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Two Different Doses of Self-administered Vaginal Misoprostol for Successful Copper Intrauterine Device Insertion in Parous Women Previously Delivered by Cesarean Section- A Double Blinded Randomized Clinical Trial

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AUTHORS' CONTRIBUTION: (A) Study Design · **(B)** Data Collection . **(C)** Statistical Analysis · **(D)** Data Interpretation · **(E)** Manuscript Preparation · **(F)** Literature Search · **(G)** Funds Collection

SUMMARY

Objective: The aim of the study was to compare the efficacy and safety of misoprostol 200 mcg plus placebo vs. 400 mcg administered vaginally prior to IUCD insertion regarding the success and ease of insertion among parous women previously delivered by cesarean section beside the rate of occurrence of adverse effects.

Methods: This double blind randomized controlled clinical trial was conducted at Ain Shams University Maternity Hospital during the period from January 2020 till July 2020. One hundred parous women previously delivered by caesarean section were randomized into 2 groups; group (1): 50 women received misoprostol 400 mcg vaginally 3 hours prior to IUCD insertion and group (2): 50 women received misoprostol 200 mcg plus placebo vaginally 3 hours prior to IUCD insertion.

Results: There was insignificant difference between both groups; VAS ranged between 1 and 5 with a mean value of 2.16 ± 0.93 in group 1 and between 1 and 5 with a mean value of 2.55 ± 1.21 in group 2. There was insignificantly different between both groups. However, group 1 showed significantly lower need of analgesia than group 2 (P = 0.004). Successful IUD insertion was insignificantly different between both groups. Woman's level of satisfaction was insignificantly different between both groups. All side effects were insignificantly different between both groups except abdominal cramping and shivering were significantly lower in group 2 than in group 1.

Conclusion: We recommend using the lowest dose of misoprostol (200 mcg) prior to IUCD insertion.

Keywords: Intrauterine contraceptive device; Cesarean section; Misoprostol

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INTRODUCTION

The intrauterine contraceptive device (IUCD) is one of the most effective contraceptive methods available in addition to one of the safest long-acting reversible contraception. Intrauterine contraceptive devices (IUCDs) are safe, reliable, and highly effective forms of long-acting reversible contraception [1].

These high rates of IUCD usage are due to its advantages such as reversible fertility immediately after removal, no need to daily reminder, no effect on breastfeeding, lack of hormonal effects, no interference with sexual activities and medications. But despite all these advantages; it doesn't always succeed [2].

The main reason associated with low IUCD use is fear of pain at insertion by women. For healthcare professionals the obstacles to use include fear of causing pain with the procedure and difficulties during the procedure that could end in failure of insertion. Insertion-associated pain is related to speculum insertion, tenaculum traction on the cervix, cervical immaturity, sounding of the uterus, passing of the insertion tube through the cervix and placement of the device within the uterine cavity [3].

Misoprostol is a synthetic and inexpensive prostaglandin estrone analogue. It may be administered orally or vaginally the night before and, if needed, again in the morning before minimally invasive gynecological procedures such as hysteroscopy, to assist cervical softening. Its use, however, is associated with side effects such as abdominal cramps, uterine bleeding, shivering, nausea, vomiting and diarrhea [4].

The aim of this study is to evaluate and compare the efficacy and safety of misoprostol 200 mcg plus placebo *vs.* 400 mcg administered vaginally prior to IUCD insertion in regard to the success and ease of insertion procedure among parous women previously delivered by cesarean section beside the rate of occurrence of adverse effects.

MATERIALS AND METHODS

Design and setting

A double blind randomized controlled clinical trial was carried out on women seeking intra uterine device

insertion at Ain Shams University Maternity Hospital (Family planning clinic) during the period from January 2020 till July 2020.

Participants

All women who come to the family planning clinic during the study period require an insertion of IUCD insertion with the following criteria: women at reproductive age group between 18 - 45 years old, parous women previously delivered by cesarean section. Timing of insertion at the last day of menstruation, during puerperium or 2 weeks after abortion, did not receive any analgesics in the 24 hours prior to IUCD insertion, have no contraindications for IUCD insertion in accordance with WHO eligibility criteria.

Exclusion criteria included nulligravidae, previous vaginal delivery, women with contraindications for misoprostol use (pregnancy, prostaglandin allergy), women with a contraindication for IUCD insertion (e.g., less than sex weeks post-partum, gynecologic malignancy, uterine bleeding of undetermined origin, fibroids or other uterine abnormalities, active vaginitis or cervicitis, a history of PID or puerperal sepsis). Women on anticoagulant therapy or having any coagulopathy, uterine fibroid with distortion of the cavity, anatomical abnormality with distortion of the cavity, current pelvic inflammatory disease, current purulent cervicitis (chlamydia or gonorrhea), pelvic tuberculosis, puerperal sepsis, immediately after septic abortion, cancer cervix and cancer endometrium.

Sample Size

The study was conducted on (100) women. They were subdivided into 2 groups: Group 1 (control): 50 women received misoprostol 400 mcg (Misotac ®, Sigma, SAE, Egypt) (2 tablets) vaginally 3 hours prior to IUCD insertion. Group 2 (experimental): 50 women received misoprostol 200 mcg plus placebo vaginally 3 hours prior to IUCD insertion (the placebo tablet has the same color, size and shape of tablet of misoprostol). The required sample size has been calculated using the IBM© Sample Power© Software (IBM© Corp., Armonk, NY, USA). The primary outcome measure is the success rate for IUCD insertion. A previous study reported that following previous IUCD insertion failure, the success rate associated with pre-emptive vaginal misoprostol or placebo was 87.5% or 61.9%, respectively [5]. So, it is estimated that a total sample size of 100 patients equally randomized into either study group (n=50 patients per group) achieved a power of 80% (type II error, 0.2) to detect a statistically significant difference between the two groups as regards the success rate for IUCD insertion using a two-sided chi-squared test with a confidence level of 95% (type I error, 0.05). The success rate is assumed to be identical in both groups and to equal 61.9% under the null hypothesis. Under the alternative hypothesis, the success rate is assumed to equal 87.5% or 61.9% in association with vaginal misoprostol or placebo, respectively.

Randomization

Randomization was done using computer generated randomization sheet using MedCalc© version 13. Allocation and Concealment: By use of sealed opaque envelopes that was given to a third party (nurse) who assigned the women to study arms. Each woman was invited to pull out an envelope. According to the number inside her envelope, women were allocated to either group 1 or group 2 according to a computer-generated random list.

Ethical consideration

The study was started after the approval of Research Ethical Committee, Faculty of Medicine, Ain Shams University. Informed consent was taken from all participants before recruitment in the study, and after explaining the purpose and procedures of the study. The investigator was obtained the written, signed informed consent of each subject prior to performing any study specific procedures on the subject.

Interventions

Participants was distributed randomly and equally into two groups: Group 1 (control): 50 women to whom two tablets (400 mg) of misoprostol (Misotac ®, Sigma, SAE, Egypt) was administered vaginally 3 h before IUCD insertion, as deep as possible, and to remain in supine position for half an hour. Group 2 (experimental): 50 women to whom one tablet (200 mg) of misoprostol (Misotac ®, Sigma, SAE, Egypt) plus placebo was administered vaginally 3 h before IUCD insertion.

All women had their copper IUCD (a T380A [Copper T 380A, ®, Egypt]). IUCD insertion was considered failed if we are unable to pass the internal cervical os with the uterine sound, metallic dilator number 3 and an os Finder, which is a tapered plastic dilator with a 1.75 mm tip to 3.8 mm outer diameter.

The invited women were signed an informed consent form and was received a sealed opaque envelope with the medication or placebo. The women were instructed to insert vaginally two tablets of misoprostol 200 mg or 200 mcg plus placebo after soaking in 5 ml saline 3hr before the woman returning to the clinic.

Outcomes

The primary outcome was the ease of IUCD insertions. Difficulty of IUCD insertion was measured by whether or not Hegar dilators with a diameter of 4 mm or smaller can pass through the internal cervical os without resistance. Any resistance or need for dilatation was recorded, as well as the degree of difficulty of the IUCD insertion judged as the resistance of the internal cervical os experienced by the investigator and classified as ‘easy’, ‘moderate’ or ‘difficult’. In addition, the investigators were asked to judge based on the ease or difficulty of insertion in each woman whether they believed that pretreatment with misoprostol had been given or not.

Secondary outcome included uterine or cervical perforation, heavy bleeding, vasovagal like reactions (dizziness, nausea and vomiting), syncope, partial- or total expulsion, pain during insertion and difficulty of IUCD insertion.

Pain was measured using a visual analog scale (VAS) pain score reported by participants during IUCD insertion. Pain score was measured using a visual analogue scale consisting of a 10 cm horizontal straight line on which 0 cm corresponds to no pain and 10 cm to the worst pain. VAS is rated as 0 no pain, 1-3 for mild pain, 4-6 for average pain and 7-9 for severe pain and 10 for extremely sever pain an individual can experience.

The treatment of side effects was in the form of: Uterine and cervical perforation: hospital admission, conservative treatment for 24 hours with antibiotics coverage. Heavy Bleeding: local examination and ultrasound then treatment of the cause e.g., Tranexamic acid. Vasovagal like reactions: analgesics, intravenous fluids and positive inotropes, with observation of vital data. Syncope: Airway, Breathing, Circulatory assessment and management of the cause. Partial or Total expulsion: Remove IUD. Pain during insertion and difficulty of IUCD insertion: Counseling, proper timing of IUD insertion (during menstruation), NSAIDs 1hr before insertion and examination for perforation.

The participants also scored side effects of misoprostol or placebo. Hereby, a box was ticked per side effect, ranging from mild, moderate to severe. The side effects queried are headache, nausea/vomiting, abdominal cramping, shivering, fever (temperature ≥ 38.08C) and diarrhea. The participant was filled out this side-effect form before IUCD insertion take place to ensure that side effects from medication/placebo aren't mistaken for side-effects related to insertion.

All patients were seen for a routine check-up 6 weeks after IUCD insertion. During this visit, vaginal examination and/or vaginal ultrasound was performed. IUCD expulsions and infections was recorded.

Elimination of bias

All IUD insertions and observation of study outcome was done by the same doctor. All procedures were done by supervisors and experts.

Statistical analysis

Data was collected, tabulated, then analyzed using IBM© SPSS© Statistics version 22 (IBM© Corp., Armonk, NY). Normally distributed numerical data was presented as mean and SD, and skewed data as median and interquartile range. Qualitative data was presented as number and percentage. Comparison of normally distributed numerical data was done using the unpaired Student to test. Skewed data was compared using the Mann-Whitney U test. Categorical data was compared using the chi-square test or Fisher's exact test, when appropriate. A two-sided p-value <0.05 was considered statistically significant.

RESULTS

In this study, 106 patients were assessed for eligibility, 4 patients not meeting inclusion criteria and 2 patients declined to participate. The remaining 100 patients were randomly allocated into two groups (50 patients in each one). All of them were followed up and statistically analyzed (**Fig. 1.**).

Tab. 1. showed patients' characteristics in both groups.

Tab. 2. showed that visual analog scale (VAS) was insignificantly different between both groups.

Regarding **Tab. 3.** group 1 showed significantly lower ease score (ES) in group 1 compared to group 2 (P <0.05).

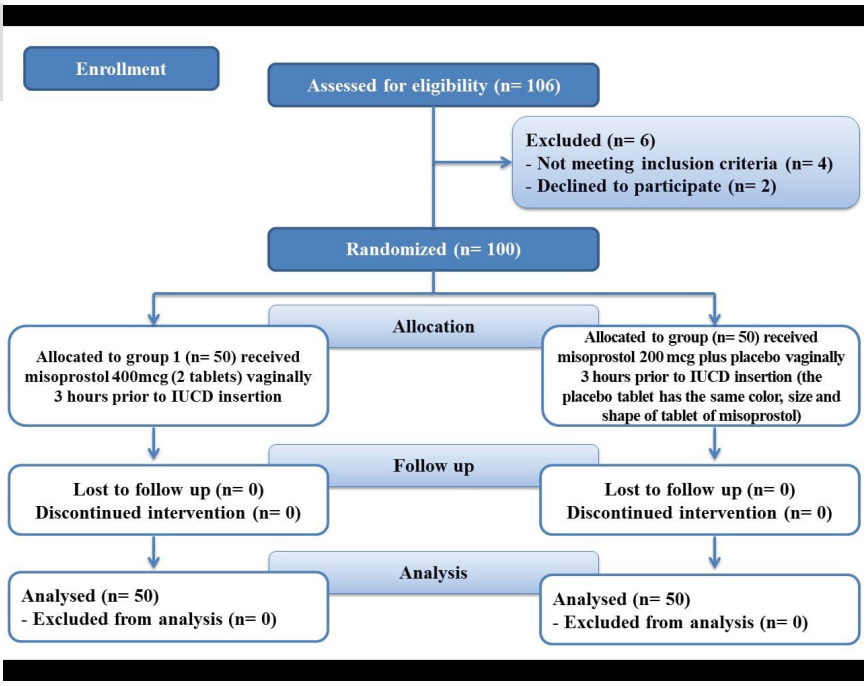

Fig. 1. The randomized trial flow diagram, including enrollment, intervention allocation, and analysis.

Tab. 1. Patients' characteristics in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
Age (years)	Mean ± SD	30.8 ± 4.64	29.98 ± 4.58	0.376
	Range	24 - 38	23 - 43	
BMI (kg/m^2)	Mean ± SD	26.64 ± 3.99	27.85 ± 4.61	0.164
	Range	20.2 - 34.4	20.1 - 33.9	
Parity	Mean ± SD	2.08 ± 0.94	1.92 ± 0.88	0.382
	Range	1 - 4	1 - 4	
Previous miscarriages		10 (20.0%)	6 (12.0%)	0.275
Previous CS		50 (100.0%)	50 (100.0%)	---
Previous use of contraceptives		22 (44.0%)	19 (38.0%)	0.542
Previous insertion of IUD		15 (30.0%)	18 (36.0%)	0.523

BMI: Body mass INDEX; CS: Cesarean Section; IUD: Intrauterine Device.

Tab. 2. Visual Analog Scale (VAS) in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
VAS	Mean ± SD	2.16 ± 0.93	2.55 ± 1.21	0.074
	Range	1 - 5	1 - 5	

Tab. 3. Ease Score (ES) in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
ES	Mean ± SD	1.6 ± 0.67	4 ± 0.99	<0.001*
	Range	1 - 4	2 - 6	

*: Significant as p value <0.05

Tab. 4. showed that successful IUD insertion was insignificantly different between both groups.

Tab. 5. showed that woman's level of satisfaction was insignificantly different between both groups.

Regarding **Tab. 6.** group 1 showed significantly lower need of analgesia than group 2 (P = 0.004).

Tab. 7. showed that all side effects were insignificantly different between both groups except abdominal and shivering were significantly lower in group 2 than group 1. (P <0.05).

DISCUSSION

Fear of discomfort during insertion is one of the primary reasons for women's limited use of intrauterine contraceptive devices (IUCDs) [6].

The insertion of the speculum, tenaculum traction on the cervix, sounding of the uterus, passage of the insertion tube through the cervix, and insertion of the instrument into the uterine cavity are all linked with discomfort [7].

Misoprostol, a synthetic prostaglandin estrone analogue, has been used to aid cervical softening before minimally invasive gynecological procedures like hysteroscopy [8].

This double blind randomized controlled clinical trial was conducted at Ain Shams University Maternity Hospital to evaluate and compare the efficacy and safety of misoprostol 200 mcg plus placebo *vs.* 400 mcg administered vaginally prior to IUCD insertion in regard to the success and ease of insertion procedure among parous women beside the rate of occurrence of adverse effects. One hundred parous women previously delivered by cesarean section were randomized into 2 equal groups; group (1): 50 women received misoprostol 400 mcg (2 tablets) vaginally 3 hours prior to IUCD insertion and group (2): 50 women received misoprostol 200 mcg plus placebo vaginally 3 hours prior to IUCD insertion (the placebo tablet has the same color, size and shape of tab of misoprostol).

Regarding baseline patient's characteristics (Age, BMI, parity, previous miscarriages, previous CS, previous use of contraceptives and previous insertion of IUD):

Edelman et al. [9] agreed with the present data and stated that there were no statistically significant differences in baseline characteristics as age, BMI, history of pregnancies and abortions between the two study groups. They examined the effects of prophylactic misoprostol prior to intrauterine device (IUD) placement in nulliparous women. A total of 40 nulliparous, reproductive- aged women desiring an IUD for contraception were randomized to receive 400 mcg of buccal misoprostol or placebo 90 min prior to IUD insertion.

Regarding visual analog scale (VAS): Espey et al. [10] disagreed with the present data and stated that providers did not indicate any difference in ease of IUD insertion between groups (P =.54). Providers in each group found it easy to place the IUD in nulliparous women with a mean ease of insertion score of 2.2 ± 2.2 in the misoprostol group and 2.5 ± 2.2 in the placebo group (P =.54) based on the VAS, this disagreement was due to lack of placebo group in current study.

Mansy [11] agreed with the present data and stated that regarding the easiness of uterine sounding, in the misoprostol group there were 43 (86%) cases with successful insertion, 27(62.8%) cases had easy sounding, 16 (37.2%) cases with difficult and 7 (14%) cases with failed sound insertion, on the other hand there were 25 (64.1%), 14 (35.9%) & 11 (22%) cases with easy, difficult and failed

Tab. 4. Successful IUD insertion in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
Successful IUD insertion	Succeeded	48 (96.0%)	47 (94.0%)	0.477
	Failed	2 (4.0%)	3 (6.0%)	

Tab. 5. Woman's level of satisfaction in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
Woman's level of satisfaction	Mean ± SD	8.33 ± 0.80	8.04 ± 0.82	0.083
	Range	7 - 9	6 - 9	

Tab. 6. Needing for analgesia in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
Needing for analgesia	Analgesia needed	5 (8.3%)	7 (11.7%)	0.004*
	Analgesia not needed	45 (75.0%)	43 (71.7%)	
*: Significant as p value <0.05				

Tab. 7. Side effects in both groups.

Variables		Group 1 (n = 50)	Group 2 (n = 50)	P value
Side effects	Uterine perforation	0 (0.0%)	0 (0.0%)	--
	Abdominal cramping	16 (26.7%)	5 (8.3%)	0.004*
	Shivering	8 (16.0%)	1 (2.0%)	0.031*
	Nausea and vomiting	3 (6.0%)	1 (2.0%)	0.617
	Headache	1 (2.0%)	0 (0.0%)	1
*: Significant as p value <0.05				

uterine sound insertion respectively, the calculated p value was 0.577, that showed no statistical difference between the two groups. He assessed sublingual misoprostol effect in reduction of pain and facilitation of IUD insertion in women with no previous vaginal delivery. The study was a double blinded randomized controlled trial included 400 cases, compared sublingual 200 mg misoprostol with placebo to facilitate IUD insertion. Also, there was no statistically significant difference as regard pain reduction in using misoprostol prior to IUD insertion.

Regarding successful IUD insertion: Dijkhuizen et al. [12] agreed with the present data and stated that three insertions failed, two in the misoprostol group and one in the placebo group P= 0.59. Most IUDs were placed during the first attempt: 88 (88%) in the misoprostol group (data for 100 patients) *vs.* 89 (94.7%) in the placebo group (data for 94 patients; P= 0.13).

Scavuzzi et al. [13] disagreed with the present data and stated that significant differences were found between the groups for all the immediate end points evaluated, with less difficulty in inserting the IUD and less risk of cervical dilatation ≤4 mm when misoprostol was used prior to insertion that was due to current study didn't include placebo group.

Regarding woman's level of satisfaction: Ibrahim et al. [14] agreed with the present data and stated that patients in both groups were satisfied about their experience, with no significant difference between the groups.

El-Gawad et al. [15] disagreed with the present data and stated that satisfaction was significantly more frequent among Misoprostol group while insertion complications were non-significantly less frequent among Misoprostol group that was due to current study didn't include placebo group.

Regarding side effects: Dijkhuizen et al. [12] disagreed with the present data and stated that they were significantly more frequent in the misoprostol group: 56 participants (56.6%) who received misoprostol experienced any kind of side effect compared with 39 (42.4%) in the placebo group (P= 0.05). The most common side-effect was cramping in the abdomen (38.2%). Fever (temperature ≥38.08C) did not occur in the misoprostol group, whereas 3.3% of patients in the placebo group experienced fever. Other side-effects included itching, exanthema, sweating and dysuria, did not differ between groups (P = 0.48). In general, all of the side-effects were mild.

Scavuzzi et al. [13] agreed with the present data and stated that there were no significant differences between the groups in relation to complications during IUD insertion. The frequency of bleeding, vasovagal reaction, cramps, nausea, vomiting and insertion failures was similar in both groups. No cases of uterine perforation occurred in either group. There were no significant differences in the frequency of the majority of the immediate side effects such as nausea, vomiting, hyperthermia and diarrhea, evaluated prior to IUD insertion. Nevertheless, there was a significant increase in cramps with the prior use of misoprostol compared with placebo. In relation to the side effects evaluated 24 h after IUD insertion, no significant differences were found between the misoprostol and placebo groups.

Ibrahim et al. [14] agreed with the present data and stated that there were no significant insertion-related complications in either group (infection, perforation or excessive vaginal bleeding). Vomiting and diarrhea were not significantly different between the groups. Nausea was the most frequent side effect noted in 19.7% of women in the diclofenac + misoprostol group, as compared to only 4.4% of those pretreated solely with diclofenac.

CONCLUSION

In cases of intrauterine contraceptive devices (IUCDs)

insertion, there was between different doses of misoprostol (400 *vs.* 200) regarding degree of pain, success of insertion, women's satisfaction or pharmacological side effects However needing for analgesia was significantly lower and adverse effects as abdominal cramping and shivering were significantly higher in women received higher doses of misoprostol.

DISCLOSURE STATEMENT

The authors declare that there is no conflict of interest associated with this manuscript.

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