Original Article

# Pain, stress, analgesia and postpartum depression: Revisiting the controversy with a randomized controlled trial


## ABSTRACT

**Background:** Pain and depression are associated, but it is uncertain if effective pain relief during labor by labor analgesia reduces the incidence of postpartum depression (PPD). This randomized, controlled study assessed whether combined spinal-epidural (CSE) labor analgesia is associated with a decreased risk of PPD. Other reported risk factors for PPD were also assessed.

**Materials and Methods:** Parturients were randomly assigned to either CSE labor analgesia or normal vaginal delivery ($n = 65$ each). CSE parturients received 0.5 ml of 0.5% hyperbaric bupivacaine intrathecally and PCEA with continuous infusion of 0.1% levobupivacaine and 2 μg/ml fentanyl @5 ml/h along with patient-controlled boluses with a lockout interval of 15 min. Parturients of both the groups were assessed using Edinburgh Postnatal Depression Scale (EPDS) for depressive symptoms at day 3 and PPD at 6 weeks (primary outcome; defined as EPDS score ≥10 at 6 weeks postpartum). Secondary outcomes included pain scores, maternal satisfaction, and Apgar scores at 1 and 5 min. Parturients were also screened for several risk factors for PPD.

**Results:** Incidence of PPD was 22.3%. The difference in incidence of PPD between the CSE group vs. control group was not significant (27.7% vs. 16.9%; Fisher's exact $P = 0.103$). Of all the risk factors analyzed in logistic regression model, perceived stress during pregnancy was the only significant predictor of the development of PPD (adjusted Odds Ratio 11.17, 95% Confidence interval 2.86–43.55; $P = 0.001$).

**Conclusion:** CSE analgesia in laboring parturients does not reduce PPD at 6 weeks. Instead, perceived high stress during pregnancy appears to be the most important factor.


**Key words:** APGAR score; epidural anesthesia; postpartum depression; VAS score

## Introduction

Postpartum depression (PPD) is a well-recognized and common clinical entity, which can cause significant burden and distress to the mother and can pose serious risk to both the mother and her infant baby. It impairs mother-baby bonding, mothering role, and responsibilities, and hence can have adverse effect not only on the mother but also on the baby's growth and development.[1]


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An estimate of the prevalence of the perinatal depression from a systematic review across the world is 6.5%–22.9% with the overall prevalence of 7.4% (during the first trimester), 12.8% (during second trimester), 12% (during third trimester), and 19.2% in the first 3 months after delivery.[1] A recent systematic review and meta-analysis focusing exclusively on 38 studies from India involving more than 20000 women found the pooled estimate of the prevalence of PPD to be 22% (95% confidence interval: 19–25).[2]

According to the latest International Classification of Diseases, 11th edition (ICD-11) by the World Health Organization, PPD is classified under the code 6E20 (Mental or behavioral disorders associated with pregnancy, childbirth and the puerperium, without psychotic symptoms), which is described as: "A syndrome associated with pregnancy or the puerperium (commencing within about 6 weeks after delivery) that involves significant mental and behavioral features, most commonly depressive symptoms. The syndrome does not include delusions, hallucinations, or other psychotic symptoms. If the symptoms meet the diagnostic requirements for a specific mental disorder, that diagnosis should also be assigned. This designation should not be used to describe mild and transient depressive symptoms that do not meet the diagnostic requirements for a depressive episode, which may occur soon after delivery (so-called postpartum blues)."[3]

The etiology of PPD remains unclear, and multiple factors may be involved, including pain during and after delivery.[4,5] The link between pain and depression is well known, but whether effective relief from pain during labor by labor analgesia impacts postpartum depression has been very sparsely studied.[6-8]

Combined spinal-epidural (CSE) analgesia has become an increasingly popular alternative to low-dose epidural analgesia for labor. It combines the rapid, reliable onset of profound analgesia resulting from spinal, reduces local anesthetic dosage and therefore toxicity, producing minimal motor block and increasing maternal satisfaction.[9] It ensures rapid onset of sacral analgesia which is particularly advantageous in a parturient in whom analgesia is initiated in late first stage or in rapid progress of labor.[6]

In this study, we aimed to investigate whether epidural labor analgesia by CSE may be associated with a decreased risk of postpartum depression development. We hypothesized that CSE labor analgesia would be associated with reduced incidence of PPD compared to normal vaginal delivery. Thus, incidence of PPD at 6 weeks was the primary objective outcome variable. Secondary outcomes included pain scores, maternal satisfaction, and Apgar scores at 1 and 5 min.

We also sought to analyze which of the many variables reported in the literature to be associated with PPD[2,4-6] are significantly predictive of PPD in our sample. For this purpose, the relevant literature was reviewed, especially with reference to studies from India. These potential risk factors included: duration of labor, duration of second stage of labor, average pain score, gender of baby, mismatch between expected and actual gender of baby, family history of psychiatric disorder, past history of depression, depressive symptoms during pregnancy, perceived stress during pregnancy, social support during pregnancy, history of domestic violence, marital disharmony, and availability of husband during childbirth.

## Materials and Methods

This randomized, controlled, prospective, parallel-group with allocation ratio 1:1, open-label study was conducted from September 2016 to August 2017 in the Department of Anaesthesia and Intensive care, in collaboration with the Department of Obstetrics and Gynaecology and the Department of Psychiatry in a tertiary care teaching hospital. The defined guidelines of Central Ethics Committee for Biomedical research on human subjects by ICMR were adhered to, in addition to the principle enunciated in the "Declaration of Helsinki".

After obtaining approval of the institute ethics committee and registration with CTRI (CTRI Trial Registration No. CTRI/2016/04/006888), and a written informed consent, 130 laboring parturients (65 in each group), of age more than 18 years, preparing to undergo normal vaginal delivery, in early spontaneous labor (cervical dilation $\leq$5 cm) of age more than 18 years, with baseline pain score >30 belonging to American Society of Anesthesiologists (ASA) physical status I-II, and able to use PCEA pump were enrolled for the study purpose.

The parturients enrolled for the study purpose were randomized into two groups ($n$ = 65 each) using computer generated random number table using coded sealed opaque envelope which included group I, who received the neuraxial block and group II, the normal vaginal delivery group. Separate investigators were responsible for participant enrolment, random order generation, and intervention assignment.

Exclusion criteria were refusal by parturient, failure to understand functioning of PCEA pump and VAS scoring,

pre-existing psychiatric disorder (Hindi version of the General Health Questionnaire 12 items [GHQ-12] score more than 2),[10] obesity (body mass index 30 or higher), systemic and local sepsis, deranged coagulation profile, parturients who had received oral or parenteral analgesics in the last 4 hours, preterm labor (<37th completed week i.e., <259 days), Obstetric complications (e.g., premature rupture of amniotic membranes), fetus with a non re-assuring non-stress test, fetus with known or suspected congenital abnormalities, allergy to study drugs, i.e., levobupivacaine, fentanyl, diabetes (either pre-existing or gestational) or history of immunosuppression, and patients on methyldopa for hypertension.

Using GHQ-12, the patients were screened for psychological issues or distress prior to randomization. Cases having GHQ-12 scores more than 2 were excluded and referred to the department of psychiatry for further evaluation and assessment. Complete history, relevant examination and investigations were done to assess the fitness for neuraxial analgesia. The patients were also asked about the potential risk factors at this stage, including expected gender of baby, family history of psychiatric disorder, past history of depression, depressive symptoms during pregnancy, perceived stress during pregnancy, social support during pregnancy, history of domestic violence, marital disharmony, and availability of husband. A baseline hemodynamic monitoring of both mother and fetus was done prior to shifting the parturient to the operation theatre. A baseline VAS score was also obtained.

Patients of group I were taken into the labor room OT and continuously monitored for HR, ECG, NIBP, $SPO_2$ and FHR. Under all the universal aseptic precautions, CSE was performed in all parturients in L3-4 or L4-5 interspace using needle through needle technique as per standard departmental protocol. CSE parturients received 0.5 ml of 0.5% hyperbaric bupivacaine intrathecally and PCEA with continuous infusion of 0.1% levobupivacaine and 2 μg/ml fentanyl @5 ml/h along with patient-controlled boluses with a lockout interval of 15 min. All the patients were monitored for HR, ECG, NIBP, $SPO_2$, FHR, VAS score, level of sensory block, lower limb motor block, time and mode of delivery, duration of second stage of labor, Apgar scores at 1 and 5 min and adverse effects, if any. Maternal satisfaction score was recorded at the end of the study.

Parturients belonging to both the groups were screened for postpartum depressive symptoms using the English/Hindi version of Edinburgh Postnatal Depression Scale (EPDS)[11] at 3 days and for PPD using EPDS at 6 weeks postpartum. The EPDS is considered a gold standard for detecting PPD and it has been used worldwide including in India.[12] PPD at 6 weeks postpartum was considered the primary outcome.

The statistical analysis was carried out using IBM SPSS statistical software version 21. Sample size was calculated using the data published by Ding *et al*.[7] (PPD prevalence: 14.0% with epidural labor analgesia and 34.6% without epidural ($P < 0.001$). Using these data and setting $\beta = 0.20$; $\alpha = 0.05$, sample size was estimated as 65 per group.

For all quantitative variables mean, median and standard deviation were calculated. Statistical analysis included Student's *t*-test or Mann-Whitney U test as appropriate. Frequencies of categorical data were compared using Chi square or Fisher's exact test whichever was applicable.

The primary outcome of this study (frequency of PPD, defined as EPDS score ≥10 at 6 weeks postpartum) was compared in the two groups by Chi-squared test. The mean scores on the EPDS in the two groups at 3 days and 6 weeks postpartum were compared by Student's *t* test.

Pain VAS scores in the two groups was compared using two-way ANOVA with post-hoc Scheffe's test. Statistical tests are two-sided and were performed at a significance level of $\alpha = 0.05$.

Finally, cases of PPD were compared with no-PPD on all relevant risk factor variables culled from the literature using univariate analysis with appropriate statistics. The risk factors that were found to be significantly associated with PPD in univariate analysis were then entered in multivariate logistic regression model with PPD vs. no-PPD as the dependent variable.

## Results

The CONSORT flow diagram is shown in Figure 1. The maternal hematological and biochemical parameters in the two groups were comparable. The baseline characteristic of study group is mentioned in Table 1.

The mean pain VAS score (mean ± S.D.) at baseline was 93.69 ± 10.20 for Group I and 77.23 ± 10.38 for Group II. The mean VAS score was compared across the group at 0 min to 12 h. The mean VAS score of the two groups when compared among them was statistically significant ($P < 0.05$) at all the times. The epidural group was found to have significantly lower mean VAS scores (28. 55 ± 12. 20) across all time periods compared to the control group (89.99 ± 5.90) and the outcome was statistically significant (*P* value = 0.001).

The mean total duration of labor was not statistically significant between the two groups. However, the mean duration of second stage of labor (mean ± S.D.) in min

**Table 1: Comparison of baseline patient characteristics in the two groups**

| Characteristics | Group I (CSE) *n*=65 | Group II (CONTROL) *n*=65 | *P* |
|---|---|---|---|
| Demographic characteristic | | | |
| Age (years) | 26.06±3.122 | 25.23±2.914 | 0.119 |
| Height (cms) | 157.154±4.3274 | 155.838±4.0975 | 0.078 |
| Weight (kgs) | 66.022±8.6671 | 63.123±8.7187 | 0.060 |
| Hematological parameters | | | |
| Hemoglobin (g/dl) | 12.008±1.3865 | 12.194±1.386 | 0.343 |
| Prothrombin time Index (%)(PTI) | 97.78±3.931 | 96.09±5.899 | 0.056 |
| International normalized ratio (INR) | 1.0343±0.05414 | 1.0378±0.06686 | 0.741 |
| Biochemical parameter | | | |
| Blood Urea (mg/dl) | 16.83±4.853 | 17.37±5.095 | 0.538 |
| Serum Creatinine (mg/dl) | 0.7385±0.09303 | 0.7369±0.17816 | 0.951 |
| Serum Sodium (meq/lt) | 137.94±0.3.191 | 139.63±0.3.677 | 0.006 |
| Serum Potassium (meq/lt) | 4.5369±0.35336 | 4.2769±0.82477 | 0.021 |

CSE: Combined spinal epidural analgesia

was 44.57 ± 34.20 min vs. 8.60 ± 4.11 min for Group I and II respectively, and the difference was statistically significant ($P < 0.05$) [Table 2].

The inter-group difference with regard to distribution of normal delivery, Cesarean section and instrumental delivery was also statistically significant with more number of instrumental delivery and cesarean sections in Group 1 ($P < 0.0001$) [Table 3].

Following delivery, the parturients were assessed for the overall satisfaction from the degree of pain relief and their desire to use it in subsequent pregnancies. All patients reported high satisfaction and the mean overall maternal satisfaction (mean ± S.D.) on a 0-100 VAS was 98.38 ± 4.34;86.2% of the parturients had a maternal satisfaction of 100%, 9.2% scored 90–99%, and 6.1% had a score between 80 and 89% satisfaction. The scores were comparable between the two groups.

The mean Apgar scores at 1 and 5 minutes between the two groups were compared which were statistically non-significant [Table 3].

Regarding postpartum depressive symptoms (EPDS score >10 at 3 days postpartum), 21 out of 65 patients in CSE group had postpartum depressive symptoms at day 3 as compared to 23 patients in the control group. The difference was not statistically significant ($P > 0.05$).

Overall, 29 patients developed PPD (22.3%), of which 18 patients were in CSE group (27.7%) compared to 11 in the control group (16.9%). The difference among the two groups was statistically non-significant (Fisher's exact *P* value 0.103) [Table 4]. Hence, the CSE did not significantly decrease the incidence of PPD compared to the control group.

**Table 2: Comparison of duration of labor (total duration and second stage) in the two groups. The data are represented as mean±SD**

| | Group I (CSE) *n*=65 | Group II (Control) *n*=65 | *P* |
|---|---|---|---|
| Total duration of labor (h) | 4.6554±2.36808 | 5.0669±2.01601 | 0.288 |
| Duration of second stage of labor (min) | 44.57±34.198 | 8.60±4.107 | <0.001 |

CSE: Combined spinal epidural analgesia

**Table 3: Mode of delivery and Apgar scores in the two groups**

| | Group I (CSE) *n*=65 | Group II (Control) *n*=65 | *P* |
|---|---|---|---|
| Mode of delivery, *n* (%) | | | |
| Normal vaginal | 47 (72.3) | 65 (100) | *P*<0.0001 |
| Instrumental | 13 (20.0) | 0 | |
| Cesarean | 5 (7.7) | 0 | |
| APGAR SCORE (1 min) | 8.71±0.861 | 8.88±0.625 | 0.202 |
| APGAR SCORE (5 min) | 8.94±0.300 | 8.97±0.174 | 0.476 |

**Table 4: Comparison of Edinburgh Postnatal Depression Score (EPDS) at day 3 and at 6th week postpartum between CSE and control groups**

| Status | Group I (CSE) *n*=65 | Group II (Control) *n*=65 | *P* |
|---|---|---|---|
| EPDS score at day 3 | | | |
| EPDS ≥10, *n* (%) | 21 (32.3) | 23 (35.4) | 0.918 |
| EPDS <10, *n* (%) | 44 (67.7) | 42 (64.6) | |
| PPD at 6th week | | | |
| PPD *n* (%) | 18 (27.7) | 11 (16.9) | 0.103 |
| No PPD *n* (%) | 47 (72.3) | 54 (83.1) | |

Following this null result with respect to CSE vs. control group with respect to PPD, we wanted to analyze which of the many variables reported in literature to be associated with PPD were significant in our sample. For this, we regrouped the entire sample ($n = 130$) into PPD and No-PPD. These two groups were then compared on all the relevant variables culled from the literature as mentioned above.

Of all these variables, only the three following variables were significantly different between PPD and No-PPD: depressive symptoms during pregnancy ($P = 0.035$); perceived social support ($P = 0.001$); and perceived stress during pregnancy ($P < 0.0001$).

Importantly, mode of delivery (Cesarean, instrumental, normal) was not significantly associated with PPD ($P = 0.291$). Neither was the duration of second stage of labor ($P = 0.225$). These null results were important because the CSE and control groups differed significantly on these two variables, raising the question whether a higher proportion of assisted deliveries or a longer second stage of labor could have led to PPD. This analysis ruled out these possibilities. The average VAS pain score was also not significantly different ($P = 0.128$).

The three independent variables that significantly differentiated PPD from No-PPD groups were then entered in a multivariate logistic regression, with PPD vs. No-PPD as the dependent variable [Table 5]. Of all the independent variables examined in the final model, after adjusting for inter-correlations among the variables, only the variable of perceived stress during pregnancy predicted PPD with a strong level of significance ($P = 0.001$). High level of perceived stress during pregnancy strongly predicted PPD compared to low level of perceived stress (adjusted Odds Ratio 11.17, 95% Confidence interval [CI] 2.86–43.55), meaning thereby that pregnant women with high perceived stress level during pregnancy had 11 times higher risk of developing PPD compared to those with low stress. Other factors were important but not statistically significant because of wide CI.

## Discussion

In the present study PPD was prospectively compared using the Edinburgh Postnatal Depression Scale (EPDS) score in the labor epidural and control group at 3 days and 6 weeks postpartum. The results demonstrate that combined spinal epidural labor analgesia in laboring parturients does not reduce depressive symptoms at 3 days and PPD at 6 weeks postpartum.

To our knowledge, there have been only four prospective observational studies on the use of epidural labor analgesia and PPD, with conflicting results.[6-8,13] To the best of the knowledge, the present study is the first of its kind in the Indian subcontinent. Our results are partly in line with those of Hiltunen *et al*.,[6] who found higher depressive symptoms in the analgesia group only at first week but not at 4 months postpartum, Tobin *et al*.[8] who reported that labor epidural analgesia did not result in lower incidence of PPD in a secondary analysis of a prospective study from South Carolina, USA, and Nahirney *et al*.[13] who too did not find any association of epidural labor analgesia with PPD in the secondary analysis of a prospective cohort in urban Canadian women. The study from China by Ding *et al*.[7] did report significantly decreased PPD in women receiving labor analgesia, but this study had selection bias (systematic exclusion of obese patients), attrition bias (differential loss at follow-up) and lack of controlling for confounding variables.

PPD involves interplay of multiple factors, the association of which has been evaluated in our study. After gleaning through available literature[2,4,5,14-19] on the factors associated with PPD both from the world and those especially relevant to the Indian subcontinent, a number of categorical variables were studied at 3 days and 6 weeks, which include past history of depression, depressive symptoms during pregnancy, family history of psychiatric disorders, perceived stress during pregnancy, perceived social support, mismatch between preferred gender of baby vs. actual gender, history of domestic violence, availability of husband during delivery, marital disharmony, education status, and type of family.

**Table 5: Logistic regression analysis for predicting postpartum depression (PPD) at 6 weeks as the dependent variable**

| Independent variables | Adjusted odds ratio | 95% CI of adjusted odds ratio) | | *P* |
|---|---|---|---|---|
| | | Lower | Upper | |
| Duration of labour total | 1.145 | 0.892 | 1.469 | 0.287 |
| Duration of 2nd stage of labour | 1.001 | 0.979 | 1.024 | 0.921 |
| Average Pain (VAS) score | 0.977 | 0.929 | 1.026 | 0.347 |
| Group (CSE vs. Control) | 2.602 | 0.575 | 11.770 | 0.214 |
| Gender Baby (male vs. female) | 0.937 | 0.351 | 2.501 | 0.897 |
| Depressive symptoms during pregnancy (absent vs. present) | 0.123 | 0.003 | 4.331 | 0.249 |
| Family history of psychiatric disorder (absent vs. present) | 2.153E8 | 0.000 | . | 0.999 |
| Perceived stress during pregnancy (high vs. low) | 11.17 | 2.86 | 43.55 | 0.001 |
| Social support (low vs. high) | 0.993 | 0.134 | 7.366 | 0.994 |
| Mismatch between expected vs. actual gender (yes vs. no) | 5.572 | 0.278 | 111.823 | 0.262 |
| History of domestic violence (absent vs. present) | 0.824 | 0.016 | 41.842 | 0.923 |
| Husband availability (present vs. absent) | 0.162 | 0.003 | 7.784 | 0.357 |
| Marital disharmony (yes vs. no) | 1.389 | 0.060 | 32.073 | 0.838 |

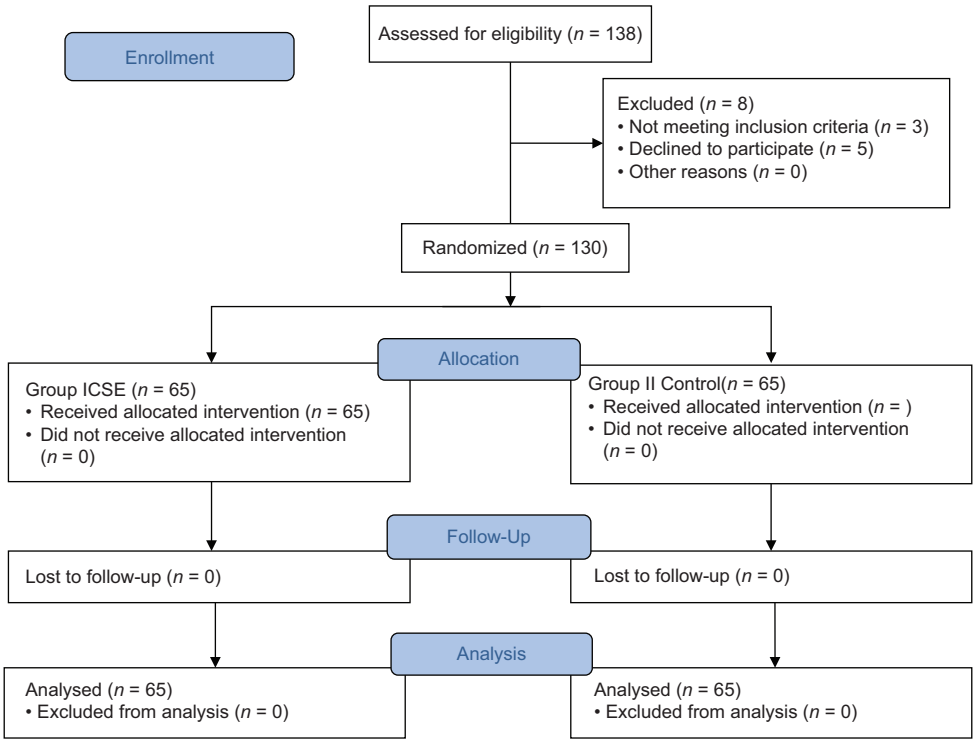


**Figure 1: CONSORT flow diagram**

Parturients with postpartum depression at 6 weeks had higher perceived stress during pregnancy which was statistically significant in both the epidural ($P = 0.036$) and control groups ($P = 0.001$). In addition, poor social support was observed in parturients with postpartum depression which was statistically significant in the control group ($P = 0.001$).

As seen in various studies on the risk factors of PPD in the Indian subcontinent,[2,14-19] birth of a female child tops the chart. It was found that of the 15 parturients with female babies and PPD, 10 (35.7%) belonged to the CSE group versus 5 (14.3%) in the control group ($P = 0.047$). Birth of the female child is associated with significant stress due to the social stigma, perceived disgrace, and rejection associated with it, which explains the higher EPDS scores in the epidural group at 6 weeks. All other parameters were statistically non-significant for both the groups at 6 weeks.

Finally, in the multivariate logistic regression analysis, of all the independent variables examined in the final model, after adjusting for inter-correlations among the variables, only the variable of perceived stress during pregnancy predicted PPD with a strong level of significance ($P = 0.001$). High level of perceived stress during pregnancy strongly predicted PPD compared to low level of perceived stress (adjusted Odds Ratio 11.17, 95% Confidence interval [CI] 2.86–43.55), meaning thereby that pregnant women with high perceived stress level during pregnancy had 11 times higher risk of developing PPD compared to those with low stress. Other factors were important but not statistically significant because of wide CI. The above findings emphasize that pain relief, although important in mitigating the stress of childbirth, its role in the sensitive interplay of a multitude of risk factors in postpartum depression needs further evaluation.

As exemplified in a recent observational study with a sophisticated design,[20] the challenges of a physically difficult delivery imposed by the prolongation of the second stage of labor, associated maternal fatigue, and the use of instrumentation could account for the negative emotions related to unfulfilled expectations and a sense of futility and personal defeat.

Several recent systematic reviews and Cochrane meta-analysis[9] have concluded that effective neuraxial analgesia does not increase caesarean sections although it may be associated with slight prolongation of second stage of labor by an hour and an increased risk of instrumental delivery. The present study had similar observations wherein the second stage of labor was significantly prolonged in the CSE group compared to the control group. However, these differences were not significantly associated with PPD.

The obstetric outcome in terms of mode of delivery in the CSE group demonstrates an incidence of 72.3% for normal vaginal delivery, 20% for instrumental delivery, and 7.7% for

caesarean section. These modes of delivery were significantly different in the control group where all the deliveries were normal vaginal. However, again these differences were not significantly associated with PPD. It was earlier seen that acute pain after delivery, but not type of delivery, predicts PPD.[21]

The strength of the present study lies in it being a randomized, prospective study. In this study, EPDS was used, which is a validated screening tool for the diagnosis of PPD and can also be administered by nonpsychiatrists.[22] The validated local version (Hindi) was applied for better understanding by the parturients. There are also a few limitations in the present study. The present study was conducted in a limited number of patients though with prior sample size calculation; however, this could possibly be replicated in future in multicentric trial with a larger sample size. Also, there is no universally accepted time point for the screening of PPD. Although DSM-5 defines PPD as the most recent episode occurring during pregnancy as well as in the 4 weeks following delivery, there is compelling evidence that real suffering often occurs during the first year.[23] While this can be explored in future studies with longitudinal design, it should be noted that most studies utilize the EPDS score at 6 weeks postpartum as the time when PPD is diagnosed.

In conclusion, this study demonstrated that combined spinal epidural analgesia in laboring parturients does not reduce postpartum depression at 6 weeks. Perceived stress during pregnancy emerged as the only factor significantly predictive of development of PPD in laboring women. This has obvious clinical and preventive implications.

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### Conflicts of interest
There are no conflicts of interest.

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