FEDERAL UNIVERSITY OF RIO GRANDE DO SUL
SCHOOL OF MEDICINE
GRADUATE PROGRAM IN HEALTH SCIENCES:
GYNECOLOGY AND OBSTETRICS

COMPARISON OF LOW-LEVEL LASER THERAPY WITH CRYOTHERAPY IN THE IMMEDIATE POSTPARTUM PERIOD OF PARTURIENTS WITH FIRST- AND SECOND-DEGREE LACERATIONS AND/OR EPISIOTOMY IN REDUCING PERINEAL AND VULVAR PAIN:

A randomized clinical trial

Nº do project GPPG ou CAAE 58569421.5.0000.5327

PORTO ALEGRE

04/2024

METODOLOGIA

1.1 Delineamento do estudo

1.2 This is a randomized clinical trial aimed at comparing the effects of cryotherapy and low-level laser therapy on postpartum women up to 24 hours after delivery. The control group will receive cryotherapy (CG), and the intervention group will receive low-level laser therapy (GL). This study was randomized by drawing lots, where there was a paper in a black bag with "LLT" or "cryotherapy" written on it, and the patient would draw the paper from the bag to select the treatment to be applied. A randomized clinical trial is the gold standard for an experimental study or clinical trial, allowing the evaluation and demonstration of cause-and-effect relationships between various independent and dependent variables (SHARMA; SRIVASTAV; SAMUEL, 2020). Randomization by randomly generated numbers by computer, tables, coin toss,

and dice games is considered appropriate (SOUZA; SOUSA; SANTOS JR. et al, 2019).

1.3 Location and Condict of the Study

The present study was conducted and validated at the Municipal Hospital of Novo Hamburgo, with application carried out by the researcher.

1.4 Data Collection

The data collection was performed through Physiotherapeutic Assessment (APPENDIX A), and the data were stored in an Excel spreadsheet.**Amostragem e amostra**

1.4.1 Sampling

1.4.2 Patients in immediate postpartum vaginal who meet the inclusion criteria.

1.4.3 Sample

1.5 The sample consisted of women admitted to a public hospital in the Vale do Sinos region who underwent vaginal delivery and experienced some complication during delivery, such as episiotomy or first- or second-degree laceration. The sample size calculation was based on studies by Santos et al. (2012) and Morais et al. (2016), using the StatCalc – Sample Size and Power tool in the EpiInfo software.

1.6 Inclusion and Exclusion Criteria

1.6.1 Inclusion Criteria

a) Patients who underwent vaginal delivery;

b) Experienced first- or second-degree laceration;

c) Underwent episiotomy;

d) Aged 18 years or older.

1.6.1 Exclusion Criteria

a) Patients who underwent cesarean section;

b) Presented with gestational diabetes;

c) With HELLP syndrome;

d) Experienced immediate postpartum hemorrhage;

e) Had unstable vital signs in immediate postpartum;

f) Under 18 years old.

1.7 Operational Definition of Variables

1.8 1.7.1 Study Factor

The comparison of two non-pharmacological techniques used for pain and edema relief, performed in immediate postpartum up to 12 hours, being evaluated

before the application of the techniques, immediately after, and reevaluated after 24 hours.

1.7.2 Main Outcome

The idea of using non-pharmacological techniques in immediate postpartum is to reduce pain, edema, and inflammatory processes, causing greater comfort and better recovery in the puerperium.

a) Primary Outcome

- Compare the two techniques to assess which is more effective in relieving pain and/or edema in immediate postpartum up to 12 hours.

b) Secondary Outcome

- Reduce pain and/or edema and promote healing in immediate postpartum.

1.9 Research Instrument

Cryotherapy was performed using a glove containing crushed ice applied to the perineal region for 20 minutes, initiated up to 12 hours postpartum. Patients were assessed before application, immediately after application, and again 24 hours after application. A glove containing crushed ice was chosen due to its anatomical fit and ability to cover the entire perineal region. Francisco et al. (2013) suggest that surface ice has the ability to decrease skin and intramuscular tissue temperature. Compared to other cryotherapy techniques such as gel and frozen pea bags, the ice bag is the most adopted technique for perineal pain relief. The application time aligns with the study by Beleza et al. (2016), indicating that 20

minutes is sufficient time to cause reduction and relief of pain in study participants.

Low-Level Laser Therapy (LLLT), like cryotherapy, was applied up to 12 hours postpartum, targeting the lesion area. Red light radiation was applied at 3 joules, punctually, with a non-contact technique, maintaining a 2 cm distance between points. Subsequently, infrared laser was applied using the conventional contact technique around the lesion extension, punctually, at 6 joules, also maintaining a 2 cm distance between points.

The LLLT device used was the DMC Therapy EC, portable, with a li-ion battery. The red laser had a wavelength of 660nm (±10 nm) and an emitter power of 100 mW (±20%). The infrared laser had a wavelength of 808 nm (±10) and an emitter power of 100 mW (±20%).

The use of infrared radiation is associated with being a superficial thermal agent, used to reduce pain and stiffness, favoring the regeneration of soft tissue injuries and skin problems. (KITCHEN; PARTIDGE, 1991; MICHLOVITZ, 1986).

LLLT application should be punctual, applying firm pressure to the tissue area to be treated, resulting in higher levels of tissue light flow. This application is characterized by the conventional contact technique, whereas the non-contact technique involves application around the wound margins. These combined techniques ensure better application and absorption of radiation. Application

should occur around the circumference of the lesion, approximately 1-2 cm from its margins, with application points spaced 2-3 cm apart. (KITCHEN, 2003).

The two most common means of LLLT application are characterized by a wavelength of approximately 633 nm (red light) and 904 nm (infrared), capable of inducing mitochondrial activity and initiating reactions at the cellular membrane level, respectively. (KITCHEN, 2003).

Patients underwent evaluation using a questionnaire, the Patient Assessment Form, developed by the researcher. Pain and edema were evaluated using the Visual Analog Scale (VAS), McGill Pain Questionnaire (MPQ), and REEDA scale before, immediately after, and 24 hours after therapy application.

Pain was assessed on a scale of 0 to 10 using the VAS, with 0 indicating no pain and 10 indicating maximum pain intensity.

The McGill Pain Questionnaire (MPQ) was used to assess other characteristics of pain, not just intensity. This questionnaire captures quantitative measures of pain, with established validity and reliability, allowing for discrimination of various pain components. The questionnaire consists of 20 items, or groups, with each group containing several words from which the patient selects the one that best identifies their pain, selecting only one word per group. The groups are subdivided into sensory responses to painful experience (Groups 1-10), affective responses (Groups 11-15), evaluative responses (Group 16), and miscellaneous

(Groups 17-20). The questionnaire takes 3 to 4 minutes to complete. (PIMENTA; TEIXEIRA, 1996).

Edema was evaluated using the REEDA scale, which assesses inflammatory processes and tissue recovery following perineal trauma. Five scar healing items are evaluated: redness, swelling, bruising, discharge, and wound edge approximation (coaptation). A score of zero to three is assigned to each item evaluated by the assessing professional, with a maximum score of 15 indicating the worst perineal healing. (ALVARENGA et al., 2015).

2 DATA COLLECTION PROTOCOL

Step 1: Contact and presentation to the head responsible of the Obstetrics Center and then to the coordinating nurse of the Obstetrics department at the Municipal Hospital of Novo Hamburgo. After introducing myself and presenting the project, I provided my contact information and made myself available to be called whenever there was a patient who fit the sample profile of this study, taking responsibility for its implementation.

Step 2: After signing the Informed Consent Form (ICF), a physiotherapeutic assessment was conducted with the patient, as per the form in Appendix B.

Step 3: The patient underwent random selection to determine which intervention group she would be assigned to.

Step 4: After group assignment, within 12 hours post-vaginal delivery, the patient underwent an assessment of edema and pain using available scales (Appendices A, B, and C).

Step 5: The randomly determined intervention, either cryotherapy or laser therapy, was administered within 12 hours post-immediate vaginal delivery.

Following the application described in this study, the patient was immediately reassessed for pain using the VAS scale.

Step 6: The patient was reassessed 24 hours post-delivery, and pain and edema scales were applied. After this period, the patient was discharged.

APPENDIX A - PHYSIOTHERAPEUTIC EVALUATION FORM

PHYSIOTHERAPEUTIC EVALUATION FORM

NAME:

DATE OF BIRTH: _____ AGE:

CITY OF RESIDENCE:

PHONE:

EDUCATION:

OCCUPATION:

MARITAL STATUS:

RELATIONSHIP DURATION:

WEIGHT: _____ HEIGHT: _____ BMI: _____

NUMBER OF PREGNANCIES:

NUMBER OF VAGINAL DELIVERIES:

NUMBER OF CESAREAN SECTIONS:

SMOKER: ( ) YES ( ) NO

ALCOHOL: ( ) YES ( ) NO

DRUGS: ( ) YES ( ) NO

PREVIOUS ILLNESSES:

ILLNESSES DURING PREGNANCY:

GYNECOLOGICAL SURGERIES: _____ WHICH:

ASSOCIATED MEDICATIONS:

VAGINAL DELIVERY: ( ) EPISIOTOMY ( ) EPISIOTOMY + FORCEPS

( ) EPISIOTOMY + 1ST DEGREE LACERATION

( ) 1ST DEGREE LACERATION ( ) 2ND DEGREE LACERATION

MEDICATIONS USED POSTPARTUM: