

A randomized controlled assessment of the effect of hand-holding and conversation alone or with midazolam premedication on preoperative anxiety

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Abstract

Aim: 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.

Methodology: It was a prospective randomised controlled trial in which patients undergoing laparoscopic cholecystectomy or appendectomy under general anaesthesia in IGIMS Patna for 1 year. Participants in the age group of 18–45 years and American Society of Anesthesiologists (ASA) grade 1–2 were enrolled. The patients were randomized to one of the three groups including 25 patients each: 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. Anxiety was measured using the Amsterdam preoperative anxiety and information scale (APAIS). The HR and MBP were measured at the brachial artery in the patient's right upper arm by non-invasive automated devices. 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 and the readings were analyzed thereafter.

Results: 75 patients, undergoing 56 laparoscopic cholecystectomies and 19 laparoscopic appendectomies were recruited in three groups ($n = 25$ each). 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. 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. 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. 5 patients complained of nausea (3 in group M, 1 each in groups HC and HCM), none of them had vomiting and 6 patients had mild sedation, i.e., 2/6 on the Ramsay sedation score (3 in group M and 3 in HCM). There were no adverse effects in terms of drug reactions.

Conclusion: 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 anxiolysis is inferior.

So we suggest combining hand-holding and conversation with midazolam to effectively reduce preoperative anxiety.

Keywords: Anxiolytic, Midazolam, Anxiety, Nervousness.

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Introduction

Anxiety is an emotional state characterized by apprehension and fear resulting from the anticipation of a threatening event. The incidence of preoperative anxiety ranges from 11% to 80% in adult patients and also varies among different surgical groups [1]. A number of patients have insufficient knowledge about anesthesia, thinking that an anaesthetist's job only consists of administering anesthetic agents into patients' bodies immediately before the start of the operation, after which they leave for other things while the patients are sleeping. Such misunderstanding may lead to higher anxiety levels and lower satisfaction levels. As a consequence, patients' postoperative recovery may be negatively affected due to psychoendocrinologic reactions [2, 3]. Preoperative anxiety may lead to various problems such as difficult venous access due to peripheral vasoconstriction, autonomic fluctuations, delayed jaw relaxation and coughing during induction of anesthesia, and increased anesthetic requirement. In addition, it also has been correlated with increased pain, nausea, and vomiting in the postoperative period; prolonged recovery; and increased the risk of infection [5]. High preoperative anxiety levels are related to an altered neuroendocrine response which might be deleterious in the postoperative period [6, 7].

A wide range of responses may be caused by anxiety. Physiological responses include tachycardia; hypertension; elevated temperature; sweating; nausea; and a heightened sense of touch, smell, or hearing [8]. Psychological responses include changes in behavior such as

increased tension, apprehension, nervousness, and aggression [9]. A lot of efforts have been made by different researchers to successfully implement the preoperative education, which resulted in the adoption of several following methods: (1) patients are verbally communicated the routine information; (2) pamphlets, PPT, short messages, video, and audio materials have been proposed; yet, previous studies have shown that these methods don't allow patients to have interactive communication with their attending anesthetists or the surgeons. Also, many patients lack the ability to fully understand them [10-12]; (3) preoperative education sessions provide the possibility of interactive communication with doctors, but the time cost may be unaffordable, and patients' compliance is not guaranteed [13].

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 [14, 15]. Hand-holding was reported to be effective in reducing anxiety during cataract surgery under local anaesthesia [16, 17]. Anaesthesiologists have been using anxiolytics to relieve stress in clinical practice [18, 19]. 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.

Methodology:

It was a prospective randomised controlled trial in which patients undergoing laparoscopic cholecystectomy or appendectomy under general anaesthesia in IGIMS, Patna for 1 year. 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 to be 25 in each groups to find the same difference with a 95 per cent confidence interval and a power of 80%. The patients were randomized 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/gastro surgery 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 [20]. The HR and

MBP were measured at the brachial artery in the patient's right upper arm by non-invasive automated devices.

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 [21]. Conversation with the patient was in the form of spoken information in their local language regarding the surgical and anaesthesia procedure and the answers to queries regarding the same by an anaesthesia resident doctor or one of the researchers. The anxiety scores and haemodynamic parameters were recorded 20 minutes after the intervention. The data was filled in a proforma prepared for the study.

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 [22]. Post-hoc analysis was done for pair-wise comparison. *P* value < 0.05 was considered as significant.

Results:

75 patients, undergoing 56 laparoscopic cholecystectomies and 19 laparoscopic appendectomies were recruited in three groups ($n = 25$ each). The baseline demographic and clinical characteristics for each group are depicted in Table 1.

Table 1: Demographic profile of patients

Variables		Group M (n=25)	Group HC (n=25)	Group HCM (n=25)
Age		35.6 \pm 5.5	35.2 \pm 5.2	34.9 \pm 5.8
Gender	Male	12	14	15
	Female	13	11	10
ASA Grade	1	19	19	16
	2	6	6	9
BMI (kg/m ²)		26.4 \pm 6.2	25.9 \pm 5.9	26.7 \pm 6.8

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

Variables		Group M (n=25)	Group HC (n=25)	Group HCM (n=25)
Heart Rate (bpm)	Baseline	84.1 ± 14.8	84.9 ± 15.7	84.4 ± 13.9
	Post-intervention	76.4 ± 12.5	79.9 ± 16.4	75.8 ± 18.3
Mean Blood Pressure (mmHg)	Baseline	97.2 ± 10.2	96.5 ± 11.4	99.6 ± 10.8
	Post-intervention	79.6 ± 9.8	80.0 ± 9.5	78.8 ± 9.2
Anxiety (APAIS)	Baseline	17.2 ± 5.2	15.4 ± 6.8	16.6 ± 5.7
	Post-intervention	14.8 ± 6.8	11.7 ± 3.6	10.2 ± 3.2

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. 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.

5 patients complained of nausea (3 in group M, 1 each in groups HC and HCM), none of them had vomiting and 6 patients had mild sedation, i.e., 2/6 on the Ramsay sedation score (3 in group M and 3 in HCM). There were no adverse effects in terms of drug reactions.

Discussion:

Patients preparing to undergo surgery should not suffer needless anxiety. Various steps have been taken to reduce preoperative anxiety like the use of premedicant drugs, preoperative visit by anesthetist, counseling, and videos. Sedative premedication is routinely administered to reduce preoperative anxiety. However, sedatives have their own side effects which can be minimized by the use of nonpharmacological interventions. Information about surgery reduces anxiety in the preoperative period [23, 24]. Preanesthetic consultation clinic

could be the right place to transmit the necessary information and clarify the patients' enquiries. A study conducted by Stephen *et al.* demonstrated that consultation at the preanesthetic checkup clinic has a statistically significant positive effect on alleviating patients' anxiety [25]. Preoperative visit by the anesthetist also plays a major role to relieve anxiety [26].

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 [27, 28]. 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 preserved autonomic reflexes and hence, the shift in HR is not reflected in the BP in them.

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 [29]. They found that the HC group did better than the hand-holding or control groups. Mokashi *et al.* used compared hand-holding to a patient alert device [30]. 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 [31]. Similarly, Moon *et al.* found that intraoperative hand-holding effectively reduced anxiety in patients undergoing cataract surgery under local anaesthesia [32]. Studies have found that multimedia information, conversation and the opportunity to ask questions helped anxious patients [33-35].

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 [36]. Kim *et al.* and Farmahini *et al.* have observed a reduction in the systolic blood pressure (SBP) in hand-holding/hand massage group [29, 36]. 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 [29, 37].

Conclusion:

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 anxiolysis is inferior. So we suggest combining hand-holding and conversation with midazolam to effectively reduce preoperative anxiety.

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