Postoperative analgesia after cesarean section by continued administration of levobupivacaine with the On-Q Painbuster system over the fascia vs ketorolac + morphine IV

E. Magnani, R. Corosu[1], P. Mancino[1], M.L. Borgia[2]

[1]Department of Gynecology, [2]Department of Anesthesiology and Intensive Care
University of Rome "La Sapienza", Rome (Italy)

Summary

Objective: This study aimed to detect if continuous local infusion of levobupivacaine with the On-Q Painbuster system provided postoperative analgesia of similar quality to morphine + ketorolac IV in patients undergoing cesarean section.

Materials and Methods: Using a randomized prospective double-blind study, 20 women undergoing cesarean section with a standardized spinal technique were randomly assigned into two groups to receive either 10 mg morphine + 120 mg ketorolac + saline solution up to 96 ml with an elastomeric pump IV (group A) or local infusion of levobupivacaine 0.2% with the On-Q PAINBUSTER system (group B). Both groups were administered ketorolac IV in bolus in case of pain.

Results: The two groups differed in their VAS scores with group A experiencing significantly less pain than group B; the consumption of analgesics was significantly lower in group A than in group B.

Conclusions: The IV system with morphine and ketorolac is more effective than levobupivacaine subcutaneous infusion in reducing postoperative pain associated with cesarean section.

Key words: Postoperative analgesia; Cesarean section; On-Q PainBuster system; Levobupivacaine.

Introduction

This study attempted to evaluate the effectiveness and safety of the On-Q Painbuster system (I-FLOW Corporation, Lake Forest, CA) [1], which provides continuous subcutaneous infusion of levobupivacaine (0.2%) into the surgical wound. After cesarean section the analgesia induced by this device was compared with a standardized protocol, of IV administration of analgesic drugs. The literature data state that the On-Q Painbuster system reduces the total dose of analgesic drugs, collateral effects and gives women better recovery and normal physical activities sooner.

Materials and Methods

Twenty patients, scheduled for elective cesarean section, were included in this double-blind, randomized study. Approval was given by the Institutional Ethics Committee and written informed consent was obtained from all patients. Exclusion criteria were preterm gestation (< 36 weeks), intrauterine fetal death, multiple pregnancy, known or suspected fetal abnormalities, breech presentation and maternal ASA class III and IV, relative and absolute contraindications to regional anesthesia [2]. Maternal age, height, weight, gestational age, type of labor, status of the membranes, use of oxytocin and medical history were recorded. Maternal blood pressure and heart rate during the last antenatal visit and just prior to analgesia were recorded. Following IV hydration with 1,000 ml of lactated Ringer's solution, regional anesthesia was performed at the L3-L4 interspace with the patient in the sitting position. Regional anesthesia was performed using 10 mg of subaracnoidal isobaric levobupivacaine 0.5% + sufentanyl 2.5 mcg + morphine 50 mcg (Table 1). The patients were placed in the supine position with a left lateral tilt and a pillow under the thigh. Arterial pressure and heart rate were monitored using a non-invasive monitor every 3 min until delivery and then every 5 min during the rest of the procedure. Patients were randomized to one of two study groups. Ten patients (group A) received 10 mg morphine + 120 mg of ketorolac + normal saline up to 96 ml with an elastomeric pump at an infusion speed of 2 ml/hr lasting 48 hours [3-5]. Ten patients (group B) received local infusion of 0.2% levobupivacaine with the On-Q PAINBUSTER system (local tissue infiltration with levobupivacaine is more effective than ropivacaine in reducing postoperative pain) [6] in a subcutaneous site, at an infusion speed of 2 ml/hr for 48 hours.

The On-Q PainBuster system used in this study, is an elastomeric pump connected to a 20 g catheter in drawn PVC, 12.5 cm long with a multiholed wall, placed in the subcutaneous layer of the surgical wound by the gynecologic surgeon. Both groups, were administered 30 mg ketorolac IV in bolus in case of pain.

Postoperative pain was assessed by the patients using a visual analogue scale (VAS, 0 cm = no pain, 10 cm = worst pain imaginable) and was rated at 6, 12, 24 and 48 hours by a visual analogue scale (VAS) score. Side-effects, temperature and external look of the wound after 24 hours, value of the WBC count, possible collateral effects, degree of satisfaction of the patients, motor block (Bromage score) and sensory block (Holmen score) and the time of first mobilization were also recorded. Data were analyzed with the Student's t-test with $p < 0.05$ considered significant.

Revised manuscript accepted for publication June 29, 2006

Table 1. — *Anesthesia used in both groups.*

	Group A	Group B
No. of patients	10	10
ASA	I – II	I – II
Anesthesia	Subaracnoidal	Subaracnoidal
Prehydratation	1000 ml Ringer's lactate	1000 ml Ringer's lactate
Local intrathecal anesthesia	Isobaric levobupivacaine (0.50% 10 mg)	Isobaric levobupivacaine (0.50% 10 mg)
OPIOIDS	Sufentanyl 2.5 mcg	Sufentanyl 2.5 mcg
Model pain reliever	Elastomeric pump IV 2 ml/h lasting 48 hours containing: 18 mg morphine + 120 mg ketorolac + normal saline up to 96 ml; 30 mg ketorolac IV, in case of postoperative pain	On-Q PainBuster 2 ml/h containing levobupivacaine 0.2% lasting 48 h in the subcutaneous site; 30 mg ketorolac IV in case of postoperative pain

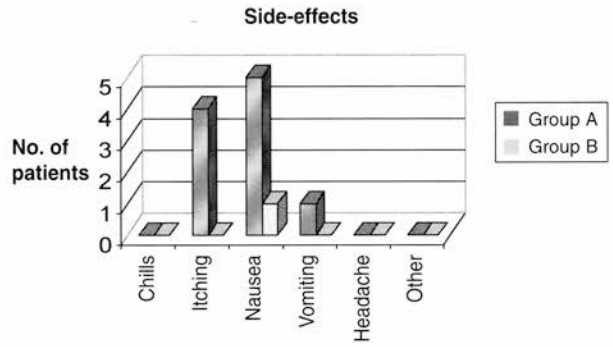

Figure 1. — Side-effects experienced by patients.

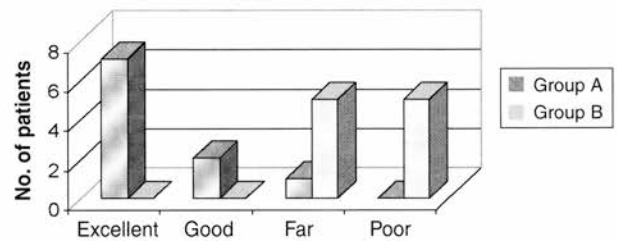

Figure 2. — Patient satisfaction with treatment.

Results

There were no differences in demographic and obstetric data. Adequate levels of sensory analgesia, evaluated with the Hollmen score, and motor block, evaluated with the Bromage score (Bromage level 2, was reached in 5 min in 100% of the patients in group A and 90% of the patients in group B). Anesthesia and motor block, allowing surgical procedures, was reached and remained optimal in both groups. The time to first analgesic request was significantly different in the two groups: 455 ± 22 min (group A) and 380 ± 30 min (group B). In particular in group A only one case (10%), eight hours after delivery, required administeration of IV NSAIDs. In all other cases in group A there was no lowering of analgesia level.

In group B five cases (50%) needed NSAIDs to be administered (30 mg ketorolac); twice during the first day after surgery (6-12 hours) and once during the second day (24 hours). The other members of group B did not need further analgesia, nevertheless they referred a light but constant sensation of "deaf pain" for about 30 hours. No signs or symptoms of local or general infection in either group were noted as well as no substantial differences at the time of the first mobilization. In group B removal of the catether and the next medication after 48 hours, turned out troublesome even if, as already said, we did not register cases of inflammatory infiltration of the wound. In group A five patients complained about nausea and vomiting, resolved with 4 mg of ondansetron IV (Figure 1). The possible local anesthetic passage in the maternal milk has been proven in a few studies [7], but this passage in the maternal milk after epidural anesthesia induced with bupivacaine and lidocaine was shown to have higher doses than those used by us. Nevertheless no deficit for any newborn was noted and most of the babies, instead, had high Apgar scores, good values on NACS adaptation tests, and no side-effects.

Conclusions

Acute postoperative pain after cesarean section, which is characterized by either visceral or somatic components, is very intensively treated. However it is still uncertain which pain method can be considered the most effective. The main concern seems to be recovery time as a predictive index of when the mother will be able to take care of her baby and eventually breastfeed. This latter issue is mostly affected by the use of drugs that may pass into the mother's milk, thus contraindicating breastfeeding. Traditionally IV administration of NSAIDS with or without opioids, intrathecal/epidural infusion of analgesic drugs, or PCA (patient controlled analgesia) seem to be widespread standards. As an alternative the On-Q PainBuster system could be considered as the subcutaneous site is used as an administration route of local anesthetics. Many authors have shown the effectiveness of such device. Particularly a double-blind study has shown how this device is able to reduce overall morphine requirements after cesarean section [1]. However other authors have proven analgesia to be absent and concluded that opioids do not need to be lowered by local infusion of anesthetic drugs. Mainly analgesic effects on visceral pain seemed to be unpredictable [7], not to mention the fact that many authors state that the device placement itself can be a source of pain. Nevertheless there are those who think it is an effective way to control somatic pain and reduce and modulate visceral pain. Givens *et al.* reported that the use of subcutaneous local anesthesia after cesarean delivery would not be expected to have any effect on uterine pain. However it is uncertain what proportion of pain after cesarean delivery is produced by superficial structures and what proportion is produced by deeper visceral structures. Furthermore, according to some neural pain pathway theories, the stimulation of

superficial pain receptors may further sensitize nervous system sensation. Thus, reduction of some of the pain after cesarean delivery could modulate the perception of deeper visceral pain [1]. In particular the On-Q Pain-Buster system, used in the patients in group B, had a good analgesic effect on somatic pain but did not give appropriate analgesia for visceral pain. Perhaps the option of increasing levobupivacaine concentrations up to 0.5% could improve the analgesic effect. Our study, evaluating both techniques (IV vs subcutaneous) showed significant differences in pain scores and consumption of supplementary analgesics between local application and IV administration. Our results clearly demonstrate that 10 mg of morphine associated with 60 mg ketorolac remains an adequate choice for cesarean section postoperative analgesia (Figure 2). Another important element to consider is the cost. In fact the IV elastomeric pump costs about 20 euro, whereas the On-Q PainBuster system costs about 250 euro.

References

[1] Givens V.A., Lipscomb G.H., Meyer N.L.: "A randomized trial of postoperative wound irrigation with local anesthetic for pain after cesarean delivery". *Am. J. Obstet. Gynecol.*, 2002, *186,* 1188.

[2] Paech M.J., Pavy T.J., Orlikowski C.E., Yeo S.T., Banks S.L., Evans S.F., Henderson J.: "Post cesarean analgesia with spinal morphine, clonidine, or their combination". *Anesth. Analg.*, 2004 *98,* 1460.

[3] Covino B.G.: "Pharmacology of local anesthetic agents". *Br. J. Anaesth.*, 1986, *58,* 701.

[4] Ruetsch Y.A., Boni T., Borgeat A.: "From cocaine to ropivacaine: the history of local anesthetic drugs". *Curr. Top. Med. Chem.*, 2001, *1,* 175.

[5] Covino B.G., Vassallo H.G.: "Local Anesthetics: Mechanism of Action and Clinical Use". New York, Grune & Stratton, 1976.

[6] Papagiannopoulou P., Argiriadou H., Georgiou M., Papaziogas B., Sfyra E., Kanakoudis F.: "Preincisional local infiltration of levobupivacaine vs ropivacaine for pain control after laparoscopic cholecystectomy". *Surg. Endosc.*, 2003, *17,* 1961.

[7] Pedersen H., Morishima H.O., Finster M.: "Uptake and effects of local anesthetics in mother and fetus". *Int. Anesthesiol. Clin.*, 1978, *16,* 73.

[8] Fredman B., Shapiro A. Zohar E., Feldman E., Shorer S., Rawal N., Jedeikin R.: "The analgesic efficacy of patient-controlled ropivacaine instillation after cesarean delivery". *Anesth. Analg.*, 2000, *91,* 1436.

[9] Dahl J., Moiniche S., Kehlet H.: "Wound infiltration with local anesthetics for post operative pain" (Review). *Acta Anaesthesiol. Scand.*, 1994, *38,* 7.

[10] Zohar E., Luban I., Zunser I., Shapiro A., Jedeikin R.: "Patient-controlled bupivacaine wound instiilation following cesarean section: the lack of efficacy of adjuvant ketamine". *J. Clin. Anesth.*, 2002, *14,* 505.

[11] Rawal N., Axelsson K., Hylander J., Allvin R., Amilon A., Lidegran G., Hallen J.: "Post operative patient controlled local anesthetic administration at home". *Anaesth. Analg.*, 1998, *86,* 86.

[12] Jakobi P., Solt I., Tamir A., Zimmer E.Z.: "Over – the – counter oral analgesia for postcesarean pain". *Am. J. Obstet. Gynecol.*, 2002, *187,* 1066.

[13] Wong P., Chadwick F.D., Karovits J.: "Intranasal fentanyl for postoperative analgesia after elective caesarean section". *Anaesthesia,* 2003, *58,* 818.

[14] Tverskoy M., Cozacov C., Ayache M., Bradley E.L, Kissin I.: "Postoperative pain after inguinal herniorrhaphy with different types of anaesthesia". *Anesth. Analg.*, 1990, *70,* 29.

[15] Ganta R., Samra S.H., Maddineni V.R., Furnes G.: "Comparison of the effectiveness of bilateral ilioinguinal nerve block and wound infiltration for postoperative analgesia after cesarean section". *Br. J. Anaesth.*, 1994, *72,* 229.

[16] Bays R.A., Barry L., Vasilenko P.: "The use of bupivacaine in elective inguinal herniorrhaphy as a fast and safe technique for relief of postoperative pain". *Surg. Gynecol. Obstet.*, 1991, *173,* 433.

[17] Kato J., Ogawa S., Nagai H., Kashiwazaki M., Saeki H., Suzuki H.: "Effects of presurgical local infiltration of bupivacaine in the surgical field on postsurgical wound pain in laparoscopic gynecologic examinations: a possible preemptive analgesic effect". *Clin. J. Pain,* 2000, *16,* 12.

Address reprint requests to:
E. MAGNANI, M.D.
Via Imperia, 12
00161 Rome (Italy)