Original Article

Clinical evaluation of preoperative three -item questionnaire and pain experienced on infiltration of local anesthetics to predict severity of acute pain after caesarean section

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Abstract

Background and Aims: Several studies have attempted to identify patients at risk of developing severe pain after caesarean section (CS) by utilizing preoperative experimental pain application and clinical tests. The three-item questionnaire and reported pain intensity on infiltration of local anesthetic (LA) on the back of patient just before administration of spinal anesthesia, are two simple tests previously shown to be promising. We aimed to study utility of these two tools in Indian patients undergoing CS and find their correlation with postoperative pain and analgesic consumption.

Material and Methods: A total of 150 parturients undergoing elective CS were enrolled. Preoperatively patients were asked to rate their level of anxiety, anticipated postoperative pain and analgesic need after surgery (three-item questionnaire). The pain intensity reported by patient upon LA injection for spinal anesthesia were recorded. In the postoperative period, pain intensity at rest, evoked pain and need for rescue analgesics were recorded. The correlation between three item questionnaire and pain on LA infiltration to postoperative pain were evaluated. To see relationship between the predictor variables to outcome, a multiple regression analysis was performed.

Results: The predictors variables and postoperative pain were found to have mild correlation (r = 0.124 to 0.239). The predictor variables were significantly correlated with postoperative pain at rest but their association was not significant to evoked pain intensity. Multiple regression analysis showed that change in the predictors explains only 7-8% variance in postoperative pain outcomes.

Conclusion: The three -item questionnaire and pain intensity reported upon LA infiltration for spinal anesthesia have mild correlation to postoperative pain in Indian parturients undergoing CS. As these variables predicts only 8% variance in pain experienced after CS, further studies are required for accurate prediction and targeted treatment of post CS pain.

Keywords: Anesthesia, anesthetics, caesarean section, infiltration, local, pain, postoperative, prediction

Introduction

There are numerous regional analgesia techniques, systemic and neuraxial medications used for post caesarean section (CS) analgesia with variable success rates.[1] The wide interindividual variability in degree of pain experienced by parturient is an important factor leading to failure of one-size-fits- all analgesia regime for patients.[2] Preoperative identification of parturient at high risk of severe acute postoperative pain after CS may allow postoperative analgesic regime to be effectively tailored to requirements.

There are four groups of tools used to predict severe pain/analgesic consumption after CS; tools utilizing quantitative sensory

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testing (QST) including patient response to electrical, thermal and pressure stimuli, using response to local anesthetic wound infiltration, using preoperative psychometric evaluations and those using combination of QST and psychometric evaluation.[3] For practical utility prediction tools that are simple to use and clinically feasible can be valuable in identifying parturients at risk of experiencing severe pain and guiding analgesia regime.

A three-item preoperative screening questionnaire is a simple tool evaluated by Booth *et al.*[4] to identify women predicted to have postoperative evoked pain scores above 80th percentile and providing them higher dose of spinal morphine combined with systemic acetaminophen. They found significant reduction in evoked pain score with movement at 24 hours using this predictive tool ($p = 0.009$). In another study Orbach-Zinger *et al.*[5] found a correlation between level of pain experienced during skin infiltration of local anaesthetics (LA) prior to administration of spinal anesthesia and post CS pain severity. They observed this predictive tool to be having sensitivity of 91.6% and specificity of 93.3%, making this an ideal method to assess severity of post CS pain.

There is paucity of studies evaluating predictive tools for intensity of acute pain experienced after CS in Indian population. We planned the present study to investigate the correlation of three -item questionnaire and pain reported upon LA infiltration for spinal anesthesia to postoperative pain in Indian parturient undergoing CS. We hypothesize that women reporting higher score on three-item questionnaire and pain upon LA infiltration prior to spinal anesthesia will more likely to report high intensity of pain after CS.

Material and Methods

After approval from Institutional Ethical Committee Approval number: F.1/IEC/MAMC/(65/05/2016/NO/60) & registration with Clinical trial Registry of India (CTRI/2019/03/018076), prospective single arm cross-sectional study was conducted at a tertiary care hospital from March to November 2019. A total of 150 patients undergoing lower segment CS under spinal anesthesia were enrolled in the study after obtaining written informed consent. Patients with category 1 emergency CS, documented psychiatric illness, history of any drug or substance abuse were excluded from the study.

Preoperatively on the day of surgery patients were asked the three-item questionnaire consisting of three questions regarding anticipated postoperative pain, analgesic requirement and anxiety. Anticipated postoperative pain was assessed using Verbal Numeric Pain Scale (VNPS) 0-10, with 0 being no pain and 10 being worst pain ever experienced. Anticipated analgesic requirement was assessed by Verbal rating scale on 0 to 5 with 0 being no analgesics, 1 being much less than average, 2 being less than average, 3 being average, 4 being more than average, and 5 being much more than average. For assessment of preoperative anxiety 6 -facial visual anxiety scale (FVAS) was utilized.

On the day of surgery, after shifting patient to operation theatre routine anesthesia monitors including electrocardiogram (ECG), pulse oximetry and non-invasive blood pressure were attached and baseline values were noted. An intravenous access (i.v.) of 18 G was secured on dorsum of non-dominant hand and co-loading with lactated Ringer solution was started. For subarachnoid block, patient was placed in sitting position and skin of the back was prepared using antiseptic solutions. LA infiltration to skin and subcutaneous tissues was done with 2 ml of 2% lignocaine using 23 G hypodermic needle.

The pain during LA infiltration was rated by parturient on VNPS (0-10). The subarachnoid block (SAB) was provided with 2-2.2 ml of 0.5% hyperbaric bupivacaine with 25 μg fentanyl using a Quincke 26G needle. After achieving sensory block level of T6 as assessed by pin prick sensation, surgery was started. Intraoperatively the case management was done as per our institutional protocol. Any significant event after start of surgery such as patchy or inadequate SAB block, requirement of additional analgesics, conversion of anesthesia technique to general anesthesia or any other complications were recorded. At completion of surgery, LA was infiltrated at surgical skin incision site with 20 ml of 0.25% bupivacaine to skin and subcutaneous tissues by operating surgeons.

In the postoperative period the patients were shifted to Obstetric high dependency unit (HDU). For postoperative analgesia injection (inj.) paracetamol 1 gm i.v. and inj. diclofenac sodium 75 mg i.v. every eight hourly were advised. If at any time in the first 24 hours postoperatively VNPS was ≥ 3, inj. tramadol 1 mg/kg i.v. was administered. If the pain relief was still not adequate inj. morphine 3 mg i.v. was planned to be given as second rescue analgesics. The assessment was done at every two hours for first 12 hours and then at four hours intervals till 24 hours after surgery. The assessment of pain and analgesic requirement was done by an independent observer who was not involved in study. At 24 hours after surgery, pain at rest, evoked pain, total opioid requirement and patient satisfaction were assessed. Evoked pain assessment was done by asking patient to sit upright with both the legs by side of bed. The primary outcomes of the study were correlation between three-item questionnaire and intensity of pain reported by patients on LA infiltration before spinal anesthesia to intensity of postoperative evoked pain assessed at 24 hours after surgery. The secondary outcomes were correlation between three-item questionnaire

and intensity of pain on LA infiltration to postoperative pain at rest and analgesic consumption.

A pilot study on 30 patients was conducted prior to commencing the trial and found that many patients had difficulty in giving response to anxiety score. The scale for measurement of anxiety was changed from Amsterdam preoperative anxiety scale to 6 facial visual anxiety scale. The data of patients from pilot group is not included in final analysis. Based on result of pilot study we found that on an average 50% of patients gave response properly and at 95% confidence level with a margin of error of ±8%, 150 patients were needed for study. All data was analyzed using Statistical Package for the Social Sciences (SPSS) 22.0. Descriptive statistics was calculated for all variables, normally distributed variables were expressed as mean ± standard deviation, median (range) was used to express variables which were not normally distributed and categorical data were presented as number (percentage). The normality was checked by Kolmogorov-Smirnov test. As they were found to be normally distributed Pearson coefficient was used to examine their association. The significance level is taken as $P \leq 0.05$. A stepwise multiple regression analysis is used to analyze relationship between anxiety, anticipated pain, anticipated analgesics and pain on LA infiltration and postoperative pain.

Results

A total of 150 patients were enrolled in the present study. Out of them 13 cases were dropped; 10 due to missing data, 2 cases had failed/inadequate SAB for CS and a patient had extended vertical incision. The majority of our patients were younger than 25 years of age, educated up to high school level and were housewives [Table 1]. The mean anxiety score, anticipated pain and anticipated analgesics requirement in our study population were 3.12 ± 1.18, 5.82 ± 2.15 and 3.23 ± 1.17 respectively. The mean pain score reported on infiltration of LA was 3.49 ± 2.35. The outcome variables mean postoperative pain score at rest was 3.51 ± 1.61 and mean evoked pain score was 5 ± 1.75. As first rescue analgesic tramadol was required by 49.6% of participants. None of the patients required second rescue analgesic. In our study population 96% of patients were satisfied with postoperative analgesia provided.

The Pearson correlation coefficient between the predictors variables and postoperative pain at rest is found to have mild correlation (r = 0.124 to 0.239). The correlation coefficient between preoperative anxiety score, pain on LA infiltration and 24 hours postoperative pain at rest was significant at the 0.05 level (2-tailed) [Table 2]. The correlation between anticipated analgesic need, sum of three item questionnaires and 24 hours postoperative pain at rest was significant at 0.01 level (2-tailed). The association between 24-hour evoked pain and predictors is also found to be mild, however their relationship is not found to be significant. The tramadol requirement by the patients was significantly correlated to evoked pain score $P < 0.01$ [Table 2]. The predictor variables were seen to be moderately correlated to each other [Table 3].

Table 1: Demographic profile of patients

	Number (Percentage)
Age	
Less than 25 years	67 (49%)
26-30 years	47 (34.3%)
Above 30 years	23 (16.7%)
Education level	
Not educated	12 (8.7%)
Below matric	44 (32.7%)
matric	23 (16.7%)
Intermediate	25 (18%)
graduates	24 (17.3%)
postgraduates	9 (6.7%)
Occupation	
Working	16 (11.6%)
Not working (Housewife)	121 (88.3%)
Parity	
Nulliparous	59 (43.3%)
Multiparous	78 (56.7%)
H/o previous surgery	
Yes	74 (54.1%)
No	63 (45.9%)
H/o any past illness	
Yes	36 (26.4%)
No	101 (73.6%)
Presence of comorbidities	
Yes	29 (21.3%)
No	108 (78.7%)

Table 2: Correlation between predictor variables and outcome variables

	Postop pain at rest	Evoked pain
Anticipated pain		
Pearson coefficient	0.124	0.076
Significance	0.15	0.379
Anxiety		
Pearson coefficient	0.185*	0.106
Significance	0.03	0.217
Anticipated analgesics		
Pearson coefficient	0.239**	0.114
Significance	0.005	0.186
Sum of 3 items questionnaire		
Pearson coefficient	0.225**	0.135
Significance	0.008	0.114
Pain score on L. A. Infiltration		
Pearson coefficient	0.195*	0.139
Significance	0.023	0.107
Tramadol requirement	0.118	0.299*
	0.341	0.014

*** Correlation is significant at the 0.01 level (2-tailed). *Correlation is significant at the 0.05 level (2-tailed)*

A stepwise multiple regression analysis was conducted to evaluate whether anxiety, anticipated pain, anticipated analgesics, their combination and combination of 3 items and pain on LA infiltration can be utilized to predict postoperative pain. The value of R in models [Table 4] is between 0.036 and 0.088 showing that the models can explain only 3-8% variance in postoperative pain in response to change in variables. On analysis of variance (ANOVA) of models [Table 5], they were found to be significant predictors of postoperative pain, except model 2 [model 1 f (1,134) = 5.045, $P = 0.026$, model 2, f (2,133) = 2.93, $P = 0.057$, model 3, f (3,132) = 3.39, $P = 0.20$, model 4 f (4,131) = 3.17, $P = 0.016$].

However, on analysis of coefficients of models, to examine the extent to which the individual predictor variables contribute to the model, it was found not to be significant. The tolerance level of independent variables in all the models were found between 0.7 to 0.9 suggesting low risk of multicollinearity.

Discussion

Post caesarean analgesia and patient satisfaction remains inadequate in many patients undergoing CS. As pain is a multifaceted phenomenon consisting of physiological, emotional, behavioral and genetic components, there is inter-individual variability in severity of postoperative pain experienced by patients. This may lead to failure of fixed analgesia regimen in postoperative period. In an attempt to optimize post CS analgesia a combination of preoperative patient response by asking three simple questions; anxiety, anticipated pain and anticipated analgesics have been utilized to yield multifactorial predictive model. Using responses to three simple questions, Pan *et al.*[6] found that it moderately predicted the severity of acute postoperative pain after CS (r = 0.24–0.33, $P < 0.00$). Their simple model accounted for 20% variance in severity of post CS pain. In a follow-up study, it was further noted that modifying standard postoperative analgesic protocol in post CS patients, predicted to experience more intense pain by three-item questionnaire can lead to improve postoperative pain control.[4]

Orbach-Zinger *et al.*[5] investigated prediction of acute pain after CS by measuring the pain intensity reported upon LA infiltration for spinal anesthesia. They found moderate correlation between pain on LA infiltration to post CS pain at rest and upon mobilization (average pain at rest r = 0.529, $P < 0.001$, average pain at mobilization r = 0.483, $P < 0.001$). However, this predictive modality has been evaluated in single study only and whether the patients predicted to experience more pain actually benefit from postoperative analgesic regime with higher dose of analgesics or addition of other adjuncts, is not established.

There is lack of studies evaluating predictors of severity of post CS pain in Indian parturients. We conducted the present study to examine the correlation of response to three-item questionnaire

Table 3: Correlation between predictor variables

	Anticipated Pain	Anxiety	Anticipated Analgesics	Sum of 3 items questionnaire	Pain on LA infiltration
Anticipated pain					
Pearson coefficient		0.228**	0.458**	0.869**	0.272**
Significance		0.007	0.0	0.0	0.001
Anxiety					
Pearson coefficient	0.228**		0.324**	0.548**	0.263**
Significance	0.007		0.00	0.0	0.002
Anticipated analgesics					
Pearson coefficient	0.458**	0.324**		0.749**	0.308**
Significance	0.0	0.00		0	0
Sum of 3 items questionnaire					
Pearson coefficient					0.303**
Significance					0

*** Correlation is significant at the 0.01 level (2-tailed)*

Table 4: Models for regression analysis

Model	R	R Square	Adjusted R Square	Std. Error of The estimates	Change stastics				
					R suare change	F change	df1	df 2	Sig. F change
1	0.190[a]	0.036	0.029	1.59554	0.036	5.045	1	134	0.026
2	0.206[b]	0.042	0.028	1.59654	0.006	0.832	1	133	0.363
3	0.268[c]	0.072	0.05	1.57786	0.029	4.116	1	132	0.043
4	297[d]	0.088	0.06	1.56958	0.017	2.397	1	131	0.123

[a] Predictors; (constant) Anxiety. [b] Predictors; (constant) Anxiety, Anticipated pain. [c] Predictors; (constant) Anxiety, Anticipated pain, Anticipated analgesics need. [d]Predictors; (constant) Anxiety, Anticipated pain, Anticipated analgesics need, Pain on LA infiltration

Table 5: ANOVA for regression analysis models

ANOVA[e]					
Model	**Sum of Squares**	**df**	**Mean Square**	***F***	**Sig.**
1					
Regression	12.842	1	12.842	5.045	0.026[a]
Residual	341.128	134	2.546		
Total	353.971	135			
2					
Regression	14.963	2	7.482	2.935	0.057[b]
Residual	339.007	133	2.549		
Total	353.971	135			
3					
Regression	25.336	3	8.445	3.392	0.020[c]
Residual	328.635	132	2.49		
Total	353.971	135			
4					
Regression	31.242	4	7.81	3.17	0.016[d]
Residual	322.729	131	2.464		
Total	353.971	135			

[a] Predictors: (Constant), anxiety. [b] Predictors: (Constant), anxiety, Anticipated pain. [c] Predictors: (Constant), anxiety, Anticipated pain, analgesic need. [d] Predictors: (Constant), anxiety, Anticipated pain, analgesic need, on LA. [e] Dependent Variable: post op evoked pain

and pain reported upon LA infiltration before spinal anesthesia to severity of postoperative pain in women undergoing CS.

The results of our study suggested that the sum of three item questions and pain reported by parturient during LA infiltration are weakly correlated to the postoperative pain at rest and these variables have only 7-8% predictive power. The difference in strength of association obtained in present study could be related to the difference in patient demographics. Majority of patients in our study were younger, unemployed and were educated up to high school. Unemployed subjects with basic level of education have been shown to experience high intensity of pain and feel strongly disabled by pain. [7,8] Despite presence of these factors signifying experience of high intensity of pain in our patient cohort only 50% of parturient requested tramadol for analgesia in first 24 hours. Difference in cultural beliefs around experience of pain could possibly explain these findings. Individuals from different cultural groups differ in their belief about the appropriateness of expressing pain. Nayak *et al.*[9] found that cultural influence accounted for 15% variance in pain response. In an experimental pain study involving volunteers from India and United States (US), they observed that Indian participants were less accepting of the overt pain expression than those in the US. Many patients in low resource countries accept the pain as a natural consequence following surgical intervention and it is not seen as a problem that requires clinical solution.[10] Sometimes patient may not volunteer to health care worker that they have pain unless directly asked. Health care workers are seen as 'all knowing' therefore should not have to ask questions regarding patient.[11] Another important consideration for discrepancy in tramadol consumption and postoperative pain severity is the relationship between reported pain and postoperative analgesic consumption, which is not linear but described as a sigmoid curve.[12,13]

We used different scale used for measurement of preoperative anxiety level. Pan *et al*.[6]. used 0-100 mm VAS score for both anticipated pain and anxiety level and 0-5 score for anticipated analgesic requirements. In our pilot group study, we found that 25% of patients had difficulty in quantifying anxiety levels separately from anticipated pain on 0-100 mm scale. We tried Amsterdam preoperative anxiety and information scale in few patients with it being translated to patient's vernacular language (Hindi). Even with this scale we noted that only some of the patients were able to use it appropriately. Finally, we used 6 Facial Visual Anxiety Scale for measurement of preoperative anxiety which has correlation coefficient level of 0.70 with State-Anxiety Inventory (STAI) questionnaire.[14]

In the present study, both postoperative pain at rest and evoked pain were observed to have weak correlation with three-item questionnaire. The association of the three-item questionnaire with evoked pain was not significant in contrast to pain at rest. Pan *et al.*[15] previously suggested that the mechanisms of resting and evoked pain are different and the psychological aspects of patient may contribute significantly in resting pain than evoked pain. They reported that resting pain after caesarean was predicted by two factors, thermal pain and unpleasantness and patient expectation ($r^2 = 0.26$, $P < 0.01$), evoked pain by thermal pain threshold in the back ($r^2 = 0.20$, $P < 0.009$).

The variability in the pain experienced by patients following same surgical procedure can be acknowledged by biopsychosocial model of pain.[16] It takes into account complex interactions between biological (e.g. genetics, hormones, endogenous opioids, surgical techniques), psychological (mood, coping, expectations) and social factors (education level, cultural belief, socio-economic status) in determining the experience of pain.

As the predictive modalities available in literature have weak to modest correlation with post CS pain, to improve the accuracy of prediction, it has been suggested to explore the combination of multiple modalities.[3] In our study we found that preoperative questions pertaining to psychological traits of patients explained only 7% variation in postoperative pain experience. Adding pain score during LA infiltration resulted in 8% prediction of variation. In the regression analysis we found that the extent to which individual predictor variables contribute to postoperative pain was not significant although

the overall models were found to be significant predictor of outcome variable. This may be attributed to the fact that predictors are moderately correlated to each other, they may carry the same information and removing one predictor doesn't make any difference. Therefore, we suggest that in future studies the predictive model for post CS pain should include the parameters from biological and social factors in addiction to psychological factors.

We acknowledge that our study has several limitations. First, similar to prior evidence previous CS being one of the common indications for elective CS, our study population had preponderance parturient with previous CS.[17,18] The experience of previous CS might have affected the predictor variables in our study. Second the anxiety scale used in present study although has good correlation with gold standard STAI, is not commonly utilized in other trials. Third, although technique of CS at our center is standardized, any variation in surgical steps which are known to influence postoperative pain such as uterus exteriorization or closure of peritoneum which might have occurred out of necessity was not accounted.[19,20]

Fourth, parturients who were in labor were not excluded; although our study population had few such patients (2%). Anxiety levels in the prenatal period in pregnant women is influenced by multiple factors such as age, parity, care and education services received in antenatal period, perceived social support. As anxiety is complex interplay of multiple factors and parturient in labor represented a small proportion of our cohort, it is unlikely that result might have been affected.

Conclusion

The three item questionnaire and pain on LA infiltration before placement of spinal anesthesia in women undergoing CS have mild correlation to postoperative pain and has low predictability to explain its variance in our patients. As our patient population was remarkably distinguished from previous studies, modification of these tools by incorporating other domains of postoperative pain would be worthwhile.

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Conflicts of interest
There are no conflicts of interest.

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