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Clinical Evaluation of Pethidine in Vaginal Labour: A Prospective Cohort Study at Soba and Saad Abo Alella University Hospitals

Walaa Ismail Abbas[a] , Ryad Moftah Alati[a]

[a] Faculty of pharmacy, Alasmarya Islamic University, Zliten, Libya

Corresponding author email: W.abbas@asmarya.edu.ly

A B S T R A C T

Background: Labour is divided into three stages. Stage one encompasses cervical dilation from 0–10 cm, stage two involves foetal descent with perineal distension and activation of somatic nociceptive pathways, and stage three concludes with placental delivery. Pethidine, a narcotic opioid analgesic classified as a pregnancy category C drug, is widely used for intrapartum pain management. **Aim:** To evaluate the impact of pethidine on pain severity, cervical dilation, uterine contractions, and delivery outcomes in vaginal labour.

Methods: A prospective cohort study was conducted at Saad Abo Alella University Hospital and Soba University Hospital, Khartoum. A total of 385 women were enrolled, comprising 317 controls and 68 who received pethidine. Pain scores, contraction frequency, duration of the second stage of labour, and mode of delivery were systematically recorded and analyzed.

Results: Pethidine administration significantly reduced pain severity ($p < 0.05$). Contraction frequency increased from 2 contractions per 10 minutes (56%) before administration to 3 contractions per 10 minutes (74%) afterward. However, caesarean section rates were higher in the pethidine group (21%) compared with controls (11.7%). The second stage of labour was prolonged in the pethidine group, with 36.8% lasting 21–45 minutes, versus 36.3% lasting 8–20 minutes in the control group.

Conclusion: Pethidine provides effective analgesia and enhances uterine contractility during labour. Nevertheless, its use is associated with prolonged stage two and increased caesarean section rates. These findings highlight the need for cautious clinical application and further investigation into optimizing opioid use in obstetric practice.

Keywords: Pethidine, vaginal delivery, labour pain, uterine contractions, caesarean section

1. Introduction

Labour pain follows distinct neurophysiological pathways across the three stages of labour. The first stage comprises the latent phase (0–4 cm cervical dilation) and the active phase, which continues until full dilation (10 cm). Pain during this stage is primarily associated with regular uterine contractions and progressive cervical stretching. Transmission occurs via the hypogastric plexus toward the spinal cord through the lumbar paravertebral sympathetic chain. Nociceptive impulses enter the dorsal roots of T10–L1 and ascend through the spinothalamic tracts to higher centres.

In the second stage, near the completion of cervical dilation, descent of the foetal head produces perineal distension and activates somatic nociceptive pathways. These impulses are transmitted predominantly through the pudendal nerves, originating from the sacral roots S2–S4.

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According to the American College of Obstetricians and Gynaecologists (ACOG), a prolonged second stage is defined as exceeding 3 hours with regional anaesthesia or 2 hours without anaesthesia. The third stage of labour is characterized by the interval between foetal delivery and expulsion of the placenta and foetal membranes, typically completed within 30 minutes (1).

Narcotic analgesics are pregnancy category C drugs, except oxycodone which is category B, and are not advised in pregnancy unless maternal benefit outweighs foetal risk. Pethidine is a synthetic opioid structurally distinct from morphine, used for acute pain. It has less effect on uterine smooth muscle than morphine and is the opioid most frequently employed in obstetrics (2).

Pethidine has faster onset and shorter duration than morphine salts. It may be administered epidural, intrathecal, intravenous, or intranasal. About 60–80% binds to plasma proteins. It is metabolized in the liver and excreted by the kidney. Pethidine crosses the placenta and is detectable in breast milk (2).

The use of narcotic analgesics such as pethidine during labour remains controversial. Although pethidine is administered for analgesia or to enhance uterine contractions, clinical evidence indicates that it may paradoxically delay labour and provide limited pain relief. This creates a clinical dilemma, particularly as pethidine is classified as a pregnancy category C drug with potential neonatal respiratory effects (3).

Despite its widespread use, the dual impact of pethidine on pain relief and labour progression continues to be debated, necessitating comprehensive evaluation.

Aim: Determining whether the benefits of pethidine in vaginal delivery outweigh its risks, especially in contexts where it remains commonly employed. Previous research has often focused on isolated aspects—either supporting its analgesic role or emphasizing its adverse effects—without integrating overall clinical outcomes. This prospective cohort study, conducted at Soba University Hospital and Saad Abo Alella University Hospital, Sudan, in 2022, aims to address this gap by systematically evaluating the clinical importance of pethidine in vaginal labour, including its effective dose, route of administration, and justification for continued use.

2. Methods and materials

Study Design and Setting: This study was conducted as a hospital- based prospective cohort at Soba University Hospital and Saad Abo Alella University Hospital, Khartoum, Sudan. The investigation spanned six months, from June to December 2022, during which eligible participants were consecutively enrolled and systematically assessed according to predefined objectives.

Study Population: The study population included pregnant women who delivered vaginally, as well as those initially attempting vaginal delivery but subsequently converted to caesarean section. Inclusion criteria were singleton term pregnancies, while women with pre-existing obstetric complications were excluded

Sample Size and Sampling Methods: A total of 385 participants were included. Sample size was determined using the formula:

$$n = \frac{z^2 pq}{e2}$$

Where e represents the desired level of precision, p the estimated population proportion, and $q = 1 - p$. This calculation yielded a sample size of 385 women, distributed into 317 controls and 68 received pethidine.

Data Collection and Analysis Data were collected using a structured questionnaire designed to capture relevant clinical and demographic information. The dataset was entered and organized with Microsoft Excel (version 10) and analyzed using SPSS (version 21). Descriptive statistics, including frequency distributions, were applied, and associations between variables were evaluated using independent chi-square tests to ensure clarity and systematic reporting. P value of 0.05 was considered significant.

Corresponding author email: W.abbas@asmarya.edu.ly

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Ethical Considerations Participation was voluntary, and patients were free to accept or decline inclusion in the study. Ethical approval was obtained from institutional review boards, and confidentiality was maintained throughout.

3. Results

Pain severity

Pain severity was assessed in Group A using the dimensional pain intensity scale both before and after pethidine administration. The findings revealed that 31% of women experienced moderate pain prior to receiving pethidine, whereas after administration, 30% reported only mild pain. Severe pain (10%) was reduced to 0% after pethidine. The reduction in pain severity was statistically significant ($p < 0.05$).These results are illustrated in Figures 1 and 2.

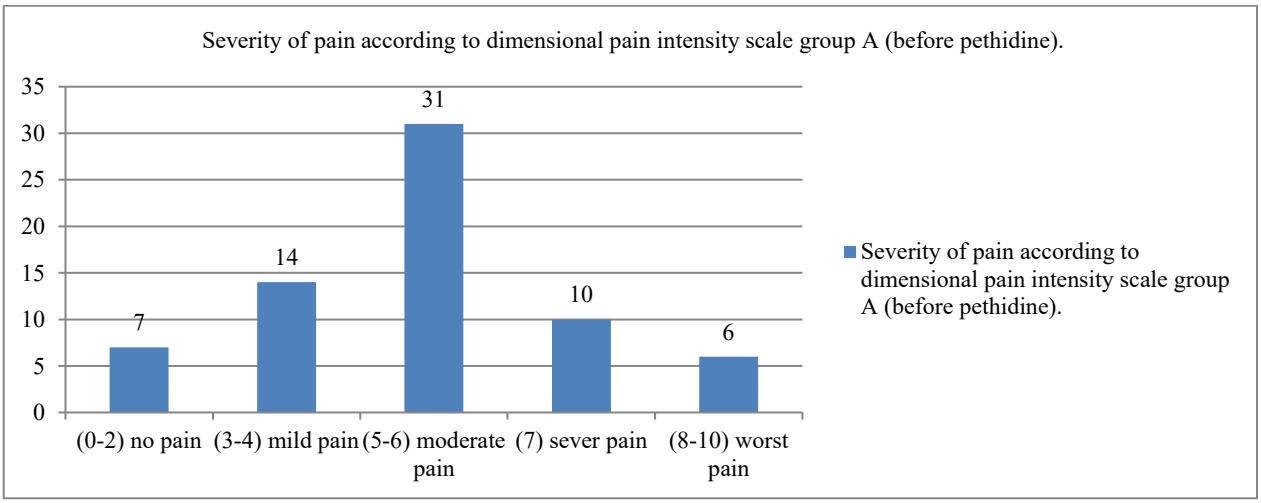

Figure1. Severity of pain according to dimensional pain intensity scale group A (before pethidine)

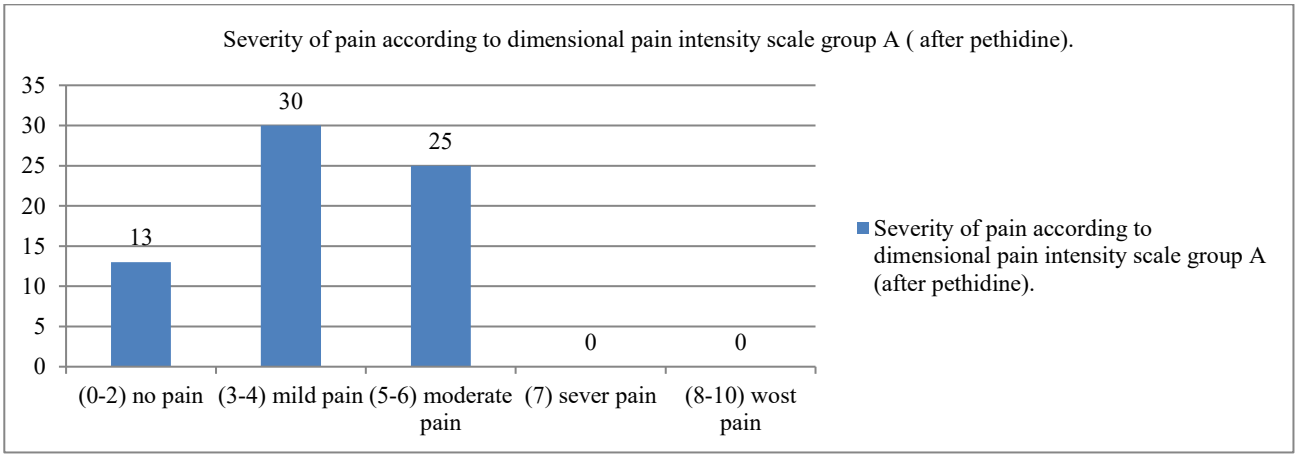

Figure2. Severity of pain according to dimensional pain intensity scale group A (after pethidine)

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The frequency of uterine contractions

Was assessed per 10-minute interval in both study groups in the control group (Group B), 56% of women experienced two contractions within 10 minutes. In the contrast, Group A showed an increase from 56% (two contractions per 10 minutes before pethidine) to 74% (three contractions per 10 minutes after pethidine). The difference in contraction frequency between groups was statistically significant (p = 0.002). See Figure 3 & 4 and Table 1.

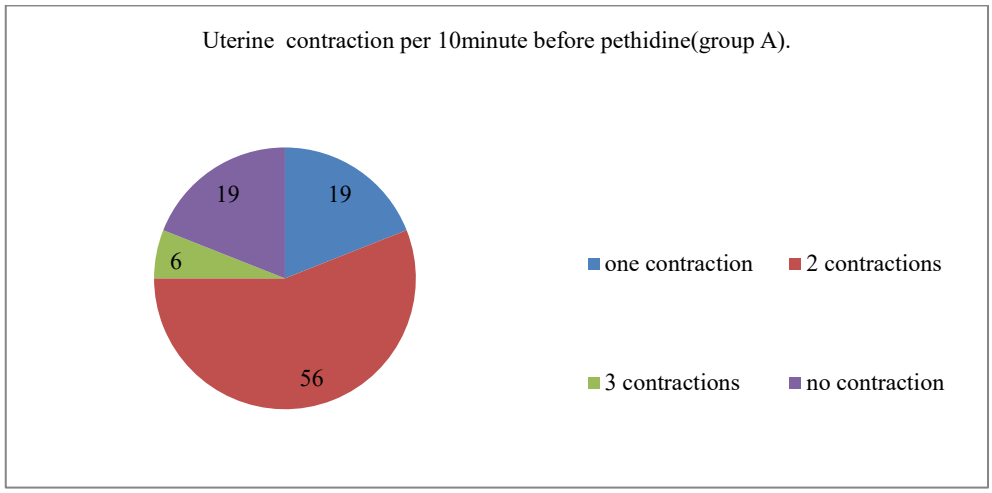

Figure 3 Uterine contraction per 10-minute (before pethidine) groups A

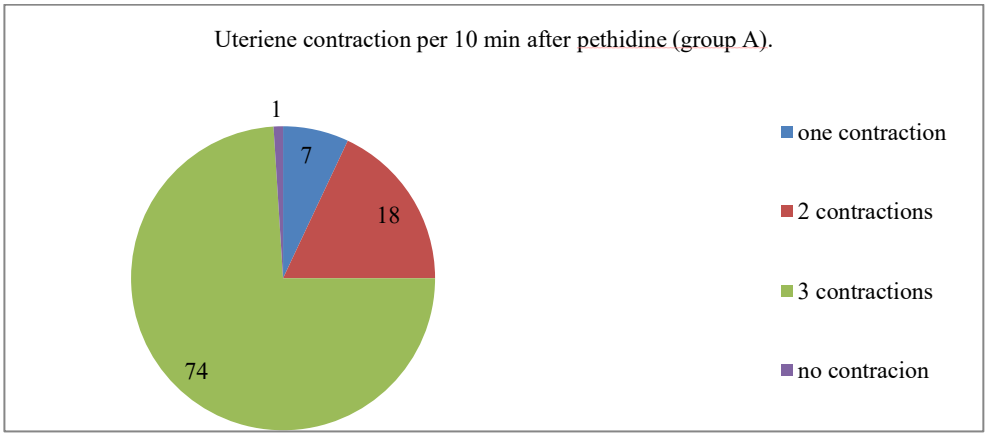

Figure 4 Uterine contraction per 10-minute (after pethidine) group A.

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Table1. Uterine contraction per 10-minute (control) group B

Group	Uterine contraction per 10-minute (control)group B	Frequency	Percent
Control group	1/10	35	11.0
	2/10	51	16.1
	3/10	214	67.5
	Non	17	5.4
	Total	317	100.0
Pethidine group	Non	68	100.0

Interventions required

Interventions such as oxytocin administration and artificial rupture of membranes (ARM) were compared between groups. In Group B, 83% of women required both oxytocin and ARM, while in Group A, 79% required oxytocin before pethidine and 19% required oxytocin after pethidine. This indicates that pethidine reduced the reliance on combined interventions compared to control.

Table 2 comparison between Interventions needed for group A and B (oxytocin before pethidine, oxytocin after pethidine or oxytocin and artificial rupture membrane (ARM) before pethidine).

Group	Intervention (oxytocin before pethidine oxytocin after pethidine or oxytocin and ARM before pethidine)	Frequency	Percent
Control group	Oxytocin	2	0.6
	Oxytocin and ARM	264	83.3
	Non	51	16.1
	Total	317	100.0
Pethidine group	Oxytocin before pethidine	54	79.4
	Oxytocin after pethidine	13	19.1
	Oxytocin and ARM before pethidine	1	1.5
	Total	68	100.0

Caesarean section outcomes

Conversion to caesarean section was more frequent in Group A (21%) compared to Group B (11.7%). This suggests that while pethidine reduced pain and enhanced contractions, it was associated with a higher rate of caesarean section.

Evaluation of the First Stage of Labour Progression

Corresponding author email: W.abbas@asmarya.edu.ly

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The duration of the first stage of labour, defined by cervical dilatation up to 10 cm, typically ranges between two to three hours. However, in some cases from both study groups, progression to the third stage of labour was not achieved, necessitating conversion to caesarean section. This highlights variability in labour outcomes and underscores the importance of monitoring stage one duration as a determinant of delivery mode. The results indicated that 36% of pregnant women experienced a stage one, duration of at least 8 minutes, with 12% subsequently converted to caesarean section (Table 3), while 37% of women had stage one lasting at least 21 minutes, with 31% requiring conversion to caesarean section (Table 4).

Table 3 length of the stage one in group B and cervical dilation.

Group	length of the stage one in group B and cervical dilation	Frequency	Percent
Group B	3-7 min	33	10.4
	8 - 20 min	115	36.3
	21 - 45 min	96	30.3
	46 - 100 min	34	10.7
	> 100 min	2	0.6
	Converted to caesarean section	37	11.7
	Total	317	100.0
Group A	Non	68	100.0

Table 4. length of the stage one in group A and cervical dilation

Group	Length of the stage one in group A and cervical dilation.	Frequency	Percent
Group B	Non	317	100.0
Group A	8 - 20 min	17	25.0
	21 - 45 min	25	36.8
	46 - 100 min	4	5.9
	> 100 min	1	1.5
	Converted to caesarean section	21	30.9
	Total	68	100.0

Gravidity Status of Participants

In this study, pregnant women from both groups were categorized according to their gravidity status into primigravida (women

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experiencing pregnancy for the first time) and multigravida (women with more than one pregnancy). The results showed that 62% of participants in Group A were classified as primigravida, whereas 61% of participants in Group B were classified as multigravida. (Figure 5)

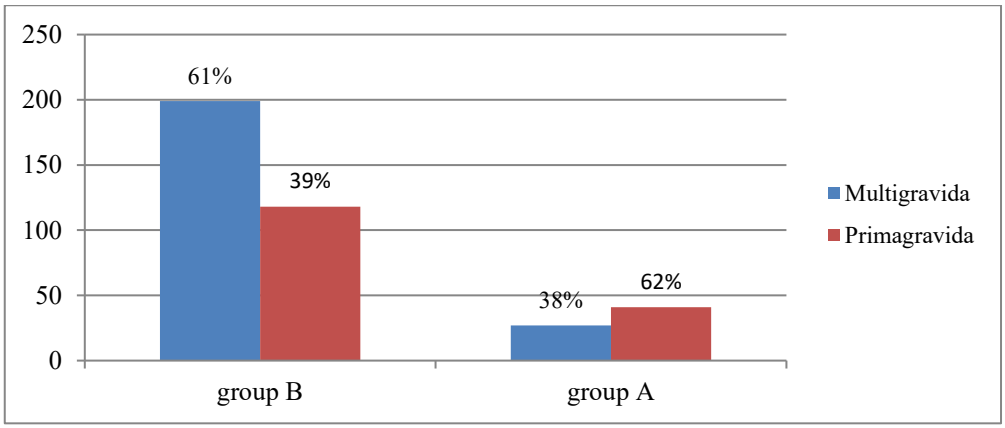

Figure5. Comparison between group A and group B in number of gravida, primigravida or multigravida

Indication of pethidine use:

Pethidine been used in Saad Abo Ella and Soba Teaching Hospital mostly to reduce the labour pain. The results showed that 95%of pregnant women taken pethidine for induction of labour and 5% take it to relief the labour pain.

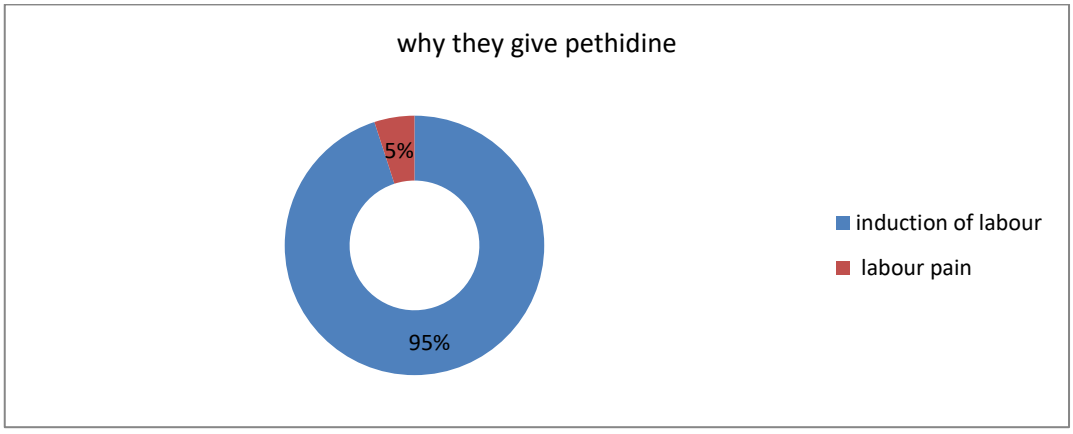

Figure 6 Indication of pethidine for been used in labour.

Evaluation of Pethidine Dose in Relation to Gravidity

In Group A, participants were further subdivided into two subgroups: the first subgroup received 50 mg of intramuscular pethidine, while the second subgroup received 100 mg of intramuscular pethidine, in order to determine the effective dose in relation to primigravida and multigravida. The results were statistically significant (*P* value=0.002), indicating that the administered dose of pethidine influenced both primigravida and multigravida participants. A dose of 50 mg produced effective outcomes in both groups; however, primigravida women demonstrated a higher overall consumption of pethidine compared to multigravida women. (Table 5)

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Table5. Correlation between the Dose of pethidine and the number of gravida (Primagravida or Multigravida)

Dose of pethidine	Number of gravida		Total
	Multigravida	Primagravida	
Group A dose 50 mg	16	22	38
	4.2%	5.7%	9.9%
Group A dose 100 mg	11	19	30
	2.9%	4.9%	7.8%
Group B	199	118	317
	51.7%	30.6%	82.3%
Total	226	159	385
	58.7%	41.3%	100.0%

Correlation between Pethidine Indication and Gravidity Status

Data were collected according to the clinical indications for pethidine use among both primigravida and multigravida participants. The women were categorized into two groups based on indication: those who received pethidine for labour induction and those who received pethidine for labour pain management.

The analysis revealed a highly significant association (P value = 0.0001), confirming that pethidine administration influenced delivery outcomes in relation to gravidity status. Specifically, primigravida women were more likely to consume pethidine for labour induction, whereas multigravida women predominantly received pethidine for pain management. (Table 6)

Table 6 Correlation between Indication of pethidine used for labour and Number of gravida: Primigravida or Multigravida.

Introduction of pethidine	primigravida or multigravida		Total
	multigravida	primigravida	
induction of labour	23	41	64
	6.0%	10.6%	16.6%
labour pain	4	0	4
	1.0%	0.0%	1.0%
Non	199	118	317

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Introduction of pethidine	primigravida or multigravida		Total
	multigravida	primigravida	
	51.7%	30.6%	82.3%
Total	226	159	385
	58.7%	41.3%	100.0%

Association between First Stage Labour Duration and Gravidity Status in Group A

The duration of the first stage of labour was documented for both primigravida and multigravida participants in Group A to allow comparison between the two categories. The analysis revealed a statistically significant difference (P value = 0.027), indicating that the length of stage one was affected by gravidity status, with notable variation in time consumption between primigravida and multigravida women. (Table 7)

Table 7. Correlation between the length of stage one and cervical dilation in (Group A) and Number of gravid (primigravida or multigravida).

length of the stage one and cervical dilation (Group A)	primigravida or multigravida	
	Multigravida	Primigravida
8 - 20 min	9	8
	2.3%	2.1%
21 - 45 min	10	15
	2.6%	3.9%
46 - 100 min	0	4
	0.0%	1.0%
> 100 min	1	0
	0.3%	0.0%
Non	206	132
	53.5%	34.3%
Total	226	159
	58.7%	41.3%

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4. Discussion

In this study, 385 pregnant women (both primigravida and multigravida) planning vaginal delivery were enrolled and divided into two groups. Group A (pethidine group) comprised 68 women who received intramuscular pethidine; of these, 31% required conversion to caesarean section. Group B (control group) included 317 women, among whom 12% underwent caesarean section due to prolonged first stage of labour without identifiable cause.

Intramuscular administration was the most frequently employed route for pethidine, consistent with the findings of Michelle H.Y. et al, who demonstrated that intramuscular pethidine provided superior analgesia compared with placebo during labour. These observations support its continued use as a simple and cost-effective therapeutic option for managing labour pain, particularly in facilities where epidural analgesia is not readily available. However, the analgesic effect of a 100 mg dose of pethidine was modest, indicating limited efficacy in achieving optimal pain control.

In accordance with Onyeoji al, the addition of 50 mg of pethidine to bupivacaine for epidural analgesia significantly prolonged the mean duration of analgesia. Conversely, Olofsson et al reported that labour pain is not responsive to systemically administered morphine or pethidine, which primarily induce sedation rather than effective analgesia. Given the well- documented adverse neonatal effects, systemic pethidine should therefore be used with caution. In the present study, pethidine reduced pain severity in Group A, with cases of severe pain decreasing from 10% to 0%, and moderate pain declining from 31% to 25% following administration.

The increased caesarean section rate observed in the pethidine group may be attributed to prolonged stage one labour, consistent with the findings of Thomson et al. A limitation of this study is the absence of neonatal outcome assessment. Cho et al likewise reported that pethidine delayed labour progression while providing only modest analgesic benefit.

The findings of this study demonstrated that pethidine influenced uterine contractions, with maximum contraction frequency increasing from 56% to 74% following administration. Kamyabi al, explained that severe pain and anxiety elevate catecholamine release, resulting in ineffective contractions and prolonged labour. By lowering catecholamine levels, pethidine may enhance contraction efficiency, although this effect remains debated.

In contrast, Thomson A.M. et al, reported a positive correlation between the amount of pethidine administered during the first stage of labour and the length of both the first ($F = 0.5687$, $P = 0.0001$, CI = 0.33–0.74) and second stages ($R = 0.3204$, $P = 0.037$, CI = 0.03–0.56). In the present study, women in the pethidine group required longer time in stage one, with 37% of Group A consuming 21–45 minutes compared with 30% in Group B. These results suggest that the addition of pethidine further prolonged the first stage of labour.

In this study, 95% of pregnant women received pethidine for labour pain and 5% for induction of labour at doses ranging from 50–100 mg. Gallen B.F. et al, reported that doses between 100–400 mg significantly shortened labour duration in primiparae, with an average dose of 300 mg. Adequate analgesia without amnesia was achieved in 72% of patients, while satisfactory amnesia was observed in 61% when pethidine was combined with a barbiturate. No adverse maternal or neonatal effects were documented in their cohort. Roby and Schumann (1943) administered intramuscular pethidine at 100 mg in combination with scopolamine at the onset of labour pains, producing satisfactory amnesia in 85% of cases. However, 14% of neonates required resuscitation, highlighting potential risks associated with this regimen.

In this study, pethidine influenced uterine contractions in Group A, with maximum contraction frequency increasing from 56% before administration to 74% after. Kamyabi al, noted that uterine contractions at the end of pregnancy facilitate cervical dilatation and foetal

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expulsion, yet they remain a painful and distressing experience for mothers. The obstetrician's objective is to minimize both the duration of labour and the intensity of pain through careful management of labour phases. In cases of severe pain resulting from uterine contractions, narcotic agents such as pethidine (meperidine) are commonly indicated.

Pain and anxiety can alter labour progression by stimulating catecholamine and cortisol release. Noradrenaline enhances uterine contractions, whereas cortisol and adrenaline reduce them. Excessive pain and anxiety often elevate adrenaline and cortisol, leading to diminished contraction efficiency and prolonged labour. In some cases, contractions become severe and frequent but fail to produce cervical progress. Pethidine reduces circulating catecholamine levels, thereby potentially accelerating delivery. Considering its effects on cervical smooth muscle and consistency, alongside prior evidence of its analgesic role, pethidine appears to relieve labour pain while maintaining contraction activity.

5. Conclusion

This study demonstrated that pethidine played a role in reducing labour pain and lowering the need for additional interventions, such as oxytocin administration and artificial rupture of membranes (ARM), particularly when administered in low doses. Intramuscular administration was the most frequent route, especially among primigravida women, and was associated with an increase in uterine contraction frequency. At the same time, the findings indicate that pethidine may contribute to prolongation of the first stage of labour and a higher rate of caesarean section. These results highlight both the potential benefits and limitations of pethidine use in labour, underscoring the need for careful clinical judgment in its application.

5.1. Recommendation

Further research is recommended to explore alternative routes of pethidine administration; as such adjustments may provide improved clinical outcomes. Optimizing administration methods could contribute to reducing the incidence of caesarean section and enhancing the overall safety and effectiveness of labour management

5.2. Limitations

A limitation of this study is that higher doses are often required with intramuscular administration, whereas intravenous or epidural routes may achieve effective analgesia with lower doses and faster onset of action. Such alternative approaches could potentially reduce the incidence of caesarean section and improve overall labour outcomes.

ETHICAL STATEMENT

The Ethics Committee of the Faculty of Pharmacy at Alasmarya Islamic University approved the study protocol (Approval No. PH03:2022).

CONFLICT OF INTEREST

Authors disclose no conflict of interest.

AUTHORS' CONTRIBUTIONS

R.A: Study design : W.A Data collection and analysis. Both authors shared writing and formatting.

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Corresponding author email: W.abbas@asmarya.edu.ly