Original Article

Efficacy of Anxiolytic and Preoperative Counseling on Preoperative Anxiety Reduction: A Randomized Comparison Study

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Abstract

Background: The incidence of preoperative anxiety is high. Anxiolytic agents have been used to reduce preoperative anxiety for many years. Recently the role of non-pharmacological interventions like preoperative information through interviews, counseling, and verbal reassurance for the reduction in preoperative anxiety has been established. But, the efficacy of these non-pharmacological interventions and the anxiolytic agent has not been compared previously. In this study, we compared the effectiveness of oral alprazolam and preoperative counseling by an anesthesiologist for the reduction of preoperative anxiety.

Materials and Methods: A total of 110 patients were randomly divided into two groups. Group A received 0.5 mg oral Alprazolam tablets, the night before surgery. Group C received counseling from an anesthesiologist with a fixed protocol the night before surgery. Anxiety was assessed with a state-trait anxiety inventory (STAI) scale, and scores were assessed in the pre-anesthetic assessment room, at night before surgery before giving study interventions, and on the day of surgery before shifting to the operation room. Hemodynamic parameters and respiratory rate were monitored along with anxiety scores. Data were analyzed using an independent t-test, Chi-square test, and repeated variance analysis measures (ANOVA).

Results: Anxiety scores and hemodynamic parameters were comparable between the groups at all times of measurement. Anxiety scores in the alprazolam group were less than counseling group on the day of surgery, but this difference was not statistically significant.

Conclusion: Although treatment with Alprazolam resulted in lesser anxiety scores, overall, both methods were ineffective in reducing preoperative anxiety.

Keywords: Anxiety, Alprazolam, Counseling, Anesthesiologist

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Introduction

Anxiety is a subjective reaction consisting of feelings of tension, apprehension, nervousness, and worry leading to activation of the autonomic nervous system. The incidence of preoperative anxiety varies across the globe and ranges from 50-90% (1). The nature of anxiety varies from patient to patient due to various predisposing factors. High preoperative anxiety can

lead to an altered neuroendocrine response leading to excessive requirement of anesthetic agents, increased postoperative pain, prolonged hospital stay, and patient dissatisfaction (2, 3).

Different pharmacological and non-pharmacological methods have been tried to reduce preoperative anxiety, and the relationship between anxiolytic agents and preoperative anxiety was not established (4-6). Non-pharmacological methods like preoperative information through interviews, brochures, multimedia clips, and verbal assurance by different ways have been proven helpful in reducing preoperative anxiety scores. However, interviews in the pre-anesthetic assessment room and sharing of information by OT personnel have been proven to be better than other methods of communication (4, 7). According to the patients, communication with the doctor is the best way to reduce anxiety (8). Some studies have proven that the efficacy of anxiolytic agents and preoperative psychological preparation was equally effective (9, 10). These studies were on the pediatric age group with parent separation anxiety rather than preoperative anxiety, and midazolam was used as an anxiolytic agent. To our knowledge, no previous study has compared the efficacy of anxiolytic agents like alprazolam against preoperative counseling by an anesthesiologist on anxiety scores. This study aimed to compare the effectiveness of additional preoperative visits and counseling against pharmacological anxiolysis for the prevention of preoperative anxiety.

Methods

Ethical considerations: The trial was registered with the clinical trial registry of India (CTRI/2018/03/012574).

This prospective randomized study was conducted over two years after approval from the institutional ethics committee. Patients between 18-60 years of age, belonging to the American Society of Anesthesiologists (ASA) I and II, undergoing elective surgery under general or regional anesthesia were included in the study. Patients with hypertension, previous surgeries, and hearing or communication difficulties were excluded from the study. Patients with trauma, history of psychiatric disorders or antipsychotic medication, chronic pain, or under antipsychotic medications, pregnant patients, and daycare surgeries were excluded from the study.

Patients were randomly divided into groups C and A by a computer-generated list of random numbers. Informed and written consent was obtained after explaining the study protocol to the patients in their language understood. Preoperative assessment was done for patients in both groups according to routine protocols before surgery in the preoperative clinic. Patients were informed about the details of the usual mode of anesthesia for the procedure planned and the starvation protocol. The patient's anxiety was noted. All the queries of the patient were answered, and the STAI-State version of anxiety score, pulse rate (PR), non-invasive blood pressure (NIBP), and respiratory rate (RR)were noted. All patients received preoperative bedside visits by an anesthesiologist around 7.00-8.00 pm. on the night before surgery. Patients in group C were counseled as per fixed protocol which included the following nine points:

1. Introduction to attending anesthesiologist
2. Explanation of preoperative and post-operative fasting protocol and need for fasting.
3. Information regarding the planned surgical procedure
4. Information regarding planned anesthesia
5. What to expect when shifted to the preoperative holding room and then to the operation room (OR)
6. What to expect during regional and general anesthesia
7. Course of events during recovery & in the post-anesthesia care unit (PACU)
8. Answering any other specific queries of patients
9. Assurance regarding complete pain relief during and after the procedure

Group A patients orally received T. alprazolam 0.5 mg (Alprax 0.5mg, Torrent pharmaceutical ltd, India) the night before surgery. Group A patients received a visit by the anesthesiologist to assess anxiety scores, but counseling was not done. During this visit and on the day of surgery after arrival to the preoperative room, state-trait anxiety inventory (STAI) scores were collected, and PR, NIBP, and RR were noted.

The state-trait anxiety inventory was used to measure anxiety (11). STAI is a commonly used tool

for measuring anxiety as it differentiates between state anxiety (transient anxiety that varies according to the situation) and trait anxiety (stable personality disposition reflecting the general level of anxiety) even in individuals with lower educational backgrounds. The state anxiety scale (STAI Form Y-1), which consists of twenty statements that evaluate how the respondent feels "right now" at this moment, was given to the patients as a self-evaluation questionnaire form. In responding to the S-anxiety scale, the patients chose the number that best described the intensity of their feelings: (1) not at all, (2) somewhat, (3) moderately, and (4) very much so. The total anxiety score was calculated as per the scoring key provided with the scale. The sum of the scores on all items was taken as an anxiety score. STAI score > 40 was taken for the presence of anxiety (12). STAI scores were noted at three times intervals. First in the pre-anesthetic assessment room, second during the anesthesiologist visit the night before surgery, and third on the day of surgery in the preoperative holding room. The study's primary outcome was to compare anxiety scores between two groups. Secondary outcomes of the study were to compare hemodynamic parameters at the time of assessment, the night before surgery, and on arrival into the preoperative room on the day of surgery.

Statistical analysis was done using the statistical package for social sciences (SPSS) version 23. (SPSS Version 23.0, IBM, Armonk, NY, USA). All variables were tested for normal distribution using the Kolmogorov-Smirnov test. Patient characteristics and parameters at three different time intervals were compared using an independent t-test and were expressed as mean ± standard deviation (SD). The incidence of anxiety was compared using the Chi-square test and expressed as a percentage. Comparison between STAI scores at three different time intervals was compared using repeated measures of analysis of variance test (ANOVA). P value < 0.05 was taken as significant for a two-sided test. Sample size calculations were done based on a previous study (6). Forty-seven patients per group were needed for a significance of 5% and power of 80%. Fifty-five patients per group were included to allow dropouts.

Results

A total of 110 patients were randomized for inclusion in the study. Fifty-five patients were allocated to each group. All 55 patients in group C received the intervention. Fifty-three patients in group A received the intervention. Two patients did not receive intervention as hospital admission was delayed. Four patients in group A and one in group C were lost to follow-up. Forty-nine patients in group A and 54 in group C were statistically analyzed.

Demographic characteristics were comparable between the groups (Table 1). Surgery-related anxiety was more in both groups compared to anesthesia-related anxiety. The assessment room parameters were comparable between the groups (Table 2). The STAI scores at night before surgery were 39.08 ± 12.15 in group A and 40.72 ± 10.51in group C. This difference was not statistically significant. Other parameters measured the night before surgery were comparable between the groups (Table 3). STAI scores on the day of surgery before shifting to OR were slightly more in group C compared to group A (Table: 4). However, this difference was not statistically significant. (*P=0.08*) The incidence of anxiety was similar in both groups in the assessment room. (Table: 5) On the day of surgery, 46.9% of patients were anxious in the alprazolam group, and 61 % were anxious in the counseling group. STAI scores at three different time

Table 1: Demographic characteristics.

Parameters		Group A	Group C	P Value
Age (mean ± SD)		34.86±14.94	34.89±14.94	0.992
BMI (mean ± SD)		49±6.06	24±5.24	0.498
Gender (M/F) no		31/18	28/26	0.242
Type of Anesthesia planned - no (%)	Regional anesthesia	17(34.7%)	17(31.5%)	0.729
	General anesthesia	32(65.35)	37(68.5%)	
Surgery related anxiety		36 (73.5)	41 (75.9)	0.476
Anesthesia related anxiety		27(55.1%)	23(42.6%)	0.205

Table 2: Assessment room parameters.

Parameters	Group A (mean ± SD)	Group C (mean ± SD)	P value
STAI*	38.63±12.36	39.59±9.82	0.663
Pulse rate	77.24 ± 8.20	77.44 ± 7.62	0.898
Systolic blood pr	118.98 ± 8.95	118.70 ± 10.28	0.885
Diastolic blood p	77.20 ± 7.70	77.67 ± 8.41	0.772
Respiratory rate	16.78 ± 3.02	16.09 ± 2.03	0.176

* State trait anxiety inventory

intervals were comparable between the groups, and no statistical difference was noted after multiple measures of ANOVA (Table 6).

Discussion

In this study, we compared the efficacy of alprazolam and counseling to reduce preoperative anxiety. We found that the anxiety scores measured on the STAI scale were comparable between the groups. The hemodynamic parameters and respiratory rate were similar between the groups. Reduction in anxiety level was not seen in both groups.

Kumar *et al.* compared anxiety levels at three-time intervals when patients received information about surgery, anesthesia from the operating surgeon, and in the preoperative room from the anesthesiologist. All the patients received alprazolam 0.25 mg the night before surgery (13).

The operating surgeon and anesthesiologist counseled the patients in two separate sessions, but none was done the night before surgery. They used Amsterdam's preoperative anxiety and information scale. They found that combined (surgery and anesthesia-related anxiety) anxiety scores were higher on the day of surgery than the night before, and both alprazolam and counseling did not help reduce anxiety on the day of surgery.

Their results are similar to our study findings. Joseph *et al.* found that 0.5 mg of alprazolam given the night before surgery reduces anxiety significantly measured on the visual analog scale (VAS) (6).

Jan et *al.* found that alprazolam 0.5 mg given 90 minutes before surgery reduces anxiety. They used a global clinical score for the measurement of anxiety where patients themselves decide about the severity of anxiety (14).

In our study, we gave alprazolam the night before surgery, but the STAI scale did not show a significant reduction in anxiety scores. STAI state scale is the gold standard for measurement of anxiety which evaluates what patients feel at that moment.

The validity of various measurement scales for anxiety is proven. Still, there exists a disparity between the results as anxiety is a subjective feeling, and multiple factors are responsible for causing the increase in anxiety (15).

An observational study conducted on patients from the major hospitals in the Netherlands did not find any relationship between anxiolytic agents and the reduction in anxiety (5).

Table 3: Parameters at night before surgery.

Parameters	Group A (mean ± SD)	Group C (mean ± SD)	P value
STAI	39.08 ± 12.15	40.72 ± 10.51	0.464
PR	80.76 ± 9.61	80.48 ± 9.24	0.883
SBP	120.37 ± 9.71	119.44 ± 10.5	0.647
DBP	79.22 ± 8.15	78.35 ± 8.84	0.605
RR	16.76 ± 3.32	16.37 ± 2.29	0.492

Table 4: Parameters on day of surgery.

Parameters	Group A (mean ± SD)	Group C (mean ± SD)	P value
STAI	37.88±11.39	41.80 ± 11.63	0.088
Pulse rate	82 ± 7.61	81.65 ± 7.66	0.615
Systolic blood pressure	120.29 ± 11.20	121.74 ± 10.03	0.488
Diastolic blood pressure	79.76 ± 8.44	79.52 ± 8.52	0.888
Respiratory rate	16.59 ± 3.0	16.26 ± 2.17	0.519

Sayedhejazi *et al.* compared preoperative psychological preparation done on the night before surgery against oral midazolam given on the day of surgery in children between 2-10 years (9). They found that both groups had reduced STAI scores comparable to those on the day of surgery. Our results are similar to theirs. Sola *et al.* compared pharmacological, non-pharmacological, and combination efficacy in reducing preoperative anxiety and did not find any difference between the three interventions (10). Our results also state that there was no difference in efficacy between alprazolam and the counseling group. Marinelli *et al.* found that the counseling group's STAI scores were significantly reduced compared to the control group. The baseline STAI scores were comparable between the groups. The STAI scores reduced significantly after counseling by a clinical psychologist and training on stress management and self-efficacy-targeted coping strategies (16). In our study, counseling was done by an anesthesiologist based on common factors responsible for preoperative anxiety, but a reduction in anxiety scores was not seen. Powell *et al.*, in their meta-analysis, could not prove the effect of psychological preparation on preoperative anxiety due to low-quality evidence (17). A previous study by Akkamahadevi *et al.* comparing various methods of preoperative counseling found a reduction in STAI scales with all the methods in patients

Table 5: Incidence of anxiety at the three stages of measurement.

	Group A N (%)	Group C N (%)	P-Value
Assessment room	25 (51%)	28 (51.9%)	0.993
Night before surgery	25 (51%)	35 (64.8%)	0.156
ODS anxious	23(46.9%)	33 (61.1%)	0.149

Table 6: STAI scores at three-time intervals.

Parameter	Group A	Group C	P value
Assessment room	38.63±12.36	39.59 ± 9.86	0.663
Night before surgery	39.08±12.15	40.72 ± 10.51	0.464
On the day of surgery	37.88±11.39	41.80 ± 11.63	0.088

undergoing surgery under regional anesthesia. In that study, STAI values and statistical significance of decrease were not mentioned (18). In our study, the decrease in STAI scales was seen in the alprazolam group but was not statistically significant. In our study, we included patients undergoing both regional and general anesthesia. We think this was the limitation of our study. Another limitation was that we did not include an additional control group which could have helped assess the efficacy of both intervention methods.

Preoperative anxiety is multifactorial, and its severity depends on the surgery and anesthesia type. More studies are needed in elective surgeries and procedure-specific anesthesia populations to assess the efficacy of pharmacological and non - pharmacological intervention. The previous study has proven that counseling by psychological experts with goal-oriented managing techniques helps reduce anxiety even in major surgeries (17). More research is needed on non-pharmacological methods, including psychological counseling on preoperative anxiety.

Conclusion

We conclude that though anxiety scores were less in the alprazolam group, the difference between the two groups could not reach statistical significance. Overall, alprazolam and anesthesiologists' preoperative counseling do not help reduce preoperative anxiety.

Acknowledgment

None.

Conflicts of Interest

The authors declare that they have no conflict of interest.

References

1. Mulugeta H, Ayana M, Sintayehu M, Dessie G, Zewdu T. Preoperative anxiety and associated factors among adult surgical patients in Debre Markos and Felege Hiwot referral hospitals, Northwest Ethiopia. BMC Anesthesiol. 2018;18(1):155.
2. Ali A, Lindstrand A, Sundberg M, Flivik G. Preoperative Anxiety and Depression Correlate With Dissatisfaction After Total Knee Arthroplasty: A Prospective Longitudinal Cohort Study of 186 Patients, With 4-Year Follow-Up. J Arthroplasty. 2017;32(3):767-70.
3. Bayrak A, Sagiroglu G, Copuroglu E. Effects of Preoperative Anxiety on Intraoperative Hemodynamics and Postoperative Pain. J Coll Physicians Surg Pak. 2019;29(9):868-73.
4. Aust H, Rüsch D, Schuster M, Sturm T, Brehm F, Nestoriuc Y. Coping strategies in anxious surgical patients. BMC Health Serv Res. 2016;16:250.
5. Bucx MJ, Krijtenburg P, Kox M. Preoperative use of anxiolytic-sedative agents; are we on the right track? J Clin Anesth. 2016;33:135-40.
6. Joseph TT, Krishna HM, Kamath S. Premedication with gabapentin, alprazolam or a placebo for abdominal hysterectomy: Effect on pre-operative anxiety, post-operative pain and morphine consumption. Indian J Anaesth. 2014;58(6):693-9.
7. Davidson S, McKendrick D, French T. Preassessment clinic interview and patient anxiety. Saudi J Anaesth. 2016;10(4):402-8.
8. Kuzminskaitė V, Kaklauskaitė J, Petkevičiūtė J. Incidence and features of preoperative anxiety in patients undergoing elective non-cardiac surgery. Acta Med Litu. 2019;26(1):93-100.
9. Seyedhejazi M, Sharabiani BA, Davari A, Taghizadieh N. A comparison of preoperative psychological preparation with midazolam premedication to reduce anxiety in children undergoing adenotonsillectomy. Afr J Paediatr Surg. 2020;17(1-2):10-4.
10. Sola C, Lefauconnier A, Bringuier S, Raux O, Capdevila X, Dadure C. Childhood preoperative anxiolysis: Is sedation and distraction better than either alone? A prospective randomized study. Paediatr Anaesth. 2017;27(8):827-34.

11. Julian LJ. Measures of anxiety: State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), and Hospital Anxiety and Depression Scale-Anxiety (HADS-A). Arthritis Care Res (Hoboken). 2011;63 Suppl 11(0 11):S467-72.
12. Knight RG, Waal-Manning HJ, Spears GF. Some norms and reliability data for the State--Trait Anxiety Inventory and the Zung Self-Rating Depression scale. Br J Clin Psychol. 1983;22 (Pt 4):245-9.
13. Kumar A, Dubey PK, Ranjan A. Assessment of Anxiety in Surgical Patients: An Observational Study. Anesth Essays Res. 2019;13(3):503-8.
14. De Witte JL, Alegret C, Sessler DI, Cammu G. Preoperative alprazolam reduces anxiety in ambulatory surgery patients: a comparison with oral midazolam. Anesth Analg. 2002;95(6):1601-6, table of contents.
15. Boker A, Brownell L, Donen N. The Amsterdam preoperative anxiety and information scale provides a simple and reliable measure of preoperative anxiety. Can J Anaesth. 2002;49(8):792-8.
16. Marinelli V, Danzi OP, Mazzi MA, Secchettin E, Tuveri M, Bonamini D, et al. PREPARE: PreoPerative Anxiety REduction. One-Year Feasibility RCT on a Brief Psychological Intervention for Pancreatic Cancer Patients Prior to Major Surgery. Front Psychol. 2020;11:362.
17. Powell R, Scott NW, Manyande A, Bruce J, Vögele C, Byrne-Davis LM, et al. Psychological preparation and postoperative outcomes for adults undergoing surgery under general anaesthesia. Cochrane Database Syst Rev. 2016;2016(5):Cd008646.
18. Akkamahadevi P, Subramanian VV. The efficacy of different methods of pre-operative counselling on perioperative anxiety in patients undergoing regional anaesthesia. Indian J Anaesth. 2016;60(1):58-60.