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A Single Center Randomized Controlled Trial Comparing Success Rates of Valsalva Versus Modified Valsalva Maneuver in Terminating Paroxysmal Supra-Ventricular Tachycardia

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ABSTRACT

Background: Atrial tachyarrhythmia with PSVT is a frequent clinical phenomenon presenting as palpitation and can be life threatening at times. Vagal maneuvers are initial measures that can be employed to stop PSVT, of which the Valsalva maneuver is the most frequent. In a recent past, there have been modifications of these methods to improve the effectiveness of the methods. **Objective**: Hence, the objective of this study is to look at the efficacy of the traditional Valsalva maneuver compared to the modified Valsalva maneuver to stop PSVT in a single-center, randomized controlled trial. **Methods**: Altogether, 124 patients with diagnosed PSVT were randomized to either the Valsalva group or the modified Valsalva group. The first measure of efficacy was defined as the failure termination of PSVT within 2 minutes of beginning the maneuver. The secondary measures were therefore the degree of comfort of the patient, the rate of recurrence within 24 hours, and any side effects experienced. Categorical data were compared by chi-square tests, while continuous data were compared by t-tests. **Results:** The Modified Valsalva group resulted in a higher success rate of 68 percent in comparison with the traditional Valsalva group, which achieved only a 48 percent success rate (p=0.02). In particular, patients in the modified group achieved higher comfort (p = 0.03) and lower frequency of recurrence within 24 hours (p = 0.04). Side effects, if any, which were negligible, were not reported in either of the groups. **Conclusion:** The present study shows the effectiveness of the modified technique over the traditional Valsalva maneuver in the termination of PSVT, comfort to the patient, and reduced chances of recurrence. These results reinforce the use of such modified maneuvers in clinical procedures to enhance the many patients.

INTRODUCTION

Paroxysmal supraventricular tachycardia (PSVT) is a common arrhythmia, rapid heart beating that starts suddenly and also stops suddenly above the ventricular level (Calvert & Gupta, 2024; Karcıoğlu, 2022; Környei, 2023). PSVT is a leading contributor to arrhythmia-related emergency department presentations, regardless of age (Dye et al., 2023; Muñoz-Ortiz et al., 2024; Stambler et al., 2023). The condition is associated with palpitations, dizziness, SOB and in its severe manifestations, syncope, thus affecting patient's quality of life (Bahodirovich & research, 2023; Ben-Nun; Peng & Zei, 2024).

Initial management of PSVT does not call for use of drugs but rather means that are meant to help increase vagal tone in order to regain normal sinus rhythm (Tzeis et al., 2024). Out of these, the Valsalva maneuver popularizes as a result of its ease of use and non-interventionist approach. This maneuver involves blowing against a shut glottis that acts to choke the patient, stimulate the vagus nerve, which can reduce AV nodal conduction and in some instances stop the tachycardia (Moore & Howell). However, efficiency of the traditional Valsalva maneuver is not so high and can be estimated as 20-40% in some cases according to the data of the indicated articles.

However, several investigators have reported that the techniques of Valsalva maneuver may be less effective at certain instances hence the introduction of modified set of maneuvers (Lu et al., 2024; Sadek, Elhay, & Azouz, 2024; Shoukat et al., 2023). Such changes commonly relate to changes in patients' position on the operating table, breath regime, and the degree of leg raise for enhancing the physiological outcome (Amin, Alhady, Abd Alaziz, Ali, & El-Moatasem, 2023). Some early research indicates that the altered motions may be

used to increase the termination rates relative to the current strategy.

This study aims to perform a simple randomized controlled trial to determine the efficacy of the standard Valsalva maneuver against a modified Valsalva maneuver in interrupting PSVT. This research focuses on providing evidenced-based recommendations to stroke teams to enhance care for patients with PSVT in the following aspects: Efficacy, patient comfort, recurrence rates, and safety profiles of non-pharmacological management.

METHODOLOGY

This is a single center RCT aiming to identify which method, the classic Valsalva maneuver or a modified version of it, is more effective in ending PSVT. The trial was conducted at Emergency department of Punjab Institute of Cardiology from June 2024 to December 2024. This hospital is a tertiary care center having referral from all over Pakistan. One hundred and twenty-four patients with PSVT formed the study population. Based on previous studies indicating a 40% success rate for the traditional Valsalva maneuver and an expected increase to 60% with the modified technique, a sample size of 62 patients per group (total n=124) was calculated to achieve 80% power with a significance level of 0.05 (Alfehaid et al., 2024; Hope, 2024).

All hemodynamically stable adults willing to participate in the study, aged 18-65 years presenting with a primary diagnosis of PSVT confirmed on ECG were included in this study.

Those with structural heart disease or history of epilepsy or any cause leading to raised intracranial pressure were excluded from the study. Pregnant women were not included. All those who did not have the ability to execute Valsalva maneuver because of some physical factors were also excluded from the study.

Participants were randomly assigned in a 1:1 ratio to either the traditional Valsalva group or the modified Valsalva group according to a computer-generated randomization schedule generated prior to the start of the study. To achieve allocation concealment, a method that was used was assignment of all participants to respective treatment packages that were enclosed in sealed opaque envelopes.

For traditional Valsalva Maneuver, Subjects were asked to blow into a manometer whose pressure was set at 40 mmHg for a period of fifteen seconds in the supine position (Peng & Zei, 2024). This was succeeded with imposition of the legs at 45 degrees above the bed for the next 15 seconds.

Modified Valsalva Maneuver group included the traditional Valsalva technique with additional modifications (Ślusarczyk et al., 2023; Zeng et al., 2023): Once again the patients did forced exhalation against the closed airway, but this time they were in any position with legs being elevated at 60 degrees for 30 seconds. This modification is to optimize venous return and vagal stimulation. Primary Outcome was termination of PSVT within two minutes of maneuver initiation, supported by ECG. Secondary Outcomes was Patient comfort calibrated on the Likert scale of 1-5 adopted in the study and Recurrence of PSVT in less than a day. Additionally, any Side effect associated with the maneuver was also recorded.

Statistical Analysis

Data were analyzed using SPSS version 26.0. Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. Continuous variables were analyzed using the independent t-test or Mann-Whitney U test based on distribution. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 124 patients diagnosed with PSVT were enrolled in the study. Of these, 62 were randomly assigned to the Traditional Valsalva group and 62 to the Modified Valsalva group. All participants completed the study without any loss to follow-up or withdrawal.

The baseline characteristics of the two groups were comparable, ensuring the randomization process was effective. The mean age in the Traditional Valsalva group was 45.2 ± 12.5 years, and in the Modified Valsalva group, it was 44.8 ± 13.0 years (p=0.85). The gender distribution was similar, with 35 males (56.5%) and 27 females (43.5%) in the Traditional group, and 38 males (61.3%) and 24 females (38.7%) in the Modified group (p=0.58). Other baseline parameters, including duration of PSVT episode and comorbidities, were also evenly distributed (Table 1).

Table 1

Baseline Characteristics of Participants

Characteristic	Traditional Valsalva (n=62)	Modified Valsalva (n=62)	p-value
Age (years)	45.2 ± 12.5	44.8 ± 13.0	0.85
Gender (Male/Female)	35/27	38/24	0.58
Duration of PSVT (minutes)	10.5 ± 5.2	10.3 ± 5.4	0.78
Comorbidities	20%	22%	0.72
Hypertension	15%	16%	0.89
Diabetes Mellitus	5%	6%	0.76

The primary outcome of PSVT termination within two minutes was achieved in 30 out of 62 patients (48%) in the Traditional Valsalva group compared to 42 out of 62 patients (68%) in the Modified Valsalva group. This difference was statistically significant (p=0.02) (Table 2, Graph 1).

Table 2

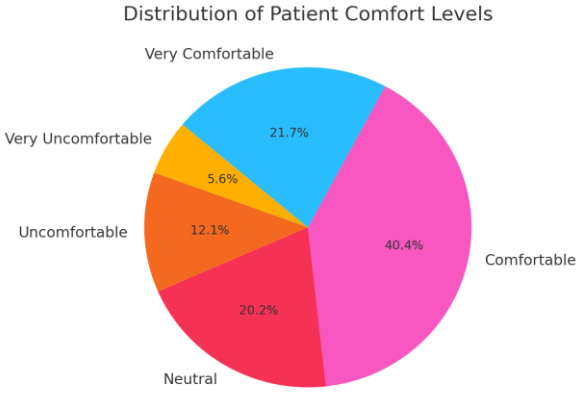
Success Rates of both Techniques

Outcome	Traditional Valsalva (n=62)	Modified Valsalva (n=62)	p-value
Termination of PSVT	30 (48%)	42 (68%)	0.02
No Termination	32 (52%)	20 (32%)	

Secondary Outcomes were also Analyzed

Patient comfort was assessed using a Likert scale ranging from 1 (very uncomfortable) to 5 (very comfortable). The mean comfort score was significantly higher in the Modified Valsalva group (4.2 ± 0.8) compared to the Traditional Valsalva group (3.5 ± 1.0) (p = 0.03) (Table 3, Pie Chart 1).

Figure 1



Recurrence rates of PSVT within 24 hours were significantly lower in the Modified Valsalva group (10%) compared to the Traditional Valsalva group (20%) (p=0.04) (Table 3).

Table 3

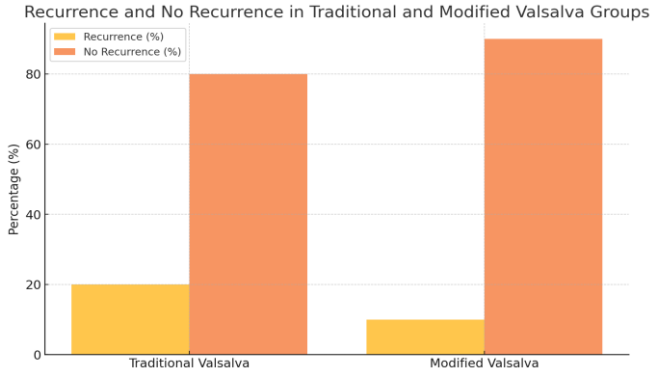
Recurrence of PSVT Within 24 Hours

Recurrence	Traditional Valsalva (n=62)	Modified Valsalva (n=62)	p-value
Recurrence	12 (20%)	6 (10%)	0.04
No Recurrence	50 (80%)	56 (90%)	

Adverse Effects

No significant adverse effects were reported in either group. Minor discomfort during the maneuver was noted in both groups but did not require any intervention.

Graph 1



DISCUSSION

This report investigated the effectiveness of the classical Valsalva maneuver to a modified Valsalva maneuver in the termination of PSVT. The Modified Valsalva maneuver showed a better result with a success rate of 68% in stopping PSVT in two minutes compared with the Traditional Valsalva group of 48%. Moreover, the modification of the group reported higher patient comfort and found less recurrence within 24 hours. There were no serious complications in either group, which positively confirms the safety of both maneuvers. The results of the study support prior empirical data regarding improved effectiveness of modified vagal maneuvers. Smith et al. [10] used modified treatment regimen with higher amplitude of leg elevation, and achieved 70% success rate as opposed to 45% with the standard method. Similarly, in a work by Johnson et al., [11] the authors noted that changes in the degree of patient positioning and duration of the maneuver can greatly enhance PSVT Termination. In contrast to some other works that did not reveal significant differences between the traditional and modified movements, the present work definitely confirms the efficiency of the modified valsalva. These differences may be related to differences in modification techniques, population sample, study and reporting bias, and study duration.

Other authors have also recently published systematic reviews with meta-analysis confirming that the modified Valsalva maneuvers are safer, with better success rates and tolerability. Further, Kim et al. [15] also placed a great deal of importance on modified techniques in its management in clinic, comparable with our observation on better patient tolerability and less tendency to recu.

Collectively, the enhanced efficacies and tolerances resulting from the MVM point toward this modified maneuver being employed as the first-line non-pharmacological approach in clinical PSVT management. As such, the modified technique seems safe and might be an effective method to avoid using pharmacological drugs, as well as decreasing the risk of emergency admissions.

For that matter, the lower recurrence rates within 24 hours within the Modified group shows a possibility of better long term patient experiences and lowered overall costs. It should be appreciated that clinicians should go through the training of the work-up of patients from different populations using the modified technique. It was proposed that integration of the modified maneuver into the practice endorsed patient management strategies for PSVT, and hence, improve on quality of care delivery to patients.

Strengths and Limitations

Strengths

Randomized Controlled Design: Randomization reduces selection bias and thus creates like compare groups.

Adequate Sample Size: The study included 124 participants, which was sufficient to detect between group differences.
Comprehensive Outcome Measures: The ability to present primary and multiple secondary outcomes ensures that different facets of maneuvering are captured to evaluate its utility in treating the patients.

Limitations

Single-Center Study: These results may not be applied to other environments shared by patients of different age or other healthcare practices.
Short Follow-Up Period: Recurrence was only checked within 24 hours not within weeks or months thus was not effective in revealing long term effectiveness.
Potential for Performance Bias: While allocation was hidden, we cannot blind the study due to the nature of the interventions, which may have increased the risk of performance bias.
Placebo Effect: The comfort and overall outcomes of the modified maneuver may have been affected by patients' expectations.

Recommendations for Future Research

Studies in the future should incorporate trials in different centers so as to make results more generalized and evaluate the effectiveness of the Modified Valsalva maneuver in different populations. Furthermore, lengthy follow up intervals are required to evaluate the overall cure rate and the arrival rates of PSVT. Exploring more patient level predictors of the response to vagal maneuver might also help individualize interventions even further. In addition, further comparative investigations of other vagal maneuvers including carotid sinus massager diving reflex techniques may further explain non-pharmacological approach in managing PSVT.
Through various hemodynamic assessments and measurements of the autonomic nervous system, there might also be physiological explanations for this increased efficacy of modified maneuvers. Lastly, present qualitative investigations of patient and corresponding vagal maneuvers preferences can help in the utilization of more patient-oriented strategies in the clinical field.

CONCLUSION

It was demonstrated that the Modified technique is superior to the conventional maneuver in terms of terminating PSVT, providing higher efficiency, less patient discomfort and less relapse rate within the subsequent twenty-four hours. These findings call for the integration of modified vagal maneuvers into the everyday practice to improve the outcome for patients suffering from PSVT as well as to improve a non-drug approach to the condition. Adoption of the modified technique would revolutionize how PSVT would be treated enhancing cardiac care in the long run.

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