

Efficacy of Comforting Manoeuvres in Reducing Anxiety in Patients undergoing Caesarean Section under Regional Anaesthesia- Randomised Control Trial

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ABSTRACT

Introduction: Comforting manoeuvres like hand holding and calming conversation with the parturients may decrease anxiety among them by establishing a rapport and building confidence and trust to alleviate fear.

Aim: Evaluation of role and effectiveness of comforting manoeuvres (hand holding and calming conversation) in relieving patient's anxiety and subjective satisfaction undergoing caesarean section in regional anaesthesia.

Materials and Methods: This was a single-blind randomised control trial conducted in the Department of Anaesthesiology and Critical Care, Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India, from February 2022 to June 2022. There were 144 parturients, in the age group 18-40 years, American Society of Anaesthesiology (ASA) II, and admitted for Caesarean section under regional anaesthesia. Patients were randomised into four groups- control group (C)- group 1, only calming conversation (CC)- group 2, only Hand Holding (HH)- group 3 and Hand Holding and Calming Conversation (CH)- group 4. Demographic details of the patient, Visual Analogue Scale (VAS) for anxiety, Blood Pressure (BP), Heart Rate (HR), Respiratory Rate (RR) and patient satisfaction score on a 1-5 Likert scale were noted preoperatively. VAS was noted preoperatively and postoperatively for all groups.

Patient Satisfaction Score (PSS) was noted postoperatively. The HR, Mean Arterial Pressure (MAP), and RR were noted every five minutes for 20 minutes, then every 10 minutes till the end of the surgery, and 30 minutes after surgery. Any anxiolytic medication used intraoperatively was documented for all groups.

Results: Total of 144 participants were analysed with 36 patients in each of four groups. Mean age (years) for group 1 was 23.36, group 2 was 23.25, group 3 was 23.17, and group 4 was 23.22. Baseline VAS was similar in all the groups. Postoperative VAS differed significantly- group 1 was 3.33±0.926, group 2 was 1.53±0.845, group 3 was 1.47±0.845 and group 4 was 1.11±0.708. PSS also differed significantly- for group 1 was 2.42±0.732, group 2 was 3.50±0.697, group 3 was 3.67±0.717 and group 4 was 3.92±0.692. Stabilisation of haemodynamics in terms of BP, HR and RR was significantly better in all three interventional groups as compared to the control group.

Conclusion: All three manoeuvres (hand holding, calming conversation alone and in combination) were equally effective in reducing perioperative anxiety, stabilising the haemodynamics and improving patient satisfaction in parturients undergoing caesarean section under regional anaesthesia. Comforting manoeuvres are simple, easy to practice and without any financial implication.

Keywords: Anxiolytic therapy, Calming conversation, Haemodynamics, Hand holding

INTRODUCTION

Anxiety is frequent in preoperative patients, which can be multifactorial in origin, including ignorance and misinformation about procedures, fear of surgery and anaesthesia, complications including nausea or inadequate analgesia, unfamiliar environment, separation from close ones, poor rapport with caregivers, or previous unpleasant experience [1-4]. Preoperative anxiety may cause an aggravated stress response that leads to increased catecholamine release, higher pulse rate, blood pressure, and respiratory rate: more autonomic fluctuations burdening patients cardiorespiratory and overall physiology [5-7]. An anxious patient may be uncooperative and affect the success of blocks while increasing the demand for perioperative anaesthetics and analgesics, making it challenging for the caregiver to manage the patient to the best outcome [4,8]. Higher anxiety can make the perioperative course unpleasant and traumatic for awake patients undergoing surgery in regional anaesthesia, hampering their overall satisfaction [9].

Patients undergoing obstetric/gynaecological procedures are more prone to have a high level of anxiety. Regional anaesthesia is the preferred technique in these subsets of patients and has become a marker of quality due to its vast benefits over general anaesthesia [10-12]. Anxiolytic pharmacological agents in pregnant females

posted for caesarean section presents a dilemma for both caregiver and patient for fear of potential harm to the foetus [13]. Use of non pharmacological strategies, including good communication with the patient, preoperative informative videos and bulletins, music, aroma therapy, companion husband during surgery, etc., are alternative approaches [14,15]. Hand holding and calming conversation may decrease perioperative anxiety among pregnant females by establishing rapport and building confidence and trust to alleviate fear [16,17]. However, no study combined hand holding and calming conversation in a parturient posted for caesarean before.

This study was aimed to assess the role and effectiveness of comforting manoeuvres of hand holding, calming conversation and a combination of hand holding and calming conversation in relieving patients anxiety undergoing caesarean section in regional anaesthesia and their effect on patients overall satisfaction. The study aimed primarily to measure the efficacy of comforting manoeuvres (hand holding and calming conversation alone and in combination) in relieving parturient's anxiety undergoing caesarean section under regional anaesthesia. Secondary outcomes being measured were overall patient's experience to regional anaesthesia in caesarean section and effect of comforting manoeuvres on usage of rescue analgesia in such patients.

MATERIALS AND METHODS

The single-blind randomised control trial was conducted in the Department of Anaesthesiology and Critical Care, Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India, from February 2022 to June 2022. The study was approved from the Biomedical Research Ethics Committee of the institute (EC/NEW/INST/2020/874). The study was registered under clinical trial registry- India (CTRI No. CTRI/2022/02/040482). Witnessed informed consent was taken from patients.

Inclusion criteria: Pregnant patients aged 18-40 years, ASA II [18] admitted for Caesarean section under regional anaesthesia were recruited.

Exclusion criteria: Those patients who had history of psychiatric/neurological disorder, head injury, drug abuse, alcohol abuse, and psychological trauma in the past six months, any life-threatening medical complications, multipara (>2 previous birth), foetal distress, patient/attendant preference for general anaesthesia and refusing to participate were excluded from the study.

Sample size estimation: It was done based on mean difference heart rate among groups in study by Sriramka B et al. This mean difference of 1.4 with 2.1 standard deviation was considered. The confidence interval was 95%, 80% power and alpha level of 0.05 [19].

Study Procedure

Patients were randomly divided into four groups, with 36 patients per group, by permuted block randomisation:

Group 1: Control group (C)

Group 2: Only calming conversation (CC)

Group 3: Only hand holding (HH)

Group 4: Hand holding and calming conversation (CH)

The group allocations were done using permuted block randomisation technique so that they were random in order but the desired proportion were achieved within each block. Patients were told about the intraoperative hand holding and calming conversation, non pharmacological intervention, and informed written consent was taken in the preoperative waiting room. Demographic details, Blood Pressure (BP), Heart Rate (HR), and Respiratory Rate (RR) of patients were noted preoperatively. Patients were asked to estimate their anxiety on a "Visual Analogue score" of 1-10 [20].

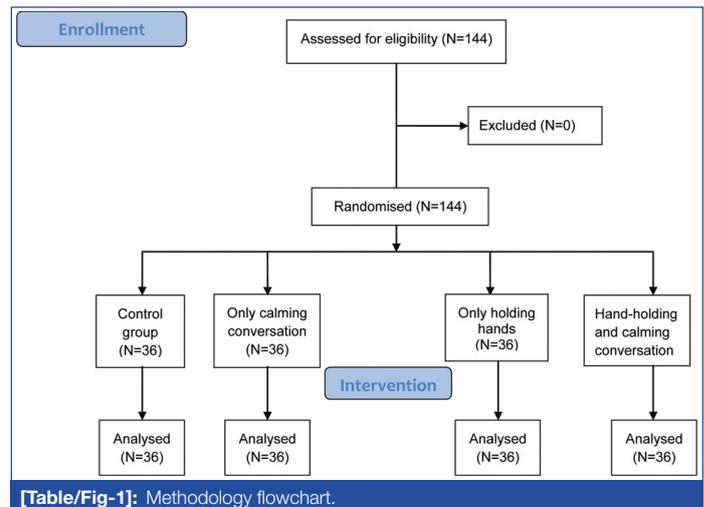
Group 1: No comforting manoeuvres were used in the control group. After recording the demographics, baseline haemodynamics values (BP, HR, RR) and preoperative VAS parturients were taken up for the procedure.

Group 2: Calming conversation was started in the preoperative waiting room by answering the patient's questions, explaining the procedure, position during anaesthesia and surgery, expected duration, and recovery. The calming conversation continued to prompt positive thinking. Simple questions were asked: What will be the baby's name? What does this name mean? Who decided? What is your job? Who came with you today? Who will help you after discharge, your mother or mother-in-law? Where are you from? Do you have a sister or brother? Where do you live? What will be the horoscope of the baby and yours? [16].

Group 3: Initial assessment was same as for Group 2. Hand of the patient was held by female resident gently ensuring the comfort of the patient after giving regional anaesthesia and was continued until the end of surgery. No calming conversation was done.

Group 4: Initial assessment was same as for Group 2 and 3. The calming conversation started in the preoperative waiting room by answering the patient's questions and explaining the procedure, position during anaesthesia and surgery, expected duration, and recovery. The calming conversation was continued to prompt positive thinking, same as for group 2. The hand of the patient was held by a female resident, gently ensuring the patient's comfort after

giving regional anaesthesia and continued until the end of surgery. Along with this, the calming conversation also continued throughout the surgery. All the group's HR, MAP, and RR were noted every 5 minutes for 20 minutes, then every 10 minutes till the end of the surgery, and 30 minutes after surgery. Any anxiolytic medication used intraoperatively was documented for all groups [Table/Fig-1].



[Table/Fig-1]: Methodology flowchart.

Postoperatively for all groups, patients were asked to give an estimate of their anxiety on a "Visual Analogue score" of 1-10 and to rate patient satisfaction on a Likert scale : 1- totally unsatisfied, 2- unsatisfied, 3- not satisfied or unsatisfied, 4- satisfied, 5- totally satisfied. Only three patients received anxiolytic in the control. However, no patient required any anxiolytic drug in the interventional groups.

STATISTICAL ANALYSIS

The data was coded and entered into a Microsoft excel spreadsheet. The software program was analysed using the Statistical Package for Social Sciences (SPSS) version 20.0 (International Business Management (IBM) SPSS Statistics Inc., Chicago, Illinois, USA). Descriptive statistics included the computation of means and standard deviations. The Analysis of Variance (ANOVA) test (for quantitative data to compare two and more than two observations) with the post hoc Tukey test was applied. Level of significance was set at p-value ≤ 0.05 .

RESULTS

All four groups were similar for their age, and preoperative VAS [Table/Fig-2].

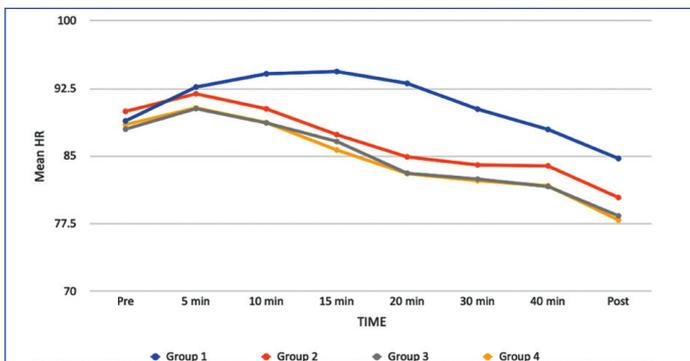
The VAS was significantly lower in all three interventional groups as compared to the control group. However, there was no significant difference observed among all three interventional groups when compared with each other (p-values > 0.05) [Table/Fig-3]. HR was found to be significantly lower at 10 minutes timepoint and afterwards in all three interventional groups as compared to the control group. However, there was no significant difference observed among all three interventional groups when compared with each other (p-values > 0.05) [Table/Fig-4]. Intragroup comparison of mean difference scores of PSS have been denoted in [Table/Fig-5].

Parameters	Group 1	Group 2	Group 3	Group 4	p-value
Age (years)	23.36 \pm 1.376	23.25 \pm 1.500	23.17 \pm 1.715	23.22 \pm 1.570	0.95
Preoperative VAS	6.78 \pm 0.898	6.64 \pm 0.931	6.56 \pm 0.969	6.47 \pm 1.055	0.58
Postoperative VAS	3.33 \pm 0.926	1.53 \pm 0.845	1.47 \pm 0.845	1.11 \pm 0.708	0.001
PSS	2.42 \pm 0.732	3.50 \pm 0.697	3.67 \pm 0.717	3.92 \pm 0.692	0.001

[Table/Fig-2]: Patient demographics, Preoperative VAS, Post VAS and PSS (data expressed as mean \pm SD). VAS: Visual analogue scale; PSS, patient satisfaction score

Variables	Groups	Mean difference	p-value	
Preoperative VAS	Group 1	Group 2	0.139	1.000
		Group 3	0.222	1.000
		Group 4	0.306	1.000
	Group 2	Group 1	-0.139	1.000
		Group 3	0.083	1.000
		Group 4	0.167	1.000
	Group 3	Group 1	-0.222	1.000
		Group 2	-0.083	1.000
		Group 4	0.083	1.000
	Group 4	Group 1	-0.306	1.000
		Group 2	-0.167	1.000
		Group 3	-0.083	1.000
Postoperative VAS	Group 1	Group 2	1.806*	<0.001
		Group 3	1.861*	<0.001
		Group 4	2.222*	<0.001
	Group 2	Group 1	-1.806*	<0.001
		Group 3	0.056	1.000
		Group 4	0.417	0.215
	Group 3	Group 1	-1.861*	<0.001
		Group 2	-0.056	1.000
		Group 4	0.361	0.411
	Group 4	Group 1	-2.222*	<0.001
		Group 2	-0.417	0.215
		Group 3	-0.361	0.411

[Table/Fig-3]: Intragroup comparison of preoperative and postoperative VAS (data expressed as mean difference). * =significant

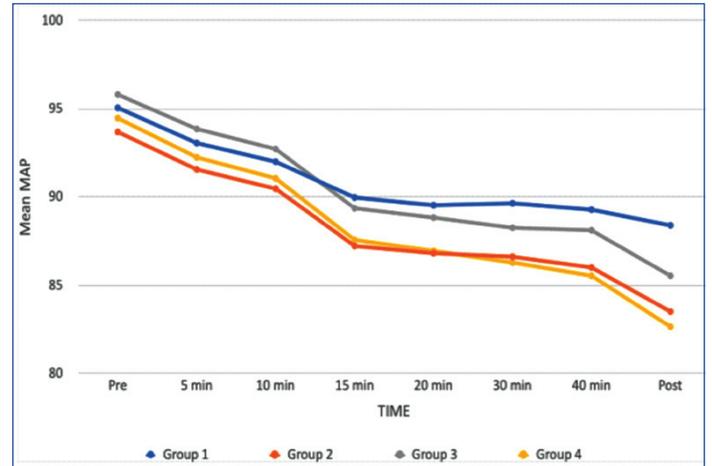


[Table/Fig-4]: Line diagram showing preoperative mean HR, mean HR at time points of 5 min, 10 min, 15 min, 20 min, 30 min, 40 min after initiation of surgery and mean HR in the postoperative period. HR: Heart rate; Pre: Preoperative; min: minute; Post: Postoperative. (significant p values with time points: 10 mins- 0.001, 15 mins- 0.001, 20 mins- 0.001, 30 mins- 0.001, 40 mins- 0.001 and postop- 0.001)

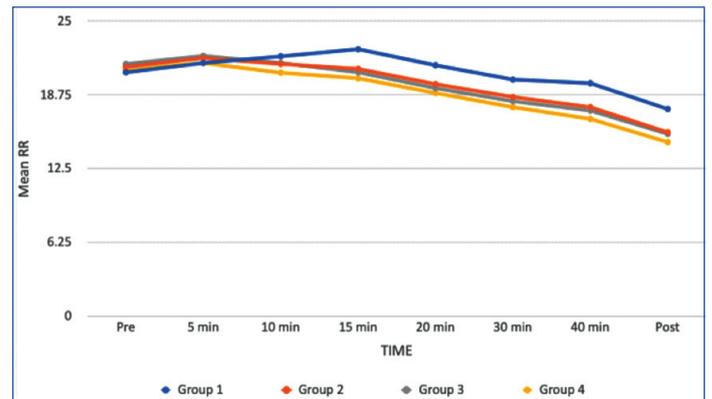
Groups	Mean difference	p-value	
Group 1	Group 2	-1.083*	<0.001
	Group 3	-1.250*	<0.001
	Group 4	-1.500*	<0.001
Group 2	Group 1	1.083*	<0.001
	Group 3	-0.167	1.000
	Group 4	-0.417	0.083
Group 3	Group 1	1.250*	<0.001
	Group 2	0.167	1.000
	Group 4	-0.250	0.824
Group 4	Group 1	1.500*	<0.001
	Group 2	0.417	0.083
	Group 3	0.250	0.824

[Table/Fig-5]: Intragroup comparison of Patient Satisfaction Score (PSS) (data expressed as mean difference). * =significant

The MAP was significantly lower at 15 min timepoint and afterwards in all three interventional groups as compared to the control group. However no significant difference among interventional groups was observed at most of time points during whole time line (p-values >0.05) [Table/Fig-6]. RR was significantly lower at 10 min timepoint and afterwards in all three interventional groups as compared to the control group. However, there was no significant difference observed among all three interventional groups when compared with each other (p-values >0.05) [Table/Fig-7].



[Table/Fig-6]: Line diagram showing preoperative mean MAP, mean MAP at time points of 5 min, 10 min, 15 min, 20 min, 30 min, 40 min after initiation of surgery and mean MAP in the postoperative period. MAP: Mean arterial pressure; Pre: Preoperative; min: minute; Post: Postoperative (significant p values with time points: 10 mins- 0.001, 15 mins- 0.001, 20 mins- 0.001, 30 mins- 0.001, 40 mins- 0.001 and postop- 0.001)



[Table/Fig-7]: Line diagram showing preoperative mean RR, mean RR at time points of 5 min, 10 min, 15 min, 20 min, 30 min, 40 min after initiation of surgery and mean RR in the postoperative period. RR: Respiratory Rate; Pre: Preoperative; min: Minute; Post: Postoperative. (significant p values with time points: 10 mins- 0.001, 15 mins- 0.001, 20 mins- 0.001, 30 mins- 0.001, 40 mins- 0.001 and postop- 0.001)

Other Outcomes

Mean patient satisfaction score was significantly higher in all interventional groups when compared to control group (p-value 0.001), but there was no significant difference among all three interventional groups (p-value 0.05) [Table/Fig-5].

DISCUSSION

The present study assessed the efficacy of comforting manoeuvres of hand holding, calming conversation, and both hand holding and calming conversation in reducing perioperative anxiety. Heart rate, mean arterial pressure, and respiratory rate was recorded, indicating not only the level of anxiety but also whether the anxiety reduction reflects the stabilisation of vitals.

In this study, patients in all four groups were comparable in age, baseline anxiety, heart rate, mean arterial pressure, and respiratory rate. A significant decrease in VAS score for anxiety, heart rate, mean arterial pressure, and respiratory rate was observed during

intraoperative and postoperatively in all three comforting manoeuvres groups compared to the control group.

Sriramka B et al., compared three groups of patients undergoing laparoscopic surgery who also received i.v. midazolam (group M), hand holding and conversation (group HC), and i.v. midazolam, hand holding and conversation (group HCM). The lowest Amsterdam Preoperative Anxiety and Information Scale (APAIS) score was in HCM, followed by group HC, and highest in group M [19]. In this study population an additional drug was used and anxiety score used was different from the present study. APAIS scale can only be used in the preoperative period. It was not used in the present study as the focus was on perioperative anxiety which included postoperative scoring as well. VAS was used in the present study as it is simple to interpret and has been validated to be used for anxiety in patients posted for caesarean section [20].

In the present study, the mean HRs were also significantly different in the groups after the intervention, but a significant difference was not found in MA. But Sriramka B et al. concluded that a combination of hand holding, conversation, and midazolam is best for alleviating preoperative anxiety in patients undergoing laparoscopic surgeries than either method alone [19]. However, in the present study, although mean postoperative VAS for anxiety was lowest in the group receiving the combination of hand holding and calming conversation, it was not significantly different from groups receiving either comforting manoeuvre alone.

Results of the present study are similar to those of Şimşek BK et al., who studied 156 patients to determine the effect of calming conversation on anxiety levels in Caesarean section [16]. They compared groups of 96 patients distracted with calming conversation during surgery and patients whose questions were answered, but no calming conversation was made. Patients completed State Trait Anxiety Inventory (STAI). Midazolam administration was higher in the control group. Thus, concluding calming conversation helps in reducing anxiety levels.

Intraoperative hand holding was found to be effective in reducing the physiological parameters such as heart rate, systolic blood pressure, and diastolic blood pressure among patients undergoing cataract surgeries in a study by Anuja BS et al., [21]. Most patients perceived intraoperative hand holding as beneficial in relieving anxiety. The potential of hand holding and hand massage for reducing anxiety in patients undergoing surgery under regional anaesthesia was validated by few others too [22,23].

Significant improvement was seen in physiological parameters of systolic blood pressure and heart rate with unaffected mean arterial pressure, diastolic blood pressure, and respiratory rate after 15 minutes of non therapeutic hand massage on same-day surgical patients by Li Z et al [24]. In the present study, all three interventional groups showed significant stabilisation in terms of haemodynamics as compared to the control group. However, no significant difference was observed in haemodynamics among the interventional groups when compared with each other.

In the present study, the overall subjective patient satisfaction score was significantly higher in all interventional groups compared to the control group. Still, no significant difference was observed when compared with each other. Similar enhanced overall clinical experience of surgical patients were reported by Li Z et al., after 15 minutes of non therapeutic hand massage, and 100% of patients recommended hand massage for other patients in their study [24]. According to a systematic review by Doyle C et al., patient experience is consistently positively associated with patient safety and clinical effectiveness across a wide range of disease areas, study designs, settings, population groups, and outcome measures [25].

Limitation(s)

Assessment of more elaborate subjective anxiety scores intraoperatively and biochemical markers like cortisol levels, norepinephrine, epinephrine,

etc., can be used to correlate variations in anxiety levels better, which can be taken care of in future studies.

CONCLUSION(S)

It is evident that hand holding and calming conversation effectively reduce perioperative anxiety and stabilise heart rate, mean arterial pressure, and respiratory rate in pregnant patients posted for caesarean section under regional anesthesia when used either alone or in combination. All three manoeuvres (hand holding, calming conversation alone and in combination) were equally effective in reducing perioperative anxiety and stabilising the haemodynamics in parturients undergoing caesarean section under regional anaesthesia. These comforting manoeuvres are simple, easy to practice, without any financial implication and increase overall subjective patient satisfaction, potentially improving patient safety and clinical outcomes. Incorporating simple practices can improve empathy and patients' confidence while having a friendly atmosphere.

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