

Original Contributions

INITIAL AND SUSTAINED RESPONSE EFFECTS OF 3 VAGAL MANEUVERS IN SUPRAVENTRICULAR TACHYCARDIA: A RANDOMIZED, CLINICAL TRIAL

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Abstract—Background: For acute termination of supraventricular tachycardia (SVT), vagal maneuvers, including the standard Valsalva maneuver (sVM), modified Valsalva (mVM) maneuver, and carotid sinus massage (CSM), are first-line interventions. There is no criterion standard technique. **Objective:** This prospective, randomized study was aimed at analyzing the success rates of these 3 vagal maneuvers as measured by sustaining sinus rhythm at the fifth minute and SVT termination. **Methods:** We conducted this prospective, randomized controlled study in an emergency department (ED). We enrolled all the patients who were admitted to the ED and diagnosed with SVT. We randomly assigned them to 3 groups receiving sVM, mVM, and CSM and recorded the patients' responses to the vagal maneuvers and SVT recurrence after vagal maneuvers. **Results:** The study was completed with 98 patients. A total of 25 (25.5%) instances of SVT were initially treated successfully with vagal maneuvers. The success rate was 43.7% (14/32 cases) from mVM, 24.2% (8/33) for sVM, and 9.1% (3/33) for CSM ($p < 0.05$). At the end of the fifth minute, only 12.2% (12/98) of all patients had sinus rhythm. Sinus rhythm persisted in 28.1% (9/32) of patients in the mVM group, 6.1% (2/33) of patients in the sVM group, and 3% (1/33) in the CSM group at the fifth minute ($p < 0.05$). **Conclusion:** mVM is superior to the CSM maneuver in terminating SVT and maintaining rhythm. We conclude that it is beneficial to use mVM, which is more effective and lacks side effects. © 2019 Elsevier Inc. All rights reserved.

Keywords—carotid sinus massage; modified valsalva; standard valsalva; supraventricular tachycardia; vagal maneuver

INTRODUCTION

Supraventricular tachycardia (SVT) is commonly presented in emergency departments (EDs) (1). Treatment options for SVT include vagal maneuvers, pharmacologic therapy, and synchronized cardioversion (2). Vagal maneuvers, such as the standard Valsalva maneuver (sVM) and carotid sinus massage (CSM), are appropriate first-line treatment options for patients with hemodynamically stable SVT. By increasing vagal tone, vagal maneuvers slow conduction in the atrioventricular (AV) node resulting in termination of AV nodal dependent re-entry tachycardias, such as AV nodal re-entry tachycardia and AV re-entry tachycardia. Studies have reported an approximately 25% success rate for vagal maneuvers, although the rate varies widely in the literature (6–54%) (2–4).

Currently, sVM likely is the most commonly used vagal maneuver to treat stable SVT. However, in sVM, patient performance of straining is often inconsistent. Many patients cannot perform a persistent blow for 15 s, and blowing pressure often is not measured. The success rate is relatively low (5–20%) (5,6). Recently, a

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study by Appelboam et al. described a modified Valsalva maneuver (mVM) as supine positioning with leg elevation immediately after the Valsalva strain with a much higher success rate of 43% (5). CSM, another vagal maneuver, is less commonly done and is not favored because of its invasiveness and potential for injury to the carotid vessel (2,3). It is important to perform the most effective vagal maneuver to reduce the number of patients who need medical emergency treatment.

Determining the effectiveness of vagal maneuvers is challenging because of the lack of randomized clinical studies. In addition, there are no up-to-date studies on SVT recurrence rates after successful attempts at vagal maneuvers before the initiation of intravenous treatment modalities. This prospective, randomized study was aimed at analyzing the success rates of 3 vagal maneuvers (CSM, mVM, and sVM) based on sustaining sinus rhythm at the fifth minute as confirmed by electrocardiography (ECG).

METHODS

Trial Design

This study was a single-center, prospective, randomized trial with stable, adult patients presenting with SVT at a research and training hospital's ED. We obtained written informed consent from the patients. The prospective study was conducted over an 18-month period from June 3, 2016, to November 10, 2017, and the university's ethics committee approved the study.

Participants

We included all patients >18 years of age who presented to the ED with SVT. We excluded the following patients: (1) those who were not confirmed to have SVT; (2) those who were not stable (instability was defined as having unstable angina, pulmonary edema, signs of poor cerebral perfusion, and indications for immediate cardioversion); (3) those who were pregnant; (4) those who had any contraindication to the Valsalva maneuver (VM) or CSM (e.g., aortic stenosis, recent myocardial infarction, glaucoma, retinopathy, cerebrovascular accident, history of transient ischemic attack, or presence of carotid bruit by direct auscultation); (5) those who had incomplete data; (6) those who had been previously included in this study; and (7) those who were unable to perform VM (i.e., lying flat and lifting the legs). Patients who met the inclusion criteria were randomly assigned (1:1:1) to undergo mVM in group 1, sVM in group 2, and CSM in group 3 using the block randomization method with a block size of 12.

Data Collection and Measurements

We performed the vagal maneuver with continuous monitoring of the patient's cardiac rhythm. We informed all the attending emergency physicians about the details of the project and the methodology of each technique. If tachycardia was not terminated by the vagal maneuver method, we administered adenosine as rescue medication and then other antidysrhythmic treatments according to guidelines (7). If the vagal maneuver was successful, we recorded a 12-lead ECG if return to sinus rhythm was achieved at 0, 1, and 5 min. If there was no recurrence of SVT at the end of the 2-h observation period, we discharged the patient with recommendations. We also recorded any adverse events, the applied maneuver and results, the time period from the beginning of symptoms, and the patients' demographic variables (e.g., age and sex), vital signs, ECGs, and medical treatment needed.

Interventions

In the CSM group, we placed the patient in a supine position with the head tilted to the opposite side, located the carotid sinus just below the angle of the mandible and applied finger pressure with a massaging motion first in an upward and downward direction then posteriorly and medially to compress the carotid sinus between the examiner's fingers and the patient's cervical vertebra for 10 s. If that was unsuccessful after 1–2 min, the carotid sinus on the opposite side was massaged in a similar manner. The first side selection was based on the nondominant hemisphere of the patient's brain.

In the sVM group, the researcher asked the patient, who was sitting vertically, to take a deep breath and push a plunger by blowing into a syringe connected to a sphygmomanometer for 20 s. The patient was required to reach an airway pressure of 30–40 mm Hg. We used standardized verbal instructions to help the participant achieve the target pressure and strain duration (6). In the mVM group, first we applied sVM. Then, the researcher suddenly brought patient to a supine position, and raised the patient's legs to a 45° angle (6).

Outcomes

The primary outcome of the study was comparison of the sustained success rates at the fifth minute of the application of the maneuver. The secondary outcome was comparison of the success rates immediately after the intervention and at the first minute of the application of the maneuver.

Sample Size Estimation

At the time of the writing of this protocol, no previous studies compared these 3 maneuvers, so this study was

planned as an interim analysis to estimate the final study sample size. After we recruited 57 patients for this prospective, randomized clinical study, we performed the first planned interim analysis. For comparison of the response rates at the fifth minutes, we calculated a sample size of 72 to achieve 90% power to detect an effect size (W) of 0.4214 using a 2 degrees of freedom χ^2 test with a significance level (alpha) of 0.05. At the first minute, a sample size of 129 achieved 90% power to detect an effect size (W) of 0.3137. For comparison of immediate response rates, a sample size of 184 achieved 90% power to detect an effect size (W) of 0.2628 for the same significance level. The sample sizes for the study's primary and secondary outcomes were estimated to be 78, 135, and 195, respectively.

Statistical Analysis

We reported normally distributed continuous variables with means, standard deviations, and 95% confidence intervals (CIs) and continuous variables with non-normal distribution with medians and interquartile ranges, while categorical variables with counts and frequencies (%). We performed analysis of variance for comparison of the means of normally distributed, continuous variables. If the assumptions of analysis of variance were violated, we used the Kruskal-Wallis test. Comparison of related categorical variables were by the Wilcoxon signed-rank test. We used MedCalc Statistical Software (version 18; MedCalc Software bvba, Ostend, Belgium) for all analyses. The accepted type I error was 5%. In a χ^2 post hoc analysis, Bonferroni correction was performed. We used CONSORT 2010 guidelines for reporting randomized clinical trials as a reference while preparing this report.

RESULTS

A total of 132 patients presented to the ED with suspected SVT. Of them, 34 were not eligible for this study. The patients who met the study criteria were randomly divided into 3 groups according to the protocol. The study was completed with 98 patients: 32 in the mVM group, 33 in the sVM group, and 33 in the CSM group (Figure 1).

As Table 1 shows, the patients' basic demographics, medical history, and vital signs were similar across groups, except for age, oxygen saturation, and diabetes mellitus history. When the 3 methods were compared in pairs based on these parameters, the mVM group was younger, and the number of diabetic patients was greater in the CSM group.

A total of 25 (25.5%) instances of SVT were initially treated successfully by vagal maneuvers. As the initial vagal technique, mVM had a success rate of 43.7% (14/

32 patients), followed by sVM of 24.2% (8/33), and CSM of 9.1% (3/33; $p < 0.05$). In pairwise comparisons between treatment groups (with Bonferroni adjustment, $p < 0.017$ accepted as significant), only the mVM and CSM group comparison was statistically significant ($p = 0.0016$). These results suggested that mVM had superior success to CSM, but that there was insufficient statistical support to distinguish between the success of sVM and CSM ($p = 0.1012$) and between mVM and sVM ($p = 0.0992$; Table 2).

When evaluating response at the end of the first minute among all patients in the study, 18 of 98 (18.4%) patients had sinus rhythm. Sinus rhythm was detected in 37.5% (12/32) of patients in the mVM group, 12% (4/33) in the sVM group, and 6.1% (2/33) in the CSM group. There were significant differences in the 3 groups' sustained success rates at the first minute of the maneuver ($p < 0.05$; Table 2). In pairwise comparisons of the treatment groups, only the mVM and CSM group comparison was statistically significant ($p = 0.0022$). The other group comparisons were not significant (mVM vs. sVM: $p = 0.0185$; CSM vs. sVM: $p = 0.3954$).

At the fifth minute, only 12.2% (12/98) of all patients had sinus rhythm. When evaluating the success rates of the treatment groups at the fifth minute, sinus rhythm persisted in 28.1% (9/32) of patients in the mVM group, 6.1% (2/33) in the sVM group, and 3% (1/33) in the CSM group. There were significant differences in the groups' success rate at the fifth minute of the maneuver ($p < 0.05$; Table 2). In pairwise comparisons, the results for the immediate response and first-minute response were similar. There was a statistically significant difference between the mVM and CSM groups ($p = 0.0054$). No differences in the in fifth-minute response were found between the mVM and sVM groups ($p = 0.0186$) and the CSM and sVM groups ($p = 0.5576$). There were no major adverse effects after vagal maneuvers in any group.

DISCUSSION

This study was a randomized, controlled trial to assess the effectiveness of sVM, mVM, and CSM in conversion of sinus rhythm and success at sustaining sinus rhythm in ED patients presenting with SVT. We showed that mVM was more effective at converting sinus rhythm than sVM and CSM (43.7%, 24.2%, and 9% respectively). mVM also had higher conversion success rates at the first and fifth minute than sVM and CSM (37.5%, 12.1%, and 6.1%; 28.1%, 6.1%, and 3.0%, respectively). Although several studies have compared the success rates of various vagal maneuvers, this study was the first to compare all 3 vagal maneuvers and to assess the sustained response (5,6,8). In the studies for comparison of vagal maneuvers, no time frame was given for length of

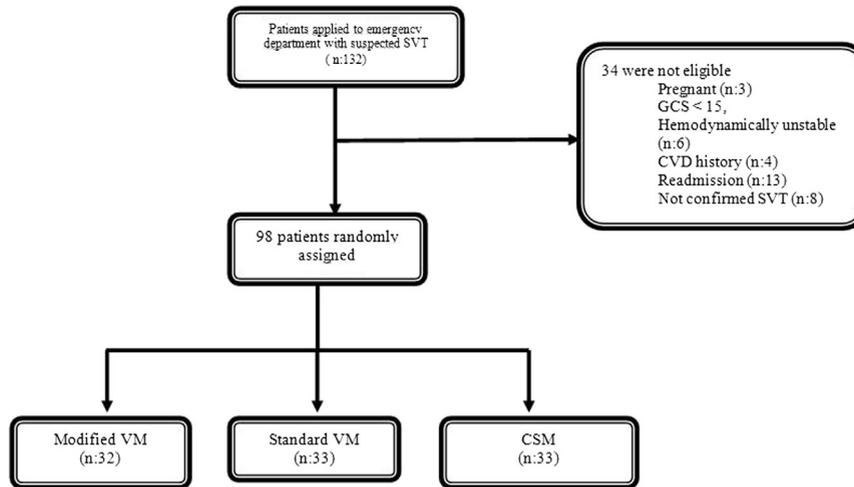


Figure 1. Flow chart of study. CSM = carotis sinus massage; CVD = cerebrovascular disease; GCS = Glasgow coma scale; SVT = supraventricular tachycardia; VM = Valsalva maneuver.

reversion until now (5–8). We wanted to search early time frame (5 min) for recurrence. Early time period is clinically important, because in the case of recurrence, early intervention of another method is essential.

A total of 132 patients applied to ED with suspected SVT. From these patients, 34 were not eligible (Figure 1). This was 25% of total and most of them were readmitted patients.

In a study by Porter, the mean age of 1754 SVT patients was 45 ± 19 years (range 5–96 years), and in another retrospective study on 10 years of screening for adenosine use in paroxysmal supraventricular tachycardia, the mean age was 60 years (range 15–94 years) (9,10). However, in

this study, the mean age of the patients with SVT was 55.8 ± 16.6 years. When the 3 methods were compared in pairs based on these parameters, the mVM group was younger. Lim et al. found that CSM was more sensitive in patients >40 years of age (8). Although the mVM group was younger than CSM group, mVM was more successful in our study.

It has been reported that paroxysmal SVT is more common in women than men. Examination of studies on SVT found that female participants constituted 51–70% of SVT patients (8,10–12). In this study, female participants accounted for most patients presenting with SVT (54.1%).

Table 1. Demographic and Clinical Characteristics of Patients

	Total, n = 98	Modified VM, n = 32	Standard VM, n = 33	CSM, n = 33	p Value
Age (years), median (IQR)	60 (44–67)	50 (36–61)	61 (46–67)	63 (52–72)	0.007 ^a
Male, n (%)	45 (45.9)	17 (37.8)	14 (31.1)	14 (31.1)	0.608
Admission time <2h, n (%)	32 (32.7)	9 (28.1)	10 (31.2)	13 (40.6)	0.588
Vital signs, median (IQR)					
SBP (mm Hg)	123 (106–136)	116 (106–136)	126 (113–138)	118 (103–129)	0.068
DBP (mm Hg)	79 (71–89)	81 (73–90)	76 (71–89)	76 (66–86)	0.337
Pulse (beats/min)	171 (158–186)	177 (165–192)	167 (147–187)	168 (147–183)	0.132
Fever (°C)	36.6 (36.3–36.8)	36.6 (36.3–36.7)	36.6 (36.2–36.8)	36.6 (36.5–36.8)	0.656
SO ₂ (%)	97 (96–99)	98 (97–99)	96 (96–98)	97 (94–99)	0.018 ^a
Medical history, n (%)					
Family history of SVT	11 (11.2)	3 (27.3)	2 (18.2)	6 (54.5)	0.273
SVT	44 (44.9)	11 (25.0)	19 (43.2)	14 (31.8)	0.161
Coronary artery disease	23 (23.5)	6 (26.1)	7 (30.4)	10 (43.5)	0.510
Diabetes mellitus	19 (19.4)	4 (21.1)	3 (15.8)	12 (36.4)	0.010 ^a
Hypertension	40 (40.8)	8 (20.0)	13 (32.5)	19 (47.5)	0.028 ^a
Anemia	12 (12.4)	1 (8.3)	4 (33.3)	7 (58.3)	0.092
Hyperthyroidism	4 (4.1)	1 (25.0)	0 (0.0)	3 (75.0)	0.166
Malignancy	8 (8.2)	1 (12.5)	5 (62.5)	2 (25.0)	0.180

CSM = carotid sinus massage; DBP = diastolic blood pressure; IQR = interquartile range; SBP = systolic blood pressure; SVT = supraventricular tachycardia; VM = Valsalva maneuver.

Variables reported with medians (IQR) were compared among groups with the Mann-Whitney U test. Others were compared with the χ^2 test.

^a Statistically significant p values.

Table 2. Responses of the Groups to Vagal Maneuvers

	Modified VM, n (%)	Standard VM, n (%)	CSM, n (%)	Total, n (%)	<i>p</i> Value
First response	14 (43.7)	8 (24.2)	3 (9.1)	25 (25.5)	0.006^a
Response at the first minute	12 (37.5)	4 (12.1)	2 (6.1)	18 (18.4)	0.003^a
Response at the fifth minute	9 (28.1)	2 (6.1)	1 (3.0)	12 (12.2)	0.004^a
Total	32 (32.6)	33 (33.7)	33 (33.7)	98 (100.0)	

CSM = carotid sinus massage; VM = Valsalva maneuver.

Percentages are presented for row total in total row, and other percentages represent column totals. *p* Values are calculated by the χ^2 test.

^a Statistically significant *p* values are presented in bold.

The use of vagal maneuvers to terminate paroxysmal tachycardia has been known since 1913. Waxman et al. reported that the success rate of CSM was 48.5%, while Mehta et al. reported a success rate of 22% (13,14). However, later studies have not achieved similar success rates (3). The efficacy of vagal maneuvers was reported to be quite high (54%) in a laboratory study. However, the success rate in clinical studies with SVT patients ranges from 5–20% (2,3). When examining studies involving any of the 2 maneuvers (sVM and CSM), both Mehta et al. and Wen et al. argued that VM was more effective than CSM in laboratory studies (14,15). In a randomized, controlled trial, Lim et al. had a 10.4% success rate in the CSM group and a 19.4% success rate in the sVM group (8). In 2015, Collins et al. reviewed evidence on the efficacy and safety of CSM in terminating SVT and concluded that CSM appeared to have modest efficacy at terminating SVT, but more efficacious alternative interventions, such as VM and pharmacologic therapy, were available (16).

Cochrane's analysis of VM's efficacy reported reversal rates of 54.3–45.9% in laboratory studies and 19.4% in clinical studies (3). A prospective, randomized case study found VM to have a success rate of 19.4%, and CSM 10.5%, while there were no detectable differences in the efficacy of VM and CSM (4). Comparing efficacy, Walker et al. reported that sVM and mVM had conversion rates of 5.6% and 31.6% ($p < 0.05$), respectively (1).

In 2015, Appelboom et al. assessed whether postural modification of the VM could improve its effectiveness (5). They performed the first randomized controlled study comparing sVM and mVM; the primary outcome of sinus rhythm at 1 min was achieved by 43% (93/214) of patients in the mVM group and 17% (37/214) in the sVM group ($p < 0.0001$) (5). In our study, the sVM success rate was found to be 24.2%, while the mVM success rate was 43.7%. These were similar to Appelboom et al., but no statistically significant differences were found in our study, probably because of the sample size (5). In addition, we evaluated the success rate of CSM. Comparing the success rates of CSM and mVM (9.1% vs. 43.7%, respectively), we can assert that mVM is superior to CSM because of its significant differences in all stages.

There are numerous case reports that described significant complications associated with CSM. Three general types of reported adverse events are local anatomic, neurologic, and dysrhythmogenic (16). Although some nonserious cardiac adverse events were reported with sVM or mVM, all these events were transient and self-limiting (5). There were no major adverse effect after vagal maneuvers in any group in our study.

The study's primary aim was to evaluate sustained success at returning to sinus rhythm in order to determine whether first responses to vagal maneuvers are permanent. When patients who returned to sinus rhythm with vagal maneuvers were evaluated after 1 min, normal sinus rhythm was found to continue after maneuvers in 18.4% of patients. This rate was 37.5% in patients who underwent mVM and 12.1% in patients who underwent sVM. At the fifth-minute evaluation, only 1 (3%) of the patients who underwent CSM continued to have normal sinus rhythm, while 28.1% and 6.1% of the patients who underwent mVM and sVM had normal sinus rhythm. Significant differences between mVM and CSM were seen at both time points. Overall, these results show that mVM is superior to the other 2 maneuvers based on the persistence of response to SVT treatment.

Limitations

This study was carried out at a single center. Patient allocation to different maneuvers was decided by the block randomization method in order to prevent bias, but the mean age of the patients who had mVM was found to be significantly lower. In addition, this study was not blind because of the nature of the maneuvers.

During the study period, we have reached the sample size for the study's primary outcome, but not the secondary outcomes. Further studies with higher number of patients are needed for more detailed results.

CONCLUSION

It is concluded that mVM is superior to CSM maneuver at converting SVT into normal sinus rhythm while maintaining sinus rhythm.

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ARTICLE SUMMARY

1. Why is this topic important?

Supraventricular tachycardia (SVT) is a common entity in the emergency department. The effectiveness of the vagal maneuvers has been challenging because of the lack of randomized clinical studies.

2. What does this study attempt to show?

This study attempts to show the success rates of 3 vagal maneuvers (carotid massage and both standard and modified Valsalva maneuvers) considering the sustaining of sinus rhythm at the fifth minute.

3. What are the key findings?

We found that the modified Valsalva maneuver was superior to the other 2 maneuvers in termination of supraventricular tachycardia and maintaining sinus rhythm at the fifth minute.

4. How is patient care impacted?

It is important to perform the most effective vagal maneuver in order to reduce the number of patients who need medical emergency treatment. It would be beneficial to use modified Valsalva maneuvers instead of carotid sinus massage, which was more effective and without serious side effects.