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ORIGINAL ARTICLE

Intramuscular Pethidine for Pain Relief in the First Stage of Labor

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ABSTRACT:

Objective: The objective of this study was to see the efficacy of intramuscular pethidine for pain relief in the 1st stage of labor.

Methods: This prospective study was carried out in the Department of Obstetrics & Gynaecology, Dhaka Medical College Hospital, Dhaka from April 2005 to December 2005. Age and parity matched 80 pregnant women were recruited in the study and were divided equally in experimental and palcebo groups (40 in each group). The Experimental group received intramuscular Inj. Pethidine HCI 1.5 mg/kg body weight in 2 ml with Inj. metoclopramide 12.5 mg and the Placebo group received 2 ml intramuscular normal saline. The intervention was started at active first stage of labor with cervical dilatation of 3-4 cm and when patients requested for analgesia. Pain was assessed at the highest point of pain at 15- and 30-minute intervals using 100 mm visual analogue scale (VAS) and patients were asked to give a verbal categorical rating of their pain as "a lot better", "a little better", "much the same", "a little worse", or "much worse". Level of sedation was also assessed at the same intervals. Details of labor, including cervical dilatation before and after analgesia, mode of delivery, duration of injection to delivery time and assessment of neonates by APGAR score at one and five minutes were recorded.

Result: All the baseline characteristics like maternal age, body surface area (BSA), parity, gestational age of the subjects between the Experimental and Placebo groups were almost identical. All the intrapartum variables like baseline cervical dilatation, VAS pain score, VAS sedation score and injection to delivery interval were also found to be fairly comparable between groups. At 15 minutes interval more than one-quarter (27.5%) of the Experimental group got mildly drowsy, while none of the Placebo group changed from their baseline status. At 30 minutes interval 27.5% were mildly drowsy, 22.5% were moderately drowsy and 1 (2.5%) was asleep in the Experimental group, while all of the Placebo group subjects were alert as before. The groups were quite different in respect to level of sedation following intervention ($p < 0.001$). Nearly three quarters (72.5%) of the Experimental group had VAS pain score at 30 minutes interval at or below median level, whereas only 25% of the Placebo group had the same level at same interval ($p < 0.001$). The Experimental group had a significantly lower demand for further analgesia (50%) compared to the Placebo group (80%) ($p=0.005$). However, 15 (37.5%) subjects of the Experimental group experienced nausea and or vomiting, whereas none of the Placebo group had such experience ($p<0.001$). Majority (82.5%) of the Experimental group and 75% of the Placebo group had normal delivery. The comparison of foetal outcome in terms of APGAR score at 1 and 5 minutes, oxygen needed and NICU admission required for resuscitation revealed no significant difference between the groups with respect to any of these variables ($p<0.05$).

Conclusion: The intramuscular Pethidine is significantly effective at providing analgesia in pregnant women in 1st stage of labor. The findings support the continued use of pethidine as a simple and cheap therapeutic option in the management of labor pain.

Key words: Intramuscular pethidine, pain relief, first stage of labor etc.

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INTRODUCTION:

Labor results severe pain in women. There are no other circumstances where it is considered acceptable for a person to experience such an acute pain. Maternal request is therefore a sufficient justification for pain relief during labor (ACOG). Pain experienced during labor is related to the uterus contracting to dilate and efface the cervix. The intensity of pain depends upon accumulation of pain producing substances due to ischaemia of the uterine arteries, distension of perineal tissue, parity, the pain threshold of the subject and pressure on other organs (bladder, rectum) or the lumbosacral plexus.[1] The uterus is a large muscular organ that has housed the baby for weeks or more & when labor commences it starts to contract, usually mildly initially but as labor progresses, becomes more powerful and painful. This is entirely normal and has a working function which enables the mouth of the womb to open fully to allow the baby to descend further into the pelvis and birth canal, culminating in the actual birth of the baby and placenta. To make the experience of labor less painful & just a wonderful memory of child birth, intramuscular pethidine 100 mg has been shown to be significantly effective in reducing the pain in the first stage of labour.[2]

Pain relief is important because when a woman in labor starts hyperventilating during contractions, the subsequent hypoventilation causes a decrease oxygen supply to her baby. So, to maintain adequate oxygenation of the baby, a mother must be relaxed during her contractions. Relief of pain allows labor to progress more rapidly by reducing the anxiety caused by pain. In addition, anxiety may cause poor progress during labor. The solution is labor analgesia. A recent survey of obstetric anaesthetic practice in hospitals in the United States showed that the use of intramuscular pethidine for labor analgesia is 39-56%. In United Kingdom the practice is similar, with 38% of woman requesting analgesia while in labor.[3]

Pethidine is the most widely used analgesic for women in labor since 1940.[3] Other narcotic drugs have been tried but none has shown any distinct advantages over pethidine. Pethidine is an opiate derivative and is given in doses of 50-150 mg intramuscularly. The effects last about 2-3 hours, after which the dose can be repeated. If an adequate dose of intramucular pethidine is given, it is usually not necessary to repeat the drug within four hours. Pethidine is indicated when the discomfort of labor merges into regular, frequent and painful contractions. One study showed that 39% of mothers expressed satisfaction with pain relief in 1-2 hours with intramuscular pethidine.[3] The intramuscular route is the commonest method of giving pethidine, especially with a cervical dilatation of less than 7 cm. Pain relief will be experienced about 30 minutes after administration of pethidine and the duration of action lasts for about 4 hours. The intravenous route may be used if the patient requires analgesia urgently and the cervix is already 7 cm or more dilated.

Researches have shown that fear and anxiety can inhibit the production of natural hormones that enable a woman to deliver. Pethidine given in the early stage of labor, can help the women relax and deliver the baby more effectively. It can be administered by a midwife, can be used at home birth also.[2] But pethidine may be detrimental to the baby in that it suppresses the baby's respiratory center making the baby less responsive and less likely to feed. Recent studies, however, have shown that this may be the case if pethidine is given in large doses or just before delivery. The baby is less likely to be affected if pethidine is given in appropriate doses and if not given within 4 hours of delivery. Though pethidine is an effective analgesic for pain relief in first stage of labor yet its use now has been decreased even in tertiary hospitals, especially in our county. That purpose the present study aimed to evaluate the analgesic effect of pethidine in labor.

METHODS:

This prospective case-control study was conducted over a period of 9 months from 1st April to 31st December, 2005 in the Department of Obstetrics & Gynaecology, Dhaka Medical College Hospital (DMCH), Dhaka. Eighty full-term pregnant women (both primi and multi) admitted in the labor ward with active 1st stage of labor (having their foetus

with cephalic presentation) under one consultant were the study population. All patients were scheduled for normal vaginal delivery having no contraindications for pethidine were the enrolment criteria. The parturients were excluded from the study if any contraindications for allowing normal vaginal delivery and allergy to study drugs were present. Before selection of the subjects, the parturients were fully explained about the procedure and written consent was taken. The parturients were randomly divided into two groups, forty in each. The group that received traditional intramuscular Inj. Pethidine HCI 1.5 mg/kg body weight in 2 ml with Inj. metoclopramide 12.5 mg taken as Experimental group and the group which received 2 ml intramuscular normal saline were assigned to Placebo group. Every alternate patient was given intramuscular pethedine or normal saline. The analgesia, either IM pethidine or normal saline was started at active first stage of labor with cervical dilatation of 3-4 cm and when patients requested for analgesia.

Pethidine was injected intramuscularly in the gluteal region. Pain was assessed at the highest point of pain at 15 and 30 minutes interval. Equal number of age and parity-matched parturients were injected 2 ml normal saline intramuscularly and at 15 & 30 minutes patients were asked to give a verbal categorical rating of their pain as "a lot better", "a little better", "much the same", "a little worse", or "much worse". The minimal clinically significant difference (MCSD) in VAS pain score was defined as the mean difference between current and preceding scores when the subject reported "a little worse" or "a little better" pain. The MCSD in VAS score in the group overall was 12 mm (95% CI 9 mm to 15 mm). All parturients in this study received intravenous oxytocin either for augmentation or induction at the time of randomization. The oxytocin infusion was begun at a rate of 1 mlU/min and the rate was increased every thirty minutes until an adequate uterine contraction was achieved. Intravenous (IV) infusion of glucose containing fluid at a rate of 1.5 ml/kg/hr was received by both groups.

Maternal blood pressure, heart rate and fetal heart rate (FHR) were recorded at 3-minutes intervals from the onset of the injection till the first 30 minutes and subsequently at 30-minutes intervals during the first stage and at 15 minutes intervals during the second stage. The analgesia was assessed by 100 mm VAS. Details of labor, including cervical dilatation before and after analgesia, mode of delivery, duration of injection to delivery time and assessment of neonates by APGAR score at one and five minutes were recorded. Data were processed and analyzed using software SPSS (Statistical Package for Social Sciences) version 16.0. The statistics used to analyze the data were descriptive statistics, Chi-square (χ^2) and Student's t-Test. The level of significance was set at 0.05 and p-value < 0.05 was considered significant.

RESULTS:

Maternal age and BSA were found to be almost identical between Experimental and Placebo groups (p=0.967 & p=0.678 respectively. Neither parity, nor gestational age of the subjects of the two groups was found to be any different (p=0.590 and p=0.967 respectively). All the intrapartum variables like baseline cervical dilatation, VAS pain score and injection to delivery interval were found to be fairly comparable between groups (p=0.799, p=0.129 and p=0.068 respectively). VAS sedation score was 0 in both the groups as patients were almost alert (Table I). Three-quarter of the Experimental group and 70% of the placebo group experienced spontaneous labor and the rest of the respective groups induced labor. The groups were not observed to be statistically different in terms of type of labor (p=0.401) (Fig. 1). The mean VAS pain scores at baseline were almost identical in both Experimental and Placebo groups (77.55 ± 4.21 mm vs. 76.28 ± 3.15 mm, p=0.129). At 15 minutes interval the Experimental group exhibited a significant reduction of VAS pain score (70.28 ± 6.98 mm) compared to that of Placebo group (75.97 ± 3.35 mm) (p < 0.001). The pain scores of both the groups were observed to be further reduced. However, the reduction was significantly faster in

Experimental group than that in the Placebo group (64.58 ± 10.53 vs. 72.63 ± 6.99 mm, p < 0.001) at 30 minutes interval (Table II).

Table III shows that all the subjects were alert at baseline because of labor pain. At 15 minutes interval more than one-quarter (27.5%) of the Experimental group got mildly drowsy, while none of the Placebo group changed from their baseline status. At 30 minutes interval 27.5% were mildly drowsy, 22.5% were moderately drowsy and 1(2.5%) was asleep in the Experimental group, while all of the Placebo group subjects were alert as before. The groups were quite different in respect to level of sedation following intervention (p < 0.001). Table IV presents the comparison of maternal outcome between groups. The outcome variables were number of subjects with VAS pain at 30 minutes at or below median, requested for further analgesia and nausea/vomiting. Nearly three quarter (72.5%) of the Experimental group had VAS pain score at 30 minutes interval at or below median level, whereas only 25% of the Placebo group had the same level at same interval (p < 0.001). The Experimental group had a significantly lower demand for further analgesia (50%) compared to the Placebo group (80%) (p = 0.005). However, 15(37.5%) subjects of the Experimental group experienced nausea and or vomiting, whereas none of the Placebo group had such experience (p < 0.001).

Majority (82.5%) of the Experimental group and 75% of the Placebo group had normal delivery. Fifteen percent of the Experimental group and 20% of the Placebo group needed Caesarean section. The rest (2.5%) of the Experimental and of Placebo group (5%) needed other instrumental aid to have their babies delivered. The groups were found to be almost similar in terms of mode of delivery they experienced (p = 0.683) (Fig. 2). Table V demonstrates the comparison of foetal outcome in terms of APGAR score at 1 and 5 minute, oxygen needed and NICU admission required for resuscitation. The groups were not statistically different with respect to any of these variables (p > 0.05 in each case). Majority of the Experimental group (87.5%) expressed some degree of satisfaction, while majority (80%) of the Placebo group was found to be totally dissatisfied and the rest 8(20%) were only partially satisfied. Among the satisfied subjects of the Experimental group, 22(55%) were partially satisfied followed by 5(12.5%) more or less satisfied and the rest 8(20%) satisfied. None was found to be highly satisfied. The groups were quite different in respect of level of satisfaction following intervention (p < 0.001) (Table VI).

TABLE I. Comparison of baseline characteristics between groups

Baseline characteristics	Group		p-value
	Experimental (n=40)	Placebo (n=40)	
Biological characteristics#			
Maternal age (years)	23.55 ± 5.27	23.50 ± 5.42	0.967
BSA (m2)	1.61 ± 0.05	1.62 ± 0.06	0.678
Obstructive Characteristics			
Parity*			
Primipara	24(60.0)	24(60.0)	
Multipara	16(40.0)	16(40.0)	0.590
Gestational age (weeks)#	38.4 ± 0.81	38.48 ± 0.75	0.967
Intrapartum factors#			
Baseline cervical dilatation (cms)	3.52 ± 0.44	3.55 ± 0.44	0.799
Baseline VAS pain score (mm)	77.55 ± 4.21	76.28 ± 3.15	0.129
Injection to delay interval (hr)	6.35 ± 1.20	6.85 ± 1.25	0.068

Figures in the parenthesis denote corresponding %;.
* **Chi-square (χ^2) Test** was employed to analyse the data.
#Data were analysed using **Student's t-Test** and were presented as **mean ± SD.**

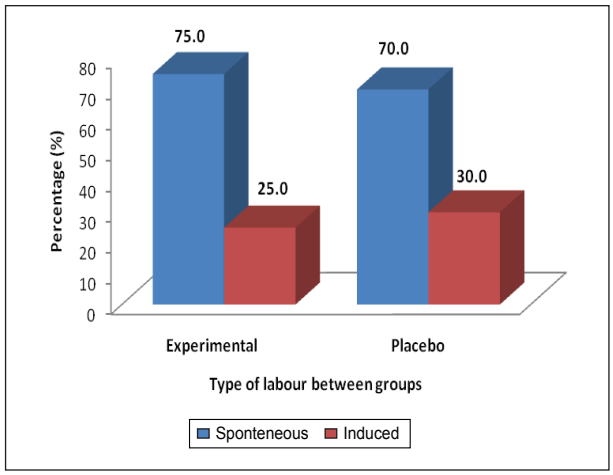

Fig 1. Comparison of type of labor between groups.

TABLE II. Comparison of changes in VAS pain score over time between groups

VAS pain score (mm)#	Group		p-value
	Experimental (n=40)	Placebo (n=40)	
Baseline	77.55 ± 4.21	76.28 ± 3.15	0.129
At 15 minutes interval	70.28 ± 6.98	75.97 ± 3.35	<0.001
At 30 minutes interval	64.58 ± 10.53	72.63 ± 6.99	<0.001

#Data were analysed using **Student's t-Test** and were presented as **mean ± SD.**

TABLE III. Comparison of changes in sedation over time between groups

Level of sedation*	Group		p-value
	Experimental (n=40)	Placebo (n=40)	
At 15 minutes interval			
Alert	29(72.5)	40(100.0)	<0.001
Mildly drowsy	11(27.5)	0(0.0)	
At 15 minutes interval			
Alert	19(47.5)	40(100.0)	
Mildly drowsy	11(27.5)	0(0.0)	<0.001
Moderately drowsy	9(22.5)	0(0.0)	
Asleep	1(2.5)	0(0.0)	

Figures in the parenthesis denote corresponding %;.
* **Chi-square (χ^2) Test** was employed to analyse the data.

TABLE IV. Comparison of maternal outcome following intervention

Maternal Outcome	Group		p-value
	Experimental (n=40)	Placebo (n=40)	
Subject with VAS pain at 30 minutes ≤ median**	29(72.5)	12(25.0)	<0.001
Requested for further analgesia*	20(50.0)	32(80.0)	0.005
Nausea/ vomiting*	15(37.5)	0(0.0)	<0.001

Figures in the parenthesis denote corresponding %;.
* **Chi-square (χ^2) Test** was employed to analyse the data.
**Median VAS pain at 30 minutes in Experimental group was 68 mm and that in Placebo group 75mm.

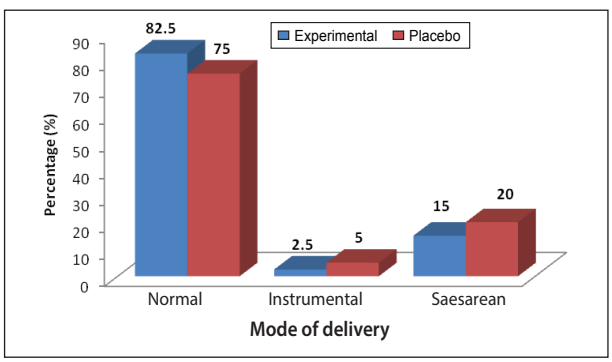

Fig. 2: Mode of delivery between groups

TABLE V. Comparison of foetal outcome following intervention

Foetal Outcome*	Group		p-value
	Experimental (n=40)	Placebo (n=40)	
APGAR score (≥ 7)			
At 1 minute	38(95.0)	37(92.5)	0.500
At 5 minutes	38(95.0)	37(92.5)	0.500
Oxygen needed	2(5.0)	3(7.5)	0.500
NICU admission needed	2(5.0)	3(7.5)	0.500

Figures in the parenthesis denote corresponding %;.
* **Chi-square (χ^2) Test** was employed to analyse the data.

TABLE VI. Comparison of level of satisfaction between groups

Level of satisfaction	Group		p-value
	Experimental (n=40)	Placebo (n=40)	
Totally dissatisfied	5(12.5)	32(80.0)	
Partially satisfied	22(55.0)	8(20.0)	
More or less satisfied	5(12.5)	0(0.0)	<0.001
Satisfied	8(20.0)	0(0.0)	
Highly satisfied	0(0.0)	0(0.0)	

Figures in the parenthesis denote corresponding %;.
* **Chi-square (χ^2) Test** was employed to analyse the data.

DISCUSSION:

This prospective hospital-based study was carried out to see the efficacy of intramuscular pethidine for pain relief in the first stage of labor. All the baseline characteristics like maternal age, BSA, parity, gestational age of the subjects between the Experimental and Placebo groups were almost identical. All the intrapartum variables like baseline cervical dilatation, VAS pain score and injection to delivery interval were also found to be fairly comparable between groups. VAS sedation score was 0 in both the groups as patients were almost alert. Morrison and associates[4] studied 1100 parturients with intramuscular Pethidine in the first stage of labor with mean maternal age being 25.2 years and gestational age 37-40 weeks. Fairlie and colleagues[5] in their study used similar criteria.

At 15 minutes interval Pain VAS scores (pain intensity) were observed to be significantly reduced in the experimental group ($p < 0.001$). In UK, intramuscular pethidine is widely used for analgesia in labour.[6] It was first used for

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intrapartum pain relief in 1947, and is the only opioid allowed to be ordered by midwives. There are, however, concerns that pethidine may not provide very effective pain relief. Some studies have suggested that fewer than 20% of women may expect a pain-free labor with this opioid.[5] Lumbar epidural anaesthesia provides excellent intrapartum analgesia in 50-80% of recipients, and may have fewer maternal and neonatal side effects.[5] But in a survey of 1000 postpartum women, Morgan et al[7] observed that those who received epidural anaesthesia were more likely to be dissatisfied, compared with women who received Pethidine. There is therefore a continuing need for intramuscular narcotic analgesia in labor. Publication of the study of Olofsson et al[8] led for a call for placebo-controlled trial to determine whether pethidine truly provides analgesia during labor.

Although pethidine is clearly not as effective for analgesia as epidurals, nonetheless, the degree of analgesia obtained may be sufficient for a large proportion of patients. Despite having an epidural on demand service, 38% of parturients in labor chose intramuscular pethidine for analgesia compared with an overall rate of epidural analgesia of 17.8%.[2] Because labor pain may increase in intensity as labour progresses, failure of opioids to decrease pain scores to below baseline does not necessarily equal to lack of effect. In the current study, although the median decrease in VAS pain score from baseline was only 14 mm at 30 min, this has more clinical significance when one takes into account the finding that pain scores in the placebo group tended towards an increase at 30 min. Ramin and peers[9] compared intravenous pethidine with epidural analgesia and reported that a small proportion of women (15.4%) who received pethidine found it ineffective and requested epidural anaesthesia. However, when the same authors subsequently repeated the study, administering pethidine by a more liberal patient-controlled analgesia regimen, pethidine was found much more effective in reducing VAS pain scores, relatively high patient satisfaction and only a few patients (1.3%) requesting epidural analgesia because of inadequate analgesia. Burnhill et al[10] recognized that pethidine lengthened or inhibited labor. Crawford[11] claimed that it did not affect the length of labor. In the current study injection to delivery interval was not significantly different between the study groups (6.35 ± 1.2 vs. 6.85 ± 1.25 hours, $p > 0.05$). Tusi and associates[2] in their study showed the interval 5.58 & 6.25 hours in the experimental and placebo groups respectively.[2] Assessment of satisfaction is, although subjective, context specific, & influenced by a number of factors including culture, environment & previous expectations, satisfaction scores at 30 minutes was greater in the pethidine group compared with control group ($p < 0.001$). In this study, 12.5% of women in the pethidine group were totally dissatisfied, compared with 80% in the control group and no woman in either group was highly satisfied. Half of the women in the pethidine group and 80% in the control requested for further analgesia. This observation is almost similar to other studies[2,5,12]

Maternal sedation was assessed on a 4-point scale as: 0 = alert; 1 = mildly drowsy; 2=moderately drowsy; and 3 = asleep.[5] Both groups were alert at the baseline. At 30 minutes interval all were alert in the placebo group, whereas in experimental group about 50% were alert, rest was mild to moderately drowsy & only 2.5% was asleep with 37.5% have had vomiting. The variation in sedation among two groups was significant which is consistent with the study by Morrison et al[4] where 33% parturient had vomiting.

In the experimental group majority (82.5%) had normal vaginal delivery and 15% caesarean section, whereas in the Placebo group 75% had normal 20% caesarean delivery. The rest (2.5%) of the Experimental and Placebo group (5%) needed other instrumental aid to have their babies delivered with no significant difference between the groups. Morrison et al[4] showed 74.7% normal, 20.6% instrumental and 4.8% caesarean section among the Pethidine group of parturients. Fairlie et al[4] showed 76% spontaneous delivery, 18% instrumental and 6% caesarean section. The comparison of foetal outcome in terms of APGAR score at 1 & 5 minutes, oxygen needed and NICU

admission required for resuscitation revealed no significant difference between the groups with respect to any of these variables ($p > 0.05$) indicating that pathedine given in early 1st stage of labor does not produce any deleterious effect on foetal well-being. Tsui et al[2] showed APGAR score ≥ 7 in 92% experimental group and 90% in placebo group.

CONCLUSION:

The intramuscular Pethidine is significantly effective at providing analgesia in pregnant women in 1st stage of labor. The findings support the continued use of pethidine as a simple and cheap therapeutic option in the management of labor pain. A further, long-term study with larger sample size may help strengthening the evidence about the efficacy of pethidine in labor pain management.

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admission required for resuscitation revealed no significant difference between the groups with respect to any of these variables ($p > 0.05$) indicating that pathedine given in early 1st stage of labor does not produce any deleterious effect on foetal well-being. Tsui et al[2] showed APGAR score ≥ 7 in 92% experimental group and 90% in placebo group.

CONCLUSION:

The intramuscular Pethidine is significantly effective at providing analgesia in pregnant women in 1st stage of labor. The findings support the continued use of pethidine as a simple and cheap therapeutic option in the management of labor pain. A further, long-term study with larger sample size may help strengthening the evidence about the efficacy of pethidine in labor pain management.

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