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Vaginal Delivery and Continuous Epidural Analgesia: Should We Change Our Clinical Approach?

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A B S T R A C T

The aim of the study was to investigate the effects of continuous epidural analgesia (EA) on the course of vaginal delivery with an emphasis on duration of labor and instrumental interventions. In a prospective 2-year trial, the study group included singleton vaginal births between 35 and 41 gestational weeks with a vertex fetus, in which continuous EA with bupivacaine or chirocaine in concentration of 0.125% combined with 2–4 μg of fentanyl or 0.5 μg of sufenta was used. The control group was created randomly from laboring patients with singleton pregnancies but without EA. The groups were adjusted for epidemiological characteristics and compared regarding the obstetric data and perinatal outcome. Student t-test and Mann-Whitney U-test were performed for normally and non-normally distributed results, respectively. Out of 1284 patients, 551 pregnant women were included in the study group and 733 in the control group. The statistically significant differences between the groups related to duration of the first and second stage of labor, frequency of premature rupture of membranes, intrapartal complications, and incidence of operative deliveries were found. Both stages of labor were significantly protracted and the incidence of operative deliveries was higher in the study group of patients compared with controls. There is a need for an active obstetric approach and management of vaginal deliveries of women who receive continuous EA, particularly if it is medically indicated.

Key words: *epidural analgesia, instrumental delivery, intrapartum complications, labor, operative delivery, outcome*

Introduction

Epidural analgesia (EA) was introduced into obstetric practice with the aim of eliminating or reducing visceral pain from uterine contractions and cervical dilatation in the first stage of labor and somatic pain from distension and tearing of the perineal tissues during the second stage of labor[1,2]. Analgesic effect of this invasive procedure facilitates cervical dilatation and commonly accelerates course of delivery in medically indicated cases. Since its introduction, continuous EA at woman's request has become widely used in many delivery rooms worldwide[3–6]. Although labor pain has been recognized as a cause of increase in medical interventions, a number of reports on higher incidence of operative deliveries associated with EA have been found in the literature[1,7–10]. This clinical observation could possibly diminish all advantages and popularity of this helpful method for pain relief. On the other hand, there are several studies with opposite results and conclusions that addressed adverse effects of EA on mode of delivery[11,12]. Therefore, additional research is recommended[4].

The aim of this clinical study was to investigate unfavorable impacts of EA on vaginal delivery with an emphasis on its instrumental ending. We also want to suggest, if proven necessary, measure(s) for effective prevention or significant reduction of unnecessary operative interventions during deliveries in which continuous EA is used.

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Materials and Methods

Our prospective cohort study encompassed 1284 pregnant patients that have given birth at our Department of Perinatology in two-year period from 2009 to 2010. Data was collected from a database, medical records, and birth protocols.

The study group included only singleton pregnancies with fetus in vertex presentation, between 35 and 41 weeks of gestation, with an attempt of vaginal delivery, in which continuous EA with *bupivacaine* or *chirocaine* in concentration of 0.125% combined with 2–4 μg of *fentanyl* or 0.5 μg of *sufenta per* milliliter of epidural infusion according to patient's height has been used. After placement of epidural catheter, the infusion was started at 8–12 mL *per* hour. Cases of stillbirths were excluded. Gestational age was calculated by information on last menstrual period and/or an early ultrasound examination prior to 22 weeks' gestation. The control group was created randomly from pregnant patients with singleton pregnancies who also underwent vaginal delivery but neither with EA nor with parenteral opioids. Both groups of patients were adjusted regarding their epidemiological characteristics which included maternal age, parity, height, weight and BMI before pregnancy. Written informed consent was obtained from each participant of the study group before onset of EA. This study was approved by Ethical Committee of the University Hospital Center. All deliveries in both the study and the control group were stimulated by oxytocin. The following obstetric parameters for each pregnancy group were considered and compared: gestational age, onset of labor (regular contractions with 10 minute intervals; premature rupture of membranes), duration of the first and the second stage of labor, indications for EA, intrapartal complications (pathologic cardiotocographic patterns, fetal blood pH<7.20, bradycardia), operative deliveries, and perinatal outcome (birth weight, 5-minute Apgar score; puerperal and neonatal morbidities). Intrapartal fetal blood pH was determined only in cases of suspicious fetal compromise indicated by pathologic cardiotocographic patterns and fetal bradycardia. Indications for EA were divided into medical (rigid or spastic cervix with cervical dilatation of 3 to 5 centimeters, previous cesarean, preeclampsia, etc.) and nonmedical ones that were based only on woman's request for pain relief.

Methods

Statistics

Statistical Package Statistica version 7.1 was used for data analysis. To evaluate means, standard deviations, medians, and other statistical parameters, descriptive statistics were calculated. Data are presented in tables. In comparative analyses Student t-test was performed for normally distributed results and non-parametric tests were done for non-normally distributed scale data (Mann-Whitney U-test). Pearson's correlation coefficient was also used. A quantification of non-numeric data (categories) inside the observed group was expressed by proportion or percentage, and the analysis was performed by using χ^2-test. Statistical significance was considered at $p<0.05$ with 95% confidence interval.

Results

Out of total number of patients, 551 pregnant women were included in the study group and 733 in the control group. The epidemiological characteristics of the study and the control pregnant populations are presented in Table 1 showing no statistical differences between the groups ($\chi^2=5.24$, $p>0.05$). The mean gestational ages were 39.7 weeks and 39.4 weeks, respectively.

The incidence of maternal hypotension during labor did not differ significantly between the EA and control groups of patients. The main differences between the epidural group and controls existed in obstetric characteristics, particularly in duration of labor, frequency of premature rupture of membranes (PROM), intrapartal complications and incidence of operative deliveries. Fetal distress (50%) and dystocia (40.8%) were the most frequent indications for cesarean deliveries. Among pathologic conditions the incidences of previous cesarean (3.8%: 2.2%, $\chi^2=2.43$, $p=0.119$) and preeclampsia (2%:1.6%, $\chi^2=0.07$, $p=0.789$) were not higher, but the incidence of gestational diabetes / macrosomia (4%:1.5%, $\chi^2=6.84$, $p<0.009$) was significantly higher in the EA group than in the control group. Detailed results are displayed in Table 2. Fever was more frequent and the systemic antibiotics and analgesics were more frequently administered in puerperal women in the study group. Regarding neonatal outcomes there was no statistically significant difference in birth weight, neonatal asphyxia was more fre-

TABLE 1
EPIDEMIOLOGICAL CHARACTERISTICS OF THE STUDY AND THE CONTROL GROUPS OF PATIENTS (n=1284)

Epidemiological characteristics	Study group (N=551)	Control group (N=733)	p
Maternal age [$\overline{X}$±SD]	29.0±5.0	29.0±4.7	0.561
Primiparous (%)	79.5	76.1	0.147
Height (cm) [$\overline{X}$±SD]	167.9±6.1	168.4±6.1	0.126
Weight (kg) [$\overline{X}$±SD]	79.9±11.0	80.6±11.9	0.712
BMI [$\overline{X}$±SD]	28.3±3.6	28.4±3.8	0.941

N – number of cases, $\overline{X}$±SD – mean ± standard deviation, BMI – body mass index, p – statistical significance ($p<0.05$)

TABLE 2
OBSTETRIC CHARACTERISTICS AND NEONATAL OUTCOME IN THE STUDY AND THE CONTROL GROUP OF PATIENTS (n = 1284)

Obstetric characteristics	Study group (N=551)	Control group (N=733)	p
Previous cesarean N(%)	21 (3.8)	16 (2.2)	0.119
GDM/macrosomia N(%)	22 (4.0)	11 (1.5)	0.009
Preeclampsia N(%)	11 (2.0)	12 (1.6)	0.789
Onset of labor N(%):			
– PROM	191 (39.4)	168 (23.4)	<0.001
– contractions	294 (60.6)	549 (76.6)	<0.001
Maternal hypotension	1 (0.2)	0 (0)	0.885
Pathologic cardiotocography	86 (15.8)	28 (3.8)	<0.001
Fetal blood pH≤7.19 N(%)	32 (5.8)	12 (1.6)	0.516
First stage of labor (minutes) [median (range)]	480 (95–1020)	315 (95–845)	<0.001
Second stage of labor (minutes) [median (range)]	45 (10–210)	30 (6–160)	<0.001
Vaginal delivery N(%)	456 (82.8)	692 (94.5)	<0.001
Vacuum extraction N(%)	19 (3.5)	8 (1.1)	0.007
Cesarean section N(%)	76 (13.8)	32 (4.4)	<0.001
Puerperium N(%):			
– fever >38°C	13 (2.4)	3 (0.4)	0.004
– use of analgesics	49 (8.9)	33 (4.5)	0.002
– use of antibiotics	140 (25.4)	65 (8.9)	<0.001
– urine retention	3 (0.55)	1 (0.14)	0.479
Neonatal outcome			
Birth weight (grams) [$\overline{X}$±SD]	3477±464	3452±464	0.334
API 5'<7 N(%)	4 (0.7)	1 (0.1)	0.093
Neonatal infection N(%)	12 (2.3)	49 (6.7)	0.001
Neonatal asphyxia N(%)	6 (1.1)	0 (0)	0.015

N(%) – number of cases (percentage), $\overline{X}$±SD – mean ± standard deviation, PROM – premature rupture of membranes, p – statistical significance (p<0.05)

quent in the study group than in controls, while the percentage of infections was significantly higher in the control group of neonates.

After deliveries with EA were divided according to indications into subgroups of medical indications (Group 1) and at woman's request (Group 2), there were statistically significant differences in the duration of the first stage of labor, as well as in incidence of operative deliveries between the compared subgroups of patients (χ^2= 13.33, p<0.001) (Table 3). On the other hand, no statistically significant differences in vacuum extractions (1.5%: 1.1%, χ^2=0.02, p=0.899) and cesarean deliveries (7.7%: 4.4%, χ^2=2.37, p=0.123) between the Group 2 and the controls were found.

Discussion and Conclusion

Wide use of continuous EA is present in many countries of the world, in some of them in more than 50% of yearly deliveries[1,3,13–15]. During the last five years the in-

TABLE 3
OBSTETRIC CHARACTERISTICS OF DELIVERIES WITH EPIDURAL ANALGESIA ACCORDING TO INDICATIONS (»MEDICAL« – GROUP 1 AND »AT WOMAN'S REQUEST« – GROUP 2)

Obstetric characteristics	Group 1 (N=355)	Group 2 (N=196)	p
First stage of labor (minutes) [median (range)]	514.8 (120-1020)	420 (95–910)	<0.001
Second stage of labor (minutes) [median (range)]	50 (18-210)	40 (10–170)	0.102
Vaginal delivery N(%)	278 (78.3)	178 (90.8)	<0.001
Vacuum extraction N(%)	15 (4.5)	3 (1.5)	0.001
Cesarean section N(%)	61 (17.2)	15 (7.7)	<0.001

N(%) – number of cases (percentage), p – statistical significance (χ^2=13.33, p<0.001)

cidence of EA at our Department exceeded 20%. This invasive method of labor pain suppression deserves obstetrician's attention, because there is higher responsibility for obstetrician if labor is influenced by use of EA. Despite many favorable effects of EA, an increased number of instrumental deliveries has been noted[5,10,16].

We hypothesized that a classic expectant approach to vaginal delivery with EA, and particularly its second stage, is mostly responsible for prolongation of labor and an increased number of obstetric interventions at the end of labor. To support this claim we decided to conduct this prospective clinical study with strictly defined study and control group of pregnancies that were adjusted for their epidemiological characteristics. Namely, our intention was to minimize or even eliminate potential influences of these confounding factors.

Our research confirmed that deliveries with EA were accompanied by a higher incidence of vacuum-extractions and cesarean sections, which is in agreement with conclusions of Anim-Somuah and coworkers who reported increased risks of instrumental vaginal birth and cesarean section due to acute fetal distress in the epidural group of patients[17]. According to indications for operative deliveries, the most frequent ones were acute fetal distress (bradycardia, acidosis), dystocia (abnormalities of cervical dilatation, presentation or rotation) and absence of the fetal head descent due to inadequate predominantly decreased uterine contractions as a consequence of protracted labor. Fetal acidosis was detected 3.6 times more frequently in the EA group of deliveries than in control cases but statistical difference was not found. In addition, it is possible that higher frequency of some pathologic conditions (PROM, GDM/macrosomia) in this group of pregnancies also contributes to higher risk of operative deliveries in the EA group. Although EA was discontinuated in these obstetric cases, analysis showed that it was done only in the late phase of second stage of labor or even later, after two hours of its duration. Therefore, this medical action could not have any favorable impact on obstetric outcome.

Our hypothesis has been proven by the most obvious study result which was a significantly prolonged duration of both the first and the second stage of labor, particularly when EA was installed for medical reasons. The same experiences were reported by others[1,11]. Time relationship between the first and the second stage of labor (480 min : 45min) remained the same in the EA group of participants (ratio 10.6) as it was in controls (315min : 30min, ratio 10.5), which means that both stages of labor were proportionally influenced by EA. It is well known that EA reduces labor pain but also removes neuromuscular reflex mechanism that commonly increases uterine expulsion forces, simultaneously with strong uterine contractions, by activating maternal abdominal wall muscles. By abandoning this important physiological reflex at the late phase of labor, EA becomes an inhibiting factor of a natural and otherwise self-limited birthing process[18,19]. That is why we consider the approach and management of vaginal delivery that are used for deliveries without EA as inefficient and insufficiently safe for deliveries with EA. Expectant management of deliveries with EA, without additional engagement of the physician most frequently leads to prolongation of the vaginal delivery without any clinical justification. Therefore, chances for intrapartal complications like fetal compromise and secondary uterine inertia as well as some puerperal morbidities and neonatal asphyxia are increased in such cases. This study showed a higher incidence of fever and a significantly increased administration of analgesics and antibiotics in puerperal period, but we found no differences in incidence of urine retention between the EA and the control group, as it was reported in studies of other authors[20].

When considering deliveries with medical indication for EA, several medical measures and procedures could be recommended with the aim of preventing specific intrapartum complications and reducing a number of unnecessary operative obstetric interventions. Most important is to always keep in mind the laboring woman who is receiving EA in the delivery room. Obstetricians should do their best to explain and inform the pregnant women before the procedure about risks and possibly higher incidence of some complications in relation to vaginal deliveries without EA (prolonged labor, intrapartal, puerperal and neonatal complications), which was clearly assigned in this clinical study. Written informed consent should be obligatory before the procedure of epidural insertion[6]. Secondly, the obstetrician should be aware of cases with PROM and primary uterine inertia, when he or she decides about EA. Controlled oxytocin augmentation must be used in all deliveries with EA. Our preliminary but till now unpublished findings suggest that an active approach to cervical dilatation by a careful and gentle digital massage of the cervical tissue during uterine contractions, particularly in cases that started with PROM should be preferred. The correctness of these recommendations is substantiated by cases of delivery with non-medical indication for EA, with no problems about cervical *ostium* and in which the first phase of labor is significantly shorter than in deliveries with EA where that is medically indicated. For now, we can only speculate that the next step should be stopping the continuous EA at the right moment, at cervical dilation of 7–8 cm, particularly if uterine contractions are insufficient despite adequate drug stimulation and/or there is no compression of fetal head on cervical *ostium*. This opinion is based on a logical premise that the discontinuation of EA can reactivate the previously inactivated reflex mechanism in approximately 20–40 minutes allowing labor to progress and to reduce labor delays and incidence of operative deliveries. A similar idea has been already proposed, but definitive conclusions are inconsistent[1,4,21]. Some authors have suggested more appropriate combinations of drugs or even some new and more appropriate epidural procedures in order to reduce the incidence of operative deliveries, particularly cesareans but also some other adverse impacts of EA[17,22,23].

It seems that catastrophizing significantly influences the pregnant woman's request for pain relief[24]. Our investigation showed no reason to quit with usage of continuous EA on woman's wish, because the rates of operative deliveries did not differ between this epidural subgroup of patients and controls. In these cases EA could be used even in early phases of labor without unfavorable consequences to duration and mode of delivery[25].

In conclusion, the obtained study results, based on analyses of strictly defined study and control group of pregnancies that were adjusted for their epidemiological characteristics, confirmed that deliveries with EA were associated with a higher incidence of vacuum-extractions and cesareans, most probably due to a significantly prolonged duration of both the first and the second stage of labor, particularly when EA was installed for medical reasons. A higher frequency of some pathologic conditions could also contribute to higher risk of operative deliveries in the EA group. Therefore, there certainly is a need for an active medical engagement but each obstetrician's decision on use of EA should also be individualized according to specific circumstances of the obstetric case. In that way, adverse effects of EA and unnecessary operative deliveries could be avoided more accurately, which is an important prerequisite for improving overall patient's satisfaction.

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VAGINALNI POROD I KONTINUIRANA EPIDURALNA ANALGEZIJA: TREBAMO LI MIJENJATI NAŠ KLINIČKI PRISTUP?

SAŽETAK

Cilj studije bio je istražiti učinke kontinuirane epiduralne analgezije (EA) na tijek vaginalnog poroda s posebnim naglaskom na trajanje poroda i operacijske intervencije. U dvogodišnjem prospektivnom istraživanju ispitivanu skupinu sačinjavali su jednoplodni vaginalni porodi u stavu glavicom, između 35. i 41. tjedna trudnoće, kod kojih je primijenjena kontinuirana EA s bupivakainom ili hirokainom u koncentraciji od 0,125 % u kombinaciji s 2–4 μg fentanila ili 0,5 μg sufente. Kontrolna skupina formirana je slučajnim odabirom također jednoplodnih poroda u kojih nije primijenjena EA. Skupine su »izjednačene« prema epidemiološkim karakteristikama, a uspoređene glede tijeka poroda (opsterički parametri) i perinatalnog ishoda. Za statističku analizu rezultata korišteni su Student t-test za normalnu raspodjelu, a Mann-Whitney U test za rezultate koji nemaju normalnu raspodjelu. Od ukupno 1284 rodilje, u ispitivanoj skupini bila je 551, a u kontrolnoj skupini 733 rodilje. Između dviju skupina ustanovljene su statistički znakovite razlike s obzirom na trajanje prvog i drugog porodnog doba, učestalost prijevremenog prsnuća plodovih ovojnica, broj intrapartalnih

komplikacija i operacijsko dovršenje poroda. U ispitivanoj skupini poroda utvrđeno je statistički znakovito duže trajanje prvog i drugog porodnog doba i veća učestalost operacijski dovršenih poroda u usporedbi s kontrolnom skupinom. Autori zaključuju da je potreban aktivan opstetrički pristup i vođenje vaginalnih poroda kod žena koje rađaju uz kontinuiranu EA, posebice ako se EA primjenjuje zbog medicinskih indikacija.