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EDITORS' CHOICE

Early versus late initiation of epidural analgesia in labor: Does it increase the risk of cesarean section? A randomized trial

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Objective: To determine whether early initiation of epidural analgesia in nulliparous women affects the rate of cesarean sections and other obstetric outcome measures.
Study design: A randomized trial in which 449 at term nulliparous women in early labor, at less than 3 cm of cervical dilatation, were assigned to either immediate initiation of epidural analgesia at first request (221 women), or delay of epidural until the cervix dilated to at least 4 cm (228 women).
Results: At initiation of the epidural the mean cervical dilatation was 2.4 cm in the early epidural group and 4.6 cm in the late group ($P < 0.0001$). The rates of cesarean section were not significantly different between the groups – 13% and 11% in the early and late groups, respectively ($P = 0.77$). The mean duration from randomization to full dilatation was significantly shorter in the early compared to the late epidural group - 5.9 hours and 6.6 hours respectively ($P = 0.04$). When questioned after delivery regarding their next labor, the women indicated a preference for early epidural.
Conclusion: Initiation of epidural analgesia in early labor, following the first request for epidural, did not result in increased cesarean deliveries, instrumental vaginal deliveries, and other adverse effects; furthermore, it was associated with shorter duration of the first stage of labor and was clearly preferred by the women.

Epidural analgesia has been established as a safe and effective method of pain relief during labor. Nevertheless, the relationship between epidural analgesia and the incidence of cesarean section remains controversial. While concerns have been raised that epidurals may possibly interfere with labor and consequently increase the rate of cesarean deliveries,[1-3] a more recent review concluded that epidural analgesia is not associated with such a risk.[4]

An additional issue of controversy is the effect of the timing of epidural placement on the incidence of cesarean delivery. Some studies suggested an increased risk in those who receive epidural analgesia before reaching

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cervical dilatation of 5 cm,[1,5] while 2 randomized trials comparing early with late epidural analgesia administration reported similar rates of cesarean section (CS) regardless of the extent of dilatation.[6,7] Any association between early epidural and increased incidence of cesarean sections may be related to factors other than the epidural. For instance, it has been shown that women who present to hospital in very early labor are more likely to have obstetric intervention than those presenting in more advanced labor.[8] Also, the degree of pain in the latent phase of labor has been shown to influence the incidence of instrumental delivery.[9]

Following an assessment of the conflicting data, the American College of Obstetricians and Gynecologists Task Force on Cesarean Delivery recommended that when feasible, obstetric practitioners should delay the administration of epidural analgesia in nulliparous women until the cervical dilatation reaches 4 to 5 cm and that other forms of analgesia be used until that time.[10]

The purpose of the present study was to determine, in nulliparous parturients, the effect of timing of initiation of epidural analgesia on obstetric outcome, in particular the incidence of cesarean deliveries. Additional aims were to assess the patients' sense of control throughout labor, their satisfaction with the epidural analgesia, and their preferences regarding the timing of its initiation.

Material and methods

The study was approved by the local ethics committee, and was conducted at the Bnai Zion Medical Center, Haifa, Israel. Nulliparous women in early labor, with cervical dilatation of less than 3 cm, were offered participation in the study. Women were enrolled to the study at their first request for regional analgesia, when the admission criteria were fulfilled, the exclusion criteria excluded, and after obtaining their informed signed consent. Admission criteria included nulliparity, at least 36 completed weeks of gestation, established labor (either spontaneous or induced), with at least 2 painful contractions in 10 minutes, and cervix at least 80% effaced and up to 3 cm dilated. Exclusion criteria included contraindications to epidural analgesia, cervical dilatation of more than 3 cm at the time of enrollment, estimated fetal weight above 4000 g, medical complications (preeclampsia, gestational and insulin-dependent diabetes), and abnormal admission fetal heart rate tracing. Women were randomized to receive either early or late epidural analgesia. Randomization was achieved by selecting the next in a series of numbered opaque envelopes, indicating the assigned group. The randomization envelopes were prepared by an uninvolved third party. The randomization process was stratified according to the onset of labor, being either spontaneous or induced. In the early group, the epidurals were started immediately following the women's request. In the late group, epidural analgesia was started when cervical dilatation was at least 4 to 5 cm, and until that time analgesia was provided by intravenous pethidine and promethazine, as clinically required. The obstetric management, apart from the timing of initiation of epidural analgesia, was similar in the 2 groups.

The epidural insertion followed intravenous prehydration with 500 mL of lactated Ringer's solution. The epidural space, at the L2-3 or L3-4 intervertebral space, was identified with use of the loss-of-resistance technique with a 17-gauge Tuohy needle. An epidural catheter was inserted 4 to 5 cm into the epidural space, and a test dose of 3 ml lidocaine 2% was followed 5 minutes later by a bolus injection of 10 mL of ropivacaine 0.2% and 50 μg fentanyl. Ropivacaine is an amino amide local anesthetic agent that is structurally similar to bupivacaine, but because of its greater selectivity for block of sensory fibers, it is associated with less motor block. Analgesia was maintained using a continuous infusion of ropivacaine 0.1% with fentanyl 0.0002% (2 μg/mL) at a 10 mL/hr rate. Further boluses of 5 to 10 mL ropivacaine 0.2% were given upon request. These requests were relayed to the anesthesiologist by the midwives attending the parturients.

Episodes of hypotension, defined as systolic blood pressure $<20\%$ of baseline and <100 mm Hg, were managed by rapid infusion of lactated Ringer's solution 5 mL/kg and intravenous boluses of ephedrine 5 mg, as required. Automated maternal blood pressure and heart rate, tocodynamometry, and continuous fetal heart rate were monitored throughout labor.

Pain score was obtained at the time of randomization using a standard visual analog pain scoring system. Participants were asked to grade their pain from 0, "no pain," at one end of the line, to 10, "worst pain imaginable," at the other end.

Within the first 24 hours after delivery women were asked to fill in the Labour Agentry Scale (LAS),[11] a questionnaire designed to measure the degree of control felt by the mother throughout the process of labor and delivery. Two additional questions were asked: 1) "Following your particular experience with the timing of initiation of epidural analgesia, would you prefer, next time, to be allocated to the other study group? (yes, no, or don't care);" and 2) "Were you satisfied with the epidural analgesia? (yes, no, or partially satisfied)."

The obstetric management of subjects in both groups was similarly left to the responsibility of the obstetric team. Decisions regarding operative deliveries were made by the obstetric team according to maternal or fetal indications. Instrumental vaginal deliveries for failure to progress were similarly performed, in both groups, following 3 hours of full dilatation in the presence of epidural analgesia, or 2 hours without it.

Table I Independent maternal and neonatal measures

	Group 1 (n = 221)	Group 2 (n = 228)	*P* value
Maternal BMI [mean (SD)]	28.5 (3.5)	28.5 (4.0)	1.00
Gestational age (wk) [mean (SD)]	39.8 (1.3)	39.6 (1.3)	.13
Birth weight (kg) [mean (SD)]	3.3 (0.4)	3.3 (0.4)	.30
Rupture of membranes at admission	45%	52%	.13
Cervical dilatation at admission (cm) [mean (SD)]	1.5 (0.6)	1.5 (0.6)	.43
Cervical effacement at admission (%) [mean (SD)]	75.6 (21.4)	74.1 (23.4)	.50
Rupture of membranes at randomization	57%	61%	.34
Cervical dilatation at randomization (cm) [mean (SD)]	2.1 (0.6)	2.1 (0.6)	.83
Cervical effacement at randomization (%) [mean (SD)]	88.8 (9.8)	90.1 (10.2)	.16
Pain score at randomization [mean (SD)]	8.5 (1.7)	8.4 (1.4)	.29

In our service the annual number of deliveries is approximately 4500. Normal deliveries are conducted by certified midwives, and operative deliveries by residents, staff obstetricians, and maternal-fetal medicine specialists. Obstetric and neonatal data were collected prospectively at the following time points: admission, randomization, start of epidural, birth, and hospital stay following birth.

The primary outcome was the incidence of cesarean sections. Secondary outcome measures were the incidence of operative vaginal deliveries, duration of labor, use of systemic analgesia and of oxytocin, incidence of meconium and fever, neonatal outcome, degree of maternal control, and maternal satisfaction with the epidural analgesia.

The sample size was calculated to detect a difference in the CS rate of 10%, in the late epidural group, and 20% in the early epidural group,[1,5] with an 80% power and a 2-sided alpha level of 0.05. The sample size required to detect this difference was 220 subjects for each group. The baseline CS rate was estimated from our rate in low risk nulliparas, which is approximately 10% (with epidurals routinely given at 4 cm cervical dilatation). The estimated difference in CS rates according to the timing of epidural analgesia was based on previous studies that found such an effect.[1,5] Data were analyzed according to the intention to treat. For statistical analysis of the data we used the chi-square, Student *t* test, and Wilcoxon 2-sample test, as required. Logistic regression analysis was performed to identify clinical variables possibly associated with cesarean section. The 2-sided *P* values were used and a value less than .05 was considered significant.

Results

The study group comprised 449 gravidas: 279 with spontaneous onset of labor and 170 in whom labor was induced. The baseline and other independent clinical data of subjects in groups 1 and 2 are shown in Table I. Both groups were similar in respect to body mass index (BMI), gestational age, birth weight, state of the cervix at admission to the delivery suite and at the time of randomization, and pain score at the time of randomization (Table I).

Dependent clinical measures pertaining to the period following randomization are shown in Table II. At the time of initiation of epidural analgesia the mean cervical dilatation was 2.4 cm in group I and 4.6 cm in group II. This difference was statistically significant ($P < .0001$). In the late group there were significantly more subjects who did not receive epidural analgesia ($P = .0008$), and systemic analgesia was required more often ($P < .0001$). The mean duration from the time of randomization to full dilatation was shorter in the early epidural group (5.9 hours) compared with the late group (6.6 hours) ($P = .04$). No significant difference was found in the duration of the second stage. The mean Apgar scores at 1 and 5 minutes were similar in the 2 groups (Table II). There were no cases of neonatal fever, and sepsis work up, which was done in all instances of maternal intrapartum fever, were negative in all cases.

The mode of delivery is shown in Table III. The rates of cesarean section were not different significantly, being 13% in the early group and 11% in the late group ($P = .77$). Similarly, no differences were found in the rates of cesarean section performed for the indication of failure to progress, either in the first or second stages of labor. The rates of instrumental vaginal deliveries in the early and late groups were 17% and 19%, respectively ($P = .63$) (Table III). Failure to progress prompted instrumental vaginal delivery in 17 of the 38 instrumental deliveries (45%) in group 1 and 23 of the 44 (52%) in group 2. This difference was not statistically significant ($P = .52$).

The multivariate analysis and stepwise selection, combining both study groups (449 subjects), and including in the model the study group (early or late start of epidural), type of labor (spontaneous or induced), BMI, cervical dilatation and pain score at admission, and fetal weight, showed that the only statistically significant

Table II Dependent clinical measures following randomization

	Group 1 (n = 221)	Group 2 (n = 228)	*P* value
Epidural not done	4.5%	13.6%	.0008
Rupture of membranes at start of epidural	60%	70%	.03
Dilatation at start of epidural (cm) [mean (SD)]	2.4 (0.7)	4.6 (1.1)	< .0001
Effacement at start of epidural (%) [mean (SD)]	91.6 (8.5)	98.0 (5.1)	< .0001
Oxytocin, 1st stage	29%	27%	.57
Oxytocin, 2nd stage	7%	10%	.28
Duration, 1st stage, from admission (h) [mean (SD)]	9.4 (3.8)	10.3 (4.4)	.04
Duration, 1st stage from randomization (h) [mean (SD)]	5.9 (2.9)	6.6 (3.5)	.04
Duration, 2nd stage (min) [mean (SD)]	95.4 (58.6)	105.2 (63.7)	.12
Fever	10%	11%	.85
Meconium	18%	14%	.30
Pethidine not given	53%	20%	< .0001
Revision of uterus	2%	4%	.37
Apgar at 5 minutes [mean (SD)]	9.9 (0.4)	9.9 (0.5)	.23
Days in hospital following delivery [mean (SD)]	2.3 (0.7)	2.3 (0.8)	.89

factor that affected the rate of cesarean section was the cervical dilatation at admission ($P = .02$).

Within each of the 2 subgroups of women with spontaneous and induced labors, no statistically significant differences were found between early and late onset of induction of epidural anesthesia when comparing the incidence of spontaneous vaginal deliveries, instrumental vaginal deliveries, and cesarean sections (in the spontaneous onset of labor subgroup, $P = .25$, .38, and .84, respectively, and in the induced subgroup, $P = .26$, 0.53 and 0.83, respectively). Similarly, further sub-analysis according to type of onset of labor between the early and late epidural groups showed no statistically significant differences in baseline characteristics, including BMI, gestational age, birth weight, state of the cervix at admission to the delivery suite and at the time of randomization, and pain score at the time of randomization.

The mean cervical dilatation at the start of the epidural was 2.6 cm (standard deviation [SD] 0.7) in the spontaneous onset of labor subgroup and 2.1 cm (SD 0.6) in the induced labor subgroup. The respective cervical dilatations in the late groups were 4.6 cm (SD 0.9) and 4.5 cm (SD 1.4). The differences between the early and late groups were statistically significant in both subgroups of spontaneous and induced labors ($P < .0001$).

The Labour Agentry Scale mean score was 48.5 in the early group and 46.7 in the late group ($P = .046$). In the late epidural group, 78.0% of subjects stated that in their next labor they would prefer to be in the early epidural group and 5.1% were undetermined. In the early group, 7.0% preferred to be allocated to the other group and 3.2% were undetermined. These differences in preferences between the 2 groups were statistically significant ($P < .0001$). No statistically significant differences were found with respect to satisfaction with the epidural analgesia. In group 1, 88.1% were satisfied and 10.8% partially satisfied, while the figures for group 2 were 90.0% and 7.8%, respectively ($P = .44$).

Table III Mode of delivery

	Group 1 (n = 221) n (%)	Group 2 (n = 228) n (%)	*P* value
Spontaneous vaginal delivery	155 (70)	159 (70)	.85
Instrumental vaginal delivery	38 (17)	44 (19)	.63
Cesarean section total	28 (13)	25 (11)	.77
Cesarean section, failure to progress: Stage I and II	16 (7)	18 (8)	.86
Cesarean section, failure to progress: Stage I	6 (3)	14 (6)	.11
Cesarean section, failure to progress: Stage II	10 (4)	4 (2)	.11

Comment

In this randomized trial, early initiation of epidural analgesia was not associated with an increased rate of cesarean section. This lack of association remained so for total rates of cesarean sections, which were 13% in the early epidural group and 11% in the late epidural group, as well as for those performed for failure to progress, 7% and 8%, respectively.

Concerns that early use of epidural analgesia in labor results in a greater likelihood of cesarean delivery were based on findings of retrospective studies and secondary analysis of prospective studies that were not primarily designed to answer this specific question.[12] Results of these studies consistently demonstrated a higher rate of cesarean sections the earlier the epidural was placed.[1,5,13-16] In some studies the risk of cesarean section

was more than 2-fold, reaching 28% if the epidural analgesia was initiated at cervical dilatation of 3 cm or less compared with 11% if placed at 5 cm or more.[12] It was such data that prompted recommendations in favor of delaying the administration of epidural analgesia in nulliparous women until the cervical dilatation reaches 4 to 5 cm.

The results of our study lend further support to the findings of the 2 studies conducted by Chestnut et al.[6,7] Before ours, these were the only published randomized studies designed specifically to compare the effect of early versus late initiation of epidural analgesia on the mode of delivery in nulliparous subjects. Both studies demonstrated a similar incidence of cesarean deliveries regardless of the timing of initiation of epidural analgesia.[6,7] In both these studies the mean cervical dilatation at the start of epidural was 3.5 cm in the early group, and 4.0 cm and 5 cm in the late groups. In our study the mean cervical dilatation at the start of epidural was 2.4 cm in the early group and 4.6 cm in the late group. This adds further assurance that the risk of cesarean sections is not increased even when the epidural is initiated in the very early stages of labor. Our results are also in accord with the recent publication of Wong et al,[17] who showed that early initiation of intrathecal analgesia followed by epidural analgesia did not increase the rate of cesarean delivery when compared with early systemic analgesia followed by late epidural analgesia, which was initiated at a cervical dilatation of 4.0 cm or greater.

Likewise, early initiation of epidural analgesia did not have an effect on the rate of instrumental vaginal delivery. The rates in our study were 17% in the early epidural group and 19% in the late group; the difference being nonsignificant statistically. This lack of effect is in agreement with the findings of Chestnut et al[6,7] and Wong et al.[17]

The baseline characteristics of our 2 groups, including maternal BMI, gestational age, birth weight and state of the cervix at the time of randomization, were similar. Because pain in the early stages of labor may be a risk marker for instrumental deliveries,[9] it was important to control for this factor as well. Self-assessed intensity of pain at the time of randomization reflected a high intensity of pain, which was similar in the 2 groups.

Early initiation of epidural analgesia did not increase the need for oxytocin augmentation, which was similar in our 2 groups, at both the first and second stages of labor. Similarly, there were no differences in the rates of fever, meconium staining of the amniotic fluid, and the need for revision of the uterus for retained placenta.

Late start of epidural analgesia, as may have been expected, was associated with a significantly increased use of pethidine for analgesia. This increased need for parenteral analgesia was related not only to shorter exposure to the epidural, but also to the significantly larger number of subjects who did not receive the epidural analgesia at all. In the early epidural group 4.5% of the gravidas did not receive the epidural, while assignment to the late group resulted in 13.6% of gravidas not receiving the epidural analgesia. Delaying the epidural analgesia until greater dilatation is reached most probably resulted in more cases of labor progressing to near completion before epidural analgesia could be started.

A meta-analysis of randomized trials that compared labors with epidural analgesia and opioid analgesia has shown that patients receiving epidural analgesia have longer labors.[18] It could be expected that if such is the effect of epidural, then the longer the duration of epidural the greater the effect on the duration of labor. Contrary to this, we found a statistically significant shorter duration of the first stage of labor in the early epidural group, but similar duration of the second stage. The mean time from randomization to full dilatation was 5.9 hours in the early epidural group, and 0.7 hours longer in the late group. In the 2 randomized studies of Chestnut et al,[6,7] the timing of epidural analgesia did not have an effect on the duration of the first stage of labor. These differences might possibly be related to the lesser mean cervical dilatation in the early epidural group of our study, which was 2.4 cm compared with Chestnut's studies, which were 3.5 and 4.0 cm.[6,7] This possibility is supported by the study of Wong et al,[17] in which neuraxial analgesia, which was started at mean dilatation of 2.0 cm, and was followed by epidural analgesia resulted in a first stage of labor that was approximately 90 minutes shorter, compared with labors started on systemic opioid analgesia, followed by epidural analgesia only when the cervix was 4.0 cm dilated or more. If, indeed, epidural analgesia, compared with systemic opioid analgesia, is associated with longer labors,[18] it could be expected that unlike the findings of our study and those of Wong et al,[17] early initiation of epidural with the more prolonged exposure to its effects would result in longer labors. We have no explanation for these apparently contradictory findings.

A possible limitation of our study is the inclusion of subjects with both spontaneous and induced labors. We therefore stratified our randomization process, and achieved a similar ratio of spontaneous and induced labors in the early and late epidural groups. Subanalysis of the data according to the onset of labor (spontaneous or induced) showed that in each of these subgroups the results were similar to the study groups as a whole. As the study was powered for the group as a whole, such subanalysis would have a lesser power. The power to detect the expected differences in CS rates (doubling of rate in the early epidural group) was calculated to be 60% for the spontaneous onset subgroup, and 45% for the induced labor subgroup. Nevertheless, in each of the subgroups, comparison between the early and late epidural groups demonstrated similar baseline

characteristics and no effect on the rate of cesarean sections and operative vaginal deliveries, while the mean dilatation of the cervix at the start of epidural was statistically significantly different (2.6 cm and 2.1 cm compared to 4.6 cm and 4.5 cm). Furthermore, a multivariate analysis of factors that may have been associated with the rate of cesarean sections showed that the type of onset of labor was not a significant factor, nor was the degree of cervical dilatation at the start of epidural analgesia.

Compliance with current recommendations[10] dictates delaying epidural analgesia until the cervix is dilated to at least 4 cm. We speculated that delaying the epidural will have a negative effect on the women's perceived control during childbirth, while immediate compliance with the request for epidural would have a positive effect. We tested this assumption by using the LAS questionnaire, which is specifically designed to test perceived control during childbirth.[11] Although there was a statistically significant higher score in the early epidural group compared with the late epidural group, the very small difference in the mean values suggests that this difference is insignificant clinically. The timing of the epidural thus appears to contribute little or not at all to the women's sense of control, and that any negative effect of delaying the epidural was temporary and became insignificant by the time the questionnaire was completed.

Because our findings demonstrate that early initiation of epidural analgesia has no adverse obstetric effects, it becomes even more important to accommodate to the preferences of the laboring women. The responses of our study participants indicate a high degree of satisfaction with the epidural analgesia, given at any stage of labor, but a marked preference to be included in the group assigned to the early epidural group.

In summary, the results of our randomized trial demonstrate that in nulliparous labors the administration of epidural analgesia in very early labor, following the first request for analgesia, compared with delaying it until cervical dilatation is at least 4 cm, does not result in an increased rate of cesarean section, operative vaginal deliveries, or any other adverse effect, while being associated with a significantly shorter duration of the first stage of labor. Furthermore, it is the preferred choice of the laboring women themselves.

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