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Diclofenac plus lidocaine gel for pain relief during intrauterine device insertion. A randomized, double-blinded, placebo-controlled study☆

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Abstract

Objective: To determine the effectiveness of diclofenac potassium combined with 2% lidocaine gel in reducing the pain of intrauterine device (IUD) insertion.

Study design: We randomized 90 parous women requesting copper T380A IUD insertion in a 1:1 ratio to active or placebo treatment. Active treatment included administration of two 50-mg diclofenac potassium tablets 1 h before IUD insertion, application of 3 mL of 2% lidocaine gel on the anterior cervical lip 3 min before IUD insertion and placement of a cotton swab soaked in 2% lidocaine gel in the cervical canal 3 min before IUD insertion. Women in the placebo group received placebo tablets and gel. Participants assessed pain intensity using a 10-cm visual analog scale (VAS). We considered a 2-cm difference in VAS pain score between both groups during IUD insertion to be a clinically significant difference.

Results: Subjects receiving active treatment, as compared to placebo, experienced less pain during tenaculum placement (1.66±0.85 vs. 2.33±1.19, p=.003) and IUD insertion (3.14±0.92 vs. 3.94±1.3, p=.001). Women who delivered only by cesarean section had higher pain scores with IUD insertion compared with women with previous vaginal deliveries (4.41±1.24 vs. 3.29±1.05, p=.001).

Conclusion: Diclofenac potassium combined with 2% lidocaine gel slightly reduced pain scores during tenaculum application and copper IUD insertion in parous women; however, the reduction in pain scores lacked clinical significance.

Implications: Although we found a statistically significant lowering of pain scores with pretreatment with diclofenac potassium and lidocaine gel in parous women having copper IUD placement, the reduction is not clinically relevant. These findings may be more relevant for nulliparous women who experience more pain than parous women with IUD insertion and support studies of diclofenac potassium and lidocaine gel in this population.

Keywords: Diclofenac potassium; Lidocaine gel; IUD; Pain; Visual analog scale

1. Introduction

The intrauterine device (IUD) is a commonly used long-acting, effective and reversible method of contraception [1]. IUD insertion is usually associated with a variable degree of pain. The majority of women experience mild pain or discomfort during IUD insertion, and some women may experience severe pain. Nulliparous women, women who delivered only by cesarean section and women remote from vaginal delivery are subgroups of women who experience more pain during IUD insertion [2]. Prophylactic pharmacological interventions for management of pain associated with IUD insertion include nonsteroidal anti-inflammatory drugs (NSAIDs), opioid analgesics and local anesthetics (gel, cervical and paracervical block). Moreover, cervical ripening with prostaglandins can facilitate the introduction of the IUD through the cervix, although at the cost of increased pain due to uterine cramping [2–3].

Several studies have reported that NSAIDs are not effective in reducing pain associated with IUD insertion [4–6]. On the other hand, a recent study including 103 women randomly

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assigned to receive 50 mg tramadol ($n=35$), 550 mg naproxen sodium ($n=34$) or placebo ($n=34$) 1 h before IUD insertion demonstrated more pain reduction during IUD insertion with tramadol than naproxen sodium and that naproxen sodium reduced pain more than placebo [7].

Studies evaluating cervically applied lidocaine gel for pain relief during IUD insertion have conflicting results. Oloto et al. [8] reported that 2% lidocaine gel was more effective than placebo gel in reducing pain experienced during IUD insertion. However, three other studies found no benefit of 2% lidocaine gel compared to placebo gel [9–11]. These inconsistent results may be due to differences in the studied population (nulliparous or parous women), lidocaine gel dose, location of lidocaine gel application (endocervical canal or anterior lip of the cervix) and time from application of lidocaine gel to insertion of IUD (1, 3 or 5 min).

We sought to determine the effectiveness of diclofenac potassium, a potent rapidly acting NSAID, at reducing pain during IUD insertion in a population of women receiving 2% lidocaine gel applied to the anterior lip of the cervix and endocervical canal. We hypothesize that diclofenac potassium and lidocaine gel could complement and augment the action of each other in women having IUD insertion: lidocaine gel by blocking the pain arising from the cervix (tenaculum application and introduction of sound and IUD through the cervical canal) and diclofenac potassium by blocking pain arising from the cervix and the uterus (tenaculum application and introduction of sound and IUD into the cervical canal and uterine cavity).

2. Material and methods

We conducted this two-arm, double-blind, randomized controlled trial at the Department of Obstetrics and Gynecology at Cairo University, Egypt, from February to September 2015. The institutional research ethics committee approved this study. We obtained written informed consent from all participants before initiating any study procedures.

We recruited nonpregnant women (aged 18–50 years) requesting copper T380A IUD insertion for contraception. We excluded women less than 6 weeks postpartum or 2 weeks after abortion, and women with uterine anomalies, fibroids distorting uterine cavity, pelvic inflammatory disease, cervicitis, a uterine depth less than 6 cm or more than 9 cm, previous IUD insertion, allergy to diclofenac or lidocaine, peptic ulcer disease, asthma, bleeding disorders and cardiac or kidney diseases.

We randomized participants in a 1:1 ratio to receive active or placebo treatment. A statistician not directly involved in the study prepared a computer-generated randomization list and placed the allocation information in sequentially numbered sealed envelopes. After signing the informed consent, the study nurse opened the sequentially numbered sealed envelopes, out of view of the participants and doctors, according to the sequence of attendance of the subjects. The study nurse provided two 50-mg diclofenac potassium tablets (Cataflam; Novartis, Stein, Switzerland) or two placebo tablets before planned IUD insertion. The study nurse instructed the subjects to administer the study tablets 1 h before IUD insertion. The study nurse then prepared a syringe containing 6 mL of 2% lidocaine gel (Xylocaine Jelly, Astra Zeneca, North Ryde, New South Wales, Australia) for women in the active treatment group or 6 mL of placebo gel (K-Y jelly, Johnson & Johnson, New Brunswick, NJ, USA). The study nurse maintained blinding of the participants and clinicians to the identity of the gel and tablets.

Before IUD insertion, we asked the subjects to fill the Arabic version of State–Trait Anxiety Inventory questionnaires to evaluate the current state of anxiety and the trait of anxiety. The clinician performed bimanual examination, introduced the speculum into the vagina and sterilized the cervix with povidone iodine. Three minutes prior to IUD insertion, 3 mL of study gel was placed on the anterior lip of the cervix, and a cotton swab soaked in 3 mL of the study gel was introduced in the cervical canal until the level of internal os and was left in place until the IUD was inserted. Eight experienced gynecologists inserted the IUDs according to the recommendations of the manufacturer. Immediate complications of IUD insertion such as uterine perforation, failure of insertion and vasovagal reaction were recorded.

The subjects rated the intensity of pain experienced during tenaculum placement and IUD insertion using a 10-cm visual analog scale (VAS) (0 indicated no pain, and 10 indicated the worst possible experienced pain). After the end of the procedure, the clinician assessed the ease of IUD insertion using a 10-cm VAS (0 indicated a very easy IUD insertion, and 10 indicated an extremely difficult insertion).

We contacted the subjects 24 h after IUD insertion to query any adverse effects of diclofenac and lidocaine such as nausea, vomiting dizziness, dyspepsia, skin reaction and allergic reaction. A follow-up visit was scheduled after the next menses to detect delayed complications of IUD (expulsion, perforation, pelvic inflammatory disease and vaginitis).

The primary outcome was the intensity of pain during IUD insertion, and secondary outcome measures were intensity of pain during tenaculum application, the ease of IUD insertion, adverse effects of diclofenac potassium or lidocaine and complications of IUD insertion.

The sample size calculation was based on data from a large randomized controlled study that compared intracervical lidocaine gel with placebo for pain relief during IUD insertion. In that study, the mean VAS pain score with IUD insertion in the control group was 5.09 cm, and the standard deviation was 3.2 cm [11]. We estimated a 2-cm difference in VAS pain score between both groups during IUD insertion to be clinically significant. A sample size of 41 women was needed in each group to detect more than 2 cm of difference in VAS pain score between both groups during IUD insertion with an alpha error level of 5% and a beta error of 20% (study power 80%). We expected that the dropout rate would be 10%, and therefore 90 women were recruited to the study.