# Effects of Pethidine Use During Childbirth on Newborns – a Single-Center Retrospective Study

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## SUMMARY

In low-income countries, epidural analgesia is not always available during childbirth. Common alternatives include parenteral application of certain opioids such as pethidine. The aim of this study was to investigate the effects of pethidine use during childbirth on vital parameters of the neonates and compare the Apgar scores of the neonates whose mothers received pethidine during labor with those whose mothers did not receive it. This retrospective study included 116 neonates from Mostar University Clinical Hospital. A total of 58 of those neonates' mothers received pethidine during labor. The women included in this study were most often primiparous (75.9%). Most of them did not have an induced delivery (68.1%) and in half of the mothers, pethidine was used in labor. Female and male neonates were almost equally represented in the sample. The results of the study indicate that pethidine did not affect the investigated variables including the Apgar score, laboratory results (bilirubin and CRP) and transfer to the Neonatal Intensive Care Unit (NICU). A correlation between the use of pethidine, the number of previous births and the mothers' age was not established. According to our results, the correct application of pethidine (50 mg IV) did not cause any significant adverse effects on the newborns. Nevertheless, the use of pethidine during childbirth should be carefully considered, as the toxicity of its intermediate norpethidine is not fully known.

## KEYWORDS

*Pethidine; Labor analgesia; Neonates*

# Introduction

## Labor pain treatment

Modern medicine can provide a variety of options to manage pain and complications that can occur during labor and delivery[1]. The aim of labor pain relief is to provide mothers with the experience of an almost painless childbirth, while at the same time retaining their sense of labor and the natural urge to push during contractions[2].

The standard for patients in labor is a neuraxial blockade with a local anesthetic, which includes a spinal, epidural or combined spinal-epidural technique[3]. Other options include the use of general anesthetics, inhalation agents such as sevoflurane and isoflurane, or systemic intravenous agents such as propofol. Some of the other agents administered to alleviate labor pain include opioids, non-opioids, nitrous oxide, patient-controlled analgesia (PCA) and distraction therapy. A commonly used method of relieving pain during childbirth is the use of analgesics; alone or in combination with anticonvulsants and sedatives[4]. This pharmacological method is simple and inexpensive, and therefore frequently used in developing countries[5].

# Parenteral opioids and labor pain relief

Opioid analgesics are the most powerful pain relievers and are a mainstay for the treatment of severe pain[6]. They act on the endogenous opioid system, including three different subtypes of opioid receptors: μ-, δ- and κ-. By inhibiting these endogenous opioid receptors, pain impulses are modulated directly at the nerve cells or their synapses in the spinal and supraspinal pain pathways. Opioids can be categorized as pure agonists (e.g. morphine), partial agonists (e.g. buprenorphine), agonists-antagonists (e.g. pentazocine) and pure antagonists (e.g. naloxone). A distinction is made between central and peripheral effects.

In the spinal cord, opioid analgesics inhibit the release of primary afferent transmitters, such as glutamate or substance P. This reduces the transmission of stimuli from the spinal cord to central areas of the brain via the spinothalamic tract. At the same time, nerve tracts descending in the midbrain are stimulated and inhibit the spinothalamic tract. In the thalamus, sensorimotor cortex and limbic system, opioid receptors are also stimulated, so that the intensity of the pain sensation and the emotional assessment of pain change.

Opioid receptors in the midbrain inhibit GABAergic interneurons. As a result, more dopamine is released and the fear of pain decreases. Contrastingly however, euphoria develops, which can contribute to the development of addiction. Chronic pain sufferers are exempt from this, because they usually do not experience a feeling of euphoria when taking opioid analgesics.

*Sedative, antitussive and emetic effects*

Opioid analgesics inhibit neurons in the ascending part of the reticular formation. This can lead to sedation, which impairs complex motor functions, such as the ability to drive. They also inhibit the excitability of the cough center and stimulate receptors in the chemoreceptor trigger zone of the medulla oblongata that can induce vomiting. In the medullary respiratory center, opioid agonists downregulate $CO_2$ sensitivity. This influences the breathing rhythm.

Peripheral nerve endings of nociceptive afferents also have opioid receptors. At this point, opioid analgesics can inhibit nociceptor sensitization. Likewise, many organs have peripheral opioid receptors, such as the gastrointestinal and urinary tract. This can lead to a wide range of

side effects. Unwanted effects of opioid use include constipation, respiratory depression, nausea and vomiting[8].

Group-specifically, opioids bind to various receptors with different strengths, whereby they can have an activating (agonist) or inhibiting (antagonist) effect, resulting in a complex pattern of action (multiple receptor theory). Pure agonists have an exclusively activating effect with a high affinity (binding strength) and high intrinsic activity (potency) for μ-receptors, and a lower affinity for κ-receptors. These drugs can be administered in many ways, including orally, transcutaneously and — most commonly — parenterally via an intravenous route. Most opioid drugs used in medicine are pure agonists; examples include tramadol, pethidine, codeine, piritramide, morphine, levomethadone, diethylthiambutene, ketobemidone and strong analgesics such as fentanyl, alfentanil, remifentanil and sufentanil. Mixed agonist-antagonists offer a complex pattern of action; this group of substances includes pentazocine, butorphanol and nalbuphine. Their pharmacological importance has declined sharply due to their tendency to cause dysphoria, hallucinations, disorientation and circulatory stimulation (σ-agonists). Parenteral opioids commonly used for providing labor analgesia include pethidine (meperidine), morphine, fentanyl, remifentanil and partial agonists including butorphanol and nalbuphine[9,10].

## Pethidine

The synthetic opioid pethidine (meperidine – Dolantin®, Sanofi-Aventis, Frankfurt, Germany) can be administered intramuscularly or intravenously in doses lower than 100 mg during labor, depending on the intensity of pain and the mother's body weight.

Its analgesic effect occurs 10–15 minutes after application, lasting for 2–3 hours. Pethidine is metabolized to the inactive pethidinic acid and to the active metabolite norpethidine, which, due to its significant lipophilicity, may cause side effects such as nausea, vomiting and hypotension in higher doses[11]. In the neonate, the apparent pethidine half-life is 2 to 7 times longer than in adults, with values ranging from 7 to 32 hours. Norpethidine is actively formed in the newborn with peak blood levels at 12–36 hours and an apparent blood half-life of 20–36 hours. It passes rapidly through the placenta and reaches 70% of the mother's concentration in fetal blood, so it is not desirable to use it within one hour before delivery. Through the process of passive diffusion, it passes to the fetus, which is why neonatal respiratory depression and hypothermia can occur. It is estimated that a newborn needs three to six days to eliminate pethidine and its metabolite, norpethidine[12]. The results of previous studies have reported effects of opioids on the newborn involving neurobehavioral changes and decreased Apgar score values[13].

## Apgar score

The Apgar score is determined by evaluating the newborn in terms of five criteria on a scale from zero to two, then adding the five values. The resulting score ranges from zero to ten. The five criteria are summarized using words chosen to form an acronym: appearance, pulse, grimace, activity and respiration[14]. The Apgar score is an important indicator of a newborn's health and is established in the first and the fifth minute after birth. While a low first-minute score is often transitory, persistence of poor health resulting in a low fifth-minute score often implies complications of clinical importance and indicates that

the newborn has not responded to initial intervention. This index is the most widely accepted system for assessing neonatal vitality, primarily because of its simplicity and speed[15].

The aim of the study was to investigate the effects of pethidine use during childbirth on vital parameters of the neonates and compare the Apgar scores of the neonates whose mothers received pethidine during labor with those whose mothers did not receive this therapy.

## Patients and methods

This was a retrospective study conducted at the Department of Obstetrics and Gynecology, University Clinical Hospital (UCH) Mostar in the period from January 1, 2020 to July 1, 2020. A total of 116 patients were examined. The sample size was calculated using the ClinCalc online tool (ClinCalc LLC, Chicago, IL, USA) based on a Z score derived from the 95% confidence interval. This study was conducted according to the institutional guidelines of the University of Mostar and follows the tenets of the Declaration of Helsinki. All of the participants signed an informed consent form.

Data regarding the medical history of the subjects were extracted from the hospital information system. The subjects were newborns whose mothers used pethidine during delivery. Newborns of mothers who did not receive an opioid analgesic during delivery were included in the control group. The study included newborns born naturally (vaginally) from healthy pregnant women, both primiparous

**TABLE 1** An overview of mothers and childbirth characteristics

| | | MIN | MAX | M | SD | No. of mothers | % |
|---|---|---|---|---|---|---|---|
| First delivery | | | | | | 88 | 75.9 |
| One or more previous deliveries | | | | | | 28 | 19.0 |
| Induced labor | Yes | | | | | 37 | 31.9 |
| | No | | | | | 79 | 68.1 |
| Use of pethidine | Yes | | | | | 58 | 50 |
| | No | | | | | 58 | 50 |
| Mother's age (years) | | 20 | 42 | 28.80 | 4.52 | | |
| Mother's height (meters) | | 1.50 | 1.86 | 1.71 | 0.06 | | |
| Mother's weight (kg) | | 52 | 128 | 81.86 | 15.51 | | |
| BMI | | 20.05 | 44.29 | 28.10 | 4.32 | | |
| First dose of pethidine (mg) | | 0 | 50 | 23.32 | 24.17 | | |
| Second dose of pethidine (mg) | | 0 | 50 | 3.23 | 12.13 | | |
| Total dose of pethidine (mg) | | 0 | 100 | 26.55 | 29.62 | | |
| Time between administered dose and start of labor (minutes) | | 0 | 7 | 1.91 | 2.14 | | |

Min = minimum value; Max = maximum value; M = mean; SD = standard deviation

**TABLE 2** An overview of newborns' characteristics (n = 116)

| | | | No (%) of newborns | (%) | Min | Max | M | SD |
|---|---|---|---|---|---|---|---|---|
| Sex | | Male | 55 | 47.4 | | | | |
| | | Female | 61 | 52.6 | | | | |
| Transfer to NICU | | Yes | 22 | 19.0 | | | | |
| | | No | 94 | 81.0 | | | | |
| Stay in NICU | | Not transferred | 94 | 81.0 | | | | |
| | | < 2 days | 22 | 19.0 | | | | |
| Apgar score | Apgar score at first minute | 10 | 106 | 91.4 | | | | |
| | | < 10 | 10 | 8.6 | | | | |
| | Apgar score at fifth minute | 10 | 113 | 97.4 | | | | |
| | | < 10 | 3 | 2.6 | | | | |
| CRP(mg/L) | | | | | 0 | 108 | 8.19 | 13.74 |
| Birth weight (g) | | | | | 1380 | 4900 | 3505 | 487.95 |
| Birth length (cm) | | | | | 48 | 60 | 54.93 | 2.01 |
| Head circumference (cm) | | | | | 32 | 39 | 35.53 | 1.21 |
| Direct bilirubin (mg/dL) | | | | | 0 | 178.4 | 9.93 | 15.98 |
| Total bilirubin (mg/dL) | | | | | 0 | 282 | 93.47 | 52.74 |

Min = minimum value; Max = maximum value; M = mean; SD = standard deviation

and multiparous, with uncomplicated pregnancies. Newborns whose mothers had complications and certain diseases during pregnancy (gestational diabetes, preeclampsia, infections, malignancies, etc.) were excluded. Newborns born by Cesarean section or with epidural or spinal anesthesia were not included in the study. Other newborn exclusion criteria included any systemic conditions that could affect the analyzed parameters — acute congenital infections, syndromic malformations, etc. Pethidine was administered intravenously, at least two hours before the expected time of delivery (based on clinical examination, such as cervical dilation and cardiotocography findings).

Outcome measures: Apgar score at the first and fifth minute, newborn transfer to the Neonatal Intensive Care Unit (NICU) and length of stay, and an analysis and comparison of bilirubin and C-reactive protein (CRP) levels between the study and control group.

Statistical processing and data analysis were performed in IBM SPSS Statistics 25. A student's t-test, the point-biserial correlation coefficient and a chi-square test were used for statistical data analysis.

## Results

The women included in this study were mostly primiparous (75.9%) and in most of them childbirth was not induced (68.1%) (Table 1). Pethidine was used in half of the mothers in this study (58) and the other half delivered without pethidine.

Female and male newborns were equally represented in the study. The vast majority of newborns (98.3%) immediately cried right after birth, and 19.0% of all newborns (n = 116) were transferred to NICU for a variety of reasons (Table 2).

### Differences in Apgar scores considering the use of pethidine

Newborns were divided into two groups regarding Apgar scores (10 or < 10), both in the first (Apgar1) and in the fifth (Apgar5) minute after birth. No statistically significant difference considering pethidine administration was found in Apgar scores in either category: ($\chi 2 = 0.0$; $P > 0.05$ and $\chi 2 = 1.04$; $P > 0.05$ in the first and fifth minute, respectively) (Table 1 and 2).

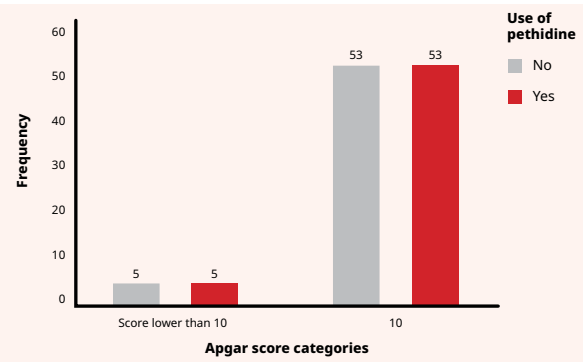


**FIGURE 1** Differences in Apgar scores in the first minute considering pethidine administration


**FIGURE 2** Apgar scores in the fifth minute considering pethidine administration

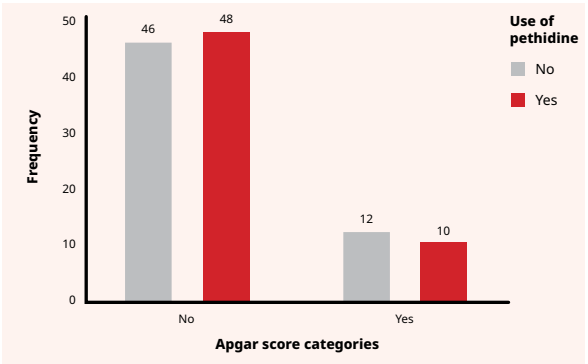


**FIGURE 3** Differences in the frequency of newborns transfer to NICU considering the use of pethidine

### Frequency of transfers to NICU considering pethidine use (%)

There was no statistically significant difference in the frequency of transfers to NICU with regards to the use of pethidine ($\chi 2 = 0.22$; $P > 0.05$) (Figure 3).

### Frequency of transfers to NICU considering pethidine dose (%)

No statistically significant difference was found between the total dose of pethidine and the transfer of neonates to NICU (r = -0.10; $P > 0.05$).

### The effects of administered pethidine on total neonatal bilirubin

The mean level of total bilirubin without pethidine administration was 96.77 ± 53.17 μmol/L, while in situations where pethidine was administered it was 90.18 ± 52.56 μmol/L. There was no statistically significant difference in total bilirubin levels considering pethidine administration ($P > 0.05$) (Figure 4).

### The influence of applied pethidine on newborn CRP levels

The mean CRP level when pethidine was not administered was 7.36 ± 9.26 μmol/L, while in cases where pethidine was administered, the average was 9.04 ± 17.12 mg/L. No statistically significant difference was found in CRP with respect to pethidine administration ($P > 0.05$) (Figure 5).

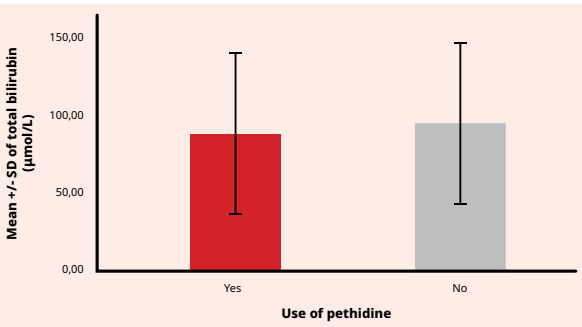


**FIGURE 4** Differences in neonatal total bilirubin levels considering pethidine administration

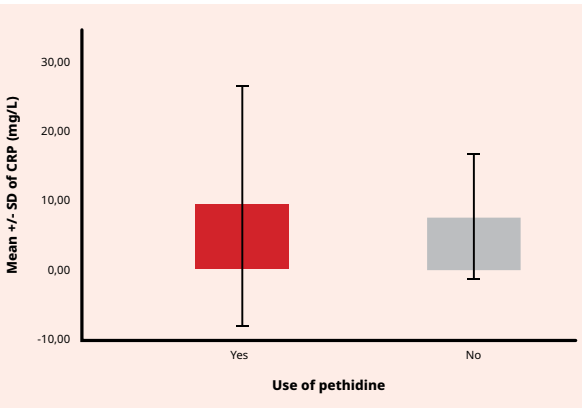


**FIGURE 5** Differences in neonatal CRP levels considering pethidine administration

## Discussion

The first thing that was noticable is the significant use of pethidine in this single-center study. However, this widespread use does not appear to cause a significant suppresion of vital parameters of the newborn. During childbirth, the activation of the sympathetic nervous system in states of pain and fear reduces blood flow through the placenta. Additionally, maternal hyperventilation interferes with the fetus's optimal oxygen supply and intensifies her pain experience. Therefore, a desirable therapeutic approach is aimed at recognizing the different dimensions of pain and removing fear and suffering, while ensuring a normal course of labor. Narcotics, sedatives and antispasmodics are preferred in the delivery room, when epidural analgesia is not available, as was the case in the maternity ward of the Department included in this study. One of the most commonly prescribed opioid analgesics for moderate labor pain is pethidine, a synthetic derivative with a pharmacological effect similar to morphine. Possible consequences of pethidine administration in the newborn are respiratory depression, hypothermia and feeding problems.

The women included in this study were mostly primiparous (75.9%) and in most of them childbirth was not induced (68.1%). Pethidine was used in half of the mothers. Female and male newborns were almost equally represented in this sample.

The Apgar score is the most widely accepted system for assessing neonatal vitality, primarily because of its simplicity and speed. The results

of the study confirmed that pethidine did not affect the Apgar score in the newborn, which was measured in the first and fifth minutes of life. Based on the obtained results, we could not confirm the hypothesis of our research, which expected lower values of the Apgar score.

According to Schneider and co-workers, 2/3 of pethidine binds to maternal plasma proteins. The remaining 1/3 of the pethidine remains free and can easily pass through the placenta tendril. Just a few minutes after the administration of pethidine, it can be detected in fetal blood and an equilibrium between maternal and fetal plasma concentrations is reached in a short time. If pethidine was administered to the mother within an hour of birth, the newborn was not affected. However, if pethidine was used 2–3 hours before birth, the risk of respiratory depression was elevated. The intramuscular administration of opioids offers, in terms of the onset of action, an analgesic effect and poor controllability of the duration of action. The incalculable tissue perfusion with different characteristics of subcutaneous adipose tissue makes the distribution and effect of an intramuscular analgesic difficult to predict. Therefore, poor controllability leads to either an overdose with possible respiratory depression or to underdosing with insufficient analgesia. Intravenous administration, in which the dosage is slowly titrated, is more controllable than intramuscular administration[16].

In terms of the frequency of transfers to NICU with regard to the applied dose, no change in Apgar scores was observed in our study. The incidence of neonatal complications was not determined for an IV dose of 50 mg of pethidine, which was the most commonly used dose in our study. Similar findings were reported by Nunes et al. in their systematic review[17].

The mean CRP level when pethidine was not administered was 7.36 ± 9.26 mg/L. When pethidine was administered, mean CRP levels were 9.04 ± 17.12 mg/L. No statistically significant difference was found in CRP in terms of pethidine administration. Also, the association of total bilirubin with administered pethidine was not established. This is in contrast with a study by Smith et al., in which the authors established a connection between changes in laboratory findings, including CRP and total bilirubin, with regard to the use of pethidine[18].

There are several limitations to this study. Firstly, the Apgar score is a somewhat subjective measurement. Also, there was a lack of precise measurements of the actual plasma concentration of pethidine and its correlation with the newborns' parameters. Measuring the concentration of the drug in newborns would also be informative. Another element that should be investigated in future studies is the role of pethidine in maternal adverse effects; an issue that might have broader implications.

## Conclusion

In the present study, the application of pethidine in the dose of 50 mg IV did not cause any significant adverse effects on the newborns. No change in Apgar score considering pethidine administration was demonstrated. It should be noted that all the newborns in this study were born vaginally and the mothers were mostly primiparous with no complications during pregnancy.

The recommendation for future research is to compare the values of all the mentioned parameters in relation to complications during pregnancy in order to identify additional risk factors for pethidine use.

Due to the strong effect of pethidine on the mother and newborn, and the fact that its intermediate norpethidine is consistently associated with neonatal sedation, its role in relieving labor pain should be studied further.

### Availability of data and materials

The datasets used and analyzed during the current study are available upon reasonable request to the corresponding author. (Kindly include reason for the same.)

### Author contributions

A.C. and I.M. conceived and designed the study; A.C., V.T., I.B. and I.M. collected the data; A.C. and I.M. analyzed the data; A.M., V.T., I.B. and I.M. interpreted the results; A.C. and I.M. prepared the figures; A.C. drafted the manuscript; A.C., V.T., I.B. and I.M. edited and revised the manuscript; A.C., V.T., I.B. and I.M. approved the final version of the manuscript. ■

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**SAŽETAK**

## Učinci upotrebe petidina tijekom poroda na novorođenčad – retrospektivna studija u jednom centru

Ante Čuljak, Vajdana Tomić, Ivica Brizić i Ivan Merdžo

U zemljama s niskim prihodima epiduralna analgezija nije uvijek dostupna tijekom poroda. Uobičajene alternative uključuju parenteralnu primjenu određenih opioida poput petidina. Cilj ove studije bio je istražiti učinke upotrebe petidina tijekom poroda na vitalne parametre novorođenčadi i usporediti Apgar-indeks novorođenčadi čije su majke primale petidin tijekom poroda s onima čije ga majke nisu primale. Ova retrospektivna studija obuhvatila je 116 novorođenčadi iz Sveučilišne kliničke bolnice u Mostaru. Ukupno 58 majki istraživane novorođenčadi primalo je petidin tijekom poroda. Žene uključene u ovu studiju najčešće su bile prvorotkinje (75,9 %). Većina njih nije imala inducirani porod (68,1 %), a u polovice majki petidin je korišten tijekom poroda. Ženska i muška novorođenčad bila su gotovo podjednako zastupljena u uzorku. Rezultati studije pokazuju da petidin nije utjecao na ispitivane varijable, uključujući Apgar-indeks, laboratorijske rezultate (bilirubin i CRP) i premještaj na neonatalnu intenzivnu jedinicu liječenja. Nije utvrđena korelacija između upotrebe petidina, broja prethodnih poroda i dobi majki. Prema našim rezultatima, ispravna primjena petidina (50 mg IV) nije uzrokovala značajne štetne učinke na novorođenčad. Ipak, upotrebu petidina tijekom poroda treba pažljivo razmotriti, jer toksičnost njegovog međuprodukta norpetidina nije u potpunosti poznata.

**KLJUČNE RIJEČI**

*Petidin; Analgezija u porođaju; Novorođenčad*