Walking epidural with low-dose levobupivacaine with fentanyl versus patient-controlled analgesia with fentanyl during painless labor

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Introduction Adequate pain relief is essential for patient healthcare, as it decreases hormonal stress response and hazards of postoperative analgesic drug effect, provides early ambulation and better wound healing, and is highly economical.

Aim The aim of this study as a primary outcome is to compare and evaluate the efficacy and duration of analgesia between walking epidural analgesia using low-dose levobupivacaine with fentanyl versus intravenous patient-controlled analgesia (IV-PCA) with fentanyl during labor, and also, maternal satisfaction by visual analogue pain scale, whereas the secondary outcomes are maternal hemodynamic stability, obstetric outcomes, postoperative complications, and neonatal outcomes in terms of APGAR score and arterial blood gases.

Patients and methods Eighty full-term primigravida patients, with American Society of Anesthesiologist status I and II scheduled for elective spontaneous vaginal delivery and requested analgesia, were divided into two groups: group I (n=40) was the epidural levobupivacaine with fentanyl (ELF) group, which received levobupivacaine 0.0625% with fentanyl 1 mcg/ml, 15 ml as initiation injection, followed by top-up doses of 5 ml in epidural catheter every 1 h or on patient's request, whereas group II (n=40) was the IV-PCA group, which received 1 mcg/kg fentanyl intravenous as bolus dose, and then fentanyl 20 mcg increment (2 ml) with lockout interval of 5 min and at basal rate of 2 ml/h.

Results On comparing ELF with IV-PCA groups, obstetric patient's satisfaction was significantly more in ELF group (P<0.001), cervical dilatation was significantly rapid in ELF group (P=0.028), and also the duration to vaginal delivery was significantly lower in ELF group (P=0.037), whereas the results were insignificant for spontaneous vaginal delivery (P=0.728), instrumental vaginal delivery (P=0.526), and occasionally cesarean section (P>0.05). Maternal visual analogue pain scale was significantly less in ELF group from the fourth hour (P<0.001). Postoperative complications were insignificantly different between both the groups (P>0.05).

Conclusion Epidural analgesia using low-concentration levobupivacaine 0.0625% with fentanyl 1 mcg/ml during early labor provided better analgesia and resulted in short duration for vaginal delivery than systemic analgesia. Patient-controlled analgesia is a good technique for the patients during labor if they refuse epidural analgesia or patients have any other contraindication to epidural analgesia.

Sci J Al-Azhar Med Fac, Girls 2019 3:302–307

The Scientific Journal of Al-Azhar Medical Faculty, Girls
2019 3:302–307

Keywords: epidural levobupivacaine with fentanyl, patient-controlled analgesia, spontaneous vaginal delivery, substantia gelatinosa Rolandi, visual analogue pain score, walking epidural

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Received 26 February 2019 **Accepted** 16 June 2019

Introduction

The 'walking epidural' first appeared in the early 1990s. In some ways, it was tested regarding how to provide effective and safe labor epidural analgesia and responded to women's requests to have effective labor analgesia without being confined to bed [1]. Many labor analgesia studies have ensured that resulted in significant changes to different techniques and the dosing strategies, and led to deeper understanding of the way in which local anesthetics and opioids work alone and synergistically in the neuraxiom [2]. Among many benefits of minimizing maternal motor block is early other ambulation [3]. However, once anesthesiologists establish management and safety protocols for ambulation, the added work belongs to the nurse, many of whom support maintaining mobility [4]. Ambulation in pregnant woman at term achieves many benefits such as more hemodynamic stability is possibly than in the woman who remains lying in bed, and the fetus probably benefits from the minimizing effects of aortocaval compression syndrome [5]; moreover, upright position in the first stage of labor and lithotomy in the second stage are beneficial, as they provide better uterine contractions, reduce the need for urinary catheterization, and achieve a spontaneous vaginal delivery (SVD) with shortened duration of labor [6]. The ideal technique used in painless labor should be simple and safe without adverse effect on either mother or fetus without affecting progress of labor [7,8] Patients may control pain by self-

administration of intravenous opioids using devices designed for this purpose [patient-controlled analgesia (PCA)]. PCA provided better pain control and greater patient satisfaction than conventional parenteral analgesia [9]. In 2004, an estimated 13 million patients received intravenous patient-controlled analgesia (IV-PCA) therapy for the management of postoperative pain in the USA [10]. Because PCA permits patients to self-administer small doses of an analgesic when needed, the PCA modality facilitates titration to the patient's individual analgesic needs and yields higher patient satisfaction as well as better pain management [11]. Epidural with opioid has become more popular as an option for painless labor, and the highly lipophilic opioid, fentanyl, has been used as an intrathecal and epidural analgesic for labor [12]. The site of action of epidural opioids remains controversial. Analgesia results from interaction of opioids with opioid receptor in spinal cord [7]. Levobupivacaine, the pure *S*(–) enantiomer local anesthetic, which is structurally similar to bupivacaine, has lower potential for cardiovascular and central nervous toxicity. In addition, levobupivacaine is superior to bupivacaine because it appears to induce less lower extremity blockade [13]. Epidural analgesia and PCA are both widely employed techniques for postoperative pain management [7]. PCA has the advantage of allowing patients to titrate the level of medication, balancing analgesia [14], and less invasive technique has been shown to achieve safe and effective postoperative pain relief. However, the negative adverse effects of opioid medications, such as respiratory depression, urinary retention, pruritus, nausea, and vomiting can limit its effectiveness in some individuals [2]. Studies in adult patients suggest epidural analgesia may provide more complete pain relief while avoiding some of the adverse effects of intravenous opioid infusion [15]. Epidural analgesia is an invasive procedure and is not free of risks such as infections, nerve damage, drug errors, and cardiac or respiratory arrest [16]. Application of this technique also requires experienced anesthesia staff to place the epidural catheter and continue its management postoperatively [17].

Aim

This study aimed to compare walking epidural with low-dose levobupivacaine 0.0625% with fentanyl versus IV-PCA with fentanyl during painless labor, where the primary outcome is to evaluate the efficacy and duration of analgesia between the two techniques and also maternal satisfaction regarding pain using visual analogue pain scale, whereas the secondary outcomes for both mother and fetus were maternal hemodynamic stability, obstetric outcomes, postoperative complications, and neonatal outcomes with respect to APGAR score and arterial blood gases.

Patients and methods

This prospective, randomized study was approved by the Clinical Research Ethics Committee of Anesthesia and Intensive Care Department, Faculty of Medicine, Al-Azhar University, Egypt, conducted in El-Hussein University Hospital, Al-Azhar University, Cairo, Egypt. Enrolment in the study started in April 2014 and ended in October 2016. Eighty full-term primigravida patients, with American Society of Anesthesiologists status I and II scheduled for elective SVD, and requested analgesia, were randomly allocated into two groups according to a computer-generated list of random numbers that were placed in opaque sealed envelopes. Inclusion criteria comprised primigravida, full-term more than 38 weeks of gestation, vertex presentation with cervical dilatation less than 6 cm at time of epidural catheter insertion or IV-PCA procedure, aged between 18 and 40 years old with no pregnancy-risk illnesses, no history of hypersensitivity to local anesthetics, and patients who understood the procedure and signed the informed consent. Patients excluded from this study were those whose illnesses involved presence of neurological or neuromuscular disease, patients with significantly co-existing disease, patients with epidural contraindications such as infection at site of insertion, patients with bleeding disorder, or patients with history of hypersensitivity to local or other anesthetics, patients with epidural catheter replacement owing to an initial incomplete onset of the block, multiparous women, those with preterm pregnancy less than 38 weeks of gestation, women with cervical dilatation more than 6 cm at the time of epidural catheter placement, and those who failed to understand the procedure or refused to sign the informed consent. Selected cases were categorized into two groups, with 40 patients each. Group I (n=40) was scheduled for epidural levobupivacaine with fentanyl (ELF), whereas group II (n=40) underwent IV-PCA. Before performing epidural or IV-PCA procedure, basic monitoring applied in the operating room included ECG, noninvasive blood pressure, and pulse oximeter; fetal heart rate and uterine activity also were recorded. In group I (ELF), all patients must be hydrated with 5–8 ml/kg intravenous crystalloid solution. After hydration, the patient was positioned in left lateral position for placement of epidural catheter after skin

disinfection, and then skin and subcutaneous tissue was infiltrated with 3–5 ml lidocaine 2%. The epidural catheter was instituted in left lateral position with a midline approach at the L2–L3 level in all subjects by a second author. The epidural space was located by 18-G Tuohy needle using the loss of resistance to air technique. After verifying no free cerebrospinal fluid was present, the epidural catheter was inserted 4 cm into the epidural space, fixed with plaster, and kept the patient lying down. After negative test, a dose of 3 ml (60 mg) plain lidocaine 2% was administered through a particle filter into a polyamide catheter, the initial dose in epidural catheter is 15 ml of levobupivacaine 0.0625% with fentanyl 1 mcg/ml. Top-up doses of 5 ml were given 1 h or as requested. In group II (PCA), 50-ml syringe was prepared with fentanyl 1 mcg/ml. PCA was commenced with bolus dose of fentanyl 1 mcg/kg. PCA device was set to deliver 2 ml of 2 mcg fentanyl increment dose with lockout interval of 5 min and at basal rate of 2 ml/h. The maximum hourly rate was set at 10 ml. PCA pump was discontinued when time to delivery was estimated to be 30 min. The patient must be taught how to use and discontinue the PCA device. Parameters studied are anthropometric parameters; hemodynamics [heart rate (beats/min) and mean arterial blood pressure (mmHg)]; and visual analogue pain score to assess maternal pain (where 0=represent no pain and 10 represent worst pain) [18], which was done at baseline (cervix was<6 cm) and then every hour, and thereafter 6 h as the primary outcome. Secondary outcomes were obstetric outcome [SVD, instrumental vaginal delivery, cervical dilatation (cm), time of vaginal delivery (min), and caesarian section]; neonatal outcome (APGAR scores at first and fifth minutes and umbilical arterial PH); and postoperative maternal complications such as nausea, vomiting, bradycardia, hypotension, pruritus, respiratory depression, and dizziness. Bradycardia (heart rate<40% of baseline) was treated with atropine (0.01 mg/kg), hypotension (decrease in mean arterial blood pressure>40% of baseline), or both decrease 20% of baseline, was treated with intravenous ephedrine (5–10 mg) or boluses of fluid (250 ml crystalloid solution). Patients complaining of nausea and vomiting were treated by metoclopramide 10 mg.

Statistical analysis

Data were collected, tabulated, coded, and then analyzed using SPSS computer software version 23.0 (IBM Corp, Armonk, NY). First, numerical variables were examined for normality and then were presented as mean±SD or median (interquartile range) whenever appropriate. On the contrary, categorical variables were presented as number of cases (percent). Unpaired Student *t*-test was used for between-group comparison of numerical variables if they showed normal distribution, otherwise Mann–Whitney test was used which was also applied for comparison between maximum sensory blockade levels among the two groups. χ^2-Test or Fisher's exact test was used, whenever appropriate, for comparison between groups regarding categorical variables. A difference with *P* value up to 0.05 was considered statistically significant, a difference with *P* value up to 0.01 was considered moderately significant, and a difference with *P* value up to 0.001 was considered highly significant, otherwise it was nonsignificant.

Results

Eighty full-term healthy primigravida patients were enrolled and complete all parameters of this randomized study (*n*=40 in each group). There were no significant differences between two groups regarding anthropometric parameters (*P*>0.05; Table 1). Regarded heart rate and mean arterial blood pressure, there were no significant differences between the groups at baseline, but at fourth, fifth, and sixth hours, they were significantly lower (but within safety margin) in ELF group when compared with IV-PCA group (*P*<0.001; Tables 2 and 3). Regarded analgesic effect with visual analogue pain score, it was significantly decreased in ELF group than IV-PCA group at first, second, and third hours (*P*<0.05), whereas at fourth, fifth and sixth hours, it was highly significantly decreased in ELF group (*P*<0.001; Table 4). Regarding obstetrical outcomes, there was significantly rapid cervical dilatation in ELF group than IV-PCA group (4±0.13 and 3.9±0.88 cm, respectively; *P*=0.028), and there was shorter time of vaginal delivery in ELF group than IV-PCA group (279±8.56 and 302±14.20 min respectively; *P*=0.037). However, there were no significant differences between the two groups regarding spontaneous, instrumental

Table 1 Anthropometric parameters of the study patients

Parameters	ELF group (*n*=40)	IV-PCA group (*n*=40)	*P* value
Age (years)	24±6	26±4	0.435
Weight (kg)	81±8.4	82±14	0.193
Height (cm)	162±5	164±3	0.257
ASA (I/II)	37/3	36/4	0.469

Values are expressed as mean±SD. ASA, American Society of Anesthesiologist; ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; *P*, independent-sample Student *t*-test values for comparison between the two groups. Insignificant at *P*>0.05, significant at *P*≤0.05, and highly significant *P*<0.001.

Table 2 Heart rate changes

Parameters	ELF group (n=40)	IV-PCA group (n=40)	P value
Baseline	92±8.86	93.54±8.9	0.568
First hour	83.23±5.38	79.49±6.82	0.590
Second hour	81.00±4.02	77.79±5.01	0.191
Third hour	79.60±3.99	77.13±4.30	0.098
Fourth hour	79.40±3.90	85.15±4.28	0.033
Fifth hour	78.35±3.88	85.49±9.20	0.014
Sixth hour	77.40±3.31	87.79±5.63	0.006

Values are expressed as mean±SD. ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; P, independent-sample Student t-test values for comparison between the two groups. Insignificant at $P>0.05$, significant at $P\leq0.05$, and highly significant $P<0.001$.

Table 3 Mean arterial pressure changes

Parameters	ELF group (n=40)	IV-PCA group (n=40)	P value
Baseline	95.90±9.08	94.80±8.70	0.763
First hour	85.50±4.77	83.55±4.15	0.167
Second hour	81.75±6.30	81.50±6.50	0.775
Third hour	79.70±5.30	79.45±5.40	0.880
Fourth hour	78.40±3.30	86.88±2.68	0.013
Fifth hour	76.80±2.60	85.80±4.70	0.026
Sixth hour	78.30±3.21	88.70±4.80	0.017

Values are expressed as mean±SD. ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; P, independent-sample Student t-test values for comparison between the two groups. Insignificant at $P>0.05$, significant at $P\leq0.05$, and highly significant $P<0.001$.

Table 4 Visual analogue pain score

Parameters	ELF group (n=40)	IV-PCA group (n=40)	P value
Baseline	7.90±0.99	7.00±1.50	0.861
First hour	4.10±1.27	4.45±1.12	0.022
Second hour	2.15±0.95	3.50±0.26	0.031
Third hour	2.60±0.07	2.95±0.88	0.025
Fourth hour	2.58±0.30	4.90±0.99	<0.001
Fifth hour	2.80±0.18	4.90±0.92	<0.001
Sixth hour	2.70±0.14	4.60±0.88	<0.001
Patient satisfaction	1.90±0.80	2.70±0.95	<0.001

Values are expressed as mean±SD. ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; P, independent-sample Student t-test values for comparison between the two groups. Insignificant at $P>0.05$, significant at $P\leq0.05$, and highly significant $P<0.001$.

vaginal delivery, and occasional caesarian section ($P>0.05$; Table 5). There were no differences in neonatal outcome as far as APGAR score at first and fifth minutes and umbilical arterial PH were concerned after SVD. There were significant decreases in APGAR score at one minute in IV-PCA group in comparison with ELF group (P=0.027), but the differences were insignificant for

Table 5 Obstetrical outcomes

Parameters	ELF group (n=40)	IV-PCA group (n=40)	P value
Cervical dilatation (cm)	4±0.13	3.9±0.88	0.028
Time to vaginal delivery (min)	279±8.56	302±14.20	0.037
Spontaneous vaginal delivery (n)	38/40	37/40	0.728
Instrumental vaginal delivery (n)	1/40	2/40	0.526
Cesarean section (n)	0/40	0/40	>0.05

Values are expressed as mean±SD. ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; P, independent-sample Student t-test values for comparison between the two groups. Insignificant at $P>0.05$, significant at $P\leq0.05$, and highly significant $P<0.001$.

Table 6 Neonatal outcomes

Parameter	ELF group (n=40)	IV-PCA group (n=40)	P value
APGAR score [median (range)]			
At first minute	9 (7–10)	7 (2–7)	0.027
At fifth minutes	10 (8–10)	10 (7–10)	0.871
Umbilical arterial PH	7.22 (0.065)	7.21 (0.063)	0.539

ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; P, independent-sample Student t-test values for comparison between the two groups. Insignificant at $P>0.05$, significant at $P\leq0.05$, and highly significant $P<0.001$.

APGAR score at fifth minute and umbilical arterial PH (P=0.871 and 0.539, respectively; Table 6). Regarding postoperative complications, only three patients in ELF group and four patients in IV-PCA group complained of nausea and vomiting and were treated by metoclopramide 10 mg; one patient only in ELF group and two patients in IV- PCA group developed bradycardia [treated with atropine (0.01 mg/kg)]; two patients in ELF group and one patient in IV-PCA group developed hypotension (treated with 250 mg ringer acetate, and only one patient in ELF group needed ephedrine sulfate 5–10 mg); and three patients in ELF group and four patients in IV-PCA group experienced pruritus, and none of the patients needed treatment. All of these complications were with no significant difference ($P>0.05$). No other postoperative complications were recorded among the two groups (Table 7).

Discussion

Neuroaxial block such as epidural analgesia when performed properly is the most effective method for pain relief during labor [18]. Recently, there has been a steady decline in the concentration of local anesthetic used such as levobupivacaine for pain relief during labor [19]. The advantage of lower concentration 0.0625% is

Table 7 Postoperative complication

Parameters	ELF group (*n*=40)	IV-PCA group (*n*=40)	*P* value
Nausea and vomiting (*n*)	3 (7)	4 (10)	>0.05
Bradycardia (requiring atropine) (*n*)	1 (2)	2 (5)	>0.05
Hypotension (requiring ephedrine) (*n*)	2 (5)	1 (2)	>0.05
Pruritus (*n*)	2 (5)	3 (7)	>0.05
Respiratory depression (*n*)	0	0	>0.05
Dizziness (*n*)	0	0	>0.05

ELF, epidural levobupivacaine with fentanyl; IV-PCA, intravenous patient-controlled analgesia; *P*, independent-sample Student *t*-test values for comparison between the two groups. Insignificant at $P>0.05$, significant at $P\leq0.05$, and highly significant $P<0.001$.

reduction in motor block and reduction in total local anesthetic consumption [20]. Adding epidural opioids significantly improves analgesia [7], lowers the minimal local analgesic concentration, and allows the use of low concentration with acceptable analgesia [19]. Levobupivacaine, the pure *S*(–) enantiomer of bupivacaine, has been claimed to be more potent than bupivacaine [21] or ropivacaine and to cause less motor impairment and also has lower potential for cardiovascular and central nervous systems toxicity [22]. Sufficient analgesia may be expected with low concentration of levobupivacaine when added with opioids, such as levobupivacaine with fentanyl [23]. In general, good pain relief was obtained 30 min after initiation of epidural anesthesia, although many patients report pain scores of 3/10, which is considered as superior limit of the definition for mild pain; this was more marked in the lower concentration drugs [20]. Maternal hemodynamic changes such as decrease in heart rate and mean blood pressure (within safety physiological margin) were owing to maternal analgesia, not to vasodilatation, which might be owing to sympathetic block, and were maximally abolished within 3 h from administration; in addition, neuroaxial block through epidural analgesia is more effective than PCA, which might be owing to effect on substantia gelatinosa Rolandi on posterior horn cell affecting type Aδ fibers carrying fast pain (in lamina I and V) and type C fibers carrying slow pain (in lamina II and III), affecting either neospinothalamic tract and paleo-spinothalamic tract, respectively, before ending in thalamus and sensory cortex. This study is in agreement with that done by Mandell *et al.* [24] – although different methodology – which studied the effect of subarachnoid opioids using fentanyl in patients under labor on hemodynamics and found that maternal hemodynamic effect with neuroaxial block by an opioid during labor is owing to start of effective analgesia and not to vasodilatation. Moreover, it was in agreement with the study done by Marx [25], who found that at the very dilute concentration used for labor analgesia at 0.0625%, it is probably a moot point because cardiac toxicity at these dose is highly unlikely when administered inadvertently IV. Regarding pain relief and potency of analgesia, the current study came in agreement with the study done by Campbell *et al.* [2], who studied fentanyl as an effective method for providing painless labor and compared with using epidural analgesia IV-PCA. They found that 20% of the patients who received PCA were not satisfied and crossed ever to the epidural group owing to inadequate analgesia. Moreover, our results were in agreement with the study done by Chua and Sia [26] who found a significantly lower pain score in the epidural analgesia group than in the PCA group in the first 3 h of delivery. This study came in agreement with that done by Polley *et al.* [8], who studied the analgesic potencies of levobupivacaine or ropivacaine for epidural analgesia in labor versus IV-PCA using fentanyl, and maternal satisfaction was very high in epidural levobupivacaine group than ropivacaine group and least for PCA by fentanyl, and also, they found that the shortest time for duration to vaginal delivery was in epidural levobupivacaine group. Moreover, for this point of view current study came in agreement with study done by Capdevila *et al.* [27] – in spite of different methodology – comparing epidural infusion with local anesthetic levobupivacaine with fentanyl and IV-PCA with fentanyl alone in 56 patients, found significantly lower pain scores at rest and during passive motion for both regional anesthesia groups. Early postoperative knee mobilization following epidural infusion and femoral block was significantly better than with PCA, and average duration of stay in the rehabilitation center was significantly shorter: 37–40 days after epidural or femoral block compared with 50 days in the fentanyl PCA group. However, this study came in disagreement with the study done by Chumbley *et al.* [28] who analyzed 32 trials in which morphine, pethidine (meperidine), piritramide, nalbuphine, or tramadol had been administered either by PCA or intramuscularly, or intravenously, and showed that in the postoperative setting, opioid PCA compared with conventional opioid treatment improves analgesia and decreases the risk of pulmonary complications. Patients prefer PCA. The explanation might owing to the different methodology, where in this study, PCA compared with epidural analgesic effect not neither intramuscular nor intravenous. Moreover, our results were in disagreement with a study done by Buyse *et al.* [22], who studied the effect of sufentanil by PCA versus epidural

bupivacaine, ropivacaine, and levobupivacaine in nullipara in early labor and found that maternal satisfaction was very high in sufentanil group. The explanation might be owing to the different methodology used, where in this study fentanyl not sufentanil was used. Regarding APGAR score, the incidence of low score at 1 min in PCA group is ~1% but in ELF group, all neonates delivered with no central depression and good APGAR score at first and fifth minutes. This study came in agreement with that done by Benhamou *et al.* [19], who studied epidural analgesia with bupivacaine 0.625 or levobupivacaine 0.625%, plus sufentanil 0.25 mcg/ml versus IV-PCA by sufentanil 0.25 mcg/ml and found that the best APGAR score was for epidural levobupivacaine- sufentanil group. Regarding the adverse effects such as nausea, vomiting, bradycardia, and hypotension between the two groups, the study came in agreement with a study done by Morey *et al.* [3], who assessed maternal hemodynamics and fetal heart rate changes with PCA versus epidural analgesia while ambulating in labor and found the same results, except for significant increase in the incidence of pruritus in epidural fentanyl plus levobupivacaine group, which might be explained this the predominant spinal site of action for epidural opioids.

Conclusion

This study confirms that levobupivacaine 0.0625% with fentanyl 1 mcg/ml provides safe and better analgesia more than PCA, especially during early stage of labor. Levobupivacaine may be a good alternative local anesthetic for walking epidural analgesia, as it does not affect time of SVD, provides long duration of postoperative analgesia, and appears safe for nulliparous women and their babies.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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