable gaps with implementation of evidence to support management of perineal trauma at postpartum period.

In this context, serious actions should be taken to accelerate the perineal trauma healing and relieve the perineal pain as possible. Most important of these actions is immediate postpartum perineal ice gel pad application, later performance of pelvic floor exercises (Kegel exercises) and perineal warm compresses. These interventions have a lot of advantages as they are not costing, appropriate to postpartum women in many situations, and

safe. Moreover, these interventions promote, accelerate the healing, decrease the perineal pain and facilitate restoration of muscle tone (Farrag, Eswi, & Badran, 2016).

In Egypt, there is a scarce of RCT studies that was conducted in this respect and they have contradicting results. Moreover, almost all these studies were conducted to test only one intervention or compare between two interventions for treatment of perineal trauma but no study tested the impact of a designed protocol of care which starts from immediate postpartum and continues throughout the first week where a combination of therapies is implemented. So, the results of this study will add to the quality of evidence on the effectiveness of postpartum interventions for improving the recovery of postpartum perineal trauma. This protocol may be used as guidelines to be implemented for better quality of patient care.

Aim of the study

The aim of the current study is to test the effect of designed protocol of care on the outcomes of postpartum perineal trauma.

Outcome measures

- **Primary outcomes**: Severity of perineal pain, delayed perineal trauma healing.
- **Secondary outcomes**: Occurrence of infection, postpartum difficulty with turning/rolling in bed, getting out of bed, sitting, walking, defecation and urination.

Research Hypotheses

To fulfill the aim of this study the following research hypothesis is formulated:

H1: Post partum women with perineal trauma who will receive the designed protocol of care will have better perineal trauma outcomes than those who will receive the routine hospital care.

Sub-hypothesis 1: Postpartum women with perineal trauma who will receive the designed protocol of care will show better perineal trauma healing than those who will receive the routine hospital care.

Sub-hypothesis 2: Postpartum women with perineal trauma who will receive the designed protocol of care will have less perineal pain score than those who will receive the routine hospital care.

Conceptual Framework

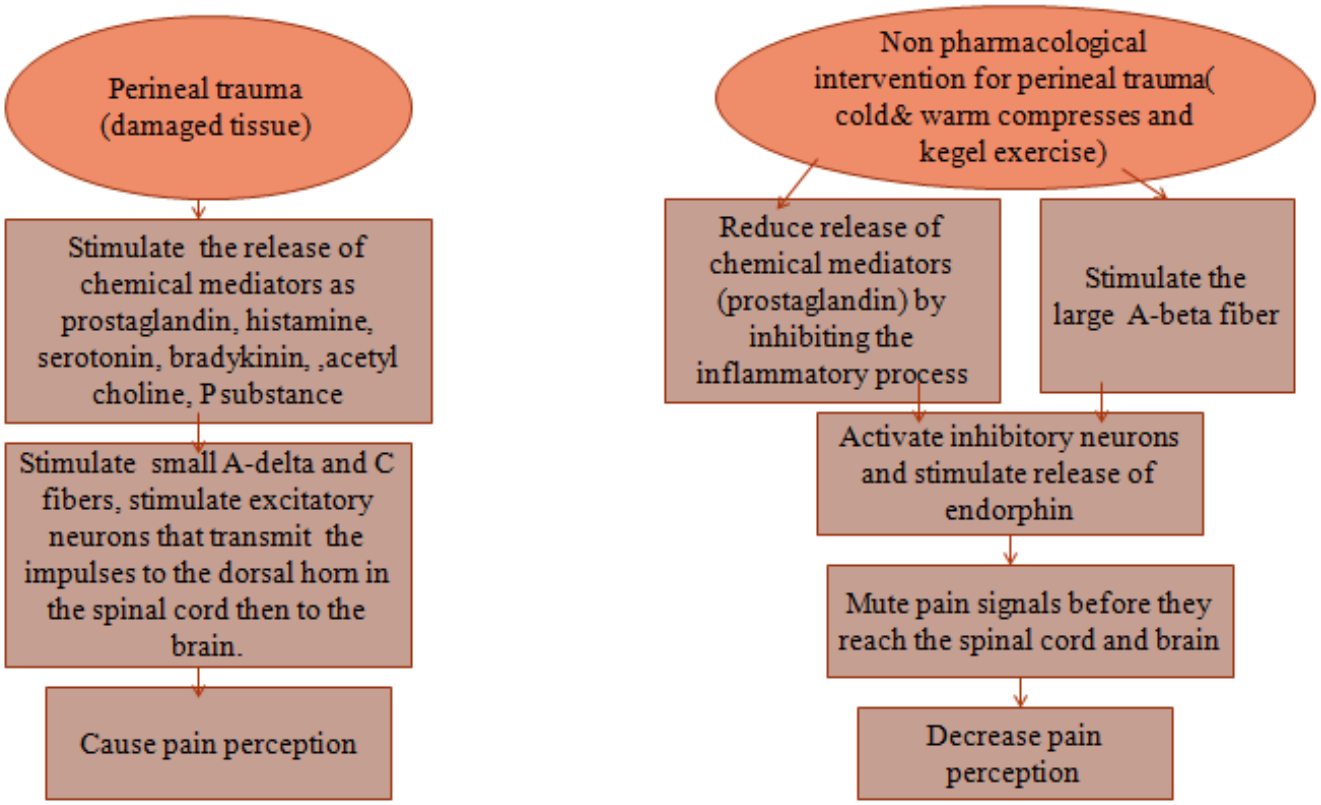
The current study will adopt its concepts from the Gate control theory as well as concepts derived from the physiological advantages of immediate postpartum perineal ice gel pad application, late postpartum performance of pelvic floor exercises (Kegel exercises) and application of perineal warm compresses.

The Gate Control theory proposed by Melzak and Walls (1965) has provided a powerful theoretical basis for management of pain associated with perineal trauma. Pain associated with perineal trauma is caused by the presence of a mechanical stimulus due to tissue damage so it will stimulate chemical mediators as prostaglandin, histamine, serotonin, bradykinin, acetyl choline, P substance, and leukotriene. These substances will be induced by nociceptors and transmitted by A-delta and C fibers to the posterior corn in the spinal cord where afferent nerves will convey the perception of pain to the brain which increases pain sensitivity.

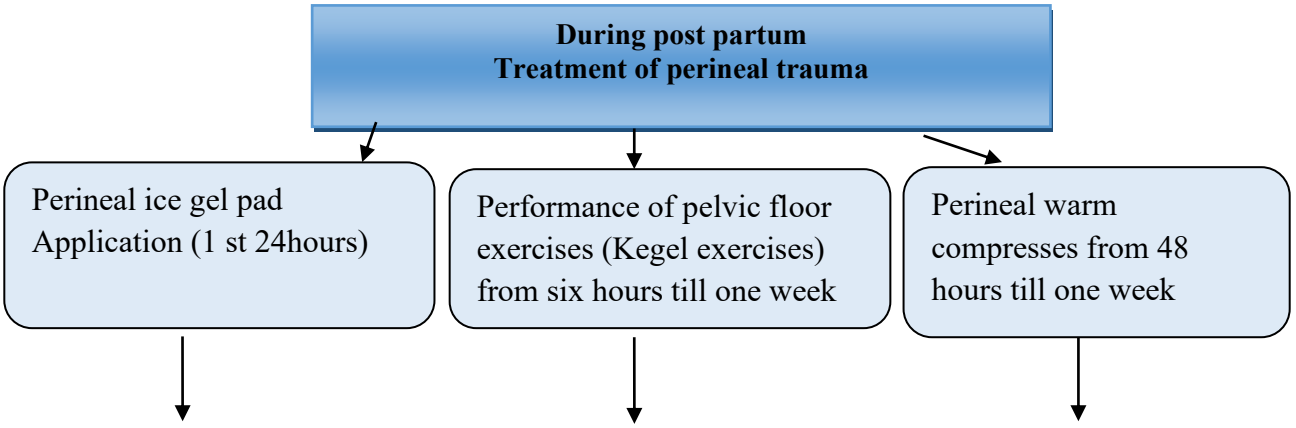
In the current study application of non pharmacological interventions for perineal trauma (cold compresses, warm compresses and Kegel exercises) can reduce the release of chemical mediators by inhibition of inflammatory process and stimulation of A-beta nerve fibers which activate inhibitory neurons and increase endorphin release. Thereby they reduce

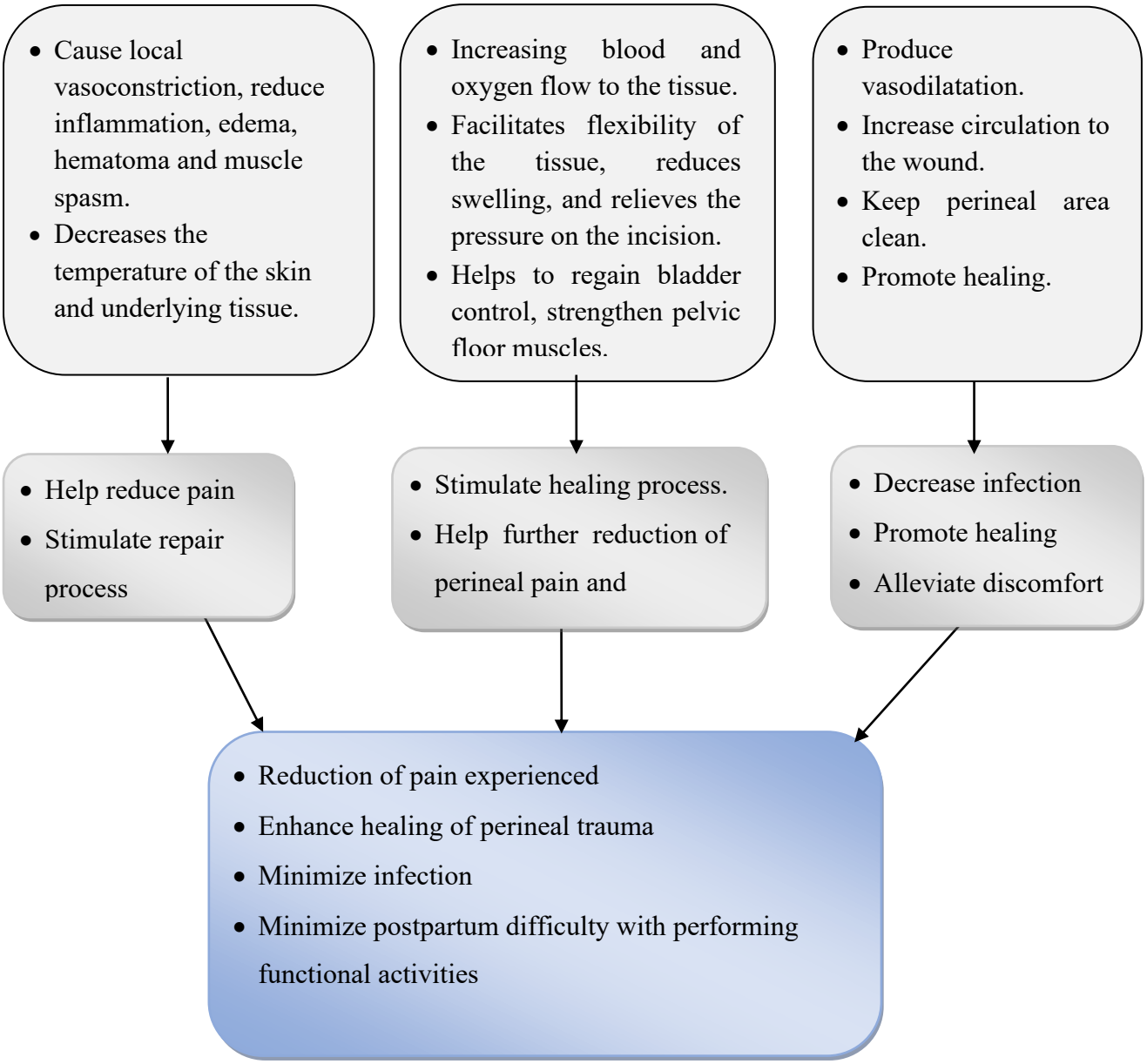
the transmission of pain impulses through A-delta fibers and C nerve fibers (closing the gate) in the spinal cord and modulate pain transmission so that pain perception decreases (Setyawati, Khasanah, & Suyanto, 2019).

The following figure represents the Gate Control theory and the role of non pharmacological interventions in closing the gate and reducing perception of pain associated with perineal trauma (figure 1)



Also, there are several theoretical physiological advantages for each of these interventions as follow (figure 2)





Operational definition of terms

1- A designed protocol of care for postpartum perineal trauma: It is a protocol developed by the investigator based on systematic reviewed studies and randomized controlled trials. The protocol entails a combination of 3 evidence-based therapies for postpartum perineal trauma; application of perineal ice gel pad, pelvic floor exercises (Kegel exercises) and perineal warm compresses applied in steps starting from immediate postpartum and continues throughout the first week in order to relief immediate and sustained perineal trauma.

2- Perineal trauma: Is any injury to the perineum during childbirth which occurs spontaneously (1st or second degree tear) or intentionally through a surgical incision (episiotomy).

3- Postpartum perineal trauma outcomes: It include the following outcomes:

a- Postpartum perineal pain: It will be assessed by Visual Analogue Scale for pain intensity (VAS).

b- Postpartum perineal trauma healing: It will be assessed by standardized REEDA scale.

c- Postpartum perineal trauma infection: It will be assessed by standardized REEDA scale.

d- Postpartum difficulty with performing functional activities: It refers to postpartum difficulty with turning/ rolling in bed, getting out of bed, sitting, walking, defecation and urination. It will be assessed by Visual Analogue Scale (VAS) for rating functional activities.

Subjects and Methods

Research Design

A randomized controlled trial will be used to fulfill the aim of proposed study. The randomized control trial (RCT) is a trial in which subjects are randomly assigned to one of two groups: one (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or control) receiving an alternative treatment (Spieth et al, 2016).

Sample

A total of (100) postpartum women with normal spontaneous vaginal delivery and having postpartum perineal trauma will be recruited for this study and randomly assigned to either study group (50) women or control group (50) women. Inclusion criteria will be according to the following; primiparous or 2nd. multiparaous women with postpartum perineal trauma either episiotomy or perineal tear (first and second degree only), age not exceeding 40 years, , body mass index (BMI)within normal 18.5-24.9 kg/m2 or overweight 25-29.9 kg/m2, free from any high risk condition affecting perineal trauma healing (e.g., diabetes mellitus or obesity), over 37 week gestation and not having any complications during labor and delivery(e.g., abnormal presentation, obstructed labor or delivered with instrument), not having any immediate postnatal complications such as postpartum hemorrhage.

The sample size was calculated using a G-power version 3.1.1 for power analysis. A Power of .95 (β = 1-.95 = .05) at alpha .05 (one-sided) was used as the significance level, and effect size= (80%).

Setting

The study will be conducted at postpartum ward of emergency department for labor and delivery in Obstetrics and Gynecology Hospital at Kasr El Aini University Hospital affiliated to Cairo University. Postpartum ward provides care for postpartum women with normal vaginal delivery and post abortion women. The capacity of the ward is 20 beds which provide care for approximately (3000) normal deliveries annually according to local statistics for the year 2020 (Kasr El Aini University Hospital Statistics, 2020).

Tools for Data collection

Required data will be collected by using 5 tools: A) Structured interview schedule; B) Visual Analogue Scale for pain intensity(VAS); C) Visual Analogue Scale (VAS) for rating functional activities; D) Standardized REEDA scale; and E) Postpartum follow up sheet.

Tool (A) Structured Interview Schedule: This tool will be designed by the investigator and will include two sections:

- The first section**:** Will include four items to assess participants' demographic data such as (age, BMI, educational level, occupation, residence).
- The second section**:** Will include four items to assess the participants current obstetric history (e.g., obstetric code), type of perineal trauma after delivery (episiotomy, or tears) and degree of perineal tear (1st or 2nd degree tear).

Tool (B) Visual Analogue Scale for Pain Intensity (VAS): It is a standardized linear scale developed by Freyd et al., (1923). It is a self-reported 10 cm horizontal line which represents the subjective estimation of pain intensity. It comprises 0-10-point numerical scale, the two opposite ends representing no pain to severe pain as follows: no pain (0), mild pain (< 4), moderate pain (4 - <8), and sever pain (8-10). This tool is valid and reliable, test-retest reliability coefficient of the VAS has been demonstrated in several studies as r =0.62 (Derya, Ergul, Senol, &Aslan, 2017).

Tool (C) Visual Analogue Scale (VAS) for rating functional activities: This tool is adopted from Karakaya et al.,(2012), the difficulty with performing functional activities as (turning/ rolling in bed, getting out of bed, walking, sitting, defecation and urination) will be evaluated by using horizontal 10 cm visual analogue scale for each functional activity, the scale will be applied six times to measure the difficulty with each activity (VAS will be

marked by the women). The scoring for each activity will be as follows: no difficulty (0), mild difficulty (< 4), moderate difficulty (4 - <8), and sever difficulty (8-10). The total score will be recorded (0-60 point), the lowest score (0) indicate no difficulties and the maximum score (60) indicate maximum difficulty. The total score will be interpreted as the following no difficulties (0), Mild difficulties (1 - < 24), Moderate difficulties (24 - < 48), Sever difficulties (48-60). This tool is valid and reliable, test-retest reliability coefficient has been demonstrated as r =0.82 (Karakaya et al., 2012).

Tool (D) Standardized REEDA Scale: This tool is adopted from Davidson (1974), REEDA scale will be used to assess condition of perineal trauma. REEDA scale is a descriptive scale having a four point categorical score (0-3) that measures five components associated with the healing process of perineal trauma. This includes: Redness, Edema, Ecchymosis, Discharge and Approximation of sutures. The total score ranged from 0 to 15 and categorized as the following; 0 to 2 cm good wound healing with no infection, 3 to 5 cm moderate wound healing, 6 to 8 cm mild wound healing, and 9 to 15 cm poor wound healing with infection . This tool is valid and reliable, test-retest reliability coefficient of the REEDA scale has been demonstrated as r =0.70 (Farrag, Eswi, & Badran, 2016).

Tool (E) Postpartum Follow up Sheet: This tool will be designed by the researcher after reviewing the related literature and will be revised by experts in gynecology and maternity nursing department and will include items to assess mother compliance with ice gel pad application through the first 24 hours and assess women's need for additional analgesia. Also, assess the women compliance with Kegel exercise performance from six hours postpartum till one week and compliance with the application of warm compresses per day from 48 hours postpartum till one week.

A designed Protocol of Care for Postpartum Perineal Trauma: It is a protocol developed by the investigator based on systematic reviewed studies done by (East; Begg; Henshall; Marchant; &Wallace (2009); Shahrahmani et al,(2016); East; Dorward; Whale;&Liu, (2020); Kridsana; Kunyanut; &Thitiporn (2020); and several studies as a quasi experimental time series study by Farrag, Eswi, &Badran,(2016); a randomized controlled trial by Derya, Ergul, Senol, &Aslan, (2017); and a quasi experimental study by Khosla &Pratibha, (2017); a quasi experimental study by Yuliani, Rizka,(2019).

The protocol entails a combination of evidence-based therapies for postpartum perineal trauma that is applied in steps starting from immediate postpartum and continues throughout the first week in order to relieve immediate and sustained perineal trauma.

Description of the protocol:

1. Application of perineal ice gel pad: Immediately postpartum (within 30 minutes to one hour) and through the first 24 hours postpartum to help reduce perineal pain, edema and stimulate repair process.
2. Postpartum performance of pelvic floor exercises (Kegel exercises): After six hours till one week postpartum to accelerate healing of perineal trauma and for further reduction of sustained perineal pain.
3. Postpartum perineal warm compresses: After 48 hours till one week postpartum to promote better healing of perineal trauma, prevent complications, prevent infection and further reduction of sustained perineal pain.

Ethical consideration

The primary official permission will be obtained from the research ethics committee of faculty of nursing, Cairo University to approve the tools and the study. Also**,** the investigator will explain to the women the purpose and nature of the study and its importance. In addition, informed written consents will be obtained from women who were willing to participate in the study after ensuring that their participation is voluntary and the trial posed no risk or hazards on them. As well, each woman will be assured that she has the right to withdraw of the trial at any time without any effect on her care. Then, confidentiality will be assured through coding of data by the investigator and keeping the data in a secret place.

Validity and reliability

Un standardized tools were submitted to 3 experts in the field of maternity nursing to test content validity, clarity of sentences and an appropriateness of content. Modifications were carried out according to the expert judgment.

Procedure

First, the primary official permission will be obtained from the research ethics committee of faculty of nursing, Cairo University to approve the tools and the study. An official permission will be granted from the hospital administrative personnel in the recommended setting to collect the data. Then, data collection will be carried out through five steps in each group: Recruitment & randomization; interviewing; initial assessment; intervention; follow up and monitoring.

Recruitment and Randomization of sample: Women who will meet the eligibility criteria will be recruited from a written list done by the investigator every day. Those plotted in the odd number will be selected until completion of the sample. Random assignment of the subjects into two groups will be done through an opaque sealed envelope reflecting the type of each group, and then the eligible women will be asked to choose an envelope to

determine their groups.

Interviewing: During interview the aim of study will be explained to the women in both groups (study & control group) to gain their acceptance to participate in the study then data related to socio-demographic status and obstetric history will be collected from both groups

Initial Assessment: Initial assessment for women in both groups (study & control group) will be carried out in relation to body mass index (BMI), type of perineal trauma after delivery (episiotomy, or tears), degree of perineal tear (1st or 2nd degree tear), and assessment of perineal trauma condition will be done using standardized REEDA scale . Also, women will be asked to indicate the degree of perineal pain using Visual Analogue Scale for pain intensity (VAS).This assessment will take 15 minutes for each woman.

Intervention:

Intervention for the study group: For the study group the intervention will be according to a designed protocol of care that entails; 1) Application of ice gel pad on perineal trauma for the first 24 hours post partum; 2) Performance of pelvic floor exercises (Kegel exercises) from six hours till one week postpartum; 3) Application of warm compresses after 48 hours and through the first week postpartum. The investigator will perform demonstration and then redemonstration by the women on each intervention will be done. A designed booklet (developed previously) that explains each intervention will be given to each woman.

Immediately after delivery (within 30 minutes to one hour after delivery), an ice gel pad will be applied to perineal trauma. It will be available in an individual package(every woman will alternate between two ice gel pads); each gel pad will have fixed standardized diameter (an approximately 5 cm width, 23 cm length, and 1.5 cm thickness) and approved by Egyptian ministry of health. It will be kept in the freezer for 45–60 minutes and

will be removed when frozen. Then, it will be wrapped in a sterile pad and applied to cover the perineum and anal region. The pad will be compatible with the anatomical structure of the perineum.

The investigator will provide a clear and concise information through oral and written instructions about the following; 1) The ice gel pad`s purpose, benefits, anticipated effects and how to apply it, 2) Apply the ice gel pad on perineum after birth within 30 minutes to an hour, 3) Instruct the women to apply the ice gel pad for about 20 minutes every two hours during the first 24 hours postpartum only, 4) The perineal pad should be changed regularly every two hours to prevent infection. This session will take 30-40 minutes for each woman. Then, six hours after the ice gel pad application, assessment of experienced perineal pain will be done using Visual Analogue Scale for pain intensity (VAS) and assessment of perineal trauma condition will be done using standardized REEDA scale.

Also, six hours after birth women will receive instructions to practice pelvic floor exercises (Kegel exercises) and will be asked to perform these exercises from 6 hours postpartum and continue at home till one week. Before applying the technique, the investigator will teach the women how to recognize the accurate muscle, whereby she imagines holding passing gases or trying to stop the flow of urine midstream at the same time. The women will be taught to insert a clean finger into the vagina before practicing the exercises and if the women feeling pressure around her finger, she is on the right track, the mother also will be instructed to place a hand on her belly during the exercises to make sure that it is kept relaxed.

The investigator will perform vaginal examination while the woman is doing the pelvic floor exercises (Kegel exercises) to ensure correct use of muscles. The investigator

will instruct the women to continue contracting the muscles for about 5 seconds and then to loosen them for 5 seconds and repeat it for five times each set, perform at least five sets per day (total 25 contractions each day will be performed). The mother will be instructed to perform these five sets of exercises at the rest period between other intervention (application of cold compresses for the first 24 hours and application of warm compresses after 48 hours) with at least two hours rest between each set.

In addition, women will be instructed to apply warm compresses on perineal trauma 48 hours postpartum +at home. This will be done by using a clean pad soaked in warm water and squeezed to remove excess water then placed gently on the perineum, the warm compresses will be applied for 15 minutes three times per day (every 8 hours), and water in the bowl will be replaced with every application. Women will be asked to apply warm compresses on perineal trauma from 48 hours postpartum till one week. Also, before discharge each woman will have an explanation of Visual Analogue Scale for pain intensity (VAS) and they will be trained to indicate level of perineal pain using it. This session will take 30-40 minutes for each woman.

Intervention for the control group: The control group will receive the routine hospital care only. Then, six hours after delivery, assessment of experienced perineal pain will be done using Visual Analogue Scale for pain intensity (VAS) and assessment of perineal trauma condition will be done using standardized REEDA scale.

Follow up and monitoring: Follow up will be done by telephone calls and by postpartum visit at the seventh day:

For intervention group follow up by telephone call will be done at 24 hours to assess the following; degree of perineal pain using Visual Analogue Scale for pain intensity (VAS),

the women compliance with ice gel pad application for the first 24 hours, the women's need for additional analgesia and assess women's postpartum difficulty with performing functional activities as turning/ rolling in bed, getting out of bed, sitting, walking, defecation and urination using Visual Analogue Scale(VAS) for rating functional activities.

Also, telephone follow up will done at third and fifth day postpartum to assess degree of perineal pain using Visual Analogue Scale for pain intensity (VAS) and assess women's postpartum difficulty with performing functional activities as turning/ rolling in bed, getting out of bed, sitting, walking, defecation and urination using Visual Analogue Scale(VAS) for rating functional activities. The investigator will also assess mother compliance with the performance of pelvic floor exercises (Kegel exercises) and application of perineal warm compresses using postpartum follow up sheet.

For control group follow up by telephone call will be done at 24 hours to assess degree of perineal pain using Visual Analogue Scale for pain intensity (VAS), the women's need for additional analgesia and assess women's postpartum difficulty with functional activities as turning/ rolling in bed, getting out of bed, sitting, walking, defecation and urination using Visual Analogue Scale (VAS) for rating functional activities. Also, telephone follow up will be done at third and fifth day postpartum to assess degree of perineal pain using Visual Analogue Scale for pain intensity (VAS) and assess women's postpartum difficulty with performing functional activities as turning/ rolling in bed, getting out of bed, sitting, walking, defecation and urination using Visual Analogue Scale (VAS) for rating functional activities.

Then, a final postpartum follow up visit for both groups at the seventh day will be conducted for assessment of perineal trauma condition and healing process using

standardized REEDA scale and assess the degree of perineal pain using Visual Analogue Scale for pain intensity (VAS).

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Statistical plan

Data were statistically described in terms of mean ± standard deviation (± SD), or frequencies (number of cases) and percentages when appropriate. Because the groups are large enough, comparison of numerical variables between the study groups was done using a student t test for independent samples (including statistical analysis of the primary outcomes as perineal pan scores and perineal trauma healing scores among the study and control groups). For comparing categorical data , the chi-square test was performed(including statistical analysis of the difficulties with functional activities; secondary outcome). An exact test was used when the expected frequency was less than 5. Two sided p values less than 0.05 were considered statistically significant. All statistical calculations were done using the computer programme IBM SPSS (Statistical Package for the Social Sciences; IBM Corp., Armonk, NY, USA), release 22 for Microsoft Windows.