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

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

International Journal of Current Pharmaceutical Review and Research 2026; 18(3); 2002-2007

Original Research Article

Comparative Evaluation of Pharmacological and Non-Pharmacological Interventions for Preoperative Anxiety in Adult Patients Undergoing Laparoscopic Surgery

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Received: 20-12-2025 / Revised: 19-01-2026 / Accepted: 20-02-2026

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Conflict of interest: Nil

Abstract:

Background: Preoperative anxiety is a common psychophysiological response among adults scheduled for laparoscopic surgery and is associated with altered haemodynamics, greater anaesthetic requirement, and poorer postoperative recovery. Both pharmacological agents and non-pharmacological strategies are used to relieve this anxiety, but comparative evidence in laparoscopic cohorts remains limited.

Objective: To compare the effectiveness of a pharmacological intervention (intravenous midazolam), a non-pharmacological intervention (structured preoperative education with guided relaxation), and a combination of both, in reducing preoperative anxiety among adults undergoing elective laparoscopic surgery.

Methods: A prospective, randomised, comparative study was conducted on 180 adult patients of American Society of Anesthesiologists (ASA) physical status I–II, aged 18–60 years, scheduled for elective laparoscopic procedures. Patients were randomly allocated into three equal groups: Group M (intravenous midazolam 0.03 mg/kg), Group NP (structured education with guided relaxation), and Group C (combined intervention). Anxiety was assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) and the State-Trait Anxiety Inventory (STAI-state) before and after the intervention. Heart rate, mean blood pressure, and patient satisfaction were recorded.

Results: Baseline demographic and anxiety parameters were comparable among groups ($p>0.05$). Post-intervention APAIS and STAI-state scores were significantly lower in Group C (10.2 ± 2.3 and 33.9 ± 5.8, respectively) than in Group M and Group NP ($p<0.001$). Heart rate and mean blood pressure showed a similar pattern, with the greatest stabilisation observed in Group C. Patient satisfaction scores were highest in the combined group (8.8 ± 1.0, $p<0.001$).

Conclusion: A combination of pharmacological premedication with non-pharmacological psychological preparation provides superior anxiolysis, haemodynamic stability, and patient satisfaction compared with either modality used alone in adults undergoing laparoscopic surgery.

Keywords: Preoperative anxiety; Midazolam; Non-pharmacological intervention; Laparoscopic surgery; Anaesthesia premedication; Patient satisfaction.

DOI: 10.25258/ijcpr.18.3.330

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Introduction

Preoperative anxiety is a state of apprehension, uncertainty, and heightened autonomic arousal that develops in patients awaiting an impending surgical or anaesthetic procedure [1]. It represents one of the most frequently under-recognised problems in perioperative care, with reported prevalence estimates ranging from 60% to 92% depending on the population studied, the type of surgery, and the assessment tool used [2]. Anxiety before surgery is not a benign emotional state; it activates the hypothalamic-pituitary-adrenal axis and the sympathetic-adrenal-medullary system, resulting in tachycardia, hypertension, elevated catecholamine and cortisol levels, and an increased requirement for induction and maintenance anaesthetic agents [3]. Several studies have also demonstrated a strong correlation between unaddressed preoperative anxiety and the severity of postoperative pain,

delayed wound healing, prolonged hospital stay, and a higher incidence of emergence delirium and maladaptive behaviour after discharge [4,5].

Laparoscopic surgery, although minimally invasive, is not exempt from this psychological burden. Patients frequently harbour fears related to general anaesthesia, unfamiliar surgical technology, conversion to open surgery, and postoperative outcome, all of which contribute to a distinct anxiety profile in this surgical subgroup [6]. Predictors of heightened preoperative anxiety identified in the literature include female sex, younger age, lower educational status, prior negative surgical experience, and lack of adequate preoperative information [7,8]. Recognising and addressing these predictors forms the basis of individualised anxiolytic strategies in modern anaesthetic practice.

Pharmacological anxiolysis, most commonly with benzodiazepines such as midazolam, has long been the mainstay of preoperative anxiety management because of its rapid onset, reliable sedative-anxiolytic effect, and amnesic properties [9,10]. Early controlled trials established that intramuscular and intravenous midazolam premedication produces significantly lower anxiety scores compared with placebo or opioid-based regimens, without unduly prolonging recovery in ambulatory settings [11,12]. However, pharmacological premedication is not without drawbacks: excessive sedation, respiratory depression, paradoxical reactions, delayed discharge, and interference with early mobilisation have all been documented, particularly in elderly or day-care surgical patients [13].

These limitations have generated growing interest in non-pharmacological approaches, including structured preoperative education, relaxation training, guided imagery, therapeutic communication, and simple physical reassurance such as hand-holding [1]. Evidence suggests that clear preoperative communication using information sheets or verbal counselling meaningfully reduces anxiety scores and improves patient cooperation without any pharmacological risk (14). A randomised trial comparing hand-holding and conversation, midazolam, and their combination in adults undergoing laparoscopic surgery found that the combined approach produced the greatest reduction in anxiety, suggesting a possible synergistic effect between pharmacological and psychological strategies [1].

Despite this accumulating evidence, direct comparative data specific to adult laparoscopic surgical cohorts remain relatively sparse, and clinical practice continues to vary widely between institutions and individual anaesthesiologists. Most anaesthesiologists endorse premedication, yet a substantial proportion simultaneously rely on non-pharmacological reassurance, indicating uncertainty about which approach — or combination — offers the optimal balance of efficacy and safety [15]. Against this background, the present study was undertaken to comparatively evaluate the effectiveness of a pharmacological intervention (intravenous midazolam), a non-pharmacological intervention (structured education with guided relaxation), and their combination, in reducing preoperative anxiety and stabilising haemodynamic parameters among adult patients undergoing elective laparoscopic surgery. We hypothesised that combined pharmacological and non-pharmacological anxiolysis would outperform either modality used in isolation.

Materials and Methods

Study Design and Setting: This prospective, randomised, comparative study was conducted in the Department of Anaesthesiology of a tertiary care teaching hospital over a period of twelve months, following approval from the Institutional Ethics Committee and registration in the institutional clinical trial registry. Written informed consent was obtained from all participants prior to enrolment.

Study Population: A total of 192 adult patients scheduled for elective laparoscopic surgery under general anaesthesia were screened, of whom 180 met the eligibility criteria and were enrolled. Inclusion criteria were age 18–60 years, ASA physical status I or II, and willingness to provide informed consent. Patients with a known psychiatric illness, chronic use of anxiolytic or sedative medication, history of substance dependence, hearing or cognitive impairment precluding participation in the educational intervention, allergy to benzodiazepines, or emergency surgical indication were excluded.

Randomisation and Grouping: Eligible patients were randomly allocated in a 1:1:1 ratio using a computer-generated random number sequence with allocation concealment through sequentially numbered, opaque, sealed envelopes into three groups of 60 patients each: Group M received intravenous midazolam 0.03 mg/kg administered in the preoperative holding area 20 minutes before shifting to the operating room; Group NP received a structured, nurse-led preoperative educational session using illustrated information sheets together with a 15-minute guided relaxation and controlled breathing exercise; and Group C received both interventions in combination.

Outcome Assessment: The primary outcome was the change in anxiety score, assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) and the State-Trait Anxiety

Inventory (STAI-state), recorded at baseline (on arrival in the preoperative holding area) and again 20 minutes after completion of the assigned intervention. Secondary outcomes included heart rate, non-invasive mean arterial blood pressure, and a ten-point patient satisfaction score recorded on the first postoperative day by an assessor blinded to group allocation.

Statistical Analysis: Data were analysed using SPSS software (version 26.0). Continuous variables were expressed as mean ± standard deviation and compared using one-way analysis of variance (ANOVA) followed by post-hoc Tukey testing. Categorical variables were expressed as frequencies and percentages and compared using the chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 180 patients completed the study, with 60 patients in each of the three groups; there were no dropouts or protocol deviations. The overall mean age of the study population was 38.0 ± 9.2 years, with the majority of patients falling within the 30–45-year age bracket, as depicted in Figure 1. The distribution of age was comparable across the three intervention groups, as illustrated in Figure 2, confirming that randomisation achieved balanced groups with respect to this potential confounding variable.

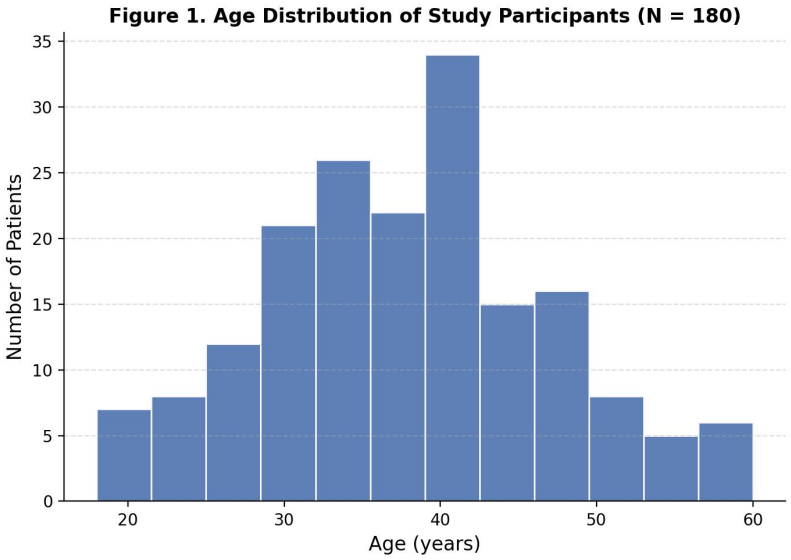

Figure 1: Age distribution of study participants (N=180)

Figure 1. Overall age distribution of study participants (N = 180). The majority of patients were between 30 and 45 years of age, with a peak in the 38–41-year interval, reflecting the typical age range of adults undergoing elective laparoscopic procedures at this institution.

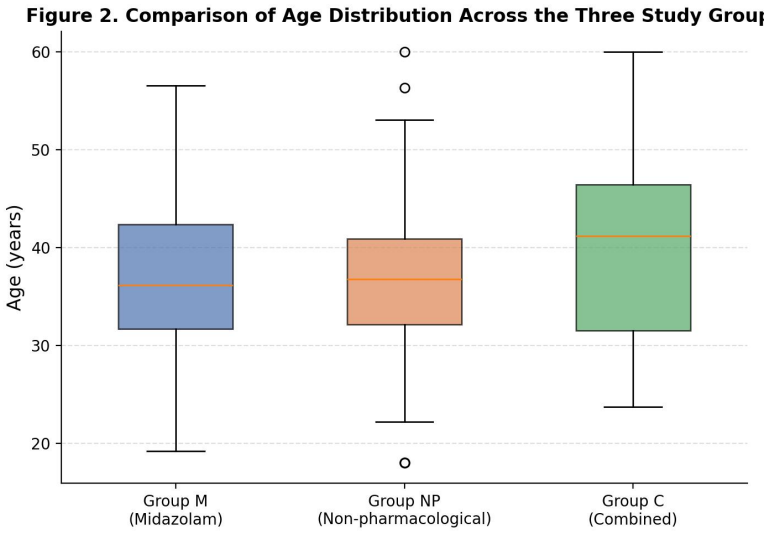

Figure 2: Comparison of age distribution across the three-study group

Figure 2. Comparison of age distribution across the three study groups (Group M, Group NP, and Group C). The median age and interquartile range were similar between groups, and no statistically significant difference in age was detected (p = 0.187), indicating adequate randomisation.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Group M (n=60)	Group NP (n=60)	Group C (n=60)	p-value
Age (years), mean ± SD	36.9 ± 8.8	37.2 ± 9.1	39.8 ± 9.2	0.187
Sex, Male/Female, n	27/33	25/35	29/31	0.642
BMI (kg/m²), mean ± SD	24.6 ± 2.9	24.9 ± 3.1	24.3 ± 2.7	0.512
ASA physical status I/II, n	38/22	36/24	40/20	0.735
Type of surgery, n (%)				
Laparoscopic cholecystectomy	34 (56.7)	32 (53.3)	35 (58.3)	0.812
Laparoscopic appendicectomy	14 (23.3)	16 (26.7)	13 (21.7)	
Diagnostic/other laparoscopy	12 (20.0)	12 (20.0)	12 (20.0)	
Previous surgical exposure, n (%)	21 (35.0)	19 (31.7)	23 (38.3)	0.699

Table 1 summarises the baseline demographic and clinical profile of the three groups. The mean age, sex distribution, body mass index, ASA physical status, type of laparoscopic procedure, and history of previous surgical exposure were statistically comparable across Group M, Group NP, and Group C ($p>0.05$ for all variables). This homogeneity confirms that the randomisation process was effective in distributing potential confounding factors evenly, allowing any subsequent differences in anxiety or haemodynamic outcomes to be attributed to the assigned intervention rather than to baseline imbalance between the study groups.

Table 2: Anxiety Scores and Haemodynamic Parameters

Parameter	Group M	Group NP	Group C	p-value
APAIS score, baseline	19.8 ± 3.2	20.1 ± 3.4	19.6 ± 3.0	0.641
APAIS score, post-intervention	12.4 ± 2.6	13.1 ± 2.8	10.2 ± 2.3	<0.001*
STAI-state score, post-intervention	38.6 ± 6.1	40.2 ± 6.4	33.9 ± 5.8	<0.001*
Heart rate (bpm), post-intervention	78.4 ± 7.9	80.1 ± 8.3	75.6 ± 7.2	0.014*
Mean BP (mmHg), post-intervention	88.3 ± 6.7	90.5 ± 7.1	85.9 ± 6.3	0.021*
Patient satisfaction score (0–10)	7.6 ± 1.2	7.9 ± 1.1	8.8 ± 1.0	<0.001*

Table 2 presents the anxiety and haemodynamic outcomes recorded before and after the intervention. Baseline APAIS scores were similar among the three groups, confirming comparable pre-intervention anxiety levels. Following intervention, Group C demonstrated the greatest reduction in APAIS and STAI-state scores, along with the lowest heart rate and mean blood pressure values, differences that were statistically significant compared with Group M and Group NP ($p<0.001$ and $p<0.05$, respectively). Patient satisfaction scores were also significantly higher in Group C, suggesting that combining pharmacological and non-pharmacological strategies produced a more favourable overall perioperative experience than either method used alone.

Discussion

The present study demonstrates that a combination of pharmacological and non-pharmacological interventions produces significantly greater reduction in preoperative anxiety, along with better haemodynamic stability and patient satisfaction, than either strategy administered independently in adults undergoing elective laparoscopic surgery. These findings are consistent with earlier work showing that combining hand-holding and conversation with midazolam premedication was superior to either intervention alone for allaying preoperative anxiety in a comparable laparoscopic surgical population [1], supporting the concept of a synergistic, rather than purely additive, anxiolytic effect when psychological reassurance is paired with pharmacological sedation.

The anxiolytic efficacy of midazolam observed in Group M corroborates decades of pharmacological evidence. Early comparative trials established that intramuscular midazolam produced anxiolysis and alertness superior to placebo and comparable to morphine-scopolamine combinations, without the sedative excess associated with strong opioid-based premedication [11]. Similarly, patient-controlled titration studies have shown that even small self-administered doses of intravenous midazolam significantly reduce anxiety scores while preserving early recovery profiles in ambulatory patients [12]. However, our results also affirm the previously reported ceiling effect of pharmacological premedication: despite significant anxiolysis, Group M patients did not achieve the

same degree of haemodynamic stabilisation as the combined group, echoing findings that midazolam premedication, while sedating, does not always translate into proportionate reductions in stress-related haemodynamic parameters [9].

The non-pharmacological arm of our study, incorporating structured education and guided relaxation, produced a meaningful reduction in anxiety scores that, although statistically smaller than the pharmacological and combined arms, remained clinically relevant. This aligns with evidence that clear preoperative communication and structured information delivery significantly lowers anxiety without any pharmacological risk, cost, or recovery delay [14]. The absence of sedation-related side effects in this group is a particularly important consideration for ambulatory or fast-track laparoscopic surgical pathways, where early mobilisation and rapid discharge are prioritised [13].

Our identification of comparable baseline anxiety across age groups, together with a fairly even age spread between 18 and 60 years, is consistent with epidemiological data indicating that preoperative anxiety is a near-universal phenomenon that is not confined to a narrow age band, although younger age has occasionally been reported as an independent predictor of higher baseline anxiety [7,8]. This reinforces the argument that anxiolytic strategies should be applied broadly across the adult surgical population rather than reserved for a specific demographic subgroup.

From a mechanistic standpoint, the superior performance of the combined intervention may be explained by the complementary pathways through which pharmacological and psychological strategies act. Midazolam produces anxiolysis primarily through gamma-aminobutyric acid (GABA)-mediated central sedation, whereas structured education and relaxation techniques act by improving the patient's cognitive appraisal of the impending procedure and reducing uncertainty-related sympathetic arousal [3]. Perioperative anxiety operates through activation of the hypothalamic-pituitary-adrenal and sympathetic-adrenal-medullary axes, and interventions addressing both the physiological and cognitive-behavioural components of this stress response would therefore be expected to yield an additive or synergistic benefit, as observed in our combined intervention group [3,5].

Our findings also carry practical implications for perioperative service design. Given that a considerable proportion of anaesthesiologists already combine premedication with reassurance-based strategies in routine practice [15], formal integration of structured preoperative education programmes alongside selective pharmacological premedication, rather than reliance on either strategy in isolation, may represent a more resource-efficient and patient-centred approach to anxiety management before laparoscopic surgery.

Limitation

This study was conducted at a single tertiary care centre with a relatively modest sample size, which may limit the generalisability of the findings to other populations and surgical settings. The non-pharmacological intervention could not be fully blinded to patients or the intervening nurse, introducing a potential for performance bias, although outcome assessors remained blinded. Anxiety was assessed using self-reported scales, which are inherently subjective, and long-term postoperative psychological outcomes were not evaluated. Cost-effectiveness analysis of the interventions was also beyond the scope of this study.

Conclusion

Combining pharmacological premedication with structured non-pharmacological psychological preparation offers superior relief of preoperative anxiety, better haemodynamic stability, and higher patient satisfaction compared with either approach used alone in adults undergoing elective laparoscopic surgery. Given its favourable efficacy and safety profile, this combined approach merits wider adoption in routine perioperative care pathways, supported by larger multicentric trials to confirm generalisability.

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