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Misoprostol for cervical preparation before IUCD insertion in patient with no previous vaginal birth

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Abstract

Background: Intrauterine devices (IUD) are extensively used as reversible contraceptives. Copper & Levonorgestrel releasing IUD (LNG) are safe, cost-effective over the long term, and just as effective in relation to others with tubal sterilization.

Aim of study: To investigate the effect of oral misoprostol on facilitating intrauterine device (IUD) placement in patients with a history of cesarean sections (Cs).

Method: It was a randomized clinical trial (RCT) study carried out on 98 women eligible for IUCD inclusion in the private outpatient clinic (obstetrics and gynecology) in search of contraception in the cities of Mosul and Erbil. This study ran from February 2020 to July 2021. All participants who requested an IUD had already had one or more cesarean sections and had never given birth vaginally. Participants were randomized into two equal groups; the first group was given misoprostol orally and the second group was given placebo 3 h before insertion of the IUD.

Result: In this clinical trial study, the mean age of the cases was (29 year) and for control group was (34.1year). The (ARR) is (0.2449), which reflects how much misoprostol lessens the risk of difficulties in IUD insertion. Women with cervical misoprostol preparation were found to have much higher abdominal cramps than those with placebo, with P value 0.0135. Inserting the IUD was a lot easier in the misoprostol group than in the placebo group, with P value of 0.0018 (<0.05) very significant. A higher incidence of complications like vaginal bleeding was also observed in the misoprostol group, with P value 0.0381 and the efficacy of the use misoprostol in the study group was (26%).

Conclusion: Our study found that a pill of misoprostol was administered orally before the insertion of an IUD in women who had not had a vaginal birth facilitated the insertion process

Keywords: Misoprostol; Intrauterine Device (IUD); Randomized clinical trial (RCT); Patient; Iraq

1. Introduction

Intrauterine devices (IUD) are extensively used as reversible contraceptives. Copper & Levonorgestrel Releasing IUD (LNG) are safe, profitable over the long term, and just as effective compared. With tube sterilizing [1], there is now a growing variety of effective birth control methods. While all have side effects, they are less at risk than pregnancy [2].

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In the United States, half of pregnancies are involuntary [3] and other half terminate with abortion [4]. There is an unsatisfied need for good contraceptive advice [5].

Birth control methods are classified by their efficacy. These include intrauterine contraception, subcutaneous birth control implants and sterilization of men and women[2]. Although intrauterine birth control is guaranteed and dependable and has a very depressed failure rate (0.2-0.6 per 100 females per year) [6, 7], it is employed by only 7.6% and 14.5% of contraceptive consumers in highly-developed and underdeveloped nations, severally [8]. In the United States, intrauterine birth control use enhanced from 2 per cent to 10 per cent for the period of 2002 to 2008 [9]. In 2015, the intra-uterine device (IUD) was selected by approximately 17% of contraceptive users in Asia, and in 12 Asian countries by over 20% of consumers [10]**.** The low rate of intrauterine contraceptive use is linked to the user's fright of pain and the insertion difficulties encountered via the supplier [11]. Integration was a concurrent concern for 86% of women and uneasiness for 41% [12]. Insertion disappointment takes place in 14% - 20% of nullipary females [13, 14]. It has been suggested that the difficulty and failure of insertion are most felt among nulliparous women and those who have already had a cesarean section (Cs) [15]. Women who had given birth only (Cs) were found to have more pain when the IUD was inserted than women who had given birth before. [16].

Misoprostol is a low-cost synthetic analogue of prostagl and inestrone. It can be administered by mouth or vaginally the day before and, if necessary, again in the morning before minimally invasive gynaecological procedures such as hysteroscopy, to help soften the cervix. However, it is linked to side effects such as abdominal cramps, uterine hemorrhages, chills, nausea, vomiting and diarrhea [17].

Conflicting studies have been conducted on the use of misoprostol prior to inserting the IUD. Some indicated easier insertion, but no impact on pain [18], and others had no positive impact [19].

The objective of the study was to examine the effect of oral misoprostol on intra-uterine device placement (IUD) facilitation in patients with a history of prior caesarean sections.

2. Patient and method

It was a randomized clinical trial (RCT) study carried out on 98 women eligible for IUCD inclusion in the private outpatient clinic (obstetrics and gynecology) in search of contraception in the cities of Mosul and Erbil. The Ethics Committee endorsed the study and all women signed informed consent prior to embarking on the study after explanation of the trial benefits and hazards. The study was conducted between February 2020 and July 2021.

All participants who applied for an IUD had already undergone one or more C-sections and had never given birth vaginally.

The study involved 98 women who qualified for IUD placement. Attendees were randomly distributed into two equal groups, first group receiving misoprostol orally and second group taking placebo 3 h prior to IUD insertion.

After advising everyone about the kinds of IUD, its benefits and drawbacks, every female has undergone a full assessment using her background as well as general, abdominal and pelvic exams.

One tablet of misoprostol (400 mg) = 2 tablets of 200 mg were given by mouth via a gynecologist; we talked to them that they may return home and Come back three hours later to get the IUD.

2.1. Statistical Analyses

95% confidence intervals (CI), of all randomized trials measures were calculated.

Chi-square test (χ^2) between the 2 treatment groups for the difference in the portion of patients with either resolved or improving versus those who not experienced treatment, was used and P-value of ≤ 0.05 was considered to denote statistical significance. Bar chart was used to present continuous variables and tables used for categorical data.

3. Results

A total of 49 cases and same number of control group have been included within this study. The average age of patients was (29 year) and for control group was (34.1year). The variables which included under the study were shown in Table 1.

Table 1 Characteristics of variables under study for cases and control groups

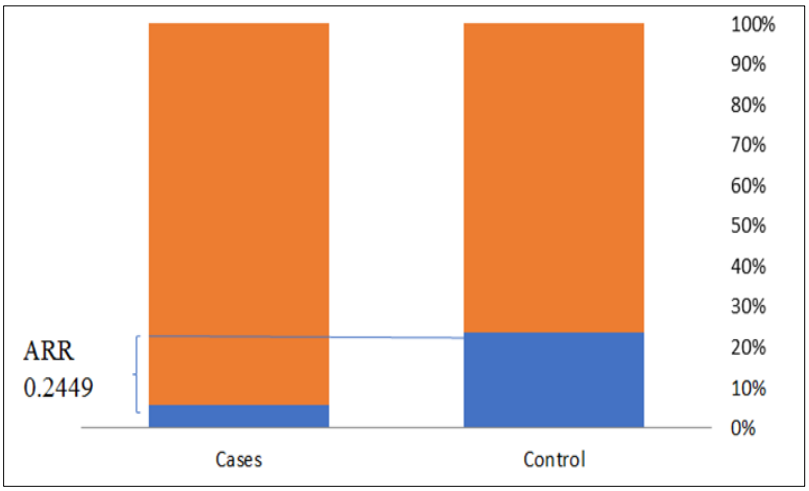
Variables		**Cases**	**Control**	**P value**
Age (mean)		29	34.1	
No. Cs	≤ 2	30	32	0.6767
	≥3	19	17	
Abortion	No	23	27	0.4213
	Yes	26	22	
Previous iud	No	41	42	0.7801
	Yes	8	7	
Abd .crum	No	40	48	0.0135*
	Yes	9	1	
VB	No	39	46	0.0381*
	Yes	10	3	
Insertion of IUD	Easy	46	34	0.0018*
	Difficult	3	15	

*Two-way Chi-squared test: significant

In this clinical trial study, the (ARR) is (0.2449), which reflects how much misoprostol lessens the risk of difficulties in IUD insertion. The reciprocal ARR gives the number required for treatment (NNT), which was (4.0), NNT is the average number of patients who would need treatment to get treatment. Relative risk (RR 0.2) is the ratio of event risk for treated topics to control risk. A relative risk (RR) of 1 would suggest that treatment has no advantage over control. Lower RR values reflect a larger treatment advantage. The (RR) may also be expressed as the relative risk reduction (RRR), which is equivalent to the subtracted RR of 1. Larger values of RRR are associated with greater benefit, as was seen in our study (0.8)**.** These results translates that the efficacy of the use misoprostol in the study group was (26%), which mean the effectiveness of misoprostol in reducing the difficulties in insertion of IUD, which was seen in Table 2.

Table 2 All randomized trials measures were calculated the effect of misoprostol uses on inserting IUD

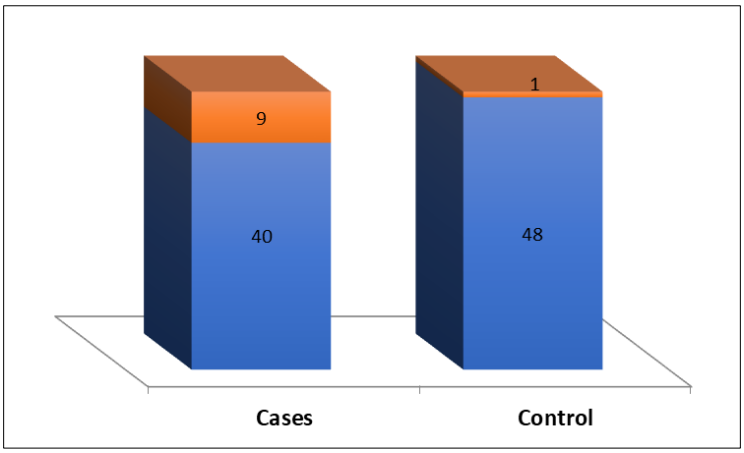
Calculating measures	**Results**	**95% CI**
Absolute Risk Reduction(ARR)	0.2449	0.092827 to 0.38974
Number Needed to Treat(NNT)	4.0000	3 to 11
Relative Risk(RR)	0.2000	0.061786 to 0.647398
Relative Risk Reduction(RRR)	0.8000	0.352602 to 0.938214
Odds ratio	0.1478	0.039629 to 0.551422
Cumulative Incidence (CI) for Misoprostol	0.938776	0.6873 to 1.2522
Cumulative Incidence (CI) for placebo	0.69388	0.4805 to 0.9696
Efficacy	26%	



Two-way Chi-squared test= 9.7, P = 0.0018: significant difference

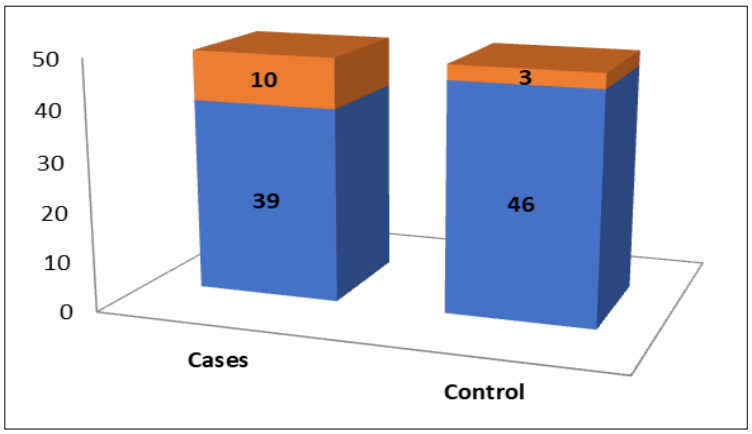
Figure 1 Cases and control groups, which show difficulties in insertion IUD with the use of misoprostol

The adverse events (abdominal cramp and vaginal bleeding), which occurred in study group and control group in relation to misoprostol uses, were shown in figures 2 and 3, these events are significant difference at p value ≤ 0.05.



Two-way Chi-squared test= 6.0985, P = 0.0135: significant difference

Figure 2 Cases and control groups, which show abdominal cramp, after the use of misoprostol



Two-way Chi-squared test= 4.3014, P = 0.0381: significant difference.

Figure 3 Vaginal bleeding in cases and control groups after the use of misoprostol

4. Discussion

The effect of misoprostol is similar to other prostaglandins which change the structure of the cervical extracellular matrix to reach maturity [20]. We found women with cervical misoprostol medication had a higher abdominal cramp compared to women who had a placebo, with P value 0.0135 (<0.05). In addition, we found that the insertion of the IUD was much simpler in the misoprostol group compared with the placebo group, with a P value of 0.0018 (<0.05) highly significant. A significantly higher impact of complications such as vaginal bleeding was also observed in the misoprostol group at P 0.0381 (P <0.05). In our study, no insertion failure occurred in both groups. Adverse events (abdominal cramps being the most frequent) happened in 18.4% and 2.04% of misoprostol group and placebo group respectively.

In a randomized controlled trials study in Egypt revealed that the difficult insertion of IUD in women who received any caesarean sections were significantly higher in the placebo group than in the misoprostol group, with P value <0.001[21], which is in line with our study, with a calculated P value of 0.0018 (<0.05). Similarly to this study, our study revealed that abdominal cramp higher in misoprostol group than in placebo group with P value of 0.0135 (<0.05). However our study revealed that, the occurrence of vagina bleeding in the misoprostol group was higher with P value 0.0381(P <0.05), while it was not significant, (with p value of 0.9) in a randomized controlled trials study in Egypt [21].

Another RCT in Egypt 2018 show a no significant difference in how misoprostol is used for successful insertion of an IUD with p value of 0.25, this was different from our study. About pelvic pain, the results was in line with our study, where pelvic pain occur only in the misoprostol group. In terms of vaginal bleeding, it was different from what we found. [22].

A different Swedish RCT, reported a perceived increase in ease of entry of the IUD in women who received misoprostol with calculated P value (0.039), which was similar to our study, regarding pelvic pain and vaginal bleeding did not demonstrate any differences among the groups in this study, with P value (0.18, 0.65), while in our study, we found a statistical difference between the two groups when it comes to pain perception and vaginal bleeding [23].

Alternative RCT in USA 2011, they did not find any improvement in ease of insertion from the provider's perspective or improvement in pain perceived by women, these results were different from what we observed. It was also found that the misoprostol group increased insertion pain, even though this is not statistically significant. Moreover, the misoprostol group reported significantly more cramping with calculated p value (0.05) and this was similar to our results [24].

5. Conclusion

Our study found that a misoprostol tablet (400 mg) 2 tablets of 200 mg was given orally 3 hours before insertion of the IUD in women without prior vaginal delivery eased the insertion process and lessened the pain felt during insertion. We therefore recommend its use in this group of women.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

No conflict of interest.

Statement of informed consent

Informed consent was taken from all participants included in the study.

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