

Epidural Labor Analgesia during the First Stage of Labor: A Double-Blind Clinical Trial

Ali Hadi Muslih, M.B.Ch.B , FICMS

Department of surgery, College of Medicine, Al-Mustansiriya University, Baghdad, Iraq.

Date Submitted: 10.6.2010

Date Accepted: 16.12.2010

Address for Correspondence:

Dr. Ali Hadi Muslih, FICMS

Abstract

Background: although severe pain is not life-threatening in healthy parturient women, it can have neuropsychological consequences. Postnatal depression may be more common when analgesia is not used, and pain during labor has been correlated with the development of post-traumatic stress disorder. In addition, one study suggested that the impairment of cognitive function in the postpartum period can be mitigated by the use of any form of intrapartum analgesia.

Aims: to compare a combination of epidural fentanyl and bupivacaine with bupivacaine alone for epidural analgesia in labor and to evaluate factors in addition to analgesia that may influence maternal satisfaction.

Patients and methods: a double blind controlled clinical trial carried on 218 multiparous parturient. The patients were randomly allocated in 2 groups. Group 1 (n=109) had received bupivacaine 0.1% with fentanyl 50µg and group 2 (n=109) (control group) had received bupivacaine 0.1% only.

Results: in the bupivacaine group, 40 cases (37.7%) had required 2 top-ups and 26 cases (23.9%) had asked for 3 top-ups. On the other hand 14 (12.8%) cases from bupivacaine fentanyl group had asked for 2 top-ups and no cases had recorded request for 3 doses, which was statistically significant ($P < 0.0001$).

Conclusions: maternal satisfactory rate is high in both groups; the bupivacaine fentanyl group had shown a good response to the effect of analgesia with the minimal medical intervention.

Keywords: Epidural Labor Analgesia, Bupivacaine, Fentanyl

INTRODUCTION

For most women labor causes severe pain, similar in degree to that caused by complex regional pain syndromes or the amputation of a finger.^[1] The American College of Obstetricians and Gynecologists and the American Society of Anesthesiologists (ASA) state, "there is no other circumstance where it is considered acceptable for an individual to experience untreated severe pain, amenable to safe intervention, maternal request is a sufficient medical indication for pain relief during labor".^[2]

Although severe pain is not life-threatening in healthy parturient women, it can have neuropsychological consequences. Postnatal depression may be more common when analgesia is not used,^[3] and pain during labor has been correlated with the development of post-traumatic stress disorder.^[4] In addition, one study suggested that the impairment of cognitive function in the postpartum period can be mitigated by the use of any form of intra-partum analgesia.^[5] Men are also affected by severe labor pain. A survey of first-time fathers showed that the men whose partners received an epidural

felt three times as helpful and involved during labor and delivery and had less anxiety and stress, as compared with men whose partners did not receive an epidural.^[6] When used alone epidural opioids have been unable to provide adequate analgesia through labor,^[7-9] but the addition of the short acting, lipid soluble opioid fentanyl to bupivacaine has been more successful.^[10-13] It remains unclear, however, whether combinations of opioids and bupivacaine appreciably reduce the incidence of operative deliveries^[14, 15] and whether enhanced analgesia outweighs the inconvenience of using a controlled drug.^[14-16]

PATIENTS AND METHODS

218 multiparous parturient were randomly selected according to computerized randomization table into 2 equal groups, each group were consisted from 109 patients. Group 1 had received 0.1% bupivacaine with 50 µg fentanyl, as an initial dose and 10 ml of 0.1 bupivacaine with 25 µg fentanyl as a top-up dose. Group 2 (control group) had received 10 ml of 0.1 bupivacaine only and 10 ml of 0.1% bupivacaine as top-up dose.

The preparation of the drugs had been done blindly from the anesthesiology and the patient by the assistant anesthetist in the labor room. The data were interpreted and then anesthesiologists who are the participants in the study. Multiparous parturient with no obstetrical problems, with cervical dilatation around 3-4 cm, normal fetal heart sounds with cephalic, occipito-anterior presentation were included. All the cases who are refused to participate, primiparous parturient, cases with abnormal presentation and any sign of fetal abnormality or distress were excluded in order to avoid interference with the results. Any hypersensitivity to bupivacaine, lidocaine or fentanyl was excluded. Any contraindication to epidural analgesia was excluded. Any bad or abnormal obstetrical history was excluded.

The ethical means had been taken into consideration. A consent form had been signed by the patients. The consent form describes the process of interference and the aim of the study with the preparations that has been taken.

The whole study had been carried out in Red Crescent Hospital for Labor, and Maternity in Baghdad, Iraq.

The patients and the instruments were prepared in the labor ward. Local infiltration with 3 ml 1% lidocaine and a wheel rose at the L3-L4 intervertebral space. Touhy's G17 (Arrow epidural needle) needle had been used, and after the proper identification of the epidural space, G19

(Arrow epidural flex tip catheter) epidural catheter were introduced round 12-15 cm from the needle hub, the needle were removed and the catheter were secured in position with the application of bacterial filter at the end of the catheter with the injection port. 1000 ml of lactated ringer were used as fluid overload. 3 ml of 2% lidocaine with 1/100000 adrenaline were used as test dose.

5 minutes after the test dose, 10 ml of the analgesic solution which had been prepared already (10 of 0.1% bupivacaine+50 µg fentanyl or 10 ml of 0.1% bupivacaine only) in the side room were given to the patients. The vital signs as, blood pressure, pulse rate, SPO₂ and fetal heart rate were registered. The cervical dilatation was assessed by the midwife in 30 minutes interval. The pain were assessed by the anesthesiologist by using verbal analog scale (0=No pain, 1=Mild pain, 2=Moderate pain, 3=severe pain and the 4=West ever pain felt) in 15 minutes interval. When the patient's pain score were 2, the top-up dose added. The top-ups which had been already prepared (10 of 0.1% bupivacaine+25 µg fentanyl or 10 of 0.1% bupivacaine only). The time of the doses and the top-up doses were recorded. The time of the first stage of labor were recorded too.

When the patient reach the second stage of labor (cervical diameter=10 cm), the patient must be put in sitting position and 10 ml of 2% lidocaine given epidurally. The time of the second stage of labor were recorded. Type of labor was registered as normal vaginal delivery, ventouse assisted, lift-out Wrigley's forceps or cesarean section. Apgar score at 1 and 5 minutes were stated.

The statistical data were summarized in frequencies, mean $\pm$ SD) and analyzed by Mann-Whitney U test for the non-parametric data and student's t test for parametric data, the $P < 0.05$ were considered significant.

RESULTS

The demographic data and patient's distribution are well summarized in table 1. The results of age (year), weight (kg), height (cm), age of gestation (weeks), and time of labor (min) are presented in mean $\pm$ SD, while the type of labor is presented in frequency and percentage. There are no differences that could carry any form of statistical significance between groups regarding the demographic data, time and type of labor.

Regarding the doses that the patients had received during the first stage of labor, those 92 patients (87.2%) had received only 1 top-up, 14 patients (12.8%) had received 2 top-ups and no cases had received 3 doses or more.

On the other hand 40 patients (36.7%) had received 1 top-up, 40 cases (36.7%) had received 2 top-up and 26 patients (23.9%) had received 3 top-up. This difference was carrying a statistical significance with $p=0.0001$. The doses are shown in table 2. Three cases from each group had received no top-ups at all (2.8%) from each group.

The results of the Apgar score in 1 minute had shown no statistical significance, while the Apgar score in 5 minutes had recorded a noticeable statistical significance of $P=0.028$ as shown in table 3.

Table 1. Patient's demographic data.

	Control group (N=109)	Bupivacaine + fentanyl (N=109)
Age in years	25.27±5.069	24.45±5.303
Weight in Kg	68.26±6.961	69±7.092
Height in cm	161.98±6.773	161.41±5.626
Age of gestation	39.05±0.907	39.06±0.97
Time of labor		
• 1 st stage	182.29±88.088	165.83±70.427
• 2 nd stage	41.79±11.971	41.51±14.264
• Total	224.45±87.774	206.24±71.382
Type of labor		
• NDV	97 (89%)	100 (91.7%)
• Ventouse	1 (0.9%)	1 (0.9%)
• Forceps	3 (2.8%)	3 (2.8%)
• Cesarean section	8 (7.3%)	5 (4.6%)

Table 2. The number of top-ups in each group.

Number of doses	Bupivacaine group			Bupivacaine + fentanyl group		
	Frequency	%	Cum. %	Frequency	%	Cum. %
0 top-up	3	2.8	2.8	3	2.8	2.8
1 top-up	40	36.7	39.4	92	84.4	87.2
2 top-ups	40	36.7	76.1	14	12.8	100
3 top-ups	26	23.9	100	0	Nil	Nil

Table 3. Statistical analysis of the Apgar score in 1 and 5 minutes.

	Apgar score in 1 min	Apgar score in 5 min
Mann-Whitney U	5651.5	5123
Wilcoxon W	11537.5	11118
Z	-0.527	-2.197
Asymp. Sig. (2-tailed)	0.599	0.028

DISCUSSION

The excessive repeated top-ups of the local analgesic agents are blamed for increase instrumentation during vaginal delivery.^[17] The addition of opiates is effective in reducing the top-ups, which well improved in this study. The low concentration of bupivacaine (0.06-0.1%) is often associated with escaping of the L1 ventral trunk from blockade,^[19] which requires the addition of local

analgesic solution. The addition of opiate as an adjunct to low concentration bupivacaine had reduced the request for further analgesic solution. In this study 84.4% of the cases had been satisfied with the analgesia during the process of labor with only 1 top-up in the bupivacaine fentanyl group. On the other hand 60.6% of the cases from the control group had asked for 2-3 top-ups.

The reduction in the total top-ups had not recorded any change or decrease in the total number of surgical interferences. To prove this effect, a larger sample may be required.

In this study we had used a small dose of fentanyl in the top-ups in comparison to other studies.^[16] For that reason no case had recorded suffering from nausea, vomiting or itching, which is well noticed in with the administration of the opiates epidurally or intrathecally. As low chance for side effects with low doses of fentanyl had been recorded.^[20]

During data collection and analysis, a side way result had been found. The Apgar score in 5 minutes had shown a higher cumulative score in the bupivacaine fentanyl group than the control group. This outcome must be studied separately in another study in the soon coming further to improve if this result was related to the medications or any other reason that we may face.

Conclusion:

The addition of fentanyl to bupivacaine in managing the labor pain during the first stage of labor will reduce the total amounts of the top-ups of analgesic solutions that are required to reach a good maternal satisfaction with no unwanted effects on both the mother and the neonate. No difference in instrumentation interferences had been noticed.

REFERENCES

1. Melzack R. The myth of painless childbirth. *Pain* 1984;19:321-37.
2. ACOG Committee Opinion #295: pain relief during labor. *Obstet Gynecol* 2004;104:213.
3. Hiltunen P, Raudaskoski T, Ebeling H, Moilanen I. Does pain relief during delivery decrease the risk of postnatal depression?. *Acta Obstet Gynecol Scand* 2004;83:257-61.
4. Soet JE, Brack GA, Dilorio C. Prevalence and predictors of women's experience of psychological trauma during childbirth. *Birth* 2003;30:36-46.
5. Eidelman AI, Hoffmann NW, Kaitz M. Cognitive deficits in women after childbirth. *Obstet Gynecol* 1993;81:764-7.
6. Capogna G, Camorcia M, Stirparo S. Expectant fathers' experience during labor with or without epidural analgesia. *Int J Obstet Anesth* 2007;16:110-5.
7. Crawford JS. Experiences with epidural morphine in obstetrics. *Anesthesia* 1981;36:207-9.
8. Husemeyer RP, O'Connor MC, Davenport HT. Failure of epidural morphine to relieve pain in labour. *Anaesthesia* 1980;35:161-3.
9. Carrie LE, O'Sullivan GM, Seegobin R. Epidural fentanyl in labour. *Anaesthesia* 1981;36:965-9.
10. Justins DM, Francis D, Houlton PG, Reynolds F. A controlled trial of extradural fentanyl in labour. *Br J Anaesth* 1982;54:409-14.
11. Vella LM, Willatts DG, Knott C, Lintin DJ, Justins DM, Reynolds F. Epidural fentanyl in labour. An evaluation of the systemic contribution to analgesia. *Anaesthesia* 1985;40:741-7.
12. Jones G, Paul DL, Elton RA, McClure JH. Comparison of bupivacaine and bupivacaine with fentanyl in continuous extradural analgesia during labour. *Br J Anaesth* 1989;63:254-9.
13. Chestnut DH, Owen CL, Bates JN, Ostman LG, Choi WW, Geiger MW. Continuous infusion epidural analgesia during labor: a randomized, double-blind comparison of 0.0625% bupivacaine/0.0002% fentanyl versus 0.125% bupivacaine. *Anesthesiology* 1988;68:754-9.
14. Reynolds F. Extradural opioids in labour. *Br J Anaesth* 1989;63:251-3.
15. Herman NL, Hussain FL, Knape KG, Downing JW. Extradural opioids in labour. *Br J Anaesth* 1990;64:528-9.
16. Lilker S, Rofaeel A, Balki M, Carvalho JC. Comparison of fentanyl and sufentanil as adjuncts to bupivacaine for labor epidural analgesia. *J Clin Anesth* 2009;21:108-12.
17. Zimmer EZ, Jakobi P, Itskovitz-Eldor J, Weizman B, Solt I, Glik A, et al. Adverse effects of epidural analgesia in labor. *Eur J Obstet Gynecol Reprod Biol* 2000;89:153-7.
18. Yancey MK, Pierce B, Schweitzer D, Daniels D. Observations on labor epidural analgesia and operative delivery rates. *Am J Obstet Gynecol* 1999;180:353-9.
19. Pawar D. Regional anaesthesia in paediatric patients. *Indian J Anaesth* 2004;48:394-9.
20. Murphy JD, Henderson K, Bowden MI, Lewis M, Cooper GM. Bupivacaine versus bupivacaine plus fentanyl for epidural analgesia: effect on maternal satisfaction. *BMJ* 1991;302:564-7.