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A DOUBLE-BLIND RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE ANXIOLYTIC AND SEDATIVE EFFECT OF PARIJATA PUSHPA ARKA IN PREOPERATIVE PATIENTS

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ABSTRACT

Preoperative anxiety is a common issue that can negatively impact the perioperative period. It can increase the need for anesthesia, cause heart problems, delay recovery after surgery, and worsen pain afterward. Ayurveda offers several herbal mixes that have calming properties. Parijata Pushpa Arka, made from the flowers of *Nyctanthes arbor-tristis*, is believed to have calming and sedative effects, but scientific proof of these claims is still lacking. This study aimed to assess the anxiolytic and sedative effects of Parijata Pushpa Arka in patients undergoing elective surgery using objective measures. The study is carried out as per international conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. We conducted a double-blind, randomized, placebo-controlled clinical study involving forty patients scheduled for elective surgeries. The participants were randomly divided into two groups. Group A received Parijata Pushpa Arka at ten milliliters twice daily for seven days before the surgery. Group B received distilled water as a placebo. We assessed anxiety levels using the State Trait Anxiety Inventory and the Amsterdam Preoperative Anxiety and Information Scale. We evaluated sedation levels with the Richmond Agitation Sedation Scale. We also recorded vital signs, including pulse rate and mean arterial pressure. We used Jamovi computer software for statistical analysis. The baseline demographic characteristics were similar in both groups. No significant differences were found between Group A and Group B regarding anxiety or sedation scores at any assessment point, with p-values greater than 0.05. The vital signs remained stable and comparable throughout the study. The study concluded that Parijata Pushpa Arka was safe and well-tolerated.

Keywords: Parijata Pushpa Arka, Preoperative anxiety, STAI, APAIS, RASS

INTRODUCTION

Preoperative anxiety is a common phenomenon among patients who are about to undergo elective surgery[1]. It is defined as the fear and apprehension, with some degree of psychologic distress, regarding anesthesia and surgical procedures associated with an operation. Anxiety is associated with increased sympathetic activity, altered hemodynamic responses, higher analgesic requirements, and prolonged recovery after surgery[2].

Traditional anxiolytic medications include benzodiazepines, which, although effective, may cause numerous adverse effects such as excessive sedation, respiratory depression, postoperative delirium, and delayed ambulation[3]. Thus, there is an increasing interest in investigating safer alternative therapies.

Ayurveda has given prime importance to Manas[4] (mind) for maintaining health and described a number of herbal drugs for mental calmness. Parijata (*Nyctanthes arbor-tristis* Linn.) is mentioned in classical Ayurvedic literature as having Tridoshaghna, Vedanasthapana, and sedative action[5]. Arka Kalpana (distillate preparation) is considered potent, quickly absorbable, and thus therapeutically effective because of its volatile principles[6-8].

Clinical evidence is, however, scant for such traditional claims about the anxiolytic and sedative effects of Parijata Pushpa Arka; hence, the present study was undertaken to scientifically evaluate its efficacy in the management of preoperative anxiety.

MATERIALS AND METHODS

Study Design and Setting

A double-blinded, randomized controlled clinical trial, with a pre- and post-test design, was conducted at Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital & Research Centre, Kuthpady, Udupi, Karnataka, India. The study is carried out as per international conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

Data Source

- Literary source: source from Classical Ayurvedic texts, contemporary medical literature, peer-reviewed journals, and electronic databases
- Medicine: Arka prepared from fresh Parijata Pushpa *Nyctanthes arbor-tristis* flowers in the Rasashastra laboratory

Sample source

Patients attending OPD of Shalyatantra at Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital & Research Centre, Kuthpady, Udupi, Karnataka, India, posted for elective surgery.

Sample Size

Sample size calculation was performed for STAI-S scores with α = 0.05 and power = 80%, yielding the required sample size of 20 patients per group.

Randomization and Blinding

Randomization was affected by the use of identical coded bottles prepared by a study coordinator. Both participants and investigators were blinded to group allocation until completion of data analysis.

Intervention

• Group A [Trial]: Parijata Pushpa Arka, 10 ml twice daily for 7 days preoperatively, is administered for 20 patients.

• Group B (Control): Only received distilled water – 10 mL twice a day, for a period of 7 days preoperatively, is administered for 20 patients.

Inclusion Criteria

- Patients aged 18-60 years
- Patients posted for elective surgery

Exclusion Criteria

- Patients on psychiatric medication
- Patients taking any form of sedatives or analgesics

Assessment Criteria

Subjective parameters

- State-Trait Anxiety Inventory (STAI)[9]
- Amsterdam Preoperative Anxiety and Information Scale (APAIS)[10]

Objective parameters

- Richmond Agitation-Sedation Scale (RASS)[11]
- Mean arterial pressure and pulse rate

Table 1: Comparison of Mean Arterial Pressure (MAP) Between Groups

MAP	Group A		Group B		Independent sample t test	
	Mean	SD	mean	SD	T	P
24 hrs BFS	99.0	7.2	97.4	5.2	0.841	0.406
12 hrs BFS	100.0	5.1	99.5	5.0	0.313	0.756
1 hr BFS	104.0	4.0	102.2	4.0	1.397	0.17
6 hrs AFS	98.7	6.1	97.2	4.2	0.862	0.394

Table 2: Comparison of Pulse rate between groups at different time points

Pulse rate	Group A		Group B		Independent sample t test	
	mean	SD	mean	SD	t	P
24 hrs BFS	78.4	8.8	78.6	8.1	0.075	0.941
12 hrs BFS	77.9	7.9	77.1	7.9	0.32	0.75
1 hr BFS	77.4	8.1	78.2	7.9	0.317	0.753
6 hrs AFS	77.7	8.3	78.2	7.0	0.206	0.838

Table 3: Comparison of Trait Anxiety (STAI T scores) Between Groups

Scale	Group A		Group B		Independent sample t test	
	mean	SD	mean	SD	T	P
STAI T	26.25	4.0	26.55	3.8	0.241	0.811

Table 4: Comparison of State Anxiety (STAI-S) Scores between groups across

STAI-S	Group A		Group B		Independent sample t test	
	mean	SD	mean	SD	t	P
24 hrs BFS	36.3	4.2	37.3	3.5	0.815	0.42
12 hrs BFS	37.4	4.2	38.25	2.5	0.772	0.445
1 hr BFS	45.5	8.6	46.1	5.8	0.26	0.796
6 hrs AFS	32.95	4.0	32.85	2.5	0.095	0.924
24 hrs AFS	28.0	3.9	28.45	3.2	0.394	0.696

Table 5: Comparison of Amsterdam Preoperative Anxiety and Information Scale Scores between groups

APAIS	Group A		Group B		Mann Whitney U test	
	Median	IQR	Median	IQR	z	P
24 hrs BFS	8	7.25 - 9	8	8 - 9	0.721	0.471
12 hrs BFS	9	8 – 9	9	8 - 9.75	0.726	0.468
1 hr BFS	11	9.25 - 12.75	11	10 - 13	0.397	0.691

Table 6: Richmond Agitation-Sedation Scale (RASS) Scores comparison between Groups at different time points

RASS	Group A		Group B		Mann-Whitney U test	
	Median	IQR	Median	IQR	z	P
1 hr BFS	0	0 – 0	0	0 - 0	0.000	1.000
1 hr AFS	-3	-3 - -3	-3	-3 - -3	0.698	0.485
2 hr AFS	-2	-2 - -2	-2	-2 - -2	0.411	0.681
6 hr AFS	-1	-1 - -1	-1	-1 - -1	0.593	0.553
24 hr AFS	0	0 – 0	0	0 - 0	0.000	1.000
3 days AFS	0	0 – 0	0	0 - 0	0.000	1.000

Statistical Analysis

Data were analyzed using Jamovi version 2.6.26.[12] Independent sample t-tests, chi-square tests, and Mann–Whitney U tests were applied [13-15]. Statistical significance was set at $p < 0.05$.

RESULTS AND DISCUSSION

Baseline demographic characteristics such as age, gender, religion, and socioeconomic status were comparable between the two groups, ensuring homogeneity. Anxiety levels assessed using STAI-S and APAIS increased progressively as surgery approached and decreased postoperatively in both groups, reflecting typical perioperative anxiety patterns.

However, intergroup comparison revealed no statistically significant difference in anxiety or sedation scores at any time point ($p > 0.05$). Hemodynamic parameters including mean arterial pressure and pulse rate remained within normal physiological limits in both groups throughout the perioperative period.

The present study evaluated the anxiolytic and sedative efficacy of Parijata Pushpa Arka in preoperative patients using validated psychometric scales and physiological parameters. Despite traditional Ayurvedic claims regarding the calming properties of *Nyctanthes arbor-tristis* the intervention did not demonstrate significant superiority over placebo.

These findings are consistent with several clinical studies on herbal anxiolytics, which report variable or nonsignificant effects when tested under controlled conditions. The strong placebo effect commonly observed in anxiety research may have contributed to the comparable outcomes in both groups.

The stability of hemodynamic parameters and absence of adverse effects indicate that Parijata Pushpa Arka is safe and well tolerated, aligning with reports that many herbal preparations exhibit minimal cardiovascular effects.

CONCLUSION

The primary objective of this double-blind randomized controlled clinical study was to evaluate the anxiolytic and sedative effects of Parijata Pushpa Arka in a population of 80 preoperative patients. Participants were randomized into two groups, each with 40 patients: Group A received Parijata Pushpa Arka (10ml twice daily) for seven days prior to surgery, while Group B received an identical regimen of distilled water. The study's primary outcome, as measured by the Amsterdam Pre-operative Anxiety and Information Scale (APAIS), the State-Trait Anxiety Inventory (STAI), and the Richmond Agitation Sedation Scale (RASS), revealed no statistically significant difference in anxiety and sedation levels between the two groups. This finding indicates that the administration of Parijata Pushpa Arka under the prescribed conditions does not produce a measurable anxiolytic or sedative effect.

This "negative" finding is a significant and valuable contribution to the scientific literature. It is essential for an evidence-based approach to clinical practice and for guiding future research away from unfruitful avenues. The lack of a demonstrable effect challenges the direct clinical applicability of traditional knowledge and prior non-human studies. Several factors may account for this outcome. The dosage of the arka may have been insufficient to produce a therapeutic concentration of active compounds, or the specific preparation method may have resulted in poor bioavailability. It is also possible that the routine preoperative psychological support and care received by all patients created a strong confounding effect, masking any potential subtle benefit of the intervention. The consistent use of the APAIS and STAI at multiple time points (seven days, 24 hours, 12 hours, and 1 hour before surgery) and the RASS measurements both before and after the procedure (2 hours before, and 2, 6, and 3 days after surgery) provides a robust dataset, strengthening the validity of this negative result.

In light of these findings, this study serves as a critical foundation for further, more refined investigations. Future research should consider exploring different dosages or alternative formulations of Parijata, or perhaps focus on a patient population with a higher baseline anxiety level. A larger-scale, multi-center trial would be necessary to definitively rule out a subtle effect that this study may have been underpowered to detect. By rigorously documenting this negative outcome, this thesis contributes to a more accurate and precise body of knowledge, helping to prevent the misapplication of a traditional remedy and directing future research toward more promising and impactful areas.

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