The Egyptian Journal of Hospital Medicine (July 2017) Vol.68 (3), Page 1520-1526

Lidocaine and Dexamethasone for Paracervical Block Anesthesia in Women with Missed Abortion (Randomized Controlled Trial)

Abdelmegeed I. Abdelmegeed, Amr A. M.Riad, Amin M. Al Ansary, Mohamed A. A. Darwish
Obstetrics and Gynecology Department, Faculty of Medicine , Ain Shams University .
Corresponding author: Abdelalim56@gmail.com, Tel: +20201020232235

ABSTRACT

Aim of the work: nerve block is a technique whereby local anesthetic solutions are infiltrated around a nerve (or perineurally) to provide anesthesia and analgesia. Nerve block for intraoperative and postoperative pain management is associated with improved analgesia, fewer opioid-related adverse events, earlier ambulation and shorter hospital stay when compared to intravenous opioid analgesia alone. This study aimed to assess the efficacy of adding dexamethasone to lidocaine for cervical block anesthesia for prolonging the duration and anesthetic effect in women with missed abortion undergoing vacuum evacuation.

Patients and methods: this study is a randomized controlled trial and it was conducted in accordance with the ethical committee protocols and informed consent procedures of Ain Shams University Maternity Hospital during the period between Augusts to December 2016. Sample size was calculated using PASS® version 11 programs, setting the type-1 error (α) at 0.05 and the power (1-β) at 0.8.

Conclusion: para cervical block can be used as a safe and effective anesthetic technique in patients who need surgical uterine evacuation of missed abortion. Adding dexamethasone can increase effectiveness and duration of para cervical block. Intraoperative pain level was accepted in 80% of patients, these patients had no or mild to moderate accepted pain. We did not detect any postoperative complications in our patients including (excessive vaginal bleeding, hematoma or general manifestations of lidocaine toxicity) and It is recommended to apply PCB for cases of first trimester missed abortion who require uterine suction evacuation. Lidocaine is preferably mixed with dexamethasone to have better results as regards pain score. It is the anesthetic method of choice especially when general anesthesia is a high risk procedure.

Keywords: anti cardiolipin antibody (ACL), Anti-phospholipid syndrome (APS), Beta-human chorionic gonadotropins (B-HCG), BPD, parietal diameter (Bi), Crown rump length (CRL).

INTRODUCTION

Nerve block is a technique whereby local anesthetic solutions are infiltrated around a nerve (or perineurally) to provide anesthesia and analgesia. Nerve block for intraoperative and postoperative pain management is associated with improved analgesia, fewer opioid-related adverse events, earlier ambulation and shorter hospital stay when compared to intravenous opioid analgesia alone [(1).]

First-trimester abortions are usually performed, while the woman is awake or minimally sedated. There is a general expectation that women will experience some pain or discomfort during the abortion. Despite various techniques, many patients still find surgical abortion uncomfortable, 78-97% of patients showed at least moderate procedural pain [(2).]

First-trimester surgical abortions are associated with pain especially during injection of the cervical block, cervical dilation, suction aspiration and postoperatively with uterine cramping despite various methods of pain control. Multiple methods of pain control in surgical abortion are available and appear safe and effective. Pain control can be in the form of local anesthesia, conscious sedation, general anesthesia or a combination of those[(3).] One of the most important aspects in treating missed abortion is the sufficient management of pain during the process of evacuating the uterus, regardless of whether patients undergo dilatation and curettage with sharp curette or manual vacuum aspiration [(4)].

METHODS

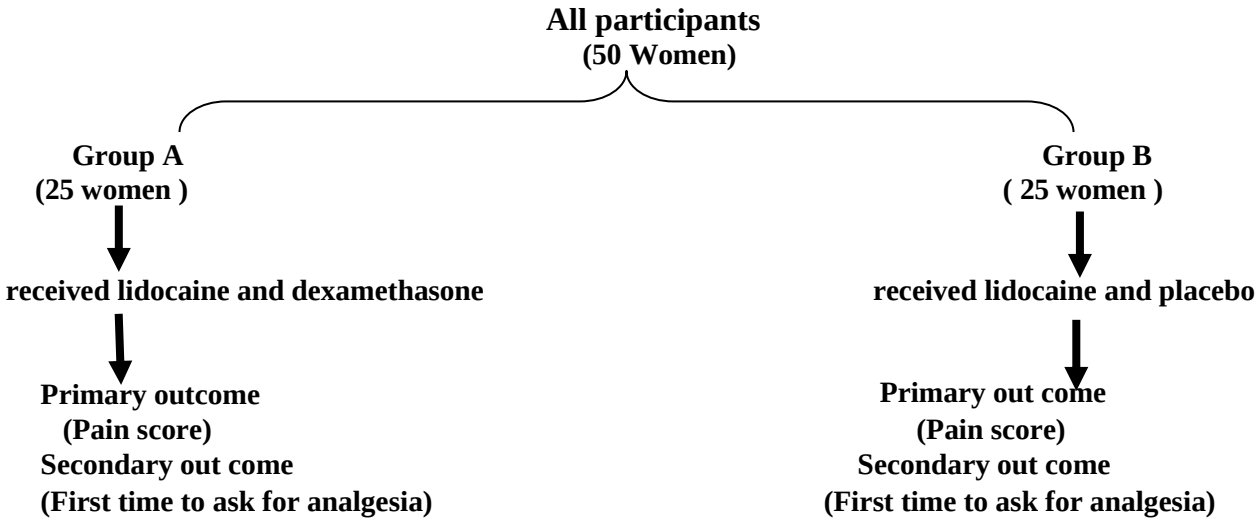
One hundred women who were diagnosed to have missed abortion and who fulfilled all selection criteria (Inclusion-Exclusion criteria shown below) were invited to participate in the study voluntarily and , when accepted , they signed the study's informed consent form . These women were selected either from the outpatient clinic or from the emergency department.

women were randomizely divided into two equal groups

Group A received paracervical block anesthesia in the form of lidocaine and dexamethasone .

Group B received paracervical block anesthesia in the form of lidocaine and placebo.

Received: 3 / 6/2017 DOI: 10.12816/0039698
Accepted: 12 /6 /2017



Inclusion criteria

- Ultrasound confirmed intrauterine pregnancy up to 12 weeks.
- Missed abortion (ultrasonographic diagnosis).
- Cervix is pretreated by 400mcg of misoprostol used vaginally just 6 hours before admission of the woman to the operating room.
- Age: 20-40 years .

Exclusion criteria

- Gestational age > 12 weeks .
- Inevitable and incomplete abortion .
- Hypovolemic or septic shock .
- Psychiatric or neurological diseases .
- Any observable pelvic pathology (mass , PID , tumors).
- Allergy to lidocaine .

OUTCOME MEASURES

***primary outcome:**

Assessment of pain relief will be performed by the patient at two points, intraoperative and postoperative, and these data will be collected 5 minutes and 30 minutes after the procedure .

Pain level will be determined using 0 – 10 visual analogue scale shown below.

[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10]

No pain Worst pain

In this scale, patient will be asked as follow " 0" means no pain and " 10" means worst pain you can imagine , what was it like during operation? How is it now? "

Pain will be classified into 4 levels:

- No pain (0)
- Slight pain (1 – 3)
- Moderate (4 – 6)
- severe (7 – 10)

If pain is not present or slight , pain relief agents will be considered (accepted), if pain is moderate or severe , pain relief agents will be considered (not accepted).

***secondary outcome:**

Duration of anesthetic agent and first time to ask for analgesic dose.

Ethical aspects

The study protocol is designed in agreement to the declaration of Helsinki for ethical committee of Obstetrics and Gynecology Department , Ain Shams University. The study purpose and procedures are to be explained to all approached and eligible women. women have to sign an informed written consent before participating in the study. Any participating woman is informed that she has the right to withdraw from the study at any phase without any adverse impact on the medical service she receives.

Consent

Before being admitted to the clinical study, the patient must consent to participate after the nature, scope, and possible consequences have been explained in a form understandable to her **.** An informed consent document, in Arabic language, contains all locally required elements and specifies who informed the patient **.** After reading the informed consent document, the patent must give consent in writing. The patient**'**s consent must be confirmed at the time of consent by the personally dated signature of the patient and by the personally dated signature of the person conducting the informed consent discussion.

If the patient is unable to read, oral presentation and explanation of the written informed consent form and information to be supplied to patients must take place in the presence of an impartial witness. consent must be confirmed at the time of consent orally and by the personally dated signature of the patient or by a

local legally recognized alternative (e,g., the patient thumb print). The witness and the person conducting the informed consent discussion must also sign and personally date the consent document.

Statistical Methods

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 t test. Skewed data was compared using the Mann-Whitney U test. Categorical data was compared using the chi-squared test or Fisher's exact test, when appropriate. A two-sided p-value <0.05 was considered statistically significant.

RESULTS

Assessed for eligibility (n=65), **excluded** (n=15), **randomized** (n=50), **allocated to study group** (n=25), **allocated to the control group** (n=25) **completed** (n=23) and **completed** (n=17).

Table 1: cases needed general anesthesia during intervention among the studied and control groups:

Condition	Study (N=25)	Control (N=25)	P
Cases needed G.A	2(8.0%)	8(32.0%)	**0.040***
Cases needed no G.A	23 (92.0%)	17 (68.0%)	

Table 1 and fig. 1 showed that requirement of general anesthesia during intervention was significantly less frequent among the studied group than among the control group. Requirement for general anesthesia was after dilatation.

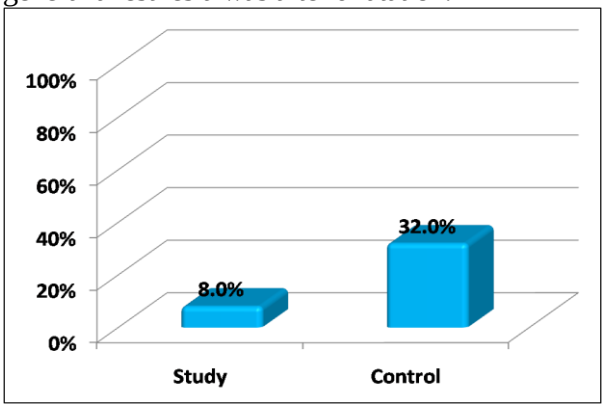


Fig.1: cases needed general anesthesia during intervention among study and control groups

Table 2: pain Score (VAS-10) among the studied and the control groups

Variables		Study (N= 25)	Control (N= 25)	P
Pre-operative Base line	**Range**	0.0-1.0	0.0-1.0	0.394
Vaginal Speculum	**Range**	2.0-3.0	2.0-3.0	0.554
Para cervical Block	**Range**	5.0-7.0	5.0-7.0	0.828
Cervical Dilatation	**Range**	**Study (N= 23)**	**Control (N= 17)**	
		2.0-3.0	3.0-6.0	^ <0.001*
Suction evacuation	**Range**	2.0-3.0	3.0-5.0	^<0.001*
Post-operative pain	**Range**	2.0-4.0	4.0-6.0	^0.001*

^Independent t-test, CI: Confidence interval, *Significant

This table showed no statistically significant difference between both studied groups as regard pre-operative base line, vaginal speculum and para cervical block pain scores but, cervical dilatation, suction evacuation and post-operative pain scores were significantly lower among the studied group than among the control group.

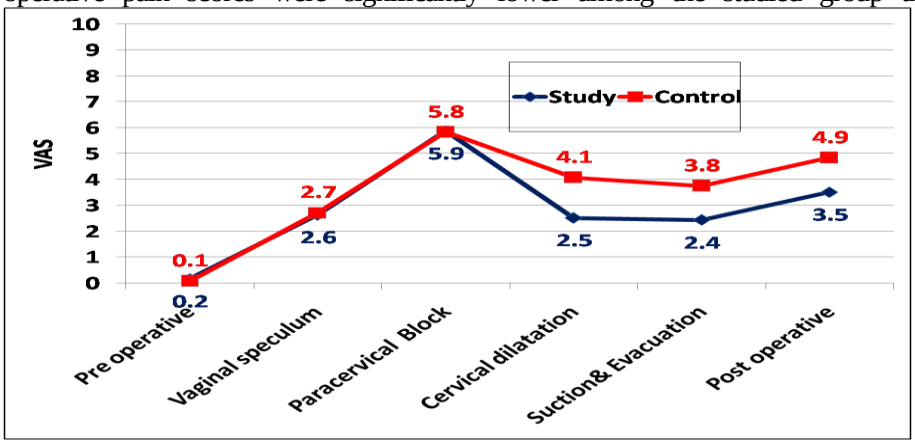


Fig. 2: pain score (VAS-10) among the studied and control groups

Table 3: pain score grades among the studied and control groups.

Variables		Study (N=25)	Control (N=25)	P
Pre-operative Base line	**No**	21 (84.0%)	23 (92.0%)	#0.667
	Mild	4 (16.0%)	2 (8.0%)	
Vaginal Speculum	**Mild**	25 (100.0%)	25 (100.0%)	#1.000
Para cervical Block	**Mild**	21 (84.0%)	22 (88.0%)	#1.000
	Moderate	4 (16.0%)	3 (12.0%)	
Cervical Dilatation	**Mild**	23 (92.0%)	17 (68.0%)	^
	Severe	2 (8.0%)	8 (32.0%)	**<0.001***
Suction evacuation	**Mild**	23 (92.0%)	17 (68.0%)	^
	Moderate	2 (8.0%)	8 (32.0%)	**<0.001***
Post-operative	**Mild**	9 (36.0%)	0 (0.0%)	^
	Moderate	16 (64.0%)	25 (100.0%)	**<0.001***

^ Chi square test, #Fisher's Exact test, *Significant

Table 3 and fig 2 showed no significant difference between the studied and control groups regarding pre-operative base line, vaginal speculum and para cervical block pain grades. Cervical dilatation, suction evacuation and post-operative pain grades were significantly lower among the studied group than the control group.

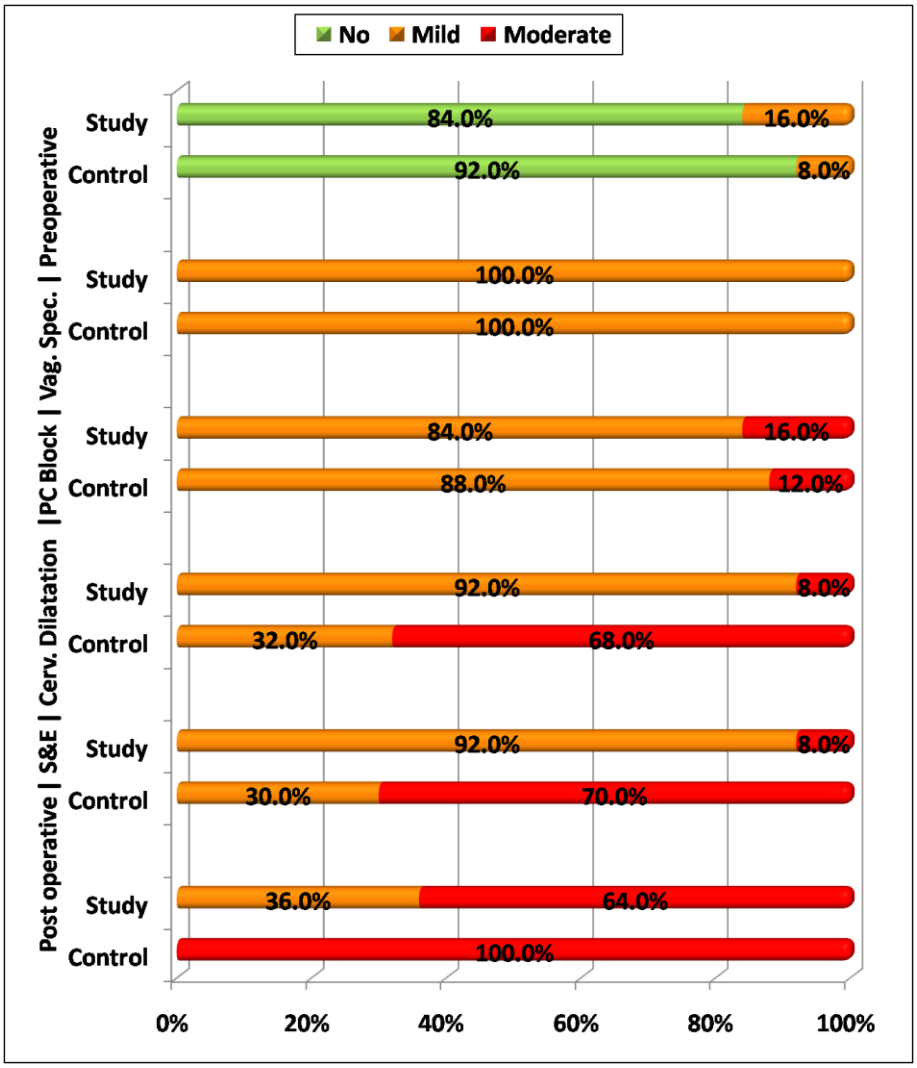


Fig. 3: pain score grades among study and control groups.

Table 4: duration of the operative procedure and postoperative analgesia (minutes) among the studied and control groups. when the patient asked for analgesia, we gave her NSAIDs

Measures	Study (N=23)	Control (N=17)	P
Operative duration (min.)	16.44+-2.3	15.32+-4.2	**0.04**
Postoperative analgesia (min.)	131.8±18.9	61.5±16.9	**<0.001***

^Independent t-test, *Significant

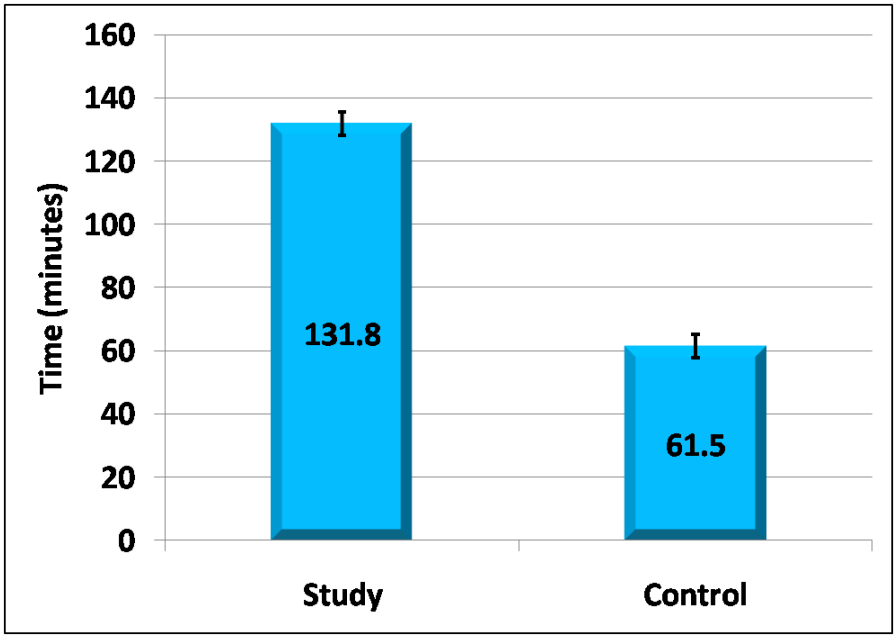


Fig. 4: duration of postoperative analgesia among study and control groups.

Finally, we did not report any postoperative complications in our patients (including excessive vaginal bleeding, uterine perforation, hematoma or general manifestations of lidocaine toxicity like numbness, headache, unconsciousness and convulsions).

DISCUSSION

Para cervical block (PCB) is a local anesthetic technique widely used worldwide for minor gynecological procedures. It depends on injection of lidocaine at para cervical region using a safe technique to block the sensory nerves of the uterine cervix. The anesthetic effect of para cervical block allows cervical manipulation with considerable pain reduction. The current study was a clinical trial performed at Ain Shams University Maternity Hospital. Fifty patients were diagnosed to have missed abortions received para cervical block preoperative then uterine evacuation was performed using electrical vacuum aspiration. This study aimed to evaluate effectiveness and safety of adding dexamethasone to para cervical block. In the current study, intraoperative pain level was accepted in 80 % of patients, these patients had no or mild to moderate accepted pain. The remaining 20 % of patients had non accepted pain of severe intensity. Only 20 % needed general anesthesia to continue the procedure of suction uterine evacuation. This may be contributed to short duration of the procedure and overestimation of pain level by some patients. Need for general anesthesia was associated with significant pain level as higher pain scores were associated with more need for general anesthesia.

These results disagree with those of **Glantz and Shomento** [6] who, in a randomized clinical trial, compared para cervical block with psychological support alone in patients undergoing uterine evacuation using manual vacuum aspiration. They reported that PCB produce non-significant pain reduction,where severe unaccepted pain occurred in almost half of the patients. However none of the patients required general anesthesia to complete the procedure. The difference in pain level in the two studied groups may come from technique of PCB administration (5 ml lidocaine 1% in 0.5 cm depth versus 10 ml in 1 cm injection depth in our study which allow more access to sensory

nerves in uterosacral ligaments and more local tissue distention) and lack of use of dexamethasone in Ivan's study.

On the other hand, **Kawanishi *et al.*** [7] designed a randomized controlled trial to test use of mefenamic acid as a NSAID alone versus para cervical block alone for relief of pain in outpatient uterine curettage. They found that the analgesic effect of oral mefenamic acid (500 mg) was not different from that of para cervical block. The mean pain score in the PCB group by visual analogue scale was 2.5 during dilatation phase and 6.5 during suction phase of fractional curettage (Compared to 2.5 in our study) and about 40% of PCB group required intraoperative sedation as they didn't tolerate intraoperative pain (Compared to 20 % in our study). Higher pain scores in Saowanee's study mostly come from use of sharp curette, more rough manipulation, in fractional curettage with longer duration of the procedure, compared to suction evacuation in missed abortion (gentle and fast procedure). Also, they did not use dexamethasone with the PCB group.

Glantz and Shomento [6] in a randomized double blinded clinical trial compared chloroprocaine and saline in two techniques for para cervical block in uterine evacuation using mechanical aspiration of contents. They concluded that chloroprocaine is superior to saline as anesthetic agent causing significant more pain reduction, however PCB did not provide adequate anesthesia. Mean pain score during aspiration was 6.3 with standard deviation of 2.3 (2.4 ± SD 0.5 in our study). ***Boonsri et al.***[4] in a randomized controlled trial also disagreed with Miller's study. They proposed that the non-significant effect of lidocaine compared to saline in PCB in Miller`s study was due to adding benzyl alcohol to saline. Benzyl alcohol has a proven analgesic effect. In addition, there was no reported waiting period between injection and curettage and lidocaine needs few minutes to exert its analgesic effect as a nerve blocker. They designed a randomized controlled trial to compare lidocaine and plain saline for pain relief in fractional curettage. They concluded that lidocaine is more effective than plain saline for para cervical block during fractional curettage and the anesthetic mechanisms of lidocaine are from both mechanical tissue distention and peripheral nerve block. Mean pain score in the study was 4 on visual analogue scale (range 2 to 6) compared to 2.4 with range of 0 to 10 in our study.

The current study revealed that there was no significant effect of patient age on level of pain during uterine evacuation under para cervical block. This is consistent with the results of **Pio Ivan *et al.***[3] who examined some factors that may affect analgesic effect of para cervical block. They found no role of patient age on intraoperative pain scores. Also, **Glantz and Shomento** [6] didn't find any significant relation between patient age and pain level during aspiration of uterine contents in induced abortion regardless local anesthetic used (Chloroprocain or saline).

The current study showed that number of vaginal deliveries has a significant negative correlation with intraoperative pain level where more vaginal deliveries were associated with less pain levels; however neither number of caesarian sections nor abortions had any significant effect on intraoperative pain score during uterine evacuation under para cervical block. This finding may contribute to the fact that more vaginal deliveries are associated with more cervical dilatation which means easier procedure and shorter duration.

This result is not consistent with those of **Glantz and Shomento** [6] who didn't find any significant relation between parity and pain level experienced by patient during aspiration of uterine contents of induced abortion. They didn't classify parity into vaginal deliveries, caesarian sections and abortions (as in our study) which mostly made difference between the two studies.

In the current study, the estimated gestational age had a significant negative correlation with pain level where more gestational age was associated with less pain scores. Our results agree wit **Glantz and Shomento** [6] where there was a trend in the multivariate analysis toward an association between gestational age and aspiration pain however it was not statistically significant (P = 0.07 compared to 0.001 in our study).

Our study revealed a significant negative correlation between cervical dilatation and intraoperative pain level where more cervical dilatation was associated with less pain scores. More cervical dilatation allows larger canola to be used and this means less uterine manipulation and shorter duration of procedure.

This result is consistent with those of **Ali and Meral** [5] who, in a randomized controlled study, examined effect of depth of injection of local anesthetic and basal dilatation of cervix in level of pain during legal abortions. They found that irrespective of depth of injection, a

significant negative correlation was reported between basal cervical dilatation and pain level where more dilated cervix was associated with significant less pain scores.

This results is consistent with those **Pio *et al.*** [(3)] who didn't report any postoperative complications (including nausea, vomiting or allergic reactions).

However, **Renner *et al.*** [(2)] reported 3 patients out of 44 (7%) who received PCB complained of dizziness and generalized numbness which mostly resulted from intravascular lidocaine injection due to unsafe injection of lidocaine at 3 and 9 o'clock (close to cervical branches of uterine vessels) and lack of intermittent aspiration technique during lidocaine administration. Also, **Leslie and Mark**[(8)] reported that 11% of their patients complained of complications of mild lidocaine toxicity including lip numbness, ear noising or dizziness. Although lidocaine injection was more superficial, safe injection (with intermittent aspiration) was not reported in Miller`s methodology.

CONCLUSION

-Para cervical block could be used as a safe and effective anesthetic technique in patients who need surgical uterine evacuation of missed abortion. Adding dexamethasone could increase effectiveness and duration of Para cervical block.

-Intraoperative pain level was accepted in 80 % of patients, these patients had no or mild to moderate accepted pain.

-We did not report any postoperative complications in our patients including (excessive vaginal bleeding, hematoma or general manifestations of lidocaine toxicity).

RECOMMENDATIONS

-It is recommended to apply PCB for cases of first trimester missed abortion who require uterine suction evacuation.

-Lidocaine is preferably mixed with dexamethasone to have better results as regards pain score.

-It is the anesthetic method of choice especially when general anesthesia is a high risk procedure.

REFERENCES

1- **Albrecht E, Kern C, Kirkham KR (2015)** : A systematic review and meta-analysis of perineural dexamethasone for peripheral nerve blocks.Anaesthesia ,(**70):71-83**.

2- **Renner RM, Nichols MD, Jensen JT, Hong Li & Edelman AB (2012) :** Paracervical block for pain control for first trimester surgical abortion. Obstetrics & Gynecology, **119(5): 1030-1037.**

3- **Pio I, Hernando G, Casilda N and Alejandro P (2004):** Paracervical block in incomplete abortion using manual vacuum aspiration. Nuestra Sen˜ ora de Altagracia Hospital . Dominican Republic. Obstet Gynecol **.,(103):943–51**.

4- **Boonsri C , Puchong L , Pratak O, Yongyoth H (2001):** Lidocaine versus plain saline for pain relief in fractional curettage : A randomized controlled trial. Department of Obstetrics and Gynecology, Ramathibodi Hospital , Mahidol University , Bangkok , Thailand. Obstet Gynecol .,**(98):592–5.**

5- **Ali C and Meral C (1997):** Effect of deep injection of local anesthetic and basal dilatation of cervix in management of pain during legal abortions, a randomized controlled study. Department of Obstetrics and Gynecology, Cumhurryet University School of Medicine, Sivas, Turkey. Contraception, **(56): 85-87.**

6- **Glantz J , Shomento S (2001):** Comparison of paracervical block techniques during first trimester pregnancy termination . Department of Obstetrics and Gynecology, University of Rochester School of Medicine and Dentistry, Rochester NY, USA. International Journal of Gynecology and Obstetrics, **(72): 171-178.**

7- **Kawanishi R, Yamamoto K, Tobetto Y, Nomura K, Michihisa K, Go R *et al*. (2014):** Perineural but not systemic lowdose dexamethasone prolongs the duration of interscalene block with ropivacaine: a prospective randomized trial. *Local and Regional Anesthesia* **,(7):5–9.**

8- **Leslie M , Mark P (2006):** A double-blind randomized comparison of lidocaine and saline for cervical anesthia. University of Washington, Seattle; and the Yakima Feminist Women Collection, Yakima, Washington. Obstet Gynecol**.,(87):600-4.**