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Role of Diclofenac Suppositories in Pain Relief During the Postpartum Period

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ABSTRACT

Objective: To investigate the effect of Entonox on labor pain and labour duration in primiparous women.

Methodology: This randomized controlled trial was conducted at the Department of Obstetrics and Gynaecology, Shifa, International Hospital, Islamabad, over a six months period from 01-09-2021 to 28-02-2022 after approval by Institutional Ethics Committee. Study population were nulliparous ladies, aged 18-40 years, presenting in active labour at gestational age. ≥ 37 weeks with any of these comorbid conditions: well controlled preexisting or gestational diabetes (deranged OGTT), non proteinuric, well controlled hypertension, (BP≥140/90), anemia (Hb<8g/dl) and morbid obesity. A total of 60 patients (30 in each group) were included the study. Group-A received Entonox while Group-B was administered with placebo. Mean pain score of first and second stage of labour was noted using VAS, duration of first and second stahe of labours was recorded. Side effects were recorded. Data was entered and data analysed using SPSS version 21.

Results: Both groups were comparable in terms of age, gestational age and BMI. Entonox inhalation resulted in shorter labour duration and lower pain score. Mean duration of first stage of labour, in group-A it was 3.73±0.45 and in group-B was 5.64.±0.88 hours(p. <0.001). Similarly mean duration of 2nd stage of labour was 1.288±0.48 hours in group-A and 1.93± 0.87 hours in in group-B(p <0.001).In group-A pain score in 1st stage of labour was 3.07±1.06 and in group-B it was 7.20±0.66 (p<0.001) while in 2nd stage of labour in group-A mean pain score was seen 4.23±1.04 and in group-B 8.81 3±0.50(p<0.001)

Conclusion: Entonox consumption showed pain relief in women during first and second stage of labour and a decrease in the length of their labour. No significant reported complication of Entonox was an advantage of this analgesic method. Therefore, to decrease labour pain, Entonox inhalation analgesia is useful.

Keywords: Pain, Postpartum, Rectal diclofenac, Oral mefenamic acid, Analgesia, Perineal injuries.

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Introduction

Childbirth is a natural process that occurs either vaginally or through caesarean section (CS). For most women, vaginal childbirth is considered the comparatively safer method due to its lower risk of morbidity and mortality.[1-3] The rising CS rates may, in part, be attributed to women's increasing requests for elective procedures. A high fear of childbirth, particularly among nulliparous women, has been shown to be significantly associated with a preference for CS without medical indications. Studies have reported that women often decline natural childbirth due to fear, pain, the long duration and unpredictability of labour, and a perceived loss of autonomy in decision-

making. Many also question their bodies' ability to deliver a baby vaginally. Consequently, researchers in recent years have focused on developing safe methods of natural childbirth with minimal pain.[4]

The analgesia employed should be safe for both mother and fetus. An ideal method of pain relief during labour should not interfere with the natural labour process, physiological functions, mobility, or maternal consciousness.[5–8] Non-pharmacological modalities for pain relief during labour include massage, heat therapy, and acupuncture. Other non-pharmacological methods, such as sterile water injections for low back pain or transcutaneous electrical nerve stimulation (TENS), are also used but with variable success.[9,10,13]

Pharmacological treatments commonly include intravenous or intramuscular opioids (such as pethidine), inhalational analgesics (such as Entonox), and epidural blocks. Intravenous pethidine is the most widely used for labour pain relief; however, it can cause several side effects, including dysphoria, sedation, respiratory depression, nausea, vomiting, and—most seriously neonatal respiratory depression. Epidural analgesia is highly effective but requires specialized skills for administration as well as intensive monitoring.[9–11,13]

Entonox® (a 50:50 mixture of nitrous oxide and oxygen) is a rapid-acting and rapidly cleared analgesic agent.[1,7,13] It is non-inflammable, tasteless, odourless, and colourless.[12–14] Nitrous oxide has been used for labour analgesia since the 1800s, yet its popularity remains limited, and relatively few studies have evaluated its efficacy during labour. Existing literature suggests some pain relief benefits, but results regarding its effect on labour duration are conflicting. Nulliparous women, in particular, tend to experience longer labours, which may result in exhaustion, anxiety, and an increased inclination toward caesarean delivery by both patients and care providers as a quicker alternative.[7,14,18,19]

The limited use of Entonox in our country may be related to its restricted availability in labour rooms and a general unfamiliarity with its proper use. Additionally, adequate instruction is required to ensure correct inhalation, as improper technique may result in low efficacy. The rationale for this study is to compare the outcomes of Entonox versus placebo administered during active labour in nulliparous women at term, in order to address the paucity of data regarding an analgesic that may reduce labour duration and promote vaginal delivery in women experiencing childbirth for the first time.

Methodology

This randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology, Shifa International Hospital, Islamabad, over a period of six months (01-09-2021 to 28-02-2022). A total sample size of 60 participants (30 in each group) was calculated, using a level of significance of 5%, study power of 80%, and taking the magnitude of mean pain score as 5.18 ± 1.29 with Entonox and 8.99 ± 1.98 with placebo during active labour.[1,7] Non-probability consecutive sampling was employed.

Eligibility criteria: Participants included nulliparous women aged 18–40 years, at ≥37 weeks of gestation (based on LMP), in active labour (cervical dilatation ≥5 cm). Women with well-controlled comorbidities—such as chronic or gestational diabetes (deranged OGTT), non-proteinuric and well-controlled hypertension (BP ≥140/90 mmHg), anemia (Hb <8 g/dl), and morbid obesity—were also included.

Exclusion criteria: Women with multifetal pregnancies, placental abnormalities (previa, accreta, abruption), cardiac disease, cervical length >4 cm, amniotic fluid index (AFI) <5 cm or >21 cm, previous caesarean delivery, meconium-stained liquor, pre-eclampsia, uncontrolled diabetes, or asthma were excluded.

After approval from the hospital's ethics committee, 60 eligible patients were enrolled. Informed consent was obtained, and demographic data (name, age, parity, BMI, gestational age) were recorded. Participants were randomized into two groups using the lottery method. In Group A, Entonox was administered through a gas mask, while in Group B, patients received oxygen via a simple mask.

All participants were instructed and demonstrated the correct use of inhalation analgesia and were supported throughout labour. They were advised to inhale and exhale deeply and uniformly through the mask, with synchronization of uterine contractions to maximize analgesic effect. Patients self-administered gases through a face mask connected to a unidirectional valve. The gas was continued until the end of contraction pain, after which patients resumed breathing room air.

The first stage was measured from admission in active labour to full dilatation, and the second stage from full dilatation to delivery.

Pain was assessed using a visual analogue scale (VAS: 0–10, with higher scores indicating greater pain) for both

the first and second stages. Scores were recorded hourly, and mean values were calculated for each stage.

Monitoring: Contraction frequency and intensity, fetal heart rate, and maternal vital signs (blood pressure, pulse, temperature, and respiratory rate) were monitored routinely by midwifery staff. Labour was managed according to WHO guidelines. All information was recorded on a standardized proforma.

Statistical analysis: Data were analyzed using SPSS v21. Continuous variables (pain scores, labour duration) were presented as mean ± standard deviation. Frequencies were calculated for stratified groups (age, gestational age, BMI). Independent samples t-tests compared mean pain scores and labour duration between the two groups. Chi-square and Fisher's exact tests were applied for categorical data. A p-value ≤0.05 was considered statistically significant. Data were further stratified for age, parity, BMI, and gestational age, followed by post-stratification comparisons using independent t-tests.

Results

A total of 60 patients (30 in each group) were included in the study. Both groups were comparable in terms of age, gestational age and BMI as shown in table I.

Table I: Baseline Characteristics of Participants (n=60)

Parameter	Group-A (Entonox)	Group-B (Placebo)	P value
Age (Years)			
18–30 years	18 (60.0%)	19 (63.3%)	0.87
31–40 years	12 (40.0%)	11 (36.7%)	
Mean ± SD	29.1 ± 5.3	29.3 ± 6.1	0.92
Gestational Age (Weeks)			
38–39 weeks	26 (86.7%)	23 (76.7%)	0.68
40–41 weeks	4 (13.3%)	7 (23.3%)	
Mean ± SD	38.3 ± 0.5	38.9 ± 0.8	0.98
BMI (kg/m²)			
<30	16 (53.3%)	20 (66.6%)	0.67
≥30	14 (46.7%)	10 (33.4%)	
Mean ± SD	29.5 ± 4.9	28.0 ± 4.0	0.83

Patients in Group A (Entonox) had shorter labours and lower pain scores as compared to Group B. After stratification according to age, gestational age and BMI, the results consistently showed shorter labour duration and lower pain scores in patients assigned to Entonox group. (Table III). No serious maternal or fetal side effects were observed in either groups. Minor side effects were comparable in both groups (Table IV).

Table II: Comparison of Pain Scores and Labour Duration.

Variable	Group-A (Entonox)	Group-B (Placebo)	p-value
Duration of Labour (Hours)			
1st stage	3.73± 0.45	5.64 ± 0.88	<0.001
2nd stage	1.28 ± 0.48	1.93± 0.87	<0.001
Pain Score (VAS)			
1st stage	3.07± 1.06	7.20 ± 0.66	<0.001
2nd stage	4.23± 1.04	8.81 ± 0.50	<0.001

Table III: Stratified Analysis of Labour Outcomes.

Stratification	Group-A (Entonox)	Group-B (Placebo)	p-value
By Age (18–30 years)			
Labour duration (1st stage)	3.33 ± 0.48	5.11 ± 0.93	<0.001
Pain score (1st stage)	2.92 ± 1.07	8.58 ± 0.50	<0.001
Labour duration (2ndstage)	1.12± 0.48	1.74± 0.93	<0.001
Pain score (2ndstage)	4.11 ± 1.65	8.73 ± 0.6	<0.001
(31-40 years)			
Labour duration (1st stage)	4.13 ± 0.51	6.17 ± 0.94	<0.001
Pain score (1st stage)	3.23± 1.02	8.76 ± 0.49	<0.001
Labour duration (2ndstage)	1.45 ± 0.48	2.12± 0.93	<0.001
Pain score (2ndstage)	4.15 ± 1.65	8.9± 0.6	<0.001
By BMI (<30 kg/m²)			
Labour duration (1st stage)	4.06± 0.45	5.12 ± 1.34	<0.001
Pain score (1st stage)	3.314 ± 1.13	6.9 9 ± 1.2	<0.001
Labour duration (2ndstage)	1.35 ± 0.48	1.67 ± 0.93	<0.001
Pain score (2ndstage)	4.25 ± 1.65	8.91± 0.6	<0.001
(≥30 kg/m²)			
Labour duration (1st stage)	4.19± 0.46	6.24± 1.23	<0.001
Pain score (1st stage)	3.21 ± 1.25	6.89 ± 0.60	<0.001
Labour duration (2ndstage)	1.37 ± 0.48	1.66 ± 0.92	<0.001
Pain score (2ndstage)	4.35 ± 1.67	8.51± 0.6	<0.001
By Gestational Age (38–39 weeks)			
Labour duration (1st stage)	4.06 ± 0.46	6.23± 1.23	<0.001
Pain score (1st stage)	3.21 ± 1.25	6.89 ± 0.60	<0.001
Labour duration (2ndstage)	1.37 ± 0.48	1.87 ± 0.92	<0.001
Pain score (2ndstage)	4.35 ± 1.67	8.51± 0.6	<0.001
40-41 weeks			
Labour duration (1st stage)	4.21 ± 0.55	6.19 ± 1.27	<0.001
Pain score (1st stage)	3.21 ± 1.25	6.72 ± 0.61	<0.001
Labour duration (2ndstage)	1.4 7 ± 0.48	1.92 ± 0.92	<0.001
Pain score (2ndstage)	4.35 ± 1.67	8.51± 0.6	<0.001

Table IV: Observed Side effects.

Variable	Group-A (Entonox) n=30	Group-B (Placebo) n=30	p-value
Nausea	2(6.7%)	3(10%)	0.92
Vomiting	2(6.7%)	3(10%)	0.45
Dizziness	3(10%)	2(6.7%)	0.8
Dry mouth	3(10%)	3(6.7%)	0.9

Discussion

The findings of this study reveal significant alleviation of labour pain and in the reduction of the duration of first and second stages of labour in nulliparous women presenting in spontaneous labour in women given Entonox. Other studies too have revealed significantly lower pain scores in patients given Entonox than those given other pain killers, non pharmacological pain relief or placebo .[1-7] Though the precise mechanism of action of inhaled Entonox remains uncertain anaesthetic actions are related to suppression of activity of the reticuloendothelial network in the brainstem. Nitrous oxide modulates NMDA receptor activity and enhances endogenous opioid release.[7,8,17,18]This also modulates pain stimuli through the descending spinal cord nerve pathways. it also increases release of endorphins leading to analgesia, euphoria, and a relaxation effect.[7,18,19] Oxygen is added to allieviate anoxia that may result from sole Nitrous Oxide inhalation. The ability of patient to titrate against her pain severity and contractions also gives patients a sense of autonomy.[1,7,18,19] Thus the psychological aspect of pain is catered to as well. Hakemzade et al.[1] reported significantly lower pain scores in patients given Entonox 5.95±1.32 vs 8.45±1.02($p<0.001$) given oxygen in placebo in first stage of labour. Similarly, in second stage of labour, patients given Entonox had score of 5.44±1.94 vs 8.12±2.16 ($p< 0.001$) in those given oxygen. In this study patients given Entonox had even lower pan score in both first and second stages of labour. Demonstrating to patients at study enrolment and presence of labour room staff that assists patients in correct use might have contributed to this effect.

The reduction in labour duration observed in this study adds to the evidence which supports Entonox's role in facilitating labour progression. In a systematic review of 15 trials, Jones et al.[13] suggested that effective pain management reduces maternal stress and catecholamine secretion which as a result enhances uterine contractility and cervical dilation. This hypothesis is mirrored in the results of this study where the first stage of labour in the Entonox group lasted 2.27 ± 0.45 hours as compared to 5.20 ± 0.88 hours in the placebo group. Mardani Hamule et al.[14] reported the similar findings with a 40% reduction in active labour duration with Entonox use ($p = 0.01$) in a cohort of 120 Iranian women. The shorter second stage in our Entonox group aligns with Masoudi et al.[16] who attributed this as an improved maternal cooperation during pushing because of reduced pain- and also related anxiety.

Stratified analysis in this study revealed consistent benefits across age, BMI and gestational age subgroups which challenges the earlier concerns about its variable efficacy in diverse populations. This contradicts the statement of Panni and Segal[17] who argued that Entonox efficacy might be diminished due to obesity-could alter pharmacokinetics and adipose tissue absorption. However improved pain relief even in women of BMI of 30 or more may be due to the fact that patients were explained the correct method of inhalation with contractions and self-administered inhalation allows patients to compensate for these factors by adjusting inhalation depth and frequency.

Further, the safety profile of Entonox in this study also reinforces its suitability for low-resource settings like Pakistan. There is no need of specialized personnel and continuous monitoring unlike epidural analgesia[19,20,21]; Entonox can be administered by midwives or nurses as demonstrated in a nurse-directed model by Pinyan et al. [19] This is particularly relevant for regions like Pakistan where inadequate trained healthcare systems is a key barrier to timely obstetric care [4]. Moreover, the absence of severe side effects like hemodynamic instability, foetal or maternal hypoxia, observed in this study suggest it to to be a safe mode of analgesia. Some studies have revealed increased risk of side effects, hemodynamic instability or poor APGAR at birth.[13,17,19] Minor side effects observed were comparable in both groups and in much less frequency than other studies. This difference may be because Entonox is used only when needed like during contractions. This limits how much is taken in overall and allows the body to quickly remove it through breathing.

The impact of socio-economic implications in this study is significant. In low-income countries, Entonox offers a cost-effective strategy to promote natural childbirth because C-sections are increasingly perceived as a safer and pain-free alternative to vaginal delivery.[1,22] Moreover, this study focus on nulliparous women who often face heightened anxiety about labour pain

highlights Entonox's potential to improve maternal satisfaction.

This study has limitations as the single-canter design and the small sample size of 60 may limit its generalizability. Additionally, the short follow-up period precluded assessment of long-term neonatal outcomes, such as neurodevelopmental effects of nitrous oxide exposure. Future research should prioritize multicentre trials with larger cohorts. Despite these limitations, the findings in this study align with global trends advocating patient-centred, non-invasive pain management in obstetrics

Conclusion

This study demonstrates that Entonox inhalation analgesia significantly reduces labour pain intensity during the first and second stages and also shortens labour duration. As Entonox have self-administered nature so it allows women to control its use in synchrony with their contractions, thereby preserving the mobility and promoting a positive childbirth experience. There were no significant complications in this study which reinforces it's suitability for diverse clinic settings particularly in resource-limited settings where access to more advanced analgesia is limited. Further multicentre research is necessary to confirm these benefits particularly in regions with rising caesarean rates which are driven by the fear of pain. In light of the persistent high caesarean rates which are mainly linked to fear of labour pain, integrating Entonox as a cost-effective, non-invasive analgesic option could play a pivotal role in promoting natural vaginal delivery and reducing unnecessary surgical interventions.

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