

Effect of hand-holding and conversation alone or with midazolam premedication on preoperative anxiety in adult patients—A randomised controlled trial

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ABSTRACT

Background and Aims: Anxiety causing stress is most profound before surgery. Anxiolytics are used routinely to combat perioperative anxiety. Studies have shown that hand-holding and communication are useful in reducing anxiety levels intraoperatively. This study compares the effectiveness of the same with pharmacological interventions in allaying preoperative anxiety.

Material and Methods: This is a three-arm parallel-group randomised controlled trial. A total of 90 adult patients aged <45 years and of American Society of Anesthesiologists (ASA) grade 1–2, undergoing laparoscopic surgery were enrolled in this study. Patients received either intravenous (IV) midazolam (group M) or hand-holding and conversation (group HC), or a combination of IV midazolam and holding and conversation (group HCM) in the preoperative room. Anxiety, heart rate (HR) and mean blood pressure (MBP) were recorded before and 20 minutes after the intervention. Anxiety was measured using the Amsterdam preoperative anxiety and information scale. The analysis of covariance (ANCOVA) test was done to analyse the difference between the groups. **Results:** The mean anxiety scores were significantly different in the three groups ($p = 0.04$) after intervention, with the lowest score in group HCM, followed by group HC and the highest score in group M. The mean heart rates were also significantly different in the three groups after intervention but MBP was not significantly different in the three groups. **Conclusion:** A combination of hand-holding and conversation and midazolam is best for allaying preoperative anxiety in patients undergoing laparoscopic surgeries than either method alone.

Key words: Anxiety, interview, midazolam, preoperative period, touch

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INTRODUCTION

Anxiety before surgery is an unpleasant feeling associated with fear and illness.^[1,2] It activates the sympathetic nervous system increasing catecholamine release, glucocorticoid levels, heart rate (HR) and blood pressure. It also affects the immune responses and is thus associated with more postoperative complications.^[3] Anxious patients require a higher dose of anaesthetics and also have more autonomic fluctuation. Studies have shown that the incidence of anxiety is high in the preoperative room ranging from 11% to 80% in adults undergoing surgery.^[1,4] The application of monitors and the noises of alarms lead to a surge in anxiety levels.^[5] Therefore, there is a need for interventions to reduce the anxiety of patients in preoperative settings.

Psychological support may inhibit stress and may decrease the intensity of pain and anxiety. Studies have found that continuous information to the patient significantly reduced the patient's anxiety.^[5,6] Hand-holding was reported to be effective in reducing anxiety during cataract surgery under local

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anaesthesia.^[7,8] Anaesthesiologists have been using anxiolytics to relieve stress in clinical practice.^[9,10] Therefore, there is a need to identify the effective intervention that could relieve the preoperative patient anxiety. The current study compares the physical intervention hand-holding with conversation and the common pharmacological drug midazolam in relieving preoperative anxiety in adult patients undergoing laparoscopic abdominal surgeries.

MATERIALS AND METHODS

It was a single centric, three-arm parallel-group and prospective randomised controlled trial with an allocation ratio of 1:1:1. Patients undergoing laparoscopic cholecystectomy or appendectomy under general anaesthesia between January and March 2020 were recruited at a single tertiary care centre in Eastern India. The study received approval from the institutional ethical committee and was registered in the clinical trial database. Participants in the age group of 18–45 years and American Society of Anesthesiologists (ASA) grade 1–2 were enrolled after obtaining a written informed consent. Patients taking beta-blocker medication and those with psychiatric disorders were not included in the study. Patients with alcohol or drug dependence and smokers were also excluded.

The sample size was calculated in Openepi software version 3^[11] based on a previous study by Brand *et al.*,^[12] in which the post-intervention anxiety scores in the intervention (hand-holding group) and control groups were 1.31 and 2.89 and SD of 1.69 and 2.58, respectively, the sample size was calculated to be 30 in each group to find the same difference with a 95 per cent confidence interval and a power of 80%. The patients were randomised to one of the three groups: Group M- received 0.05 mg/kg of midazolam made up to a volume of 5 ml with normal saline intravenously (IV); Group HC received hand-holding and conversation with 5 ml of normal saline IV and or Group HCM received hand-holding and conversation and 0.05 mg/kg of midazolam made up to a volume of 5 ml with normal saline IV in the preoperative room of general surgery/gastrosurgery operation theatre complex. The IV line was secured by the indoor nurse in the ward or cabin before shifting to the preoperative room.

The primary outcome was anxiety which was measured using the Amsterdam preoperative anxiety and information scale (APAIS). The secondary outcomes were HR and mean blood pressure (MBP). The APAIS score

has a total of six questions, each with a score of 0–4.^[13] The HR and MBP were measured at the brachial artery in the patient's right upper arm by noninvasive automated devices (GE Datex ohmeda aspire, Madison, USA).

After recording the baseline parameters (HR, MAP and APAIS scores), the patients were given IV midazolam or saline as per the group allocation and then the patient's hands were touched with warm hands and held with medium pressure by one of the three nurses (trained for hand-holding) by the method used by Knable *et al.* for 20 minutes.^[14] Conversation with the patient was in the form of spoken information in their local language (Odiya) regarding the surgical and anaesthesia procedure and the answers to queries regarding the same by an anaesthesia resident doctor or one of the researchers (BS, DM, MK and JS). The anxiety scores and haemodynamic parameters were recorded 20 minutes after the intervention. The APAIS questionnaire score was translated in Odiya using forward–backward translation and validated. The data was filled in a proforma prepared for the study.

Randomisation was done using a computer-generated sequence number by a statistician. The group allocation was concealed in a sealed, opaque envelope that was opened when the patient arrived in the preoperative room. The blinding of participants and observers was only partial, i.e., Group HC and HCM but not for group M as it was not feasible.

Any untoward effect like sedation, adverse reaction due to drugs, tachycardia, or hypertension ($\geq 20\%$ of base value post-intervention) was also recorded. Sedation was assessed using the Ramsay sedation score.^[15]

Data were analysed using International Business Machine Statistical Package for Social Sciences (IBM SPSS) v20.0 licensed to the university. Normality of the data was checked using a Kolmogorov–Smirnov test/Shapiro–Wilk test. Analysis of covariance (ANCOVA) was used to compare the groups after correction for multiple comparisons. Post-hoc analysis was done for pair-wise comparison. *P* value < 0.05 was considered as significant.

RESULTS

Ninety patients, undergoing 69 laparoscopic cholecystectomies and 21 laparoscopic appendectomies were recruited in three groups (*n* = 30 each). As shown in the flow diagram,

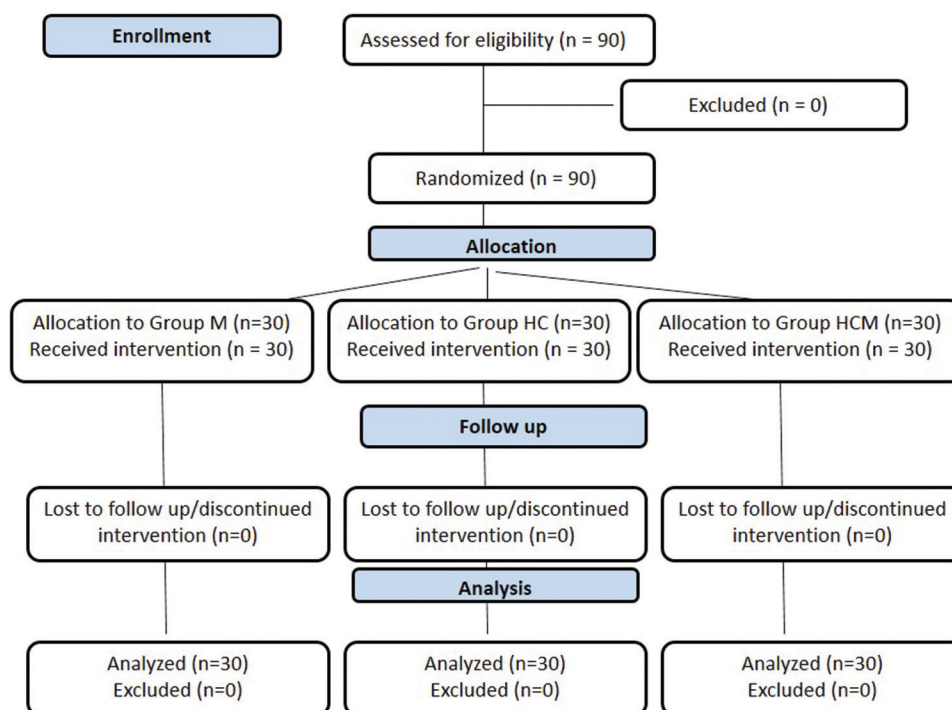


Figure 1: CONSORT flow diagram of patients

there were no losses or exclusions in any of the groups [Figure 1]. The baseline demographic and clinical characteristics for each group are depicted in Table 1.

The data were found to be normally distributed. The HR and APAIS scores were significantly different in the three groups after intervention but MBP was not significantly different in all the three groups [Table 2].

On pair-wise comparison, there was a significant difference in the HR between groups HCM and HC. However, the HR in group M did not significantly differ from HR in groups HCM and HC, as seen in the post-hoc analysis [Table 2]. The APAIS score showed a significant difference between the three groups with group HCM showing the lowest anxiety scores, followed by group HC and group M showing the highest anxiety scores [Table 2].

Four patients complained of nausea (two in group M, one each in groups HC and HCM), none of them had vomiting and five patients had mild sedation, i.e., 2/6 on the Ramsay sedation score (two in group M and three in HCM). There were no adverse effects in terms of drug reactions.

DISCUSSION

Surgery is an event associated with stress leading to fear and anxiety besides physical

Variables	Group M (n=30)	Group HC (n=30)	Group HCM (n=30)	
Age (years)	37.3 (4.2)	37.5 (4.6)	37.0 (5.4)	
Gender	Male	10 (33.3)	18 (60.0)	17 (56.6)
	Female	20 (66.6)	12 (40.0)	13 (43.3)
ASA grade	1	22 (73.3)	23 (76.7)	19 (63.3)
	2	8 (26.7)	7 (23.3)	11 (36.7)
BMI (kg/m ²)	25.9 (5.1)	25.4 (4.1)	25.7 (3.9)	

ASA - American Society of Anesthesiologists; BMI - Body mass index. Data is presented as mean (standard deviation) or number (%)

discomfort.^[16,17] Preoperative anxiety is an essential factor for intraoperative haemodynamic instabilities and postoperative complications (POC). Like increased pain, delayed healing and discharge from the hospital, POC leads to reduced patient satisfaction.^[18,19] Unfortunately, there are not many studies on interventions involving preoperative anxiety. This study investigated the role of hand-holding and conversation with a known anxiolytic used alone and in combination, looking at the preoperative anxiety levels. We found one method that effectively alleviated the anxiety in all the three parameters (HR, MBP and APAIS). Interestingly, the combination group fared better among the groups than the hand-holding group in terms of anxiety score and HR, though the MBP changes were insignificant. Our patient population included young ASA grade 1 and 2 cases; they have

Table 2: Primary and secondary outcomes in the three groups at baseline and post-intervention

Variables		Group M (n=30)	Group HC (n=30)	Group HCM (n=30)	P
Heart Rate (bpm)	Baseline	83.5 (15.6)	84.9 (12.6)	84.7 (15.2)	0.042 M vs. HC: 1 M vs. HCM: 0.26 HC vs. HCM: 0.04
	Post-intervention	77.9 (11.5)	80.5 (13.0)	74.9 (13.6)	
Mean Blood Pressure (mmHg)	Baseline	96.9 (9.9)	95.8 (9.9)	99.4 (8.7)	0.247
	Post-intervention	80.8 (9.7)	78.9 (12.4)	77.0 (11.5)	
Anxiety (APAIS)	Baseline	17.4 (4.3)	14.9 (5.1)	16.6 (4.9)	<0.001 M vs. HC: <0.001 M vs. HCM: <0.001 HC vs. HCM: 0.01
	Post-intervention	15.00 (3.6)	10.0 (3.8)	9.1 (2.7)	

APAIS - Amsterdam preoperative anxiety and information scale. Data is presented as mean (standard deviation) and compared between groups using ANCOVA. Adjustment for multiple comparisons done using Bonferroni

preserved autonomic reflexes and hence, the shift in HR is not reflected in the BP in them.

Moon *et al.* found that intraoperative hand-holding effectively reduced anxiety in patients undergoing cataract surgery under local anaesthesia.^[6] Similarly, Mokashi *et al.* used compared hand-holding to a patient alert device.^[7] They found a notable drop in anxiety levels in both groups. However, hand-holding was not significantly better when Anuja *et al.* evaluated the same.^[20] Studies have found that multimedia information, conversation and the opportunity to ask questions helped anxious patients.^[5,21,22] Kim *et al.* extrapolated the same in their review of patients undergoing vertebroplasty, wherein they made three groups namely control, hand-holding and hand-holding with a conversation.^[23] They found that the HC group did better than the hand-holding or control groups. Hence, we decided to club both hand-holding and communication as a single intervention in our study.

Habib *et al.* studied the effect of intravenous midazolam (0.015 mg/kg) in patients undergoing cataract surgery.^[24] Their results did not significantly differ among those who received versus those who did not, possibly because of the low dose in their elderly patients who needed to be awake. The researchers concluded that the diminished anxiety levels could be attributed to reassurance by health professionals. We have used a higher dosage (0.05 mg/kg) and found useful sedation in 2 of the 30 patients. Pekcan *et al.* studied the premedication drugs (diazepam 10 mg in the evening and midazolam 1.5 mg 15 minutes before) and found it to significantly reduce pre-anaesthetic anxiety levels as compared to placebo.^[25]

HR and blood pressure are markers of physiological anxiety. Farmahini *et al.* studied and found a decrease

in HR with another technique of tactile stimulation.^[26] Kim *et al.* and Farmahini *et al.* have observed a reduction in the systolic blood pressure (SBP) in hand-holding/hand massage group.^[23,26] We used MBP in place of SBP, considering it to be a better parameter from previous studies.^[27] We found a decrease in HR but not MBP. SBP is HR dependent and hence changes as seen by Kim *et al.*, whereas MBP (considers both SBP and diastolic blood pressure) might not change significantly as a result of auto-regulation.^[23]

Studies have found that surgeries in cancer patients and gynaecological procedures have higher anxiety levels among patients.^[16,17,28] We chose to study preoperative anxiety in less-morbid abdominal laparoscopies including appendectomy and cholecystectomy, which is easier to discuss with patients and more reassuring.

The strength of our study is that it is the first study discussing hand-holding and conversation both in the preoperative period, unlike others that are intraoperative. We also compared the pharmacological and physical methods in our research that makes it unique. The limitation of our study was that complete blinding was not possible in the study. Another limitation was that we did not assess patient satisfaction and anaesthetic or analgesic requirement in our study.

Future research can be directed to high-risk patient groups such as malignancy patients or patients with mutilating surgery. Studies can also be carried forward to intra-operative and post-operative periods to see anaesthesia requirements and post-operative recovery.

CONCLUSIONS

The study found that hand-holding and conversation, when included with midazolam, effectively reduced

anxiety in preoperative settings. While hand-holding with conversation alone is effective, only midazolam as premedication for anxiety is inferior. So we suggest combining hand-holding and conversation with midazolam to effectively reduce preoperative anxiety.

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Conflicts of interest

There are no conflicts of interest.

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