ORIGINAL ARTICLE

COMPARISON OF RECTAL DICLOFENAC SODIUM VERSUS INTRAMUSCULAR TRAMADOL FOR PAIN RELIEF IN MANUAL VACUUM ASPIRATION

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Background: Manual Vacuum Aspiration using paracervical block is commonly employed for management of first trimester miscarriage. Opioids like tramadol and non-steroidal anti-inflammatory drugs like diclofenac are employed in addition to paracervical block for analgesia. This study was conducted to compare efficacy of rectal diclofenac sodium versus intramuscular tramadol for pain relief in Manual Vacuum Aspiration. **Method:** This randomized controlled trial was conducted at Mother and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad from 21 January to 20 July 2017. A sample size of 114 was calculated, 57 in each group. In Group A, patients received injection tramadol 100 mg intramuscularly 20 minutes before Manual Vacuum Aspiration. In Group B patients received diclofenac suppository 100 mg rectally 60 minutes before procedure. Within three minutes of completion of procedure patients were asked to rate their pain scores on Visual Analogue Scale. **Results:** Both groups were comparable in terms of age, parity and gestational age. The mean pain score of Group A (intramuscular tramadol) was 5.05±0.72 whereas that for Group B (diclofenac suppository) was 2.88±0.85 (p<0.001). Frequency of patients for group A in mild, moderate and sever pain categories was 13 (22.8%), 41 (71.9%) and 2 (5.3%) respectively, whereas for group B it was 52 (91.2%), 5 (8.8%) and zero respectively. The difference in frequency was significant (p<0.001). **Conclusion:** Rectal diclofenac leads to better pain relief as compared to intramuscular tramadol in Manual Vacuum Aspiration.

Keywords: Manual Vacuum Aspiration, Tramadol, Diclofenac, Rectal Suppository

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INTRODUCTION

Early pregnancy loss is common, every fourth woman experiencing it in her lifetime.[1] World over complications linked to abortion lead to 13% maternal mortality and adverse consequences in two to seven million women. In addition, it carries emotional, social and financial burden for woman, her family and high healthcare costs.[2] Amongst the management options of first trimester miscarriages, manual vacuum aspiration (MVA) is cost effective, fastest method leading to fewer serious complications.[1,3] Nevertheless, the pain caused by cervical and uterine manipulation during MVA is the main disadvantage of the procedure.[3,4] In spite of several analgesic approaches, many patients find surgical abortion extremely uncomfortable and up to 97% report at least moderate procedural pain.[3]

Local anaesthesia in form of paracervical block is usually employed for surgical abortion, as for other day care gynaecological procedures. Apart from clinic logistical concerns, risks and cost associated with general anaesthesia, surgical abortions are also mostly performed under local anaesthesia due to the short procedure time.[4–6] Paracervical block, injected into the cervix targets S2 to S4 parasympathetic fibres innervating lower part of uterine body and cervix thus reducing pain caused by cervical dilatation and movement.[5,6] Paracervical block cannot fully access sympathetic fibres from T10 to L1 that run via inferior hypogastric nerve and ovarian plexus innervating fundus and lower part of uterine body. They run along the ovarian vessels, higher in the pelvis where local infiltration does not reach. Therefore, adequate pain relief requires additional analgesics.[4–6]

The choice of analgesia depends upon doctor's preference, drug availability, affordability, safety and the hospital policy. In a developing country, the ideal analgesic should be economical, easily administrated and requiring minimal resuscitation equipment.[3] Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Opioids are usually employed to combat this pain. In our institution tramadol, a μ-opioid receptor agonist[7] is the commonly used analgesic adjuvant to paracervical block. So far, studies have compared tramadol and opioids with oral, intravenous and intramuscular NSAIDs for analgesia during surgical abortion and MVA.[6] This study was undertaken to determine whether rectal diclofenac sodium as compared to intramuscular tramadol results in better pain relief during MVA, when given adjunct to paracervical block.

MATERIAL AND METHODS

This study, a randomized controlled trial was conducted at Mother and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad from 21 January to 20 July 2017, after approval of Ethical Review Board. Women attending the gynaecological emergency and out-patient

clinic of MCHC, with first trimester miscarriage and who consented to participate in the study were included. Miscarriage was diagnosed by clinical evaluation and ultrasound. Patients with missed miscarriage, anembryonic pregnancy and incomplete miscarriage were included. Patients who had history of allergy to drugs used, with two or more previous lower segment caesarean sections, septic induced abortion, haemodynamic instability, asthma, haemorrhoids, known coagulation disorder and failed medical management of miscarriage were excluded.

Sample size was calculated using WHO sample size calculator. Considering the values of level of significance as 5%, power of test as 80%, population standard deviation as 2.14, test value of mean pain score for tramadol as 5 and test value of mean pain score for diclofenac sodium as 4.2, a sample size of 114 was calculated.[3,8]

Patients were allocated to the two groups by simple randomization each group having 57 patients. Allocation was done by lottery method. Written, informed consent was taken from each patient. In Group A, injection tramadol was given intramuscularly at dose of 100 mg, 20 minutes before manual vacuum aspiration. In Group B, diclofenac suppository 100 mg was placed rectally 60 minutes prior to procedure. The manual vacuum evacuation was completed in keeping with standard clinical protocol including paracervical block.[5] Visual Analogue Scale (VAS) was used in first three minutes to rate pain during the procedure. VAS of 0 indicated no pain and VAS of 10 indicated the worst possible pain. The vital signs were monitored every 15 minutes till patient was stable for one hour. The procedure was completed in all cases and no complication like haemorrhage or anaphylaxis occurred.

SPSS-21 was used for data analysis, Mean and SD was calculated for quantitative data. Frequency and percentages were calculated for qualitative data. Chi-square test was employed for comparing qualitative variables. Independent samples *t*-test was applied to compare mean pain score between rectal diclofenac sodium and intramuscular tramadol group, and $p \leq 0.05$ was taken as significant.

RESULTS

Both groups were comparable in terms of maternal age, parity, gestational age and having undergone caesarean section (Table-1). Table-2 shows comparison of mean pain score between the two groups. Frequency of patients with mild, moderate and severe pain was compared between the two groups (Table-3). The need for additional analgesia, adverse effects and patient satisfaction have been compared in Table-4 between the two groups.

Table-1: Comparison of possible confounders between the two groups

Variables		Group A	Group B	*p*
Mean Age		27.89±4.55	29±4.39	0.19
Mean Gestational Age		9.19±1.54	9.54±1.58	0.23
Mean Parity		2.70±1.56	2.25±1.60	0.12
Mean Previous Pregnancy Loss		0.33±0.57	0.51±0.63	0.12
History of Caesarean Section	Yes	4 (7%)	7 (12.3%)	0.53
	No	53 (93%)	50 (87.7%)	

Table-2: Comparison of mean pain scores between the two groups

Groups	Mean pain score	*p*
Groups A (Intramuscular Tramadol)	5.05±0.95	<0.001*
Group B (Rectal Diclofenac)	2.79±0.92	

*Significant

Table-3: Frequency comparison of pain categories between the two groups

Groups	Mild (0–4)	Moderate (5–7)	Severe (8–10)	*p*
Groups A Intramuscular Tramadol	13 (22.8%)	41 (71.9%)	2 (5.3%)	<0.001*
Group B Rectal Diclofenac	52 (91.2%)	5 (8.8%)	0	

*Significant

Table-4: Comparison of additional pain related variables between the two groups

		Group A	Group B	*p*- value
Need for Additional Analgesia	Yes	4 (7%)	0	0.12
	No	53 (93%)	57(100%)	
Adverse Effects	No	49 (47.60%)	54 (52.4%)	0.20
	Yes	8 (14%)	3 (5.3%)	
Patient Satisfaction	Satisfied	48 (84.20%)	56 (98.2%)	0.02*
	Neither satisfied nor dissatisfied	4 (7%)	1 (1.8%)	
	Dissatisfied	5 (8.80%)	0	

*Significant

DISCUSSION

Pain relief is important in ambulatory surgery like MVA for successful and safe completion of surgery.[9] This study demonstrated better analgesia with diclofenac rectal suppository as compared to intramuscular tramadol when given adjunct to paracervical block for pain relief during MVA.

Tramadol is a central analgesic and binds with μ-opioid receptor. It inhibits serotonin and norepinephrine neuronal reuptake.[7,10] Analgesic action of diclofenac on the contrary is multimodal and more diverse, acting both at central and peripheral level.[11–13] Diclofenac acts by inhibition of prostaglandin synthesis by inhibiting cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2). It also inhibits thromboxane-prostanoid receptor, inhibits lipoxygenase enzymes and activates the nitric oxide-cGMP antinociceptive pathway. So it reduces chemical agents causing pain and decreases pain transmission.[11,14]

Decrease in prostaglandin production diminishes response of peripheral and central nervous system to stimuli. It thereby reduces sensitization of peripheral and central nervous system making it an ideal drug to administer preceding noxious stimulus like surgery.[15] Moreover, rectal route bypasses enterohepatic circulation thus making more active drug available.[16,17] This may explain patients in diclofenac suppository having lower mean pain score and none reporting severe pain. Also, no patient required additional analgesia in diclofenac group as compared to tramadol group due to adequate pain relief with the former, although the difference did not reach statistical significance.

Literature review did not reveal any study comparing tramadol and diclofenac administered through these routes during MVA. Diclofenac and tramadol rectal suppositories have been compared for analgesia in patients undergoing abdominal hysterectomy[7] and caesarean section[10] with better pain relief with diclofenac suppository, as seen in the present study.

Out results also showed better satisfaction in patients receiving diclofenac suppository as compared to the group receiving tramadol. Better patient satisfaction has been reported with superior pain relief in other studies as well.[3,18] Patient satisfaction might also have been linked with the route of administration.[17,19] Furthermore, rectal administration avoided the painful intramuscular injection and gastrointestinal symptoms associated with oral route. However, overall patient satisfaction was good in both groups as pain relief is just one feature contributing to patients' satisfaction with the procedure.[18,20] Other factors like shorter hospital stay and fewer side effects might have contributed to patient satisfaction as well.

Patients in diclofenac suppository group reported lesser side effects as compared to intramuscular tramadol although the difference was not statistically significant. Diclofenac has been shown to have lesser side effects than tramadol in other studies too.[7]

Another reason may be that rectal route of diclofenac leads to lesser side effects than oral and intramuscular routes.[7,21] Frequency of side effects was lower in patients given tramadol too as lower dose of tramadol was given due to dual analgesia used, that is, tramadol was given in addition to paracervical block. In the current study we could not do blinding of patients and surgeons to the administered drug due to separate routes of administration.

CONCLUSION

Rectal diclofenac leads to better pain relief as compared to intramuscular tramadol in Manual Vacuum Aspiration.

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