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Evaluating the efficacy of vaginal misoprostol as a pre-insertion adjunct for intrauterine contraceptive device placement in women with a history of previous cesarean deliveries

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Abstract
Double blinded randomized controlled clinical trial carried out in gynecological and obstetric department in Tikrit Teaching Hospital from 1st October 2023 to 28th July 2024. A sample of 100 women candidates for intrauterine device insertion was enrolled in the study; divided randomly into 2 groups; group A (50 women) received 400 microgram of misoprostol vaginally 3 hours before intrauterine device insertion and group B (50 women) as a control group.
Most of the cases and control group had ≥2 caesarian section (c/s) 26(52%), 32(64%) respectively. In most of the cases group and control group the uterine position was anteverted uterus (AVU), 48(96%), 49(98%) respectively, while retroverted uterus (RVU) found among 2(4%) of the cases and 1(2%) of the controls, this relation was statistically not significant, Failed insertion significantly lower among cases 1(2%) than controls 2(4%), the easy insertion was significantly higher among cases 35 (70%) than controls 23(46%), while difficult insertion was significantly lower among cases 14(28%) than controls 25(50%). The mean visual analogue scale (VAS) scores of cases group (3.4±0.7) was significantly lower than control group (5.3±0.8). The mean patient satisfaction score of cases group (9.1±0.5) was significantly higher than control group (7.8±0.6). Non-significant difference in analgesia needed among cases group 6(12%) and control group 13(26%) of the. The commonest side effect reported among cases was abdominal cramping 10(20%), was significantly higher than control group 3(6%), followed by diarrhea 7(14%), 0(0%) respectively, and nausea 7(14%), 1(2%) respectively.

Keywords: Misoprostol women with previous cesarean deliveries, misoprostol as a pre-insertion adjunct for IUCD

Introduction
An intrauterine device (IUD) is a contraceptive device that is shaped like the letter T and is inserted into the uterus to prevent pregnancy [1].
This contraceptive method is both effective and suitable for women of all age groups, including adolescent girls. The item can be easily removed at any given moment and restore fertility without any impact on reproductive capabilities [2]. The intrauterine device (IUD) can be left in the uterus for up to 7 or 10 years. It is safe to use while breastfeeding and does not interfere with breastfeeding. Additionally, it provides protection against blood spots that can be caused by birth control pills. Occasionally, the intrauterine device (IUD) can result in bleeding, pelvic infection, general infections, facial acne, headaches, and tension. There exist various types of intrauterine devices (IUDs) [3].
Nevertheless, the utilization of this technology is restricted due to its exorbitant expense in certain environments and apprehension regarding the discomfort experienced during the insertion process. Healthcare professionals face several barriers to using the procedure, including insufficient training, concerns about causing pain, and challenges that may result in insertion failure [4, 5]. Insertion failure or difficulty is frequently observed in adolescents and nulligravidas, which is a significant barrier to the use of intrauterine contraceptive devices (IUCDs) in these groups, despite the existing evidence and recommendations in favor of their use [6]. While the majority of IUCD insertions do not necessitate pain control, a notable percentage of nulliparous (17%) and multiparous (11%) women encounter considerable pain and will need proactive pain management [7].

Misoprostol is a cost-effective analogue of prostaglandin E1, known for its minimal side effects [4]. It is commonly used to soften the cervix prior to inducing labor or performing surgical evacuation of the uterus [8]. This medication effectively reduces the amount of force needed to dilate the cervix [9, 10]. The aim of study is to evaluate the role of vaginal Misoprostol (400 mcg) administration 3h prior to IUCD insertion in women delivered only by caesarean section.

Materials

Double blinded randomized controlled clinical trial carried out in gynecological and obstetric department in Tikrit Teaching Hospital from 1st October 2023 to 28th July 2024. A sample of 100 women candidates for intrauterine device insertion was enrolled in the study; divided randomly into 2 groups; group A (50 women) received 400 microgram of misoprostol vaginally 3 hours before intrauterine device insertion and group B (50 women) as a control group. Inclusion Criteria include: All women were 20 to 40 years of age, desired intrauterine device placement and will be able to participate, negative pregnancy test, follow- up in 6-8 weeks for a standard intrauterine device follow-up visit and delivered only by cesarean section only. Exclusion Criteria include; active cervical infection, current pregnancy, uterine anomaly, fibroid in uterus, copper allergy/ Wilson's disease. Undiagnosed abnormal uterine bleeding, cervical or uterine cancer, allergy to misoprostol previous vaginal delivery. Data were collected by direct interview with the women, taking information about demographic variables, obstetrical history, visual analogue scale for pain intensity, and patient satisfaction scale. The doctor who inserted the intrauterine device was asked about the ease of insertion, using ease of insertion score.

Results

The mean age AMOG cases was 27.5±5.4 in comparision to control group 29.1±6.8. The mean BMI AMOG cases was 25.3±4.8 in comparision to control group 26.7±3.7. Most of the cases were rural area 27(54%) in comparision to the control group 24(48%). Most of the cases and controls had 1 ry school education 15 (30%), 14(28%) respectively, followed by read and write 11(22%), 12(24%) respectively. Most of the cases were housewife 28(56%) in comparision to the control group 30(60%). All the above were in statistically not significant relation, P value > 0.05, as shown in table 1. Most of the cases group had ≥2 caserian section (c/s) 26(52%) in comparision control group 32(64%). In most of the cases group and control group the uterin position was anteverted uterus (AVU), 48(96%), 49(98%) respectively, while retroverted uterus (RVU) found among 2(4%) of the cases and 1(2%) of the controls. All the above were in statistically not significant relation, P value > 0.05, as shown in table 2. Failed insertion found AMOG 1(2%) of the cases group and 2(4%) of the control group, the easy insertion found among 35 (70%) of the cases and 23(46%) of the controls, while difficult insertion found among 14(28%) of the cases group and 25(50%) of the control group, this relation was statistically significant P value < 0.05, as shown in table 3.

The mean visual analogue scale (VAS) scores of cases group (3.4±0.7) was siginficatly lower than control group (5.3±0.8), P value <.05, as shown in figure 1. The mean visual patient satisfaction score of cases group (9.1±0.5) was siginficatly higher than control group (7.8±0.6), P value <.05, as shown in figure 2. Analgesia was needed among 6(12%) of the cases group and 13(26%) of the control group, this relation was statistically not significant as shown in table 4. The commonest side effect reported among cases was abdominal cramping 10(20%), was significantly higher than control group 3(6%), followed by diarrhea 7(14%), 0(0%) respectively, and ausea 7(14%), 1(2%) respectively, these relations was statistically significant as shown in table 5.

Discussion

Intrauterine contraceptive devices (IUCDs) are a highly effective form of long-acting reversible contraception (LARC) used by 14.3% of women aged 15-49 years. Among all LARC methods, IUCDs have one of the highest contraceptive efficacy and patient satisfaction rates. According to our findings, misoprostol premedication reduced the risk of IUCD insertion failure in women with previous caesarean section [10]. In current study most of the cases and control group had ≥2 caesarian section (c/s) 26(52%), 32(64%) respectively. This goes with Abdellah MS *et al*. [11] in 2017 who found that most of the women requested IUD had ≥2 caesarian 75% among cases and 69% among control group. Abdul-Aziz *et al*. [12] found that the mean number of previous CS among cases was 2.1±0.7 and among control group was 1.9±0.6.

In most of the cases group and control group the uterin position was anteverted uterus (AVU), 48(96%), 49(98%) respectively, while retroverted uterus (RVU) found among 2(4%) of the cases and 1(2%) of the controls. Abdul-Aziz *et al*. [12] in 2022 found that the anteverted uterus found among 65.9% of the cases and 75. 6% of the controls. Failed insertion significantly lower among cases 1(2%) than controls 2(4%), the easy insertion was significantly higher among cases 35 (70%) than controls 23(46%), while difficult insertion was significantly lower among cases 14(28%) than controls 25(50%). This goes with Salama S *et al*. [13] in 2022 found that the Mirena IUD insertion in group 2 and group 3 (Misoprostol groups) was significantly easier than in group 1 (Placebo group) 71.05%, 76.92%, 45.95%, respectively.

This goes with Abdellah MS *et al*. [11] in 2017 who found that failure of IUD insertion was present in 1.4% in the misoprostol group and 12.9% of the women in the placebo group (p=.003). Successful insertion found in 98.6% in case group and 87.1% of control group. Also Hussein *et al*., 2020 [14] who reported 12.8% failed insertions among advanced practice clinicians. The current study confirmed low pain levels with IUD insertion in women who had only delivered by elective C/S, the mean visual analogue scale (VAS) scores of cases group (3.4±0.7) was significantly lower than control group (5.3±0.8). This goes with Scavuzzi *et al*., 2013 [15], reported significantly more abdominal cramps in the misoprostol group (61.6% vs. 44.1% than the control group. Vaginal administration of misoprostol reduce the severity of side effects than the oral route especially nausea, vomiting and abdominal cramping.

Salama S *et al*. [13] in 2022 found that nausea and/or vomiting and uterine cramps were found significantly more frequently among women who had misoprostol 400 mcg (21.05%) compared to women in control group (0%), Diarrhea was presented only in misoprostol groups, making a significant difference when compared with control group

(P=0.003), there were no significant differences between all groups regarding fever or perforation. The Pain during IUD insertion is multifactorial; application of the tenaculum on the cervical lip elicits severe pain. In addition, transcervical maneuvers as the introduction of sound and IUD inside the uterine cavity add to pain perception [15].

El-Gawad *et al.* [16] in 2021 found that, in women who delivered exclusively via elective caesarean section, misoprostol at a dose of 400 mcg taken vaginally 3 hours before to IUD insertion had a substantial influence on the ease of insertion and reduced the incidence of pain during the procedure Pain is transmitted from the uterus through two different pathways; parasympathetic one (S2-S4) provides sensory innervation to lower part of the uterus with the cervix, and sympathetic (T_{10}-L_1) provides sensory innervation to the uterine fundus [17]. The mean patient satisfaction score of cases group (9.1±0.5) was significantly higher than control group (7.8±0.6). this goes with This goes with Abdellah MS *et al.* [11] in 2017 who found that patient satisfaction level among misoprostol group 8.9±0.4 was significantly higher than control group 7.9±0.2.Khalaf M *et al.* [12] in 2017 found that found that patient satisfaction level among misoprostol group 8.9±0.4 was non significantly higher than control group 8.4±0.3.In a systematic meta-analysis in 2020, Tassi *et al.* concluded that sublingual misoprostol did not show improvement in the facilitation of insertion. However, the use of misoprostol is usually associated with patient comfort [18]. Lopez LM *et al.* 2015 [20] did not demonstrate enhancement in the facilitation of insertion. The commonest side effect reported among cases was abdominal cramping 10(20%), was significantly higher than control group 3(6%), followed by diarrhea 7(14%), 0(0%) respectively, and nausea 7(14%), 1(2%) respectively. This goes with Asia Ahmed Zghair *et al.* [19] in 2024 who found that abdominal cramping and shivering occurred more in misoprostol group (22.9% vs. 4.3% and 14.3% vs. 2.9%, respectively), with no difference between both groups in other side effects. Misoprostol acts through increasing the amount of fluid in the cervical stroma with dissolution of the collagen fibers, thus lead to cervical effacement [20]. So, it was useful before many gynecological procedures as curettage, evacuation, hysterosalpingography and office hysteroscopy [21].

Table 1: The general Characteristics of Study Groups

Characteristics	Cases		Control		P value
	No.	%	No.	%	
Age	27.5±5.4		29.1± 6.8		> 0.05
BMI	25.3± 4.8		26.7±3.7		> 0.05
Residence					
urban	23	46	26	52	> 0.05
rural	27	54	24	48	
Education level					
illiterate	9	18	8	16	> 0.05
read and write	11	22	12	24	
1 ry school	15	30	14	28	
2ndry school	10	20	12	24	
High education	5	10	4	8	
Job					
Housewife	28	56	30	60	> 0.05
Employer	22	44	20	40	
Total	50	100	50	100	

Table 2: Obstetrical and Anatomical Characteristics of Study Groups

Characteristics	Cases		Control		P value
	No.	%	No.	%	
Previous C/S					
1	24	48	18	36	>0.05
≥2	26	52	32	64	
Uterine position					
AVU	48	96	49	98	>0.05
RVU	2	4	1	2	
Total	50	100	50	100	

Caserian Section (c/s), Anteverted Uterus (AVU), Retroverted Uterus (RVU)

Table 3: The ease of Insertion of IUCD among Study Groups

Ease Of Insertion	Cases		Control		P Value
	No.	%	No.	%	
Failed	1	2	2	4	< 0.05
Easy	35	70	23	46	
Dificult	14	28	25	50	
Total	50	100	50	100	

Table 4: The Need for Analgesia among Study Groups

Need for analgesia	Cases		Controls		P value
	No.	%	No.	%	
Yes	6	12	13	26	> 0.05
No	44	88	37	74	
Total	50	100	50	100	

Table 5: The Side Effects among Study Groups

Side Effects	Cases		Controls		P Value
	No.	% denominator =50	No.	% denominator =50	
Abdominal Cramping	10	20	3	6	< 0.05
Shivering	0	0	0	0	
Nausea	7	14	1	2	< 0.05
Diarrhea	7	14	0	0	< 0.05
Head Ache	1	2	1	2	> 0.05

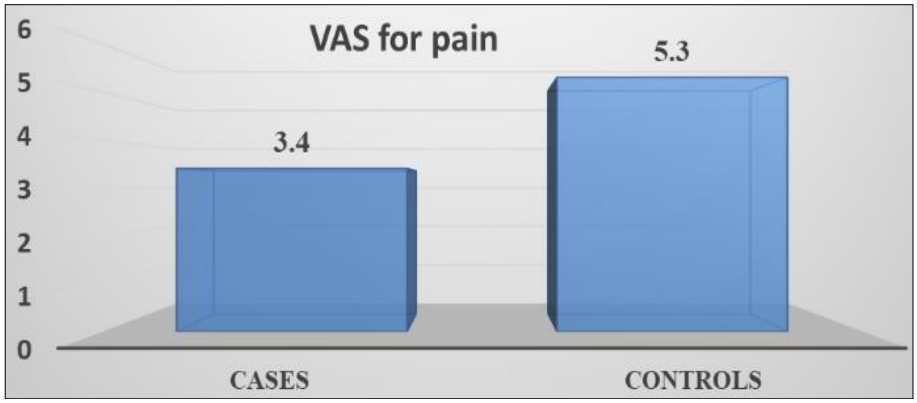

Fig 1: The VAS for Pain of Insertion of IUCD among Study Groups

Fig 2: The Patient Satisfaction Score among Study Groups

Conclusion

Women who had only delivered by elective CS benefited from administration of misoprostol vaginally prior to IUD insertion; however, these women will still experience the misoprostol disadvantages of adverse symptoms and increased waiting time. Access to training and ongoing support for practitioners willing to develop and maintain this procedural skill are essential to enhance uptake of intrauterine contraception in Iraq. Health educational program for health personal about the benefit of misoprostol use prior to IUD insertion. More research with larger sample size needed for study the use of misoprostol in different doses and routs of administration.

Conflict of Interest: Not available.

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References

1. Alle RH, Goldberg AB, Grime DA. Expandi access to intrauterine contraception. American Journal of Obstetrics and Gynecology. 2021;201(5):456.e451-456.e455.
2. Baldw MK, Rodrigu MI, Edelma AB. Lack of insurance and parity influence choice between long-acting reversible contraception and sterilization in women postpregnancy. Contraception. 2020;86(1):42-47.
3. Eeckhaut MC. Intersecting inequalities: education, race/ethnicity, and sterilization. Journal of Family Issues. 2020 Oct;41(10):1905-1929.
4. Mishra N, Panda M, Pyne S, Srinivas N, Pati S, Pati S, et al. Barriers and enablers to adoption of intrauterine device as a contraceptive method: A multi-stakeholder perspective. J Family Med Prim Care. 2017 Jul-Sep;6(3):616-621.
5. Hussein MR, Ahmed DK. Maternal and Fetal Outcome in Patients with History of Polycystic Ovary Syndrome. Indian Journal of Forensic Medicine & Toxicology, 2019, 13(4).
6. Lopes-Garcia EA, Carmona EV, Monteiro I, Bahamondes L. Assessment of pain and ease of intrauterine device placement according to type of device, parity, and mode of delivery. The European Journal of Contraception & Reproductive Health Care. 2023 May 4;28(3):163-167.
7. Levine LD. Cervical ripening: Why we do what we do. In Seminars in perinatology, WB Saunders. 2020;44(2):151216.
8. El-Garhy I, Labib M, Galal M. Cervical priming with sublingual misoprostol prior to insertion of an intrauterine device in women with no previous vaginal delivery A randomized controlled trial. Al-Azhar Medical Journal. 2020 Jul 1;49(3):971-978.
9. Sarkar A, Dhanure S. Safety, Tolerability and Bioequivalence Assessment of Misoprostol 200 µg Tablet. International Journal of Engineering Science Invention. 2017;6(8):12-18.
10. Hussein MR. Evaluation of relationship between obesity biomarker and Anti mullerian Hormone in obese infertile woman. Biochemical & Cellular Archives, 2019, 19(1).

11. Richards MJ, Coleman-Minahan K, Sheeder J. Long-acting reversible contraceptive attitudes and acceptability in adolescents and young adults: a key to patient-centered contraceptive counseling. Journal of pediatric and adolescent gynecology. 2020 Dec 1;33(6):673-680.
12. Abdellah MS, Abbas AM, Hegazy AM, El-Nashar IM. Vaginal misoprostol prior to intrauterine device insertion in women delivered only by elective cesarean section: A randomized double-blind clinical trial. Contraception. 2017 Jun 1;95(6):538-543.
13. Khalaf M, Amin AF, Sayed Z, El-Nashar IM, Abbas AM. A randomized double-blind controlled trial of two different doses of self-administered vaginal misoprostol for successful copper intrauterine device insertion. Middle East Fertility Society Journal. 2017 Dec 1;22(4):264-268.
14. Abdul-Aziz HI, Hussein MR. Effect of Subchorionic Hematoma on Outcomes of Pregnancy in Women with Recurrent Miscarriage.
15. Dermish A, Turok DK, Jacobson J, Murphy PA, Saltzman HM, Sanders JN. Evaluation of an intervention designed to improve the management of difficult IUD insertions by advanced practice. Contraception. 2016;93(6):533-538.
16. Hussein MR, Mohammed RJ, Jameel AA. The umbilical coiling index in term of pregnancy as a marker of perinatal outcome. Ann Trop & Public Health. 2020;23(7):816-823.
17. El-Gawad A, Elshahid E, ATIK A. Vaginal Misoprostol Prior to Intrauterine Contraceptive Device Insertion in Women Who Delivered Only By Elective Caesarean Section: Randomized Clinical Trial. Evid. Based Womens Health J. 2021;11(1):74-82.
18. Caine M, Monaghan S, Macnab WR. Uterine physiology. Anaesthesia & Intensive Care Medicine. 2022 Jun 1;23(6):341-343.
19. Alrawi AAZ, Hussein MR. Comparison between ultrasound and hysteroscopy in the diagnosis of intra-uterine space-occupying lesion in Tikrit teaching hospital. Int. J Gynaecology Sci. 2024;6(2):21-25. DOI: 10.33545/26648393.2024.v6.i2a.35
20. Lopez LM, Bernholc A, Zeng Y, Allen RH, BartzD, O'Brien PA, *et al*. Interventions for pain with intrauterine device insertion. Cochrane Database Syst. Rev., 2015, (7).
21. Afreen N, Jamal S. Misoprostol: A pharma marvel. Res Rev Drugs Drugs. Dev. 2019;2:11-13.

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