**EDITORIAL**

5835  Understanding the immunopathogenesis of COVID-19: Its implication for therapeutic strategy  
*Shimizu Y*

**OPINION REVIEW**

5844  What is the gut feeling telling us about physical activity in colorectal carcinogenesis?  
*Cigrovski Berkovic M, Cigrovski V, Bilic-Curcic I, Mrzljak A*

**REVIEW**

5852  Latest developments in chronic intestinal pseudo-obstruction  
*Zhu CZ, Zhao HW, Lin HW, Wang F, Li YX*

**ORIGINAL ARTICLE**

**Case Control Study**

5866  Correlation between ductus venosus spectrum and right ventricular diastolic function in isolated single-umbilical-artery foetus and normal foetus in third trimester  
*Li TG, Nie F, Xu XY*

**Retrospective Cohort Study**

5876  Clinical efficacy of integral theory–guided laparoscopic integral pelvic floor/ligament repair in the treatment of internal rectal prolapse in females  
*Yang Y, Cao YL, Zhang YY, Shi SS, Yang WW, Zhao N, Lyu BB, Zhang WL, Wei D*

**Retrospective Study**

5887  Treatment of Kümmell’s disease with sequential infusion of bone cement: A retrospective study  
*Zhang X, Li YC, Liu HP, Zhou B, Yang HL*

5894  Application value analysis of magnetic resonance imaging and computed tomography in the diagnosis of intracranial infection after craniocerebral surgery  
*Gu L, Yang XL, Yin HK, Lu ZH, Geng CJ*

5902  Focal intrahepatic strictures: A proposal classification based on diagnosis-treatment experience and systemic review  
*Zhou D, Zhang B, Zhang XY, Guan WB, Wang JD, Ma F*

5918  Preliminary analysis of the effect of vagus nerve stimulation in the treatment of children with intractable epilepsy  
*Fang T, Xie ZH, Liu TH, Deng J, Chen S, Chen F, Zheng LL*
<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>5926</td>
<td>Scoring system for poor limb perfusion after limb fracture in children</td>
<td>Zhu T, Shi Y, Yu Q, Zhao YJ, Dai W, Chen Y, Zhang SS</td>
</tr>
<tr>
<td>5935</td>
<td>Overexpression of CD155 is associated with PD-1 and PD-L1 expression on immune cells, rather than tumor cells in the breast cancer microenvironment</td>
<td>Wang RB, Li YC, Zhou Q, Lv SZ, Yuan KY, Wu JP, Zhao YJ, Song QK, Zhu B</td>
</tr>
<tr>
<td>5944</td>
<td>Application of computer tomography-based 3D reconstruction technique in hernia repair surgery</td>
<td>Wang F, Yang XF</td>
</tr>
<tr>
<td>5962</td>
<td>Genetic diagnosis history and osteoarticular phenotype of a non-transfusion secondary hemochromatosis</td>
<td>Ruan DD, Gan YM, Lu T, Yang X, Zha YB, Yu QH, Liao LS, Lin N, Qian X, Luo JW, Tang FQ</td>
</tr>
<tr>
<td>5976</td>
<td>Abdominal ventral rectopexy with colectomy for obstructed defecation syndrome: An alternative option for selected patients</td>
<td>Wang L, Li CX, Tian Y, Ye JW, Li F, Tong WD</td>
</tr>
<tr>
<td>5999</td>
<td>Efficacy and economic benefits of a modified Valsalva maneuver in patients with paroxysmal supraventricular tachycardia</td>
<td>Wang W, Jiang TF, Han WZ, Jin L, Zhao XJ, Guo Y</td>
</tr>
<tr>
<td>6009</td>
<td>Duodenal giant stromal tumor combined with ectopic varicose hemorrhage: A case report</td>
<td>Li DH, Liu XY, Xu LB</td>
</tr>
<tr>
<td>6026</td>
<td>Pleomorphic adenoma of the trachea: A case report and review of the literature</td>
<td>Liao QN, Fang ZK, Chen SB, Fan HZ, Chen LC, Wu XP, He X, Yu HP</td>
</tr>
<tr>
<td>6036</td>
<td>Neoadjuvant targeted therapy for apocrine carcinoma of the breast: A case report</td>
<td>Yang P, Peng SJ, Dong YM, Yang L, Yang ZY, Hu XE, Bao GQ</td>
</tr>
<tr>
<td>6043</td>
<td>Huge encrusted ureteral stent forgotten for over 25 years: A case report</td>
<td>Kim DS, Lee SH</td>
</tr>
<tr>
<td>Page</td>
<td>Title</td>
<td>Authors</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>6048</td>
<td>Roxadustat for treatment of erythropoietin-hyporesponsive anemia in a hemodialysis patient: A case report</td>
<td>Yu WH, Li XJ, Yuan F</td>
</tr>
<tr>
<td>6056</td>
<td>Suspected SARS-CoV-2 infection with fever and coronary heart disease: A case report</td>
<td>Gong JR, Yang JS, He YW, Yu KH, Liu J, Sun RL</td>
</tr>
<tr>
<td>6080</td>
<td>Forty-nine years old woman co-infected with SARS-CoV-2 and Mycoplasma: A case report</td>
<td>Gao ZA, Gao LB, Chen XJ, Xu Y</td>
</tr>
<tr>
<td>6095</td>
<td>Small-cell neuroendocrine carcinoma of the rectum — a rare tumor type with poor prognosis: A case report and review of literature</td>
<td>Chen ZZ, Huang W, Wei ZQ</td>
</tr>
<tr>
<td>6103</td>
<td>Laparoscopic left lateral sectionectomy in pediatric living donor liver transplantation by single-port approach: A case report</td>
<td>Li H, Wei L, Zeng Z, Qu W, Zhu ZJ</td>
</tr>
<tr>
<td>6110</td>
<td>Malignant meningioma with jugular vein invasion and carotid artery extension: A case report and review of the literature</td>
<td>Chen HY, Zhao F, Qin JY, Lin HM, Su JP</td>
</tr>
<tr>
<td>6130</td>
<td>Hemophagocytic lymphohistiocytosis caused by STAT1 gain-of-function mutation is not driven by interferon-γ: A case report</td>
<td>Liu N, Zhao FY, Xu XJ</td>
</tr>
<tr>
<td>6136</td>
<td>Single door laminoplasty plus posterior fusion for posterior atlantoaxial dislocation with congenital malformation: A case report and review of literature</td>
<td>Zhu Y, Wu XX, Jiang AQ, Li XF, Yang HL, Jiang WM</td>
</tr>
<tr>
<td>6144</td>
<td>Occipital nodular fasciitis easily misdiagnosed as neoplastic lesions: A rare case report</td>
<td>Wang T, Tung GC, Yang H, Fan JK</td>
</tr>
<tr>
<td>Page</td>
<td>Title</td>
<td>Authors</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>6150</td>
<td>Postoperative secondary aggravation of obstructive sleep apnea-hypopnea syndrome and hyposxia with bilateral carotid body tumor: A case report</td>
<td>Yang X, He XG, Jiang DH, Feng C, Nie R</td>
</tr>
<tr>
<td>6158</td>
<td>Uncontrolled central hyperthermia by standard dose of bromocriptine: A case report</td>
<td>Ge X, Luan X</td>
</tr>
<tr>
<td>6164</td>
<td>Acute celiac artery occlusion secondary to blunt trauma: Two case reports</td>
<td>Li H, Zhao Y, Xu YA, Li T, Yang J, Hu P, Ai T</td>
</tr>
<tr>
<td>6172</td>
<td>Multiple ectopic goiter in the retroperitoneum, abdominal wall, liver, and diaphragm: A case report and review of literature</td>
<td>Qin LH, He FY, Liao JY</td>
</tr>
<tr>
<td>6181</td>
<td>Symptomatic and optimal supportive care of critical COVID-19: A case report and literature review</td>
<td>Pang QL, He WC, Li JX, Huang L</td>
</tr>
<tr>
<td>6190</td>
<td>Primary breast cancer patient with poliomyelitis: A case report</td>
<td>Wang XM, Cong YZ, Qiao GD, Zhang S, Wang LJ</td>
</tr>
<tr>
<td>6206</td>
<td>Novel triple therapy for hemorrhagic ascites caused by endometriosis: A case report</td>
<td>Han X, Zhang ST</td>
</tr>
</tbody>
</table>
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Randomized Clinical Trial

Efficacy and economic benefits of a modified Valsalva maneuver in patients with paroxysmal supraventricular tachycardia

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Author contributions: Guo Y designed the study; Wang W, Jin L, Jiang TF, and Zhao XJ conducted the research; Han WZ and Wang W analyzed the data and wrote the first draft of the manuscript; Han WZ and Guo Y revised the paper; and all authors contributed to writing or critically reviewing the manuscript.

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Clinical trial registration statement: This study is registered at Shandong Provincial Hospital Affiliated to Shandong First Medical University. The registration identification number is 2019-084.

Abstract

BACKGROUND
A modified Valsalva maneuver (VM) has been suggested to be superior to the standard VM for conversion of paroxysmal supraventricular tachycardia (PSVT).

AIM
To evaluate the efficacy and economic benefits of a modified VM in Chinese patients.

METHODS
Patients with PSVT admitted to our center between October 2017 and September 2019 were randomly assigned to the modified and standard VM groups. Conversion via VM was performed up to three times. The primary outcome of the study was the success rate of PSVT conversion to sinus rhythm. The secondary outcomes included the incidence of adverse events, economic cost during the visit, and the degree of patient acceptance of the treatment.

RESULTS
Overall, 361 patients were enrolled, with 180 allocated to the modified VM group and 181 to the standard VM group. Baseline characteristics were well matched in the groups. Overall, the modified VM group had higher success rates of PSVT conversion after single (47.78% vs 15.38%, P < 0.001) and multiple (62.22% vs 19.78%, P < 0.001) VM sessions. No significant differences in the incidences of adverse events and rates of patient acceptance were detected between the two
groups (both $P > 0.05$). Moreover, the economic cost of the clinic visit was significantly lower for the modified VM group than for the standard VM group ($P < 0.05$).

**CONCLUSION**

The modified VM may confer both therapeutic and economic benefits as compared with the standard VM for conversion of PSVT.

**Key Words:** Paroxysmal supraventricular tachycardia; Modified Valsalva maneuver; Cost-effective analysis

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**INTRODUCTION**

Paroxysmal supraventricular tachycardia (PSVT) is a common arrhythmia that is primarily caused by re-entry dysfunction of the atrium and atrioventricular junction. Clinically, PSVT is characterized by sudden onset and sudden termination of tachycardia. Patients with PSVT may suffer from palpitations, chest tightness and fatigue, which severely affect their quality of life\(^1\). Prolonged PSVT, particularly with an elevated heart rate, usually causes hemodynamic dysfunction, characterized by hypotension, and insufficiency of peripheral perfusion, such as cerebral ischemia, syncope, convulsions (A-S syndrome)\(^2\), angina pectoris, heart failure, and even sudden death\(^3\). Therefore, timely conversion of PSVT to sinus rhythm is important in clinical practice.

Currently, the standard Valsalva maneuver (VM) is recommended as the first-line strategy for termination of PSVT by many international guidelines\(^4\). Although the standard VM is safe, cost-free, and can be easily performed by nurses or doctors, the success rate of cardioversion by standard VM in PSVT patients is relatively low (5%-20\%)\(^5\). Moreover, termination of PSVT by antiarrhythmic drugs or electrical conversion seems effective. However, these strategies may have additional adverse effects or lead to further damage in patients, with some patients even experiencing a feeling of dying during the conversion process\(^6\). Therefore, efforts to identify effective physical techniques to improve the success rate of PSVT conversion by standard VM are of clinical significance. Previous studies in western countries suggested that a modified VM may improve the success rate of PSVT conversion\(^6\). However, to the best of our knowledge, the relative efficacy and economic benefits of a modified VM as compared with the standard VM in Chinese patients with PSVT have not been evaluated. Therefore, in this study, we aimed to compare the clinical efficacy and economic efficiency, as well as the safety of a modified VM vs standard VM in Chinese patients with PSVT.
MATERIALS AND METHODS

Study population
This study included adult patients (aged older than 18 years) with electrocardiography (ECG)-confirmed PSVT who were admitted to the Cardiology Department of Shandong Provincial Hospital between October 2017 and September 2019. The potential patients were screened for enrollment in the study before receiving any emergency cardioversion treatment. Patients with a systolic blood pressure < 90 mmHg; atrial fibrillation or atrial flutter; any contraindication to VM, such as severe pulmonary insufficiency, aortic stenosis, myocardial infarction, glaucoma, and retinopathy; a need for urgent cardioversion (e.g., pregnant or critically ill); or an inability to tolerate supine positioning or leg raising movements were excluded.

General information
All patients were randomized into the modified VM group or standard VM group using opaque-sealed envelopes. Written informed consent was obtained from all participants. The study protocol was approved by the ethics committee of Shandong Provincial Hospital Affiliated to Shandong University.

Procedures
The recruiting doctors or nurses randomly selected the envelope and instructed the patient to undergo the modified VM or standard VM according to the instructions in the envelope. The doctors, nurses, and patients were all blinded to the distribution plan. Patients in the modified VM group were placed in a semi-recumbent position or sitting position at an angle of 45° to 90° to the bed surface for completion of a normal inhalation in a tidal volume state. The patients were then asked to blow into 10 mL syringes to move the plunger to achieve the recommended intrathoracic pressure of 40 mmHg. The state of exertion was maintained for 15 s, and the signs of acceptable motion included jugular vein filling, increased abdominal muscle tension, and flushing. Then, the patient was suddenly placed in the supine position and his/her legs were raised at a 45° angle, which was maintained for 15 s by the researcher. The participants then returned to the semi-recumbent position at an angle of 45° to the bed surface. The nurse guided participants to close the glottis after completing a normal inhalation in a tidal volume state. Participants closed the glottis and exhaled vigorously for 10-15 s. Then, the participants relaxed and resumed normal breathing before maintaining this posture for 1 min. The 12-lead ECG or ECG monitoring was used to determine the cardioversion. In both groups, the procedure for standard VM or modified VM was repeated up to 3 times in unresponsive patients. The outcomes regarding success rates after one or multiple sessions of VM were recorded.

Definitions of clinical characteristics and outcomes
Basic demographics, past history and vital signs in both patient groups, including gender, age, history of PSVT, history of coronary heart disease, and the presence of diabetes, hypertension, valvular heart disease, pneumonia, and chronic obstructive pulmonary disease were recorded. Blood pressure, heart rate, and serum potassium levels were also recorded. The success rates of cardioversion after one or multiple sessions of VM in the two patients groups were recorded. The recovery of sinus rhythm confirmed by ECG was defined as successful cardioversion. Potential adverse events during the modified or standard VM were observed. The economic cost of successful conversion during the clinical visit for each patient (including consumable costs, drug costs and labor costs) were calculated and recorded. Patient acceptance of the treatment was rated according to the following 5-point scale: Very easy to accept = 5 points, easy to accept = 4 points, general = 3 points, not easy to accept = 2 points, and very difficult to accept = 1 point.

Statistical analysis
Statistical analyses were performed using SPSS version 18.0. Continuous data were described by mean and standard deviation, while categorical data were expressed as numbers and percentages. The success rate of cardioversion was analyzed by the χ² test. The 95% confidence intervals (95%CIs) were calculated when appropriate, and a P value of < 0.05 was considered statistically significant.
RESULTS

Clinical characteristics of the included patients
Overall, 361 patients were enrolled, 180 in the modified VM group and 181 in the standard VM group. No significant differences were observed between the two groups in terms of the proportion of males, age, weight, systolic blood pressure, diastolic blood pressure, heart rate, serum potassium at admission, previous onset of PSVT, history of hypertension, coronary heart disease, and prevalence of pneumonia ($P > 0.05$, Table 1).

Comparison of the success rate of cardioversion
The success rates of sinus rhythm restoration after a single session or multiple sessions of VM were both higher in patients allocated to the modified VM group than in those allocated to the standard VM group ($\chi^2$ values were 33.724 and 22.008, both $P < 0.001$, respectively; Table 2).

Comparison of adverse events
The incidence of adverse events did not differ significantly between the two groups during treatment. Non-serious adverse events occurred in patients in both groups, and the incidences were comparable between the groups. These adverse events resolved spontaneously without any treatment (Table 3).

Analysis of economic benefit
The average cost of the clinical visit for patients in the modified VM group was RMB 113.32 ± 45.22, whereas that for patients in the standard VM group was RMB 140.91 ± 37.08, which showed that the modified VM was cost-effective compared with standard VM ($P < 0.05$) (Table 4).

Degree of patient acceptance
According to the scores on the scale of acceptance, acceptance among patients in the modified VM group did not differ statistically from that of patients in the standard VM group (3.67 ± 0.69 vs 3.54 ± 0.66, Kruskal-Wallis test, $\chi^2 = 1.855$, $P = 0.064$) (Figure 1, Table 5).

DISCUSSION

PSVT is one of the most common arrhythmias. Due to its characteristics of sudden onset and sudden termination, effective, economic and safe strategies for conversion of PSVT to sinus rhythm under emergency conditions are urgently needed. The method of vagal nerve stimulation is commonly used in the physical transformation technique, which uses a tongue depressor to induce nausea and vomiting or the standard VM at the base of the tongue. These strategies may be suitable for patients with no structural heart disease and no obvious heart failure. However, the success rate of conversion is reported to be less than 20% using these methods. Specifically, it has been reported that the success rate of conversion by standard VM is only 5%-20%. In 2015, a large randomized controlled trial published in the Lancet showed a significantly higher rate of successful restoration of sinus rhythm at 1 min when the modified VM was used compared with when the standard VM was used (43% vs 17%)\(^1\). A pilot cohort study in China\(^2\) also showed that the success rate of conversion via the modified VM was 77.5%, which was higher than that with the standard VM of 30.0%\(^3\). Our study confirmed that the success rate of PSVT conversion was higher in the modified VM group after single (47.78% vs 15.38%) and multiple (62.22% vs 19.78%) VM sessions. The potential mechanisms underlying the additional benefits for PSVT termination may include the following: First, the patient’s inhalation at the end of the breath and then forceful exhalation can increase the pressure in the chest, pressing the sternum to also increase the intrathoracic pressure. Moreover, the erect position in the modified VM group can quickly reduce the amount of blood flow, increase left atrial pressure, stimulate the carotid baroreceptor and synergistically improve vagal nerve tension to interrupt the prolongation of supraventricular tachycardia and cause the termination of PSVT\(^4\-7\).

The other commonly used physical transformation methods include eye reflex, carotid sinus massage, and the diving reflex. There are certain risks in the application of the above treatments. The pressure of the eyeball is not suitable for retinal
Table 1 Baseline characteristics of the patients included in each group

<table>
<thead>
<tr>
<th>Group</th>
<th>Modified VM</th>
<th>Standard VM</th>
<th>χ²/t</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>180</td>
<td>181</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men [n (%)]</td>
<td>84 (46.7)</td>
<td>74 (40.88)</td>
<td>1.226</td>
<td>0.290</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>51.76 ± 12.02</td>
<td>49.29 ± 13.59</td>
<td>1.823</td>
<td>0.069</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>64.89 ± 20.82</td>
<td>68.22 ± 13.27</td>
<td>-1.815</td>
<td>0.070</td>
</tr>
<tr>
<td>Duration of PSVT (yr)</td>
<td>7.27 ± 7.38</td>
<td>8.60 ± 8.10</td>
<td>-1.630</td>
<td>0.104</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>127.42 ± 28.67</td>
<td>132.35 ± 19.46</td>
<td>-1.913</td>
<td>0.057</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>79.61 ± 18.17</td>
<td>82.77 ± 12.81</td>
<td>-1.912</td>
<td>0.057</td>
</tr>
<tr>
<td>Pulse (bpm)</td>
<td>75.71 ± 18.26</td>
<td>79.18 ± 15.22</td>
<td>-1.962</td>
<td>0.051</td>
</tr>
<tr>
<td>Serum potassium (mmol/L)</td>
<td>3.94 ± 0.89</td>
<td>4.08 ± 0.51</td>
<td>-1.826</td>
<td>0.069</td>
</tr>
<tr>
<td>Coronary heart disease [n (%)]</td>
<td>2 (1.11)</td>
<td>8 (4.42)</td>
<td>3.668</td>
<td>0.105</td>
</tr>
<tr>
<td>Hypertension [n (%)]</td>
<td>36 (2.00)</td>
<td>44 (24.31)</td>
<td>0.972</td>
<td>0.375</td>
</tr>
<tr>
<td>Diabetes [n (%)]</td>
<td>10 (5.56)</td>
<td>10 (5.52)</td>
<td>0.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Pneumonia [n (%)]</td>
<td>2 (1.11)</td>
<td>0 (0.00)</td>
<td>2.022</td>
<td>0.155</td>
</tr>
</tbody>
</table>

PSVT: Paroxysmal supraventricular tachycardia; VM: Valsalva maneuver.

Table 2 Comparison of success rate of paroxysmal supraventricular tachycardia conversion between the two groups (data are presented as number and percentage)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Sinus rhythm after multiple VM</th>
<th>Sinus rhythm after single VM</th>
<th>χ² value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified VM</td>
<td>180</td>
<td>112 (62.22)</td>
<td>86 (47.78)</td>
<td>66.860</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Standard VM</td>
<td>181</td>
<td>36 (19.89)</td>
<td>28 (15.47)</td>
<td>43.599</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

VM: Valsalva maneuver.

Table 3 Comparison of the incidence of adverse events in both groups (data are presented as number and percentage)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Chest tightness</th>
<th>Dizziness</th>
<th>Chest pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified VM</td>
<td>180</td>
<td>10 (5.56)</td>
<td>6 (3.33)</td>
<td>4 (2.22)</td>
</tr>
<tr>
<td>Standard VM</td>
<td>181</td>
<td>8 (4.40)</td>
<td>4 (2.20)</td>
<td>2 (1.10)</td>
</tr>
</tbody>
</table>

VM: Valsalva maneuver.

detachment, and in a few cases, fatal arrhythmia has occurred[18-24]. Patients undergoing cardiac sinus-sensitivity may experience cardiac arrest, with many contraindications; thus, the nurse cannot operate independently[25-27]. The diving reflex may increase the risk of adverse reactions such as cough and suffocation[28]. In addition to the above physical techniques, other cardioversion techniques using medications or electrical cardioversion may also cause serious adverse events. For example, the application of adenosine triphosphate may cause facial flushing, nausea, dizziness, chest tightness, hypotension, sinus arrest, atrioventricular block, and even cardiac arrest[29,30]. Excessive use of propafenone can cause adverse reactions such as bradycardia and dizziness, and inhibit left ventricular function[31]. Electric
**Table 4 Comparison of the cost-effective in both groups (data are presented as mean ± SD)**

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Cost-effective (mean ± SD, yuan)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified VM</td>
<td>180</td>
<td>113.32 ± 45.22</td>
</tr>
<tr>
<td>Standard VM</td>
<td>181</td>
<td>140.91 ± 37.08</td>
</tr>
</tbody>
</table>

\( t \) value: -6.346  
\( P \) value: 0

VM: Valsalva maneuver.

**Table 5 Comparison of the degree of patient acceptance in both groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Degree of acceptance (mean ± SD)</th>
<th>&lt; 3 (%)</th>
<th>3' (%)</th>
<th>&gt; 3' (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified VM</td>
<td>180</td>
<td>3.67 ± 0.69</td>
<td>6 (3.33)</td>
<td>58 (32.22)</td>
<td>116 (64.44)</td>
</tr>
<tr>
<td>Standard VM</td>
<td>181</td>
<td>3.54 ± 0.66</td>
<td>8 (4.42)</td>
<td>76 (41.99)</td>
<td>97 (53.59)</td>
</tr>
</tbody>
</table>

\( t/\chi^2 \) value: 1.855, 2.286, 3.688, 4.495  
\( P \) value: 0.064, 0.786, 0.064, 0.042

VM: Valsalva maneuver.

**Figure 1** Comparison of the degree of patient acceptance in both groups. VM: Valsalva maneuver.

Cardioversion is often used in patients with hemodynamic instability, which may cause additional damage to the body\(^3\). In this study, the incidence of adverse events after modified VM was only 11.1%, and most of these adverse events resolved without treatment. Our study, consistent with previous findings in Chinese patients\(^1\), showed that the modified VM is relatively safe as compared with the standard VM.

In previous studies, a pressure measuring device is recommended for the patient’s insufflation, and the pressure must reach 40 mmHg. If the hospital or clinic is not equipped with a pressure measuring instrument, it can also be replaced with an empty 10-mL syringe. Research has shown that the lip will fill 10 mL of the tip of the syringe. Upon blowing into the syringe to just move the piston, the pressure is approximately equal to 40 mmHg\(^3\)\(^3\)\(^3\). Therefore, using a 10-mL syringe to temporarily replace the pressure gauge, patients may perform a modified VM by themselves with the assistance of family members at home. An adequate VM can be recognized by signs of jugular vein filling, abdominal wall muscle tension and facial flushing.

It could be expected that terminating PSVT via physical therapy such as VM is much more cost-effective than other therapies. Moreover, our study showed that the cost of consumables, drug costs and labor costs for the conversion of PSVT by modified VM was lower than that for standard VM, which showed that the modified VM has better economic benefits as compared with the standard VM, although costs in both groups were already relatively low.
Limitations
A limitation of this study was the generalizability of results. Participants were recruited from one large general hospital, and the number of subjects was small, which limited the characteristics of the resulting data. In addition, the economic benefit analysis was not very professional. This research can be expanded to community hospitals or community clinics, multi-center large sample research can be carried out, and a professional and detailed economic benefit analysis can be conducted.

CONCLUSION
In summary, the modified VM can effectively improve the success rate of cardioversion in patients with PSVT. The modified VM is more effective and involves less cost than standard VM, and the safety and acceptance of the treatments among the PSVT patients were comparable. Termination of PSVT via the modified VM can be managed by primary healthcare professionals and patients themselves.

ARTICLE HIGHLIGHTS
Research background
Previous studies in western countries suggested that a modified Valsalva maneuver (VM) may improve the success rate of paroxysmal supraventricular tachycardia (PSVT) conversion. However, the relative efficacy and economic benefits of a modified VM as compared with the standard VM in Chinese patients with PSVT have not been evaluated.

Research motivation
The relative efficacy and economic benefits of a modified VM as compared with the standard VM in Chinese patients with PSVT have not been evaluated; therefore, we aimed to compare the clinical efficacy and economic efficiency, as well as the safety of a modified VM vs standard VM in Chinese patients with PSVT.

Research objectives
In this study, we aimed to compare the clinical efficacy and economic efficiency, as well as the safety of a modified VM vs standard VM in Chinese patients with PSVT.

Research methods
This study included adult patients (aged older than 18 years) with electrocardiography (ECG)-confirmed PSVT who were admitted to the Cardiology Department of Shandong Provincial Hospital between October 2017 and September 2019. All patients were randomized into the modified VM group or standard VM group using opaque-sealed envelopes. Written informed consent was obtained from all participants. Conversion via VM was performed up to three times. The 12-lead ECG or ECG monitoring was used to determine the cardioversion. In both groups, the procedure for standard VM or modified VM was repeated up to 3 times in unresponsive patients. Basic demographics, past history and vital signs of patients in both groups were recorded. The success rates of cardioversion after one or multiple sessions of VM in the two patients groups were recorded. The recovery of sinus rhythm confirmed by ECG was defined as successful cardioversion. Potential adverse events during the performance of the modified or standard VM were observed.

Research results
Overall, 361 patients were enrolled, 180 in the modified VM group and 181 in the standard VM group. No significant differences were observed between the two groups in terms of the proportion of males, age, weight, systolic blood pressure, diastolic blood pressure, heart rate, serum potassium at admission, previous onset of PSVT, history of hypertension, coronary heart disease, and prevalence of pneumonia. The success rates of sinus rhythm restoration after a single session or multiple sessions of VM were both higher in patients allocated to the modified VM group than in those allocated to the standard VM group ($\chi^2$ values were 33.724 and 22.008, both $P < 0.001$, respectively). The incidence of adverse events did not differ significantly between the two groups during treatment. Non-serious adverse events occurred in patients in both
groups, and the incidences were comparable between the groups. These adverse events resolved spontaneously without any treatment. The average cost of the clinical visit for patients in the modified VM group was RMB 113.32 ± 45.22, whereas that for patients in the standard VM group was RMB 140.91 ± 37.08, which showed that the modified VM is cost-effective compared with standard VM (P < 0.05). According to the scores on the scale of acceptance, acceptance among patients in the modified VM group did not differ statistically from that of patients in the standard VM group (3.67 ± 0.69 vs 3.54 ± 0.66, Kruskal-Wallis test, χ² = 1.855, P = 0.064).

Research conclusions
In summary, the modified VM can effectively improve the success rate of cardioversion in patients with PSVT. The modified VM is effective and involves less cost than standard VM, and the safety and acceptance of the treatments among the PSVT patients were comparable. Termination of PSVT via the modified VM can be managed by primary healthcare professionals and patients themselves.

Research perspectives
This study focused on the effect of physical manipulation on supraventricular tachycardia. The intervention scheme was designed by random control, and the effect was evaluated by various evaluation indices. It has important guiding significance for clinical work. The maneuver is simple and easy to operate, has good safety, a low incidence of adverse reactions, can reduce personal and medical insurance expenses, has good economic benefits, and can be popularized in community hospitals and other primary hospitals.

REFERENCES


paroxysmal supraventricular tachycardia. Shi Yong Xun Nao Fei Xue Guaan Bing 2017


