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RESEARCH ARTICLE

Quest for Labor Analgesia in Second Stage in Resource Poor Setup

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Aim: To assess the analgesic effect of pudendal nerve block (PNB) as labor analgesia in the second stage of labor, its effect on the duration of the second stage and to assess any adverse maternal and fetal outcome.

Materials and methods: The prospective, randomized, case-control study (parallel group trial) was conducted with a total of 110 parturient women. They were randomly allocated to either study group (n = 55) or control group (n = 55). The study was performed after the approval of the institutional ethical committee. All the women recruited for the study were given first stage analgesia. The pain was assessed using the verbal rating scale. In the second stage of labor, the women in the study group were given transvaginal PNB (5 mL of 1% Lignocaine + 5 mL of 0.25% bupivacaine) bilaterally, whereas, in control group, no added analgesia was given.

Statistical analysis: Quantitative data were compared using the unpaired t-test and qualitative data was compared using chi square test. $p \leq 0.05$ has been taken as the level of statistical significance. The data were analyzed by Statistical Package for the Social Sciences (SPSS) statistical software version 17.0.

Results: It was observed that in the second stage of labor, Pudendal Nerve Block produced pain relief in 98.2% women, out of which 14.6% had excellent pain relief and 52.7% had moderate pain relief. This was found to be statistically significant ($p < 0.05$). The mean duration of the second stage of labor was longer in the study group (29.02 minutes) than in the control group (16.86 minutes) ($p < 0.05$). There was no significant adverse maternal and fetal outcome.

Conclusion: The PNB provides an effective analgesia in the second stage of labor without the major neonatal and maternal morbidity.

Clinical significance: The PNB can be provided by obstetricians in any delivery setup, even in low resource settings, without the need for skilled anesthetists.

Keywords: Analgesia, Case-control study, Pudendal nerve block (PNB), Randomized clinical trial, Second stage of labor

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INTRODUCTION

The vaginal birth is one of the most painful experiences in a woman's life. Pain relief by any means during this period is a boon for them. Providing effective and safe analgesia during labor has remained an ongoing challenge, especially in low resource settings.

Over the years, various methods have been used for pain relief during labor, i.e., non–pharmacological methods, pharmacological drugs, neuraxial methods and local anesthetic techniques.[1-3]

Neuraxial techniques have become the most popular method and considered the gold standard techniques for pain control in labor.[3] The biggest drawback is that these are completely dependent on skilled anesthesiologists and well-equipped setup. Globally, there is a large section of the population where these facilities are not available. So, there is a need for an analgesia method which is safe, effective and can be used by obstetricians themselves at any delivery setup. In those establishments where facility for epidural anesthesia is not available, parenteral analgesia has been used to provide pain relief during labor.

In the second stage of labor, the intensity of pain rises dramatically, even in women who have received analgesia in the first stage of labor. But there is no drug regime especially for this stage of labor.

It is known that the pudendal nerve transmits (PNT) the pain of the second stage of labor. PNB is commonly used for instrumental vaginal delivery. Blocking the PNT can achieve analgesia during the normal second stage of labor. A PNB is relatively simple, safe and effective method. It has not been extensively evaluated as a labor analgesic method. The advantage of this method is that it can be provided by obstetricians themselves without any delay and at even a small delivery setup.

AIM

The study was conducted to assess the analgesic effect of PNB as labor analgesia in the second stage of labor, its

effect on the duration of the second stage and to assess any adverse maternal and fetal outcome.

MATERIALS AND METHODS

This prospective, randomized, case-control study (parallel group trial) was conducted in the Department of Obstetrics and Gynecology, Vardhman Mahavir Medical College and Safdarjung Hospital in New Delhi over a period of one year from January 2013 to January 2014. All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional committee and with the Helsinki declaration of 1975 and its later amendments or comparable ethical standards. The study was performed in accordance with the protocol and registered at the Clinical Trial Registry–India (CTRI).

A total of 135 women were selected in the study from the labor room of the department as per the inclusion and exclusion criteria. Inclusion criteria were as follows: Women who were primigravida at term pregnancy, with vertex presentation, who were in an active phase of labor, and without any complications. Exclusion criteria were as follows: Women with cervical dilatation 6 cm on admission, multiple pregnancy, cephalopelvic disproportion, pregnancy-induced hypertension, moderate and severe anemia, heart disease, other medical and surgical illness, known allergy to any of the drugs to be used and who were not willing to participate in the study.

Out of 135 women, 19 women declined to participate, and six were excluded from the study before the second stage of labor because of development of meconium-stained liquor in three, fetal distress in two and non-progression of labor in 1. Thus, 110 women underwent randomization. It was done using a computer generated random number of tables with an allocation ratio of 1:1. So 55 women were allocated to the study group, and 55 women were in the control group (Flowchart 1). The Sample size was calculated using software G- power 3.1.

Informed written consent was obtained from all the women who participated in the study. Complete work-up was done as per the institutional protocol. Pain assessment was done by using verbal rating scale: 0–no pain, 1–mild pain, 2–moderate pain, 3–severe pain. Pain relief was assessed on the following scale: 0–no pain relief, 1–mild pain relief, 2–moderate pain relief, 3–excellent pain relief.[4,5]

All the women recruited in the study were given injection (inj) pentazocine 6 milligram (mg) intravenously (i.v.), inj diazepam 2 mg i.v., inj tramadol 1 mg/kg intramuscularly (i.m.) and inj drotaverine 40 mg i.m. in first stage of labor.[2] Close monitoring of labor was done as per labor room protocol. When each woman entered the second stage of labor (cervical os fully dilated or near 8 to 9 cm), pain score was noted. Each woman was then treated according to the group in which she was allocated:
Study group: Transvaginal bilateral PNB[6-8] was given, using 10 mL of drugs (i.e., 5 mL of 1% Lignocaine + 5 mL of 0.25% bupivacaine) on each side.
Control group: No added analgesia was given in the second stage.

Pain relief assessment was done in the second stage of labor in both the groups. The assessment was done every 15 minutes. Duration of the second stage of labor,

Flowchart 1: Randomization and follow-up of study subjects

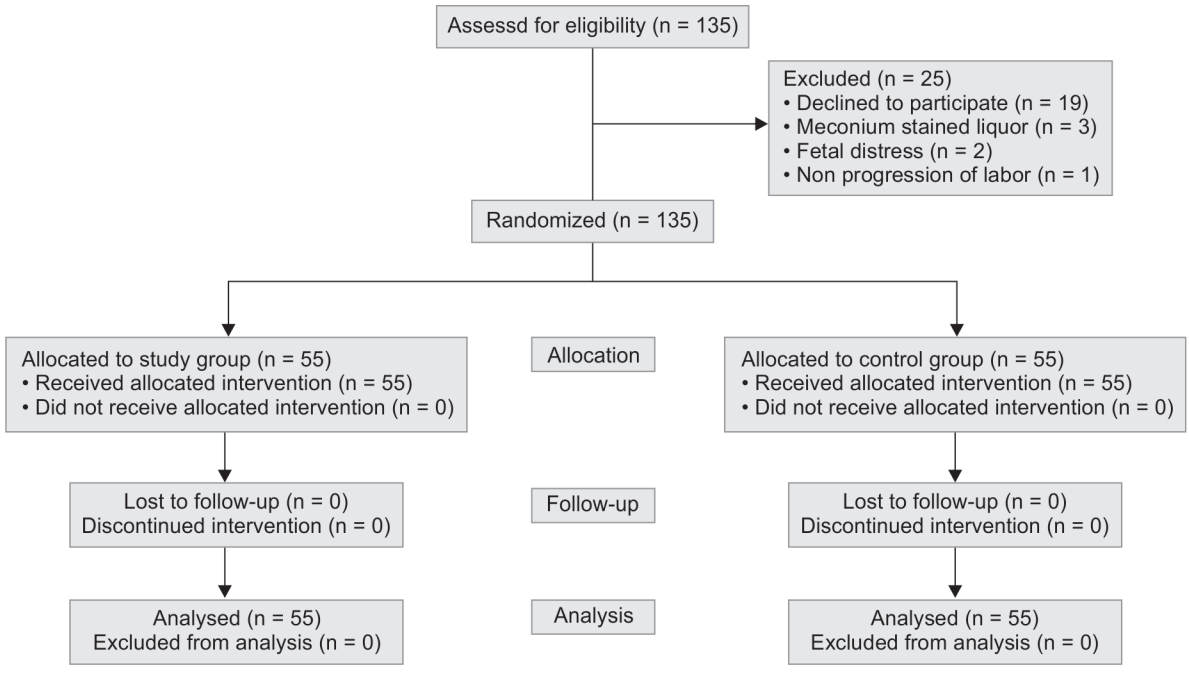

Table 1: Baseline characteristics

		Study group (n = 55)		*Control group (n = 55)*		*p value*
Age (years)		23.89	± 2.11	24.40	± 2.23	0.222
Parity	primigravida	48	87.27%	47	85.45%	0.781
	G_2A_1	7	12.73%	8	14.55%	
Cervical dilatation at recruitment (centimeters)	4cm	48	87.27%	45	81.82%	0.599
	5cm	7	12.73%	10	18.18%	

Data are expressed as mean SD, frequency (percentage), as appropriate.

Table 2: Pain relief score

Score	*Study group (n = 55)*		*Control group (n = 55)*	
3	8	14.6%	0	0
2	29	52.7%	0	0
1	17	30.9%	0	0
0	1	1.8%	55	100%

mode of delivery, any adverse effects on the mother and the fetus were evaluated and compared. Women were assessed again after 24 hours and after 7 days for any signs of vaginal hematoma, infection, and fever.

Statistical Analysis

Quantitative data were compared using the unpaired t-test and qualitative data was compared using chi-square/Fisher's exact test. A $p \leq 0.05$ has been taken as the level of statistical significance. The data were analyzed by Statistical Package for the Social Sciences (SPSS) statistical software version 17.0.

RESULTS

A total of 135 women were recruited over 1 year study period, out of which 110 women were randomized into the study group and control group and underwent final analysis.

Both the groups were statistically similar regarding baseline characteristics including age, parity and cervical dilatation at the time of recruitment (Table 1).

Women in both the groups had similar pain score at recruitment ($p = 0.841$). Duration of the first stage of labor was statistically similar in both groups ($p = 0.066$).

At the beginning of the second stage, pain score was assessed in all the 110 women, both the groups had similar pain score ($p = 0.823$), after which women in the study group were given PNB and women in the control group were not given any analgesia.

Table 2 represents pain relief in the second stage of labor which shows that in the study group, 98.2% women had pain relief, out of which 14.6% had excellent pain relief and 52.7% had moderate pain relief, while in control group, there was no pain relief. This difference was statistically significant ($p < 0.05$). So PNB was able to produce significant pain relief in the second stage of labor.

The effect of PNB the duration of the second stage of labor was assessed. It was observed that in the study group, 52.73% women had duration of the second stage between 16 minutes to 30 minutes and 9.09% had duration of second stage between 46 minutes to 1 hour whereas in control group, 69.09 % of the women were delivered within 15 minutes and none of the women had duration of more than 45 minutes. This observation was found to be statistically significant ($p < 0.05$). The PNB was responsible for prolongation of the second stage Table 3.

In the study group, 5.45% of the women were delivered using forceps and rest had normal vaginal delivery while in the control group all women had normal vaginal delivery (Table 4). This difference, however, was not statistically significant ($p = 0.243$).

There was no statistically significant difference in the apgar score and nursery admission between the two groups. There was no complication observed in women of study group immediately after giving the PNB, 24 hours and 1 week after delivery.

DISCUSSION

Obstetricians have extensively used PNB has been extensively used by obstetricians for instrumental deliveries and repair of episiotomy and lacerations. The PNB can be given by two approaches. Klink demonstrated the

Table 3: Duration of second stage

Duration of second stage (minutes)	*Study group (n = 55)*		*Control group (n = 55)*	
Up to 15	3	5.45%	38	69.09%
16–30	29	52.73%	11	20.00%
31–45	18	32.73%	6	10.91%
46–60	5	9.09%	0	0

Table 4: Mode of delivery

Mode	*Study group (n = 55)*		*Control group (n = 55)*	
Normal vaginal	52	94.55%	55	100%
Forceps	3	5.45%	0	0
Vacuum	0	0	0	0
Cesarean	0	0	0	0

transperineal approach in 1953 and Kohl described the transvaginal approach in 1954.[7,8] In both the approaches, the nerve is blocked proximal to its terminal branches. In this study, the transvaginal approach was used.

Till date, it has not become popular as labor analgesia because of development of neuraxial techniques as the gold standard method for management of labor pain. But in poor resource settings, it is necessary to provide analgesia to poor people. This can be provided by PNB as it does not require anesthetists and skilled training. This study was conducted to evaluate the efficacy of the pudendal nerve block as labor analgesia in the second stage of labor.

Both the groups were statistically similar at recruitment concerning age, parity, cervical dilatation, and pain score. Both the groups had similar pain score in the first stage, and also there was no statistical difference in the duration of the first stage. So both the groups were similar at the beginning of the second stage.

Regarding pain relief in the second stage of labor, it was observed that PNB produced statistically significant pain relief. Cochrane reviews reported that local anesthetic nerve blocks, including pudendal block, and paracervical block, were more effective than placebo, opioids, and non-opioids for pain management in labor.[9]

Most of the articles available in the literature discuss labor analgesia in whole labor and that too with epidural analgesia. Studies by Mousa et al. and Fan et al., where epidural analgesia was used for pain relief in labor, found decreasing trend in pain score throughout the labor including the second stage.[10,11] Similarly, Joel et al. used ketamine infusion to maintain pain relief throughout the labor till the delivery occurred.[12] In this study, second stage labor analgesia has been specifically studied because it is the stage of labor when women experience most severe pain and anesthetists are not available in resource-poor setups to provide epidural analgesia.

In the present study, the mean duration of the second stage was found to be longer in the study group (29.02 minutes) than in the control group (16.86 minutes), and it was statistically significant. Daftary et al. and Veronica et al. have used injection. Ketamine as second stage analgesia and their findings were similar to the present study.[2,13] This increased duration of the second stage can be due to effective pain relief which reduces the stretch reflex leading to lack of bearing down efforts.

In the present study, it was observed that 94.55% of the women had spontaneous vaginal delivery and 5.45% had instrumental delivery where as in the control group, there was no instrumental delivery. This difference was not statistically significant (p = 0.243). The studies, where the combination of parenteral opioids and antispasmodic was used as labor analgesia, the percentage of instrumental delivery was found to be higher than the present study.[2,3,14] Mousa et al. and Fan et al reported that 87.5% and 83.33% patients had normal vaginal delivery, 5%, and 10% had instrumental delivery and 7% and 6.67% had cesarean section respectively. They had used epidural anesthesia as labor analgesia.[15,11] Joel et al. observed 62.85% patients had normal vaginal delivery, 25.71% had a forceps delivery, and 11.43% had a cesarean section. The rate of operative vaginal delivery was found to be much higher as compared to the present study.[12]

There was no statistically significant difference in the Apgar score between the study group and the control group and all the newborns in both groups had satisfactory Apgar scores. Similar findings were observed by Daftary et al. and Kshirsagar et al.[2,14]

In this study, no maternal complications were observed immediately, 24 hours and 1 week after giving PNB. Kshirsagar et al. reported drug-related side effects like nausea, vomiting, and drowsiness that subsided after 12 hours, hypertonic contractions (5%).[14] Joel et al. reported side effects of ketamine such as nystagmus in 5.71% parturients and light-headedness in 48.5%.[12]

Although the limitation of this study is small sample size but the strength of this study is that second stage analgesia has been studied separately.

CONCLUSION

Pudendal nerve block (PNB) provides an effective analgesia in second stage of labor without any major neonatal and maternal morbidity. So, PNB can be recommended not only for operative vaginal deliveries and minor surgical procedures, but also for routine vaginal deliveries for pain relief in second stage of labor, although to implement it in current practice, a large sample sized study is required.

CLINICAL SIGNIFICANCE

The PNB can be provided by obstetricians themselves in any delivery setup, even in low resource settings, without the need of skilled anesthetists.

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