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THE USE OF DICLOFENAC FOR PAIN RELIEF IN THE FIRST STAGE OF LABOUR

Ali F. Al-Assadi†

ABSTRACT

A prospective case control study was conducted in Basrah maternity and children hospital between April /2008 and September 2009 to evaluate the efficacy of diclofenac on reducing pain during the first stage of labour in *primigravidae* and *multigravidae*. The control group (group I) were given a single dose of normal saline (2 ml) by deep intramuscular injection in the gluteal region. Group II (the study group) were given a single injection of 75 mg diclofenac in 2 ml solution (Olfen / Mepha Company) by deep intramuscular injection in the gluteal region. The clinical trial involved a total of 193 unselected pregnant women, 97 women were randomly enrolled into group I, 47 of them were *primigravidae* and 50 were multigravidae. Group II included 96 randomly selected pregnant women, 48 of them were *primigravidae* and the rest were *multigravidae*.

There was no decrease in pain score, in fact increase in pain score, in group I in both *primigravidae* and *multigravidae* after administration of normal saline with a mean increase in pain score of (0.34) and (0.24) in *primigravidae* and *multigravidae* respectively. While in group II there was a statically highly significant reduction in pain score in both *primigravidae* and *multigravidae* after diclofenac administration with a significant reduction in pain score (2.23) and (2.277) in *primigravidae* and *multigravidae* respectively. There was neither statistically significant effect of diclofenac administration on the duration of first and second stages of labour in both *primigravidae* and *multigravidae*, nor neonatal or maternal side effects were detected. In conclusion diclofenac was found to be safe and effective as an analgesic agent in the first stage of labour.

KEYWORDS: Diclofenac, analgesia in the first stage of labour.

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage and described in the term of such damage [1].

The management of labor pain is a major goal of intra-partum care. There are two general approaches: pharmacologic and non-pharmacologic. Pharmacologic approaches are directed at elimination of the physical sensation of labor pain, whereas non-pharmacologic approaches are largely directed toward prevention of suffering. Suffering may be defined in terms of any of the following psychological elements: a perceived threat to the body and/or psyche; helplessness and loss of control; distress; insufficient resources for coping with the distressing situation; even fear of death of the mother or baby [2].

Although pain and suffering often occur together, one may suffer without pain or have pain without suffering [2]. The non-pharmacologic approach to pain management includes a wide variety of techniques that address not only the physical sensations of pain, but also attempt to prevent suffering by enhancing the psycho-emotional and spiritual components of care[(2)]. some of these techniques include (Childbirth preparation classes, Help from a support person, Touch and massage, Being active during labour rather than staying in bed, Pleasing surroundings with the use of music, dim lights and aromatherapy, Use of a warm water bath or shower, Sterile water injections, Hypnosis and acupuncture [3]. The pharmacological techniques are also many and include regional and non-regional (inhalational and non-inhalational) [4]. Regarding the non-inhalational analgesia, although opioids have been used in obstetrics for over 100 years, sufficient evidence for their efficacy and safety is lacking [5,6]. Inhalational analgesia (Entonox) 50/50 mix of oxygen and nitrous oxide is significantly reducing pain in 50% of patient compare to placebo [7]. Among the regional analgesia, epidural analgesia is considered the gold standard for effective pain relief in labour [8]. Diclofenac sodium is one of the nonsteroidal anti-inflammatory drugs, in a single dose they have analgesic effect and in a regular full dose they have both analgesic and anti-inflammatory action [9]. For acute pain it is given in a dose of 75 mg once or twice daily by deep intramuscular injection [9].

Diclofenac has been assigned to pregnancy category C prior to 30 weeks gestation and to category D starting at 30 weeks of gestation by the Food and Drug Administration (FDA). Use of diclofenac or other NSAIDs late in pregnancy (after 30 weeks gestation) may cause premature closure of the ductus arteriosus and prolong labor and delivery. If diclofenac is used after 30 weeks of pregnancy, the patient should be warned of the potential hazard to the fetus. Animal studies have failed to reveal evidence of teratogenicity, despite the induction of maternal toxicity and fetal toxicity. There are no controlled data on human pregnancy. Diclofenac should be given during pregnancy only when the potential benefits outweigh the potential risks [10].

The severity of pain can be assessed using different pain scaling systems, ***Behavioral measure scale*** [11] is especially useful for measuring pain in a patient who have a poor language command or when mental clouding and confusion limit the patient's ability to communicate meaningfully. Under these circumstances behavioral

measures provide important information that is otherwise unavailable from patient self-report.

AIM OF THE STUDY

The aim of this study was to evaluate the efficacy of diclofenac as an analgesic drug during the first stage of labour and to study the unwanted maternal and fetal effects. Despite the few reports of maternal and fetal toxicities, animal studies have failed to reveal any evidence of teratogenicity. Our paper therefore will try to shed some light on this and confirm our belief that Diclofenac can be safely used not only in postpartum period but also during labour.

MATERIALS AND METHODS

This is a case control prospective study which was conducted at Basrah maternity and children hospital during the period from the 15th of April 2008 to the 21st of October 2009. In our society reassurance, guidance, encouragement, and support are the main methods used to help laboring women to cope successfully with pain and stress of labour so it was easily accepted by those women to participate in this study (receiving either placebo or diclofenac for pain relief).

Table 1. The patients' characteristics

Character	Normal saline		Diclofenac	
	Primigravidae (No = 47)	Multigravidae (No = 50)	Primigravidae (No = 48)	Multigravidae No =(48)
Mean patient age	24.42 ± 5.78	28.52 ± 6.05	22.58 ± 5.1	28.25± 6.4
Mean gestational age	38.97 ± 0.87	38.56± 0.70	38.54± 1.8	38.87± 0.86
Mean Bishops score	4.97 ± 0.79	5.18 ± 0.74	5.12 ± 0.76	4.89± 0.77

After a proper counseling about the probable side effects of diclofenac and obtaining their written consent unselected primigravidae and multigravidae were enrolled in the study.

Inclusion Criteria

Primigravidae and *multigravidae* (Para 1–4) with a term pregnancy were admitted to the labour room in the active phase of labour with a cervical dilatation from (4–8 cm) with no any contraindication for the use of diclofenac.

Exclusion Criteria

This involves history of the previous uterine scar and history of medical diseases (Diabetes Mellitus, hypertension, cardiac deceases, chronic renal disease and bronchial asthma).

Primigravidae and *multigravidae* were randomly divided into two groups:

Group I (Study group)

After a review of the history and examination, their pain was assessed according to (Behavioral pain scale)[11] as described in the introduction. They were given a single dose of 75mg diclofenac ampule (Olfen) by deep I.M injection in the gluteal area. Pain was reassessed after (half hour)by the same doctor .Further management of Labour (first and second stages) were carried out as usual with intermittent fetal heart auscultation every hour, uterine contractions were monitored by uterine palpitation.

Group II (Control group)

After reviewing the history and examination, their pain was assessed according to (Behavioral pain scale) [11]. They were given a single dose of normal saline (two ml) by intramuscular injection in the gluteal region, pain was reassessed after half hour by the same doctor, and further management of labour was carried out as in the group I.

After delivery neonates were assessed using Apgar score at 1 and 5 minutes by the obstetrician, pediatrician was informed if necessary. Data were analyzed using t-test.

RESULTS

Analysis of data revealed that the total number of women in group 1 (normal saline group) was 97, 47 of them were *primigravidae* and 50 were *multigravidae*.

Table 2. Effect of type of analgesic agent on pain score

Analgesic / Pain Score	Normal saline		Diclofenac	
	Primigravida	Multigravida	Primigravida	Multigravida
First Pain Score	9.489± 0.5	8.92±0.6	8.25± 1.494	7.95± 1.47
Second Pain Score	9.829± 0.43	9.2± 0.63	6.02± 1.37	5.18± 1.79
Mean Improve-Ment in Pain Score	-0.34	-0.28	2.23	2.77

In group 2 the total number was 96, 48 of them were *primigravidae* and the rest were *multigravidae*.

The P- values for independent sample t-test showed no statistically significant differences between *primigravidae* in both groups and between *multigravidae* in both groups regarding the three characters.

Paired sample t-test for pain score

Test of significance	Primigravidae		Multigravidae	
	Normal Saline	Diclofenac	Normal Saline	Diclofenac
t–value	-3.49	14.61	-3.69	14.85
P–value	0.000	0.000	0.000	0.000

This table shows the mean pain scores before (first) and after (second) drug administration and the mean improvement in pain score.

In group I in both *primigravidae* and *multigravidae* there was statistically significant increase in pain score after administration of normal saline with a mean increase in pain score of 0.34 and 0.24 in *primigravidae* and *multigravidae* respectively.

While in group II there was statistically highly significant reduction in pain score in both *primigravidae* and *multigravidae* after diclofenac administration with a mean improvement (reduction) in pain score (2.23) and (2.277) in *primigravidae* and *multigravidae* respectively.

Table 3. Effect of the drug on the duration of the first and second stages of labour

Character	Normal saline		Diclofenac	
	primigravidae	multigravidae	primigravidae	Multigravidae
Duration of 1st stage (hours)	5.8936±1.088	3.88± 0.84	5.479± 1.2	4.14± 1.16
Duration of 2nd stage (minutes)	38.93±9.9	35.2± 16.03	38.75± 13.28	35.83± 21.42

Paired sample t- test of duration of labour

Stage of labour	Primigravidae	Multigravidae
First stage (hour)	0.93	0.202
Second stage (minute)	0.938	0.869

Table 3 shows there was no statistically significant effect of diclofenac administration on the duration of the first and second stages of labour in both *primigravidae* and *multigravidae*.

There was no neonatal adverse effect from diclofenac administration with a mean Apgar scores at 5 minutes above 9 in all groups.

DISCUSSION

Non regional pharmacological techniques are the most frequent employed technique for labour analgesia [12,13] of which Pethedine remains popular in many obstetric units . Narcotic analgesia are frequently associated with a lot of maternal and fetal side effects [12,14].

The duration of use of pharmacological analgesia is itself a risk factor: as an example, the duration of epidural analgesia is associated with the likelihood of maternal fever and all the clinical concerns that go with it. The cumulative dose, which increases over time, affects the woman's mobility and effectiveness in expulsion [15]. In addition to that it needs a highly trained person for administration and monitoring.

In this study we compare the effect of diclofenac to a placebo (normal saline) on pain relief in the first stage of labour. The second pain scores were higher in both *primigravidae* and *multigravidae* after normal saline administration and this is because pain severity increases with advancing labour and this confirm the fact that normal saline has no relieving effect on labour pain neither it gives any placebo effect.

Diclofenac was effective in significantly reducing pain severity in both *primigravidae* and *multigravidae*. Walker et al (the only published study about the use of NSAID as analgesic in labour) compared ketorolac (NSAID) and pethidine for pain relieve in labour, they have found that pethidine was statistically more effective compared with ketorolac. Maternal sedation and fetal depression were statistically less in the ketorolac group [16].

Similarly diclofenac, unlike Meperidine, does not cause maternal sedation and respiratory depression, also lacks the neonatal sleepiness, and the less ability to establish breast feeding which are adverse effects of narcotic analgesia [12].

In this study no maternal and fetal adverse effects were reported which is a finding similar to that reported by Walker et al [16]. Diclofenac is easily administered by deep intramuscular injection and this requires little training of the paramedical staff unlike regional analgesia. Inhalational analgesia also causes maternal drowsiness, disorientation and brief episode of loss of consciousness (0.4 % of prolog users) [17].

There is concern by mid-wives and clients about the potential harmful effects that pharmacological analgesia has upon the mother's birth experience, coupled with the potential compromise of the fetus, is not reflected by the common and widespread use of pethidine within normal midwifery practice [18]. In this study no adverse effect of diclofenac was reported on the duration of the first and second stages of labour.

CONCLUSION

Diclofenac was found to be a suitable analgesic for pain relief during the first stage of labour, it was found to be effective, easily administer and lack serious maternal and fetal side effects.

RECOMMENDATION

Further studies are needed to compare diclofenac with meperidine and regional anesthesia.

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