J Anesth (2004) 18:262–266
DOI 10.1007/s00540-004-0265-1

Journal of
Anesthesia

Comparison between a disposable and an electronic PCA device for labor epidural analgesia

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Abstract
Purpose. The aims of the present study were (1) to investigate if a disposable patient-controlled analgesia (PCA) device can be used for labor analgesia and (2) to evaluate the device by midwives and parturients.
Methods. Forty healthy parturients were divided into two groups and received combined spinal epidural analgesia for labor pain relief. Following intrathecal administration of 3 mg ropivacaine and 1.5 μg sufentanil, either a disposable PCA device (Coopdech Syrinjector; Daiken Medical, Osaka, Japan) or an electronic PCA device (IVAC PCAM PCA Syringe Pump; Alaris, Basingstoke, UK) was connected to the epidural catheter, and 0.15% ropivacaine with sufentanil 0.75 μg/ml was used for continuous infusion and PCA. For an electronic PCA device, continuous infusion rate, bolus dose, lockout time, and hourly limit were set at 4 ml/h, 3 ml, 15 min, and 16 ml, respectively. For a disposable PCA device, continuous infusion rate, bolus dose, and an hourly limit were set at 4 ml/h, 3 ml, and 16 ml, respectively, but lockout function was not available.
Results. No differences were observed between the groups concerning demographic data, obstetric data, and outcome of labor. Anesthetic requirements (disposable, 9.7 ± 4.7 ml/h; electronic, 8.2 ± 4.0 ml/h) and VAS score during the delivery (disposable, 26 ± 25; electronic, 21 ± 22) were similar between the groups. Midwives praised the disposable PCA device as well as the electronic one.
Conclusion. The present results imply that the disposable PCA device can be an alternative to the electronic PCA device for labor analgesia.

Key words PCA · Labor analgesia · Disposable PCA device

Introduction

The benefits and advantages of patient-controlled analgesia (PCA) for labor pain relief have been widely recognized [1–3], and electronic PCA devices have been used for this purpose. However, some disadvantages seem to exist in using an electronic PCA device for labor analgesia [4]. Most electronic PCA devices are heavy and large, making parturient relaxation and ambulation difficult. Furthermore, complicated manipulations and irritating alarms bother both midwives and parturients.

A disposable PCA device may settle these disadvantages and may become an alternative to an electronic one. To our knowledge, however, a disposable PCA device covering the regimen for labor analgesia has not been developed, although some disposable PCA devices have been available for postoperative pain treatment [5]. For the present study, we customized a disposable PCA device developed for postoperative pain treatment to fit the regimen of labor analgesia requiring a larger hourly dose. The customized disposable PCA device was used for labor analgesia to be compared with an electronic PCA device. The aims of the present study were (1) to investigate if a disposable PCA device can be an alternative to an electronic one for labor analgesia and (2) to evaluate the acceptability of the devices by midwives and parturients.

Materials and methods

The study was carried out at Katholieke Universiteit Leuven and University Hospitals (Leuven, Belgium) after institutional ethical approval. After written informed consent, 47 parturients requesting labor analgesia were recruited to this randomized, prospective, controlled study. Study inclusion criteria were ASA physical status I or II, term gestation, singleton pregnancy in the vertex presentation, and cervical dilation less than 5 cm at the last examination.

Parturients were randomized using a computer-derived random number sequence to use a disposable

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Received: February 23, 2004 / Accepted: July 22, 2004

PCA device or an electronic PCA device. Parturients who delivered within 60 min from initiation of labor analgesia were excluded from data analysis because these parturients might be unable to evaluate the PCA device due to the limited duration of use. Parturients who delivered by cesarean section were also excluded from data analysis to minimize bias due to delayed delivery. As a result, 47 parturients were enrolled into the study, and 40 (20 in each group) were analyzed.

All parturients received combined spinal epidural (CSE) for labor analgesia. Following 1000 ml i.v. lactated Ringer's solution, the epidural space was identified with an 18-gauge Tuohy needle at the L2–L3 or L3–L4 vertebral interspace, with the patient in the sitting position. The dura was punctured with a 27-gauge spinal needle; 3 mg ropivacaine and 1.5 μg sufentanil was then administered intrathecally. An epidural catheter was inserted 3–5 cm into the epidural space and the epidural catheter was connected to the PCA device. For epidural administration, 0.15% ropivacaine with sufentanil 0.75 μg/ml was used for continuous epidural infusion (CEI) and PCA. For each PCA device, CEI was set at 4 ml/h and an hourly limit was set at 16 ml. Additional epidural doses were administered at the discretion of the attending anesthesiologist if required.

For an electronic device, an IVAC PCAM PCA Syringe Pump (Alaris, Basingstoke, UK), which had been in use for more than 7 years at the hospital, was used. CEI, lockout time, and bolus dose were set at 4 ml/h, 15 min, and 3 ml, respectively; hence, the hourly limit was 16 ml.

The disposable PCA device (Coopdech Syrinjector; Daiken Medical, Osaka, Japan) was originally developed for postoperative pain treatment and has been widely used in Japan for this purpose. A set of disposable PCA device consists of two plastic syringe infusers and one plastic PCA plunger (Fig. 1). The plastic syringe infuser generates a constant flow of anesthetics by using atmospheric pressure as its driving force and resistance of a microtube to regulate the flow rate. One plastic syringe infuser is intended to be connected directly to an epidural catheter for continuous infusion and another indirectly via a PCA plunger for the demand dose. The PCA plunger consists of a PCA button, PCA reservoir, and inlet and outlet valves. As both valves are one way and the outlet valve can be opened only by pushing the PCA button, the syringe infuser stops a supply to the PCA reservoir when filled. A demand dose can be determined by the capacity of the PCA reservoir, but the patient can push the PCA button to administer a smaller dose before the PCA reservoir is filled up. An hourly limit can be determined by the flow regulator connected to the PCA plunger, but the device does not have lockout function.

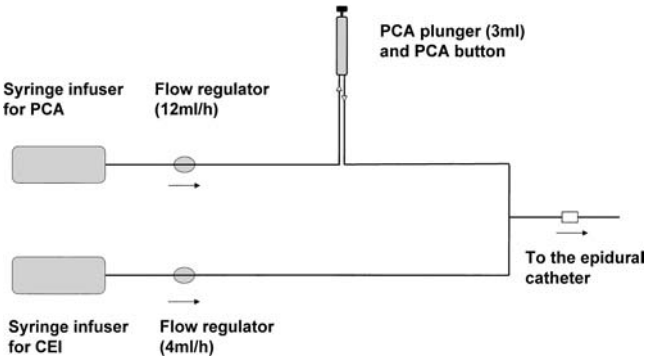

Fig. 1. Schema of a disposable patient-controlled analgesia (PCA) device set. A disposable PCA device set consists of two plastic syringe infusers and one plastic plunger. Flow regulators for *CEI* (continuous epidural infusion) and *PCA* (patient-controlled analgesia) are 4 ml/h and 12 ml/h, respectively; hence, the hourly limit is 16 ml. The PCA plunger has inlet and outlet valves. Both valves are one way, and the outlet valve does not open unless the PCA dose is requested. As the capacity of the PCA reservoir is 3 ml, the maximum bolus dose is 3 ml, but it is possible to administer a smaller dose before the PCA reservoir is filled up

Wide line-ups of the products have been provided for postoperative pain treatment by combining various rates of flow regulator and various capacities of PCA reservoir. However, there has not been a suitable type for labor analgesia, which requires a larger hourly dose in comparison with postoperative pain treatment. Hence, a special version for labor analgesia was customized by combining a flow regulator of 4 ml/h for CEI and a flow regulator of 12 ml/h for PCA. As the capacity of the PCA reservoir was 3 ml, the maximum bolus dose was 3 ml, but it was possible to administer a smaller dose. Both syringe infusers had a capacity of 120 ml, and total weight of a set of disposable PCA device was about 500 g when the infusers were full.

Data recorded included demographics, mode of delivery (spontaneous, vacuum extraction, or forceps), the duration from initiation of PCA to delivery, and Apgar scores at 1 and 5 min. Analgesic consumption was recorded every hour, and additional interventions by anesthesiologists (dose and time) were recorded. Parturients were asked to rate the pain score using a VAS (0 = no pain to 100 = worst pain imaginable) and the satisfaction score (0 = not satisfied at all, 100 = fully satisfied) every hour. The upper level of sensory block was assessed hourly as loss of sensation to cold stimulus, and the degree of motor block was measured hourly by modified Bromage score (1–6) as used by Breen et al. [6]. All episodes of nausea and pruritus were also recorded.

The day after the delivery, parturients were asked to rate their satisfaction score for labor analgesia (0 = not satisfied at all, 100 = fully satisfied), and if they would

like to receive labor analgesia at a next pregnancy. Furthermore, they were asked to rate their satisfaction score for the PCA device, and if they would like to use the same device at a next pregnancy. The evaluation of the device by midwives was performed by sending questionnaires to all midwives involved in the cases after the study period. The number of times they worked with the PCA device, and evaluation (Poor, Fair, Good, and Excellent) and preference of the device were questioned.

Statistical analyses

Data are presented as the mean ± SD or median (range). Statistical analysis was performed using the Student *t* test, Wilcoxon–Mann–Whitney test, or the χ^2 test, as appropriate. $P < 0.05$ was considered to be significant.

Results

In total, 47 parturients were enrolled into the study, but 7 cases were excluded from analysis because 5 of them completed delivery within 60 min after labor analgesia was initiated and 2 delivered by cesarean section.

Demographic data were similar between the groups (Table 1). Anesthetic requirement was similar and the percent of parturient requiring additional interventions were similar between the groups (Table 2). There were no significant differences between the groups in terms of pain score and satisfaction score during patient-controlled epidural analgesia (PCEA) (Table 3). The level of sensory block, the degree of motor block, and the incidence of nausea and pruritus were similar between the groups (Table 3).

The evaluation by parturients did not show any significant difference between the groups (Table 4). Overall satisfaction with labor analgesia was quite high in both groups, and all the parturients answered that they would request labor analgesia at their next pregnancy. Satisfaction with the PCA device was also high in both groups; however, two parturients refused to use the same device for the next delivery in both groups.

In total, 13 midwives were involved in the study. Although their evaluation (Table 5) and preference did not show any significant difference between the groups, 8 midwives preferred the disposable device and 2 midwives preferred the electronic one, while 3 midwives did not show any preference.

Table 1. Demographic data and obstetric characteristics

	Disposable PCA	Electronic PCA
Age (years)	30.7 ± 5.3	29.1 ± 4.0
Weight (kg)	79.6 ± 15.7	77.8 ± 13.0
Height (cm)	167.5 ± 8.3	167.1 ± 6.8
Gestation (weeks)	39.4 ± 1.3	39.5 ± 1.1
Nulliparous/multiparous	12/8	12/8
Interval from spinal administration to delivery (min)	249.8 ± 124.5	216.7 ± 110.0
Interval from spinal administration to commencement of PCEA (min)	34.8 ± 13.9	32.6 ± 31.6
Mode of delivery (spontaneous/vacuum/forceps)	15/4/1	13/2/5
Apgar score (1 min)	9 (3–10)	9 (5–9)
Apgar score (5 min)	10 (5–10)	9 (8–10)

Data are mean ± SD or median (range); there were no significant differences
PCA, patient-controlled analgesia

Table 2. Anesthetic requirement

	Disposable PCA	Electronic PCA
Total dose of anesthetic consumption (ml)	30.4 ± 15.4	26.1 ± 17.1
Hourly dose of anesthetic consumption (ml/h)	9.7 ± 4.7	8.2 ± 4.0
Parturient required additional intervention	55%	55%

Data are mean ± SD; there were no significant differences

Table 3. Effect of patient-controlled epidural analgesia (PCEA)

	Disposable PCA	Electronic PCA
Pain score		
Highest value during PCEA	26 ± 25	21 ± 22
Lowest value during PCEA	7 ± 11	6 ± 9
Patient satisfaction		
Highest value during PCEA	92 ± 21	99 ± 3
Lowest value during PCEA	86 ± 24	90 ± 12
Side effect		
Sensory block (upper dermatome, Th)	7 (4–10)	7 (4–10)
Motor block (Bromage score)	5 (4–6)	6 (4–6)
Nausea	10%	5%
Itching	90%	70%

Data are mean ± SD or median (range); there were no significant differences

Table 4. Evaluation by patients

	Disposable PCA	Electronic PCA
Satisfaction with labor analgesia	92 ± 11	90 ± 10
Would you like to try labor analgesia again?	YES = 20	YES = 20
Satisfaction with the PCA device	92 ± 13	90 ± 15
Would you like to use the same device again?	YES = 18	YES = 18

Data are mean ± SD; there were no significant differences

Table 5. Evaluation by midwives

	Poor	Fair	Good	Excellent
Disposable PCA device	0	0	4	9
Electronic PCA device	0	0	7	6

Discussion

The present results showed that a disposable PCA device could provide very satisfactory labor analgesia for parturients, implying that it can be an alternative to an electronic PCA device. Furthermore, the midwives, who had been accustomed to using an electronic PCA device, praised the disposable device as well as the electronic one.

The concerning disadvantages of the disposable PCA device are the absence of lockout function and alarm. In spite of the absence of lockout function with the disposable PCA device, the anesthetic requirement was similar between the groups. Without a lockout function, it was possible to administer a small amount of drug by pushing the PCA button very frequently. In such a case, an effect of bolus injection contributing to a wider distribution of the administered drug [7] might have been sacrificed. As the disposable PCA device did not have a recording function of PCA demand, it was impossible to know the number of PCA attempts by parturients in the present study. However, based on the present findings, the absence of the lockout function in the disposable device did not significantly affect local anesthetic consumption, quality of analgesia, and patient satisfaction.

The absence of alarm was another concern in using the disposable PCA device for labor analgesia. Therefore, midwives were asked to pay attention to malfunction of the PCA device, and neither overdosing nor occlusion occurred in the present study. Although the disposable device has been widely used for postoperative pain treatment and no critical malfunction has been reported, the absence of alarm cannot be justified from the present result with 20 cases, and special attention must be paid to a parturient and the PCA device during PCEA.

Evaluation of labor analgesia and PCA device by parturients was very satisfactory and similar between the groups. In the present study, the parturients were not encouraged to ambulate during labor. However, because the disposable PCA device is small and light, and easy to carry, it might have been shown its superiority if an ambulation was encouraged during labor. Although it is still controversial if ambulation accelerates

progress of labor or not [8–10], the disposable PCA device with portability seems to be more preferable to the electronic one for the case of walking epidural.

Evaluation of PCA device by midwives showed that most of them preferred the disposable PCA device to the electronic PCA device. This result was somewhat unexpected because midwives had used the electronic device for many years. At the beginning of the study period, the midwives had some difficulties in getting used to the new device, but it did not take too long until they got used to it. As a result, all midwives who used a disposable device for more than five cases preferred the disposable device. Their comments showed that they dislike the electronic PCA device because it is heavy to carry, difficult to manipulate, and its alarm is irritating.

Using a disposable PCA device for labor analgesia seems to have some additional advantages. With a disposable PCA device, it is possible to adapt to a large number of deliveries at the same time, while the numbers of an electronic PCA device limit the numbers of cases for PCA. Furthermore, a disposable PCA device may have some economical advantages for hospitals treating very small number of annual deliveries, as it is not necessary to purchase an expensive electronic device.

The electronic PCA device used in the present study was not the newest model, and more compact models with fewer false alarms are available now. Therefore, it could be claimed that it is not fair to compare between the newest model of a disposable device and the old model of an electronic device. The claim sounds reasonable, but it also hints at the disadvantage of an electronic device in that its high cost makes it difficult to renew the device regularly. In conclusion, the present results implied that a disposable PCA device could be an alternative to an electronic PCA device for labor analgesia. However, as the disposable device does not have flexibility in setting the regimen, an optimal regimen of labor analgesia using the disposable device should be further studied to provide the most suitable device.

Acknowledgment. This study was supported by Daiken Medical Co., Osaka, Japan, which produced the disposable PCA device used in the study.

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