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Research

Effect of Diclofenac Versus Misoprostol on Pain Perception During Copper IUD Insertion in Cases of Stenosed Cervix

Abo Gharam MA; Farahat MA; EL-Ahwal LM; EL-Gharib MN*

Department of Obstetrics and Gynecology Faculty of Medicine - Tanta university, Tanta, Egypt

Correspondence to: Mohamed Nabih EL-Gharib; Professor of Obstetrics and Gynecology, Faculty of Medicine, Tanta University, Tanta, Egypt; Tel. +201117040040;

E-mail: mohgharib2@hotmail.com

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ABSTRACT

Background

The current work levels to assess the analgesic effect of vaginal misoprostol versus intramuscular diclofenac sodium and in facilitating IUCD insertion in women with cervical stenosis.

Study Design

A randomized double-blind controlled trial. The work was conducted in the Outpatient Clinic of Tanta university hospital between June 2017 and September 2018. Sixty parous women with the stenosed cervix, meanwhile eligible for copper IUD insertion were recruited and randomized in a 1:1 ratio to vaginal misoprostol 400 ugs or diclofenac sodium 75 mg ampule intramuscularly, 2 hours before insertion of IUD.

Results

Sixty women were enrolled (n = 30 in each group). Misoprostol significantly facilitated the insertion of IUD whereas diclofenac sodium has lowered the average pain score during all steps of IUD insertion. Side effects were higher in the misoprostol group.

Conclusion

This study depicts that the use of 400 ugs of misoprostol vaginally, prior to IUD insertion in women with stenosed cervix facilitates the introduction and IM injection of 75 mg diclofenac sodium reduced the pain perception.

Keywords: *Diclofenac Sodium, IUD, Misoprostol, Setenosed Cervix.*

INTRODUCTION

Intrauterine contraceptive devices (IUDs) are employed by more than 180 million women globally.[1] In spite of the safety and efficacy profiles, IUDs are still underutilized due to pain and difficulty with insertion.[2] Fear of pain is a major concern and disincentive to use the IUD,[3] besides the health care provider worry of difficult insertion.[4]

Validation of an optimal method for reducing pain during IUD insertion will increase the rate of its utilization.[5] Pain during IUD insertion may be due to using of the tenaculum to grasp the cervix and straighten the uterus for proper insertion; transcervical actions, including measuring uterine depth, inserting the IUD insertion tube, and removing the tube; and placement of the device in the uterus.[6]

Frequent systematic reviews have evaluated different medications through various routes for pain relief with IUD insertion.[5,7]

Misoprostol, which is inexpensive prostaglandin E1 analogue-associated with few side effects, is an effective method for treatment of missed and incomplete abortion, induction of provocative abortion as well as for labor induction and prevention and treatment of postpartum

hemorrhage. Moreover, several studies have shown the benefit of misoprostol as a cervical ripening agent in nonpregnant women.[8]

Diclofenac is a nonsteroidal agent with marked analgesic, anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase. It has been used in obstetrics and gynecology to control acute and chronic postoperative pain, menstrual pain, pain related to medical abortions, menorrhagia, intrauterine device insertion, and administrated as tocolytics in preterm labor.[9]

AIM OF THE WORK

The current work aims at assessment of the analgesic effect of vaginal misoprostol versus intramuscular diclofenac sodium and in facilitating IUCD insertion in women with cervical stenosis.

PATIENTS AND METHODS

The current study was a randomized double-blind controlled trial comparing the efficacy of vaginal misoprostol versus intramuscular diclofenac sodium for decreasing pain in sixty women with cervical stenosis undergoing CuT 380A IUCD insertion, during the period from June 2017 to September 2018. The Ethical Board of Tanta Faculty of Medicine approved the study, and we obtained written informed consent from all participants before enrollment.

Inclusion Criteria

Women between (18-40) years of age, wish for IUCD insertion, have already cervical stenosis, or had a history of cervical stenoses, such as premature delivery by cesarean section, history of surgical manipulation of the cervix, cervical inflammation and radiation therapy.

Exclusion Criteria

Active cervical infection, uterine anomaly, fibroid uterus, undiagnosed abnormal uterine bleeding, malignant pelvic tumors and, allergy to misoprostol or diclofenac sodium.

Exclusion Criteria

Patients were randomized to two groups (30 patients each) using simple randomization (closed envelope), they will classify into:

- Group I [Misoprostol Group]: Includes 30 women who received two tablets (400 μg) of misoprostol in the posterior fornix of the vagina (mistake ®, Sigma, Egypt) 2 hours before IUCD insertion.
- Group II [Diclofenac Group]: Includes 30 women who received diclofenac sodium 75 mg ampule intramuscularly (Voltaren ®, Novartis Pharma, Cairo, Egypt) 2-hours before IUCD insertion.

Methods

All patients were submitted to complete history taking, general and pelvic examinations, pelvic ultrasound to evaluate the uterus, cervix, and adnexa, before insertion of CuT 380A IUD.

RESULTS

The results of the current study are depicted in 6 tables:

- Table (1) shows that there was no substantial difference between misoprostol and diclofenac groups as regards age, parity, gravidity, BMI and mode of delivery.
- Table (2) displays that there were insignificant differences between misoprostol and diclofenac groups as regards the history of a genital infection (p-value 0.071).
- Table (3) depicts a significant difference between the misoprostol and diclofenac groups as regards the easiness of IUD insertion. It is clear that misoprostol facilitates the insertion of IUD better than diclofenac sodium.
- Table (4) indicates that there were insignificant differences between misoprostol and diclofenac groups as regards pain score (p-value 0.173). Diclofenac sodium caused relief of pain more than misoprostol.
- Table (5) demonstrates that there is no significance between misoprostol and diclofenac group. Table (5) shows that there were insignificant differences between misoprostol and diclofenac groups as regard standard deviation of pain p-value 0.811
- Table (6): expresses that side effect in IUD insertion were nausea and vomiting in 36.7% and syncopal attack in 3.3% in the misoprostol group in the diclofenac group only gastritis in 20% of patients. Table (6) illustrates that the occurrence of nausea and vomiting was more in the misoprostol group and while gastritis was more in the diclofenac group.

Table 1. Comparison between misoprostol and diclofenac groups as regard demographic data

		Misoprostol	Diclofenac	*T. test*	*p. Value*
Age	Range	18–40	19–39	0.029	0.866
	Mean±SD	26.53±6.65	26.27±5.51		
Parity	Range	1–4	1–4	0.015	0.866
	Mean±SD	2.10±1.03	2.07±1.11		
Gravidity	Range	1–4	1–4	0.015	0.866
	Mean±SD	2.10±1.03	2.07±1.11		
BMI	Range	20–34.2	20.2–35.3	0.008	0.930
	Mean±SD	26.92±3.51	27.0±4.08		
Mode of delivery	NVD	3 (10%)	3 (10%)	0.0	1.0
	CS	27 (90%)	27 (90%)		

Table 2. History of genital infection of both misoprostol and diclofenac groups of the study

History of Genital infection		Misoprostol	Diclofenac	Total
Yes	N	18	11	29
	%	60.0%	36.7%	48.3%
No	N	12	19	31
	%	40.0%	63.3%	51.7%
Total	N	30	30	60
	%	100.0%	100.0%	100.0%
Chi-square	X^2	3.270		
	p-value	0.071		

Table 3. Demonstrate the difficulty of IUD insertion in both groups

Difficulty of IUD insertion	Misoprostol		Diclofenac		X^2	*p. Value*
	N	%	N	%		
Extremely easy	2	6.7	1	3.3	0.352	0.553
Easy	8	26.7	1	3.3	6.413	0.011*
Moderate	14	46.7	13	43.3	0.073	0.795
Difficult	5	16.7	9	30	1.492	0.222
Extremely difficult	1	3.3	6	10	4.043	0.044*

Table 4. The grades of pain by visual analogue scale (VAS) due to IUD insertion in both groups

Pain			Misoprostol	Diclofenac	Total
No (0–4 mm)		N	5	10	15
		%	16.7%	33.3%	25.0%
Mild (5–44 mm)		N	13	6	19
		%	43.3%	20.0%	31.7%
Mild		N	8	11	19
		%	26.7%	36.7%	31.7%
Mild		N	4	3	7
		%	13.3%	10.0%	11.7%
Total		N	30	30	60
		%	100.0%	100.0%	100.0%
Chi-square	X^2		4.985		
	p-value		0.173		

Table 5. Standard deviation of visual analogue scale in both groups

		Misoprostol	Diclofenac	*T. test*	*p. Value*
VAS	Range	0–100	0–100	0.058	0.811

Table 6. The side effects of IUD insertion in both groups

Side effect of IUD insertion	Misoprostol		Diclofenac		X^2	*p. Value*
	N	%	N	%		
Nausea & vomiting	11	36.7	0	0	13.467	0.001*
Syncobal attack	1	3.3	0	0	1.023	0.313
Bleeding	0	0	0	0	-	-
Perforation	0	0	0	0	-	-
Gastritis	0	0	6	20	6.667	0.010*

DISCUSSION

There is no consensus in the literature as regards the optimal method of pain relief for IUD insertion.[10]

The aim of the current study was to evaluate the efficacy of vaginal misoprostol versus intramuscular diclofenac sodium in facilitating IUCD insertion in women with cervical stenosis.

In the present work, we found that there was no strong relationship between both groups as regard to age, parity, gravidity, BMI, mode of delivery and history of genital infection. These findings concur with those of many other authors.[11-13]

In the contemporary investigation, we found that vaginal applications of 400 Aug 2-hours before insertion of IUD led to the easy insertion of the IUD in comparison to IM administration of 75 mg of diclofenac sodium, 2-hours before IUD insertion (p-value 0.001 & 0.044 respectively).

In accord with our result, Mohammed et al. found that 400 micrograms of sublingual misoprostol 2-hours before IUCD insertion reduces the number of failed insertions and pain during insertion. A facilitating effect of misoprostol on IUD insertion was also found.[12,14]

Saav and associates demonstrated that misoprostol facilitates insertion of an IUD, and trims down the difficulty of insertion and number of failed attempts of insertions in women with a narrow cervical canal.[15]

On the contrary to our finding, some authors showed that there is no benefit for the role of misoprostol prior to IUD insertion. However, there is a tendency for possible harm regarding side-effects.[16,17]

In a Cochrane review by Lopez and associates that examined 7 randomized control trials included both oral and intramuscular NSAIDs, it was described that the six studies showed no difference in pain relief between women given NSAIDs or placebo,[5] while only one study showed a beneficial effect of oral naproxen sodium.[18]

In our current work, we found that there was an insignificant difference between misoprostol and diclofenac groups as regards to pain score (*p*-value 0.173).

Fouda and coworkers reported a beneficial consequence of oral diclofenac combined with topical lidocaine in reducing pain with IUD insertion; however, the reduction in pain scores lacked clinical significance.[19]

Several authors reported that non-steroidal anti-inflammatory agents (NSAID) to be effective in reactively treating post-insertion pain, but no benefit was found with prophylactic use. NSAID manages the prostaglandin-mediated side effects.[20,21]

In a Swedish study of 80 nulliparous women randomized to misoprostol and diclofenac versus diclofenac alone an hour before IUD insertion, there was no difference in patient-reported pain scores or side effects; a small statistically significant increase in provider ease of insertion was reported in the misoprostol group.[15]

Espey and his allies found that 400 mg of buccal misoprostol 2-8 hours before insertion of an IUD for nulliparous women did not decrease pain or improve the ease of insertion of an IUD. Most women were willing to wait for a medication that decreases pain, indicating a need to pursue alternatives for pain control with IUD insertion. In addition, they found no differences between misoprostol and placebo groups regarding symptoms of nausea, vomiting, or diarrhea.[11]

In the current survey, we found that side effects in IUD insertion were nausea and vomiting in 36.7% and syncopal attack in 3.3% in the misoprostol group in the diclofenac group only gastritis in 20% of patients.

Mohamed and his companions reported abdominal cramps in 22.3% of participants using misoprostol and in 5.4% using a placebo. Nausea occurred in 6.9% of participants using misoprostol and in 1.5% using a placebo.[12]

Inconsistent with our result Maged et al., found that a higher number of women experienced nausea, regurgitation, and cramps in the misoprostol group compared with the placebo group. The difference was statistically significant, however, only in women who experienced cramps.[13]

Dijkhuizen and co-workers showed that major complications such as perforation or major bleeding did not occur. Vasovagal-like responses such as dizziness, nausea, and vomiting occurred in 20 participants in the misoprostol and 15 participants in the placebo group. Syncope was reported in three participants in the misoprostol group compared with two participants in the placebo group.[16]

Ibrahim and Ahmed investigated whether sublingual misoprostol administered one hour before intrauterine device (IUD) insertion reduces failed insertions, insertion-related complications and pain

in parous women delivered only by elective cesarean section (CS). They found that sublingual administration of misoprostol one hour before IUD insertion in parous women with no previous vaginal delivery does not facilitate the procedure and may cause undesirable side effects.[22]

Maged and associates found that the most usual 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, dysuria, and did not differ between groups.[13]

CONCLUSION

This study depicts that the use of 400 ugs of misoprostol vaginally, prior to IUD insertion in women with stenosed cervix facilitates the introduction and IM injection of 75 mg diclofenac sodium reduced the pain perception.

CONFLICTS OF INTEREST

We have no conflict of interests with no body and have nothing to declare.

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