PROTOCOLOS DE INVESTIGACIÓN - MEDICINA

THE EFFECT OF PHOTOBIOMODULATION ON PAIN DURING INSERTION OF THE COPPER INTRAUTERINE DEVICE T380 IUD: A RANDOMIZED, DOUBLE-BLIND, CONTROLLED CLINICAL TRIAL.

Anna Carolina Nunes Ferraz (a.c.ferraz@uni9.edu.br)

Maria Aparecida Traverzim (mtraverzim@gmail.com)

Lara Jansiski Motta (larajmotta@uni9.pro.br)

Raquel Agnelli Mesquita-Ferrari (raquel.mesquita@gmail.com)

Cinthya Cosme Gutierrez Duran (cinthya.cgduran@gmail.com)

Sandra Kalil Bussadori (sandra.skb@gmail.com)

Kristianne Porta Santos Fernandes (kristianneporta@gmail.com)

Anna Carolina Ratto Tempestini Horliana (annacrth@gmail.com)

Introduction: Unplanned pregnancy affects up to 65% of women in some regions of Brazil, contributing to maternal mortality. The copper IUD is an effective and long-lasting contraceptive option, but its use is still limited in Brazil. One of the main barriers is the pain associated with its insertion. Since pain can be of visceral or somatic origin, traditional approaches such as anti- inflammatories and anesthetics have shown inconclusive results in reducing this discomfort.

Photobiomodulation (PBM) has anti-inflammatory and analgesic effects, and has shown positive results in managing pelvic pain in other clinical contexts. Objective: This study will evaluate the efficacy of PBM as a preemptive analgesic method during the insertion of the IUD. Methodology: A randomized, double-blind clinical trial will be conducted with 60 participants. The study will follow the Ministry of Health guidelines. Pain will be assessed at different time points using the Visual Analog Scale (VAS) during the insertion phases (Pozzi, hysterometry, and IUD insertion), at 5 and 15 minutes, and 24 hours after IUD insertion. Additionally, analgesic use and quality of life (WHOQOL-100) will be assessed over a 24-hour period, along with anxiety levels (GAD-7), satisfaction with the procedure immediately after insertion (15 minutes), and adverse and side effects within 24 hours. The duration of pain in hours from the moment of IUD insertion until its resolution will also be evaluated, as well as the success rate of the procedure. Statistical analysis will be performed using SPSS software version 24.0, with a significance level of 5% ($p < 0.05$). Data normality will be assessed using the Shapiro-Wilk test. Student's t-test or the Mann-Whitney test will be used for continuous variables, while the chi-square test or Fisher's exact test will be applied for categorical variables.

Palavras-chave: keywords: intrauterine device (iud); pain management; photobiomodulation therapy.