e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2024; 16(3); 302-306

Original Research Article

Determining the Effect of Pharmacological and Non-Pharmacological Approach in Relieving Preoperative Anxiety in Adult Patients Undergoing Laparoscopic Abdominal Surgeries

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Received: 10-01-2024 / Revised: 17-02-2024 / Accepted: 18-03-2024
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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to compare the physical intervention hand-holding with conversation and the common pharmacological drug midazolam in relieving preoperative anxiety in adult patients undergoing laparoscopic abdominal surgeries.

Methods: The present study was conducted at ESIC Medical College, Bihta, Patna, Bihar, India and patients undergoing laparoscopic cholecystectomy or appendectomy under general anaesthesia were recruited. 150 patients, undergoing laparoscopic cholecystectomies and laparoscopic appendectomies were recruited in three groups.

Results: There were females in all the groups except group M where males were predominant. Majority of the patients belonged to ASA I grade. 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.

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.

Keywords: Anxiety, interview, midazolam, preoperative period, touch

Introduction

Anxiety is common before any surgery which gives an unpleasant feeling and may lead to cognitive, behavioral and physical complaint that results in negative effects in their recovery. [1] Approximately one-third of individuals under regional anaesthesia are extremely nervous before the procedure. [2] High preoperative anxiety level is found in females, young patients and patients without prior history of surgery. [3,4] This anxiousness, may be due to many factors like fear of surgery, postoperative pain, need for assistance, type of surgery, prior anaesthesia experience and preoperative information, as well as being in a unfamiliar surroundings, financial insecurities and seeing advanced medical machinery in the hospital. [5-8]

Preoperative anxiety affects the postoperative outcomes in these patients, such as perception of pain, analgesic consumption, recovery time and length of hospital stay. [9-11] The activation of sympathetic nervous system releases catecholamines leading to tachycardia, hypertension, hyperthermia, increased muscle tone and sweating. [12] An increase in glucocorticoids due to this anxiety induced stress, causes reduced immune responses, a longer wound healing time,

increased infection rates, and electrolyte imbalance. [13-15]

Due to this negative impact of preoperative anxiety, different treatments have been evaluated including pharmacological and nonpharmacological approaches. [16] In pharmacological intervention benzodiazepines, mainly midazolam is most commonly used as premedication to decrease preoperative anxiety. Midazolam acts on GABA receptor to reduce anxiety, leading to sedation, anterograde amnesia, anticonvulsant effects and centrally produced muscle relaxation. [17] Midazolam has a fast onset of action and also allows rapid recovery.18 However, its use is associated with side effects like paradoxical reactions, over-sedation, decreased blood pressure, and respiratory depression.

The aim of the present study was to 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

The present study was conducted at ESIC Medical College, Bihta, Patna, Bihar, India and patients undergoing laparoscopic cholecystectomy or appendectomy under general anaesthesia were recruited. The study received approval from the institutional ethical committee and was registered in the clinical trial database. 150 patients, undergoing laparoscopic cholecystectomies and laparoscopic appendectomies were recruited in three groups. 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 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/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.[19] 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.[20] 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 (≥20% of base value post-intervention) was also recorded. Sedation was assessed using the Ramsay sedation score.[21]

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

Table 1: Demographic profile of patients in the three groups

Variables		Group M (*n*=50)	Group HC (*n*=50)	Group HCM (*n*=50)
Age (years)		38.4 (4.2)	36.4 (4.6)	39.0 (5.4)
Gender	Male	16	30	28
	Female	34	20	22
ASA grade	1	36	38	32
	2	14	12	18
BMI (kg/m^2)		25.9 (5.1)	25.4 (4.1)	25.7 (3.9)

There were females in all the groups except group M where males were predominant. Majority of the patients belonged to ASA I grade.

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

Variables		Group M (*n*=50)	Group HC (*n*=50)	Group HCM (*n*=50)	*P*
Heart Rate (bpm)	Baseline	82.6 (14.6)	85.6 (11.7)	83.7 (14.2)	0.044
	Post-intervention	78.6 (11.5)	80.7 (13.0)	75.8 (13.6)	M vs. HC: 1 M vs. HCM: 0.26
					HC vs. HCM: 0.04
Mean Blood Pressure (mmHg)	Baseline	97.8 (9.9)	94.6 (9.9)	98.2 (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
	Post-intervention	15.00 (3.6)	10.0 (3.8)	9.1 (2.7)	M vs. HC: <0.001
					M vs. HCM: <0.001
					HC vs. HCM: 0.01

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.

Discussion

Anxiety before surgery is an unpleasant feeling associated with fear and illness. [22,23] 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. [24] 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. [22,25] The application of monitors and the noises of alarms lead to a surge in anxiety levels. [26] Therefore, there is a need for interventions to reduce the anxiety of patients in preoperative settings.

Moon et al [27] found that intraoperative hand-holding effectively reduced anxiety in patients undergoing cataract surgery under local anaesthesia. Similarly, Mokashi et al [28] used compared hand-holding to a patient alert device. 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. [29] There were females in all the groups except group M where males were predominant. Majority of the patients belonged to ASA I grade. 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.

Kim et al [30] 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. 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 [31] studied the effect of intravenous midazolam (0.015 mg/kg) in patients undergoing cataract surgery. 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 [32] 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.

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.

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