

Does the use of pharmacological analgesia influence childbirth outcomes?

O uso de analgesia farmacológica influencia no desfecho de parto?

Mariana Santos Felisbino-Mendes¹

Luiza Oliveira Santos¹

Torcata Amorim¹

Isabela Nascimento Costa¹

Eunice Francisca Martins¹

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Corresponding author

Mariana Santos Felisbino-Mendes
Av. Alfredo Balena, 190, 30130-100,
Santa Efigênia, Belo Horizonte, MG, Brazil.
marianafelisbino@yahoo.com.br

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Abstract

Objective: To investigate the association between pharmacological analgesia and childbirth outcomes.

Methods: A cross-sectional study using a representative sample of childbirth performed in 2013, at a maternity hospital in Belo Horizonte, Minas Gerais. Data from 978 childbirths were included, excluding elective cesareans. The main exposure was the use of pharmacological analgesia during labor, with the outcome classified as vaginal, instrumental vaginal, or cesarean delivery. The association between analgesia and childbirth outcomes was assessed using multinomial logistic regression to obtain Odds Ratio (OR) estimates with their respective 95% confidence intervals. The final model was adjusted for the woman's age, number of previous births, presence of companion or doula, and cervical dilatation at the time of analgesia.

Results: Among the total number of births, 87.1% were vaginal and 12.9% were cesarean. The prevalence of the use of pharmacological analgesia was 34.2%, and delivery with instrumentation was 8.4%. About 70% of the women had a normal risk pregnancy. Even after adjusting for confounding variables, the use of analgesia increased the chance of delivery with instrumentation by 3.5 times ($p < 0.0001$); for women with high-risk pregnancies, this increase was even higher ($OR = 4.62$; $p < 0.0001$). There was no association between analgesia and cesarean section ($p = 0.320$).

Conclusion: The use of pharmacological analgesia modifies the outcome of childbirth, increasing the chances of delivery with instrumentation, especially in women with high-risk pregnancies. In this context, it is important to guide women about the potential risks and benefits of analgesia so they may make a safe choice.

Resumo

Objetivo: Investigar associação entre analgesia farmacológica e desfechos do parto.

Métodos: Estudo transversal que utilizou amostra representativa dos partos realizados em 2013, em uma maternidade de Belo Horizonte, Minas Gerais. Foram incluídos dados de 978 partos, excluindo-se as cesarianas eletivas. A exposição principal foi o uso de analgesia farmacológica durante o trabalho de parto e o desfecho classificado como parto vaginal, vaginal instrumentalizado e cesariana. Verificou-se a associação entre analgesia e os desfechos do parto por meio de regressão logística multinomial para obter as estimativas de *Odds Ratio* (OR) com seus respectivos intervalos de 95% de confiança, e o modelo final foi ajustado por idade da mulher, número de partos anteriores, presença de acompanhante ou doula e dilatação cervical no momento da analgesia.

Resultados: Do total de nascimentos, 87,1% foram vaginais e 12,9% cesariana. A prevalência do uso de analgesia farmacológica foi 34,2% e do parto instrumentalizado de 8,4%. Cerca de 70% das mulheres tiveram gestação de risco habitual. Mesmo após ajuste por confundidores, o uso da analgesia aumentou em 3,5 vezes a chance de parto instrumentalizado ($p < 0,0001$) e para as mulheres com gestação de alto risco esse aumento foi ainda superior ($OR = 4,62$; $p < 0,0001$). Não houve associação do uso da analgesia com a cesariana ($p = 0,320$).

Conclusão: O uso de analgesia farmacológica modifica o desfecho do parto, aumentando as chances de parto instrumentalizado, principalmente em mulheres com gravidez de alto risco. Nesse contexto considera-se importante orientar as mulheres quanto aos potenciais riscos e benefícios da analgesia para uma escolha segura.



¹Universidade Federal de Minas Gerais, Belo Horizonte, MG, Brazil.
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Introduction

Pain management is one of the main objectives of care during labor, with two approaches for its relief: pharmacological and non-pharmacological.⁽¹⁾ The non-pharmacological approach includes a wide variety of techniques that include not only physical sensations of pain, but also to avoid suffering by improving the psycho-emotional and spiritual components of care. The pharmacological approach is aimed at eliminating the physical sensation of pain, and includes several substances and techniques.^(1,2) Epidural neuroaxial analgesia is the most often discussed and present in studies, due to its great effectiveness for pain relief.⁽¹⁻⁴⁾

The provision of methods for pain relief during labor, in Brazil, still occurs less frequently than desired, even though the woman's right to receive care that offers pain control methods has been instituted by the Ministry of Health,⁽⁵⁾ and was reinforced by the *Rede Cegonha* strategy in 2011,⁽⁶⁾ and by normal birth guidelines in 2016.⁽⁷⁾ The National Demographic and Health Survey in 2006, showed that only 30.4% of the Brazilian women had access to non-pharmacological and pharmacological measures for pain relief.⁽⁸⁾ More recently, the "*Nascer in Brazil*" (Birthing in Brazil) survey indicated that 33.9% of women with normal risk pregnancies used epidural analgesia for pain relief, but restricted to a certain profile of women: 35 years or more, with a higher educational level, and who received care in a private institution.⁽⁵⁾

The pharmacological approach for pain relief is a practice that has increasingly been studied and used, in order to provide as pleasurable of a labor and delivery experience as possible for the mother.⁽⁷⁾ Thus, the right of women to the pharmacological approach is recognized. When non-pharmacological measures are insufficient to comfort women, the pharmacological approach must be used.^(7,8) However, a controversy exists related to its use and impact on the progress of labor and its outcomes.⁽⁹⁾

When comparing epidural analgesia with alternative forms of pain relief, or no relief, a systematic review with 38 randomized clinical trials and a population of 9,658 women demonstrated an association of this analgesia with adverse obstetric consequences, including a prolonged second stage of labor, increased oxytocin use, and increased chance of a instrumental vaginal delivery.⁽³⁾

A instrumental vaginal delivery is understood as one that requires forceps or use of a vacuum extractor to assist in the expulsive period,⁽¹⁰⁾ and can be indicated by fetal or maternal conditions during the second stage of labor.⁽¹¹⁾ It is an important resource for minimizing risks, such as in cases of fetal distress, and may prevent fetal morbidity or death.⁽¹⁰⁾ In contrast, it has been associated with a higher risk of fetal morbidity and mortality, as well as maternal morbidities.^(10,12,13) Laceration of the anal sphincter and of the birth canal, and displacement of the muscles of the pelvic floor are among maternal morbidities;^(10,12,13) the neonatal morbidities are facial lesions, cephalo-hematomas, intracranial hemorrhage, ocular lesions, and fractures of the skull bones.⁽¹⁰⁾

Obvious benefits are achieved by analgesia, despite the adverse conditions of its use. The most important is a possibility of effective pain relief, less time to perceive its effect, and decrease in the need for a new dose of medication.^(3,7) Considering the benefits and the potential risks of pharmacological analgesia, its relatively frequent use, and a great demand by the parturient for this treatment, it is necessary to elucidate the cause-effect relationship of analgesia. Thus, the question is: does the use of analgesia modify the childbirth outcome, and is there a real association between analgesia and instrumental vaginal delivery? Thus, we sought to investigate the association between pharmacological analgesia and delivery outcomes. It is believed that this study has the potential to support discussions on the use of pharmacological methods in relieving labor pain, and their potential risks.

Methods

This was a cross-sectional study, with a random and representative sample of all childbirths performed in 2013, in a philanthropic maternity unit, exclusively attended by the Unified Health System in the city of Belo Horizonte, Minas Gerais. It is a reference center in the country for humanization of care, and attends approximately 920 childbirths per month, with a pharmacological analgesia rate of 30%.⁽¹⁴⁾

The sample calculation considered a 95% confidence level, 80% power, 2% error, totaling a minimum sample of 918 childbirths. Considering the possibility of a 30% loss rate, we obtained a sample of 1200 births that were collected from random sweeps, including day and night shifts, even-and odd-numbered days, during each month of 2013, using the Open epi software (<http://www.openepi.com>). A hundred random numbers were drawn for each month of 2013, with 50 for each shift, including single-term, full-term newborns, cephalic presentation, and live births; elective cesarean sections, multiple gestations, prematurity, anomalous presentations, and fetal deaths were excluded.

Data collection was conducted using a structured form containing 27 objective questions on the variables of interest of the study, which were completed using data extracted from the chart and the clinical progress sheet, analgesia record sheet, partogram, and the Latin American Center for Perinatology (CLAP) form. The collection occurred between February of 2013 and May of 2015, with 978 childbirths included in the study. The loss of 222 events refers to records that could not be located (41.4%), noncompliance with the inclusion criteria (39.6%), and inadequate records within the patient files (18.9%), making access to the medical records impossible, or leading to unselected medical records.

The use of pharmacological analgesia during childbirth was defined as the main exposure of this study. Pharmacological analgesia was considered to be the suppression of pain obtained by means of medication,⁽¹⁾ categorized as yes or no. The main outcome was instrumental vaginal delivery n, using a vacuum extractor or obstetric forceps.⁽¹⁰⁾ This

variable was categorized as vaginal delivery, instrumental vaginal delivery of forceps or vacuum, and cesarean delivery. The covariates studied were: age (13-19, 20-29, ≥ 30); education (zero to eight, nine to eleven, twelve or more years); number of previous childbirths (0, 1, >1); gestational risk classification (normal; high risk); number of prenatal visits (zero to five, six or more); duration of labor (hours); presence of companion and/or doula (yes or no); use of non-pharmacological methods for pain relief (yes or no); obstetric interventions before and after analgesia (yes or no) and cervical dilation when receiving analgesia (in cm).

The gestational risk was defined according to parameters established by the Ministry of Health, by the presence of only one risk factor, as follows: neurological diseases, intrauterine growth restriction, polyhydramnios, oligohydramnios, hypertensive disorders of gestation, HIV infection, syphilis infection, recurrent urinary infections, gestational age > 41 weeks, severe anemia, severe pneumopathologies, diabetes, endocrine pathologies, gestational toxoplasmosis, and hepatitis B.⁽¹⁵⁾

The duration of labor was computed from the partogram, a graphic document recording the development of labor and maternal and fetal conditions.⁽¹⁶⁾ The obstetric interventions were analyzed before and after analgesia, and were: use of prostaglandin, artificial rupture of membranes, and use of oxytocin.

Initially, we calculated the absolute and relative frequencies, means and standard deviations. Statistical differences were assessed using Pearson's chi-square and student t-tests, to compare means with a significance level of 5%. The association between analgesia and instrumental vaginal delivery was then investigated using multinomial logistic regression, to estimate the unadjusted odds ratios (OR) and 95% confidence intervals (95% CI). The same analysis was performed in normal and high-risk pregnancies, separately. Afterwards, the analysis was repeated with the introduction of possible confounding variables, and the OR was adjusted for the woman's age, number of previous deliveries, presence of companion and/or doula, and cervical dilation at the time of analgesia. The statistical pro-

gram, STATA, version 14.0 (Stata Corp., College Station, TX, USA) was used.

This research was approved by the Ethics Committee of the Federal University of Minas Gerais (CONEP/UFMG), Opinion 898.375, and by the Ethics Committee of the Sofia Feldman Hospital/Foundation for Comprehensive Health Care Opinion No. 943,689.

Results

The sample studied ($n = 978$) had a mean age \pm SD of 24.4 (± 6.4) years. The minimum age was 13 years and the maximum was 45, with 20-29 being the most frequent age group (50.6%), followed by 13-19 (27.0%). Most of the women had nine or more years of education (63.4%), were primiparous (53.7%), had a gestational age of 37-40 weeks (84.9%), and had more than five antenatal visits (78.8%). About 70% of the women presented a normal risk pregnancy, and 34.2% received analgesia (Table 1).

A significant association between the number of previous births and the use of analgesia ($p < 0.0001$) was found, which was more frequent among nulliparous women, with a greater use of analgesia among the more educated women, but without statistical significance. The majority of women had a companion in the delivery room, and some non-pharmacological methods were used for pain relief (97.8% and 89.7%, respectively). The mean \pm SD of labor duration was 5.5 (± 3.3) hours, with zero as the minimum time, and 19 hours as the maximum. Women who received analgesia had a longer duration of labor than those who did not ($p < 0.0001$) (Table 2).

The most used method of analgesia was epidural (98.1%, $n = 317$), with a combined block being the other. The women received analgesia with a mean of 7.3 (± 1.3) cm of cervical dilation, with a minimum dilation of 3 cm and the maximum of 10 cm (data not shown).

Regarding the interventions performed before and after analgesia, measured for those who received analgesia, 56.9% had some intervention before re-

Table 1. Sociodemographic and gestational characteristics of the women studied, according to analgesia use*

Sociodemographic and gestational characteristics and labor	Analgesia use		Total n(%)	p-value
	Yes n(%)	No n(%)		
Age				0.743**
13 - 19 years	92(35.0)	171(65.0)	263(27.0)	
20 - 29 years	171(34.6)	323(65.4)	494(50.6)	
31 years or more	70(32.0)	149(68.0)	219(22.4)	
Years of education				0.077**
0 - 8	72(30.9)	161(69.1)	233(36.6)	
9 - 11	126(34.3)	241(65.7)	367(57.7)	
12 or more	18(50.0)	18(50.0)	36(5.7)	
Number of previous deliveries				<0.0001**
None	206(39.5)	315(60.5)	521(53.7)	
1 or more	126(28.0)	324(72.0)	450(46.3)	
Gestational age (weeks)				0.792**
37 - 40	282(34.0)	547(66.0)	829(84.9)	
41 or more	52(35.1)	96(64.9)	148(15.1)	
Number of antenatal visits				0.136**
0 - 5	60(29.6)	143 (70.4)	203(21.2)	
6 or more	265(35.2)	489 (64.8)	754(78.8)	
Gestational risk classification				0.641**
High risk	96(32.9)	196(67.1)	292(30.3)	
Normal risk	231 (34.4)	440(65.6)	671(69.7)	
Presence of companion and/or doula				0.047**
Yes	322(35.1)	595(64.9)	917(97.8)	
No	3(14.3)	18(85.7)	21(2.2)	
Nonpharmacological methods used				<0.0001**
Yes	246(41.0)	354(59)	600(89.7)	
No	8(11.6)	61(81.4)	69(10.3)	
Mean time of labor, in hours	7.2(± 3.1)	4.5(± 2.9)	5.5(± 3.3)	<0.0001***

*Excluded cases with information ignored; **Pearson's Qui-square; ***Student test

ceipt, and 41.4% had some after. Oxytocin use was the most frequent; followed by artificial rupture of membranes. Most women were subjected to only one intervention (Table 2). When comparing women who received interventions before and after, artificial rupture of membranes was the most frequent, and there were also more interventions before analgesia ($p < 0.05$) (data not shown).

Among the total number of births ($n = 978$), 87.1% were vaginal ($n = 850$) and 12.9% were by cesarean section ($n = 128$). Among the vaginal births, the occurrence of the use of forceps or vacuum was 8.4% ($n = 71$), of which 64.8% ($n = 46$) occurred in women who had received analgesia (data not shown). The association between analgesia use and delivery outcomes showed that women who received analgesia were almost four times as likely to have a forceps or vacuum delivery, compared to those who did not receive analgesia ($p < 0.0001$) even after adjustments by age, number of

Table 2. Characteristics of the type and number of obstetric interventions used before and after analgesia

Interventions	Before	After
	n(%)	n(%)
No intervention	143(43.1)	191(58.6)
Artificial rupture of membranes	100(29.9)	22(6.8)
Oxytocin use	118(35.3)	120(36.8)
Use of synthetic prostaglandin	46(13.8)	-
Number of interventions		
1 intervention	121(36.5)	128(39.3)
2 interventions	61(18.4)	07(2.2)
3 interventions	07(2.11)	-

previous deliveries, presence of companion and/or doula, and cervical dilation at the time of analgesia. In high-risk pregnancies, the women who used analgesia had almost five times the chance of having a instrumental vaginal delivery ($p < 0.0001$), even after adjustments. Women whose pregnancies were normal risk were also more likely to have a delivery with instrumentation when they used analgesia. There was no relationship between the use of analgesia and cesarean section ($p = 0.320$) (Table 3).

The medical record that had the forceps or vacuum use reason registered ($n = 71$), 72.3% ($n = 34$) justified their use because of a non-reassuring fetal state, 19.2% ($n = 9$); due to a prolonged expulsive period, 6.4% ($n = 3$); lack of labor progress; and 2.1% ($n = 1$), maternal fatigue (data not shown).

Table 3. Multinomial regression model of the association between pharmacological analgesia and delivery outcomes of the women studied

Exposure of interest	Childbirth outcomes Instrumental vaginal delivery x Vaginal delivery			Childbirth outcomes Cesarean x Vaginal delivery		
	OR	95% CI	p-value	OR	95% CI	p-value
	All deliveries					
Use of unadjusted analgesia (n=978)	3.87	2.33-6.44	<0.0001	0.86	0.57-1.30	0.489
Use of adjusted analgesia* (n=931)	3.49	2.05-5.90	<0.0001	0.80	0.52-1.24	0.320
Normal risk pregnancy						
Use of unadjusted analgesia (n=671)	3.24	1.80-5.85	<0.0001	0.97	0.54-1.74	0.908
Use of adjusted analgesia* (n=642)	3.30	1.79-6.08	<0.0001	0.85	0.45-1.60	0.610
High risk pregnancies						
Use of unadjusted analgesia (n=292)	6.76	2.36-19.41	<0.0001	0.83	0.44-1.53	0.548
Use of adjusted analgesia*	4.62	1.53-13.96	0.007	0.76	0.40-1.46	0.415

*Adjusted for: woman's age, number of previous deliveries, presence of companion or doula, and cervical

Discussion

The study showed that the use of pharmacological analgesia during labor is positively associated with instrumental vaginal delivery, with the aid of forceps or vacuum extractor, and this relationship is even greater among those with high-risk pregnancies, regardless of the woman's age, number of previous deliveries, presence of companion or doula, or cervical dilatation at the time of analgesia. The women who received analgesia had a longer duration of labor. There was no relationship between the use of analgesia and cesarean section.

The findings corroborate those found in a previous systematic review, confirming that the use of analgesia was associated with the occurrence of instrumental vaginal delivery, but not with cesarean section.⁽³⁾ However, there are results that differ from those found by the present study, as a cohort involving 210,708 Australian women showed epidural analgesia associated with an increased risk of cesarean section (RR = 2.5, 95% CI: 2.5-2.6).⁽¹⁷⁾ The relationship between analgesia and cesarean section is still controversial and not fully established. It should be noted that the prevalence of cesarean section in the sample studied was relatively low compared to the national results,⁽¹⁸⁾ as a result of inclusion criteria and the institution's own care model that promotes vaginal delivery.

There is no consensus in the literature on a longer duration of labor observed among women who received analgesia compared to those who did not receive it, and this specific relationship has inconsistent results.^(3,19) A possible biological explanation for the association found is the effect of epidural analgesia on motor function, relaxing the pelvic floor musculature and causing motor blockade, which leads to a decrease in effective maternal pushing and involuntary reflex.^(5,19) This motor depression has been questioned as a minimum, depending on the concentration of medication used.^(19,20) Another explanation may be that most pregnant women are primiparous, whose labor is usually longer.⁽²¹⁾ This finding points to the need to expand studies to better evaluate this association, as well as to inform women about this possibility when using pharmacological analgesia.

The presence of a companion with almost all the women studied is positive, and indicates that the “Companion Law” is respected in the institution, which can contribute to reduced instrumental vaginal delivery, by offering women continuous support. The presence of a companion during labor has been related to the lower probability of instrumental vaginal delivery,⁽²²⁾ in addition to reducing the duration of labor, and increasing satisfaction with the experience. In the present study, this relationship was not observed, but the occurrence of instrumental vaginal delivery was relatively low.

Considering the possibility of several factors influencing the outcome of the study, it was noticed that this positive association between pharmacological analgesia and instrumental vaginal delivery was found both in high-risk and normal risk pregnancies, because high risk pregnancies may suggest additional reasons for the need for instrumentation. Thus, regardless of gestational risk, the association between the use of analgesia and the occurrence of instrumental vaginal delivery was observed, although women considered to be at risk had a greater chance of having instrumentation at birth.

The importance of this finding is due to the fact that instrumental vaginal delivery is an intervention that can be associated with maternal and neonatal morbidities,^(10,12,13) such as pelvic floor injuries and fecal and urinary incontinence in the mother,^(10,12) in addition to shoulder dystocia and facial nerve palsy in the neonate.^(10,13) It is important to highlight that these instruments are handled only by qualified professionals, as this reduces the chances of injury.^(10,13)

The use of non-pharmacological strategies for pain relief, such as a shower, immersion bath, massage, and the birthing ball, which are very common in the institution where this study was conducted, should be considered prior to the application of analgesia. However, the access to pharmacological analgesia is also a right and a demand of women, and should be within their reach when requested during labor, after the conclusion of non-pharmacological methods, as recommended by the

new National Guideline on Assistance in Normal Childbirth. Still, the use of pharmacological analgesia should follow clinical protocols based on up-to-date scientific evidence, especially with regard to dosages, since it has been shown that less concentrated doses do not cause motor blockade, allowing the parturient to continue to participate actively in the labor process.^(3,7,19)

Instrumental vaginal delivery can be considered a rare event (8.4%) in the institution studied, indicating that humanized practices contribute to better delivery outcomes, even though the use of analgesia may increase the chance of delivery with instrumentation. In addition, it is imperative that all women be informed of the risks and benefits of using pharmacological analgesia, including their recurrent use, so that they become more secure and are protagonists of their birth process and the decisions involved in it.^(5,19)

It should be noted that some practices that may possibly influence the incidence of instrumental vaginal delivery were not analyzed and consists in limitations of this study. These include maternal position during labor, information about which was absent in more than one-third of the charts, and analgesia dosages, which were not documented in the medical records. The lack of data and the inadequate completion of the birth registration charts made it impossible to use these variables.

Incomplete or missing records were an important obstacle to identifying the duration of each phase of labor, to evaluate its progression through the partogram, and hampered the analysis of medications dosages and solutions used. Another aspect to be observed in relation to the partogram, and which may constitute a possible limitation of our analysis, was the records in this instrument that, sometimes, can begin with an already advanced labor, causing an underestimation of the labor time. It should be emphasized that the results were adjusted by important confounding variables that, together with the possibility of comparing use with the non-use of pharmacological analgesia, reinforces the relevance of this study when evidencing the possible outcomes of labor.

Conclusion

The use of pharmacological analgesia modifies the outcome of childbirth, increasing the chances of instrumental vaginal delivery, and can increase the duration of labor, especially in women with high-risk pregnancies. It is believed that these results can contribute to the nursing care of pregnant women in antenatal and labor periods, not in the sense of discouraging the use of pharmacological methods for pain relief, as their use is a right and is often necessary and fundamental for women to be able to continue their labor. However, it is important in order to proactively discuss the meaning of pain in labor, and to advise them about potential risks and benefits of analgesia, so that the choice of its use is made by the parturient. Finally, it should be emphasized that the rational use of interventions is fundamental to avoid the iatrogenic delivery and the devaluation of effective, although less invasive care.

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Contributions

MSFM contributed to the project design, data analysis and interpretation, writing, and relevant critical review of the intellectual content, and final approval of the version to be published; LOS contributed to the project design, data analysis and interpretation, writing and final approval of the version to be published; TA contributed to the project design, relevant critical review of the intellectual content, and final approval of the version to be published; INC contributed to the project design, data analysis and interpretation, and writing; EFM contributed to the project design, data interpretation, relevant critical review of the intellectual content, and final approval of the version to be published.

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