

Postural modification to the standard Valsalva manoeuvre for emergency treatment of supraventricular tachycardias (REVERT): a randomised controlled trial



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Summary

Background The Valsalva manoeuvre is an internationally recommended treatment for supraventricular tachycardia, but cardioversion is rare in practice (5–20%), necessitating the use of other treatments including adenosine, which patients often find unpleasant. We assessed whether a postural modification to the Valsalva manoeuvre could improve its effectiveness.

Methods We did a randomised controlled, parallel-group trial at emergency departments in England. We randomly allocated adults presenting with supraventricular tachycardia (excluding atrial fibrillation and flutter) in a 1:1 ratio to undergo a modified Valsalva manoeuvre (done semi-recumbent with supine repositioning and passive leg raise immediately after the Valsalva strain), or a standard semi-recumbent Valsalva manoeuvre. A 40 mm Hg pressure, 15 s standardised strain was used in both groups. Randomisation, stratified by centre, was done centrally and independently, with allocation with serially numbered, opaque, sealed, tamper-evident envelopes. Patients and treating clinicians were not masked to allocation. The primary outcome was return to sinus rhythm at 1 min after intervention, determined by the treating clinician and electrocardiogram and confirmed by an investigator masked to treatment allocation. This study is registered with Current Controlled Trials (ISRCTN67937027).

Findings We enrolled 433 participants between Jan 11, 2013, and Dec 29, 2014. Excluding second attendance by five participants, 214 participants in each group were included in the intention-to-treat analysis. 37 (17%) of 214 participants assigned to standard Valsalva manoeuvre achieved sinus rhythm compared with 93 (43%) of 214 in the modified Valsalva manoeuvre group (adjusted odds ratio 3·7 (95% CI 2·3–5·8; $p < 0\cdot0001$). We recorded no serious adverse events.

Interpretation In patients with supraventricular tachycardia, a modified Valsalva manoeuvre with leg elevation and supine positioning at the end of the strain should be considered as a routine first treatment, and can be taught to patients.

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Introduction

The Valsalva manoeuvre is a safe and internationally recommended first-line emergency treatment for supraventricular tachycardia, a common and ubiquitous group of cardiac arrhythmias.^{1–6} However, cardioversion is rarely successful in clinical practice (5–20%),^{7–9} and patients who remain in supraventricular tachycardia are usually treated with intravenous adenosine. Adenosine causes transient asystole and is associated with substantial side-effects: many patients report a sense of impending doom or feel that they are about to die and find this very unpleasant and frightening.^{10,11}

Modifications to increase relaxation phase venous return and vagal stimulation, including supine positioning with leg elevation immediately after the Valsalva strain (the modified Valsalva manoeuvre), might improve the Valsalva manoeuvre's effectiveness,^{12–18} but have not been assessed in controlled trials with patients

presenting with acute supraventricular tachycardia.¹⁹ An improvement in the success rate of the Valsalva manoeuvre with a simple, safe, and cost-free modification to patient positioning during the manoeuvre would be an important finding, with benefits for patients and health-care providers worldwide, including regions with few health-care resources.¹⁸

We did a randomised controlled trial (REVERT) to assess whether a modified Valsalva manoeuvre is more effective than a standard Valsalva manoeuvre at restoring sinus rhythm in patients presenting to hospital with supraventricular tachycardia.

Methods

Study design and participants

We did this pragmatic, randomised, multicentre parallel group trial in ten emergency departments (two teaching hospitals, eight district general hospitals) in southwest

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Research in context

Evidence before this study

We searched MEDLINE, Embase, and CINAHL databases for “Valsalva manoeuvre AND supraventricular tachycardia OR re-entrant tachycardia” using MeSH terms and appropriate variations in 2009, before our study began. We excluded studies of children and those that did not describe the Valsalva manoeuvre. 269 citations were reviewed and six studies were relevant to our research question. We also searched the Cochrane and Bandolier databases using the terms “Valsalva” and “supraventricular tachycardia”, and found no relevant articles. A repeat of the search on April 15, 2015 identified a Cochrane Review (updated from 2013), which included three studies, all of which we had reviewed in 2009.

Of the six studies reviewed, only two directly assessed the effect of posture on Valsalva manoeuvre effectiveness. One compared supine and sitting Valsalva manoeuvre for induced supraventricular tachycardia in an electrophysiology laboratory and the other was an uncontrolled trial of Trendelenberg Valsalva manoeuvre for acute supraventricular tachycardia in an emergency department. No randomised controlled trials compared posture for the management of

patients with acute supraventricular tachycardia presenting to hospital.

Added value of this study

This study is the first randomised controlled trial to assess the effect of posture modification to the Valsalva manoeuvre in patients presenting with acute supraventricular tachycardia. A standard strain was used to ensure that the Valsalva manoeuvre, other than the change in posture, was the same for both groups. This study was pragmatic, done in a clinical setting to which patients often present, and used usual treating staff. The proportion of cardioversions should therefore occur in normal practice if the modified technique is adopted, and serves as a baseline against which future studies can be compared.

Implications of all the available evidence

In patients presenting with stable supraventricular tachycardia, a 15 s, 40 mm Hg Valsalva strain in the semi-recumbent position should be followed immediately by supine repositioning and passive leg elevation. It should be repeated once if unsuccessful. Consideration should be given to enabling patients to do this themselves, and for making this a standard initial treatment.

England between Jan 1, 2013, and April 30, 2015. The study was run according to a previously described design,²⁰ through the Peninsula Clinical Trials Unit at Plymouth University, overseen by an independently chaired trial steering committee.

Patients with suspected supraventricular tachycardia (at emergency department triage or initial assessment) were screened for participation, including routine 12-lead electrocardiogram (ECG), before any emergency arrhythmia treatment. We included patients aged older than 18 years presenting to the emergency department with supraventricular tachycardia (regular, narrow complex tachycardia with QRS duration <0.12 s on ECG). We excluded unstable patients with systolic blood pressure less than 90 mm Hg or an indication for immediate cardioversion and those in atrial fibrillation or flutter. Other exclusion criteria were suspected atrial flutter requiring a trial of adenosine, the presence of any contraindication to Valsalva manoeuvre (aortic stenosis, recent myocardial infarction, glaucoma, retinopathy), inability to performing a Valsalva manoeuvre, to lie flat, or have legs lifted (or any reason identified by the patient as to why this manoeuvre would cause discomfort or pain), third trimester pregnancy, or previous inclusion in this study.

The study was approved by the South West—Exeter Research Ethics Committee, and done in accordance with Good Clinical Practice principles. All participants provided written informed consent.

Randomisation and masking

Participants were randomly assigned (1:1) to a standard Valsalva manoeuvre (control) or modified Valsalva manoeuvre (intervention) as their first treatment with permuted blocks of size two, four, and six, stratified by centre. Allocations were prepared by an independent statistician and placed in serially numbered, opaque, sealed, tamper-evident envelopes by the clinical trials unit.

Treatment was determined by selecting the next randomisation envelope in sequence and was checked against a randomisation log. The recruiting doctor or nurse had to sign and date the envelope across the seal to confirm that the next available and lowest numbered envelope of the batch had been taken and that it had not been opened previously. Correct and sequential use of envelopes as described in the protocol was strictly audited by the site research team and clinical trials unit. This process enabled effective randomisation and immediate availability of trial paperwork, without the need for telephone or computer use, and was specifically chosen to aid successful consecutive recruitment in the emergency department.

Treating clinicians could not practically be masked to the allocation. Trial paperwork and explanations disguised from participants which was the study intervention and which was the control by use of descriptive terms for each Valsalva manoeuvre. All analyses were done by investigators masked to treatment allocation.

Procedures

For both groups, the Valsalva manoeuvre strain was standardised to a pressure of 40 mm Hg sustained for 15 s by forced expiration measured by aneroid manometer with the target pressure marked and visible to the participant and treating team.¹⁹ Standardised verbal instructions were used to help participants to achieve target pressure and strain duration.

The control manoeuvre was termed the “stay sitting Valsalva” to reduce bias. Participants, positioned semi-recumbent (at 45°) on a trolley, were directed to perform the standardised strain and remained in the same position for 60 s before reassessment of cardiac rhythm, initially by 3-lead ECG. A training video was given to all participating centres.

The modified Valsalva manoeuvre (intervention) was termed “lying down with leg lift Valsalva” (video). Participants performed the standardised strain in the same semi-recumbent position but immediately at the end of the strain, were laid flat and had their legs raised by a member of staff to 45° for 15 s. Participants were then returned to the semi-recumbent position for a further 45 s before re-assessment of cardiac rhythm, initially by 3-lead ECG.

If sinus rhythm was not restored, participants were invited to undertake one further attempt at the allocated Valsalva manoeuvre. A 12-lead ECG was recorded if return to sinus rhythm was achieved at 1 min after Valsalva manoeuvre, and 1 min after the second manoeuvre even if unsuccessful.

Treating clinicians or the research nurses recorded whether the allocated Valsalva manoeuvre was performed, the peak pressure and the total duration of strain achieved, whether sinus rhythm was restored, and any adverse events.

Subsequent management was entirely at the discretion of the treating clinical team according to standard guidelines. At discharge, participants were given written instructions on how to perform both types of Valsalva manoeuvre themselves using a 10 mL syringe²¹ and provided with the website address of the Arrhythmia Alliance, a patient support charity.

Participants were followed up until discharge from the emergency department. Participant demographics, details of past medical history, subsequent emergency department treatment, and time spent in the emergency department were also recorded. We retrospectively screened all emergency department attendances during the trial period to get local feedback of missed, but potentially eligible patients, and to more fully describe the population from which our participants were recruited.

Outcomes

The primary outcome was the presence of sinus rhythm as recorded by the treating clinician 1 min after Valsalva manoeuvre and confirmed by ECG in the intention-to-treat population. All trial ECGs were retrospectively assessed

by an independent cardiologist, masked to treatment allocation. Disagreement with the treating clinician’s ECG interpretation was arbitrated by an independent electrophysiologist masked to treatment allocation. Primary outcome data were corroborated by an independently chaired endpoint committee when necessary. Every attempt was made to retrieve missing data. In cases where the post-Valsalva manoeuvre ECG was missing, primary outcome was confirmed by endpoint committee. Such cases were reviewed in detail with all available evidence to confirm the primary outcome. For the purpose of the intention-to-treat analysis only, spontaneous cardioversion that occurred after randomisation but before intervention, was considered a treatment success, but all such cases were also reviewed by the endpoint committee.

Secondary outcomes were the use of adenosine, the use of any emergency treatment for supraventricular tachycardia (including adenosine), the need and reason for admission to hospital, the length of time participants spent in the emergency department, and adverse events. We also compared the adequacy of the Valsalva manoeuvre strain. To enable a per-protocol analysis and description of the cohort, participants’ presenting arrhythmias were also retrospectively classified by the clinicians’ final diagnoses and expert ECG reports with recourse to the arbiter when there was disagreement.

Statistical analysis

To calculate the required sample size, we estimated that the standard Valsalva manoeuvre would cause cardioversion in 15% of patients with supraventricular tachycardia on the basis of local audit data and previous studies.^{8,9,14} We powered our study to be able to detect at least a 12% absolute improvement with the modified Valsalva manoeuvre, using the available evidence and the minimum improvement we thought would effect a change in practice. We estimated that this difference would require 186 patients per group (assuming a two-tailed test of statistical significance with an α of 0.05 and power of 0.8), and a 22 month recruitment period across ten centres.

We expected that some patients would spontaneously revert to sinus rhythm between randomisation and intervention. We closely monitored rates of spontaneous cardioversion, recruitment, and emergency department final diagnoses. We recruited ahead of target but noted that 5% of participants had spontaneous cardioversion after randomisation and before intervention, and a higher than expected recruitment of participants with non-eligible tachycardia (mainly atrial flutter). It was therefore decided, with agreement of the steering committee, to continue recruiting until the end of the planned recruitment period to maximise the number of participants with eligible supraventricular tachycardia, to meet our initial sample size assumptions and increase trial precision.

See Online for video

For the Arrhythmia Alliance see <http://www.arrythmiaalliance.org.uk>

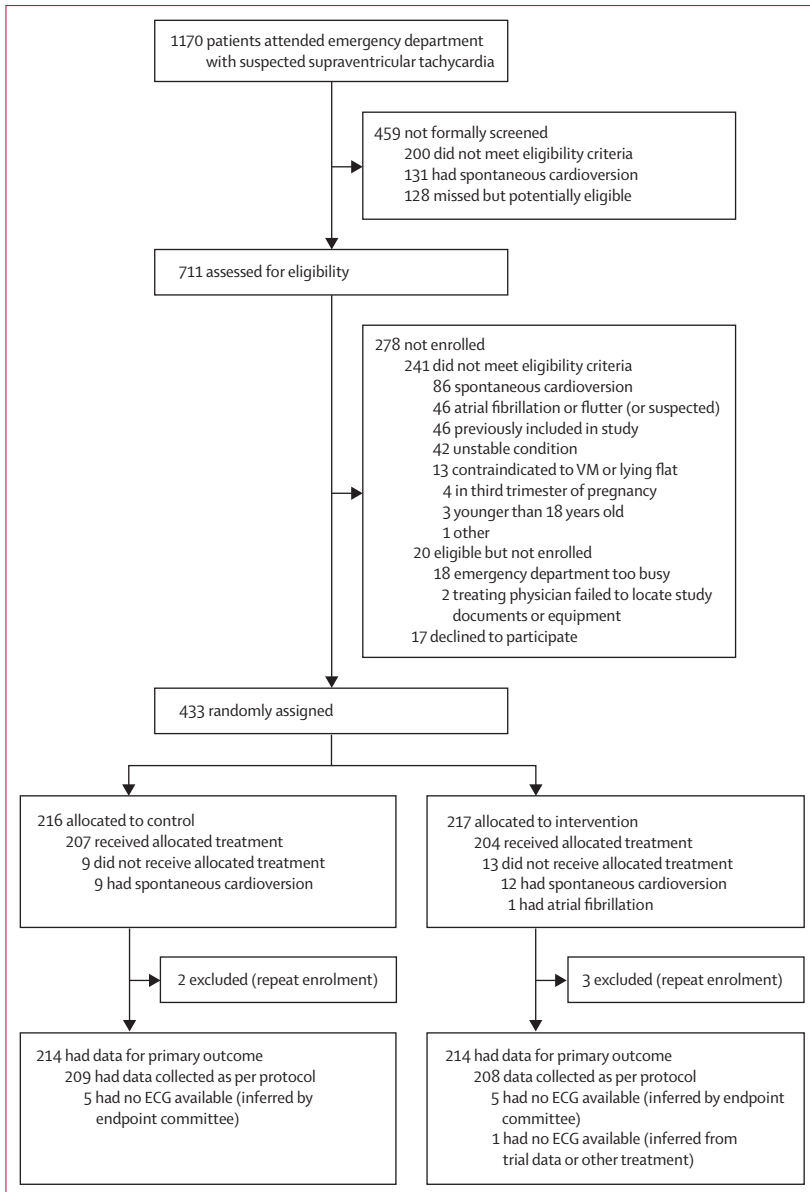


Figure: Trial profile

VM=Valsalva manoeuvre. ECG=electrocardiogram.

There was no opportunity for crossover of trial treatments except in the case of error, and participants were analysed according to intention to treat. In accordance with the statistical analysis plan, second episode data from patients recruited in error for a second time were excluded.

We report baseline data descriptively by group. We compared binary outcomes (including the primary outcome) using mixed effects logistic regression with allocation group as a fixed effect and centre as a random effect. We analysed time spent in the emergency department using Cox proportional hazards regression with a shared frailty model (for centre).

We also did a per-protocol analysis excluding participants who did not undertake at least one trial Valsalva manoeuvre and those with trial ineligible tachycardias (protocol violations). These patients were identified by a final emergency department diagnosis of ineligible tachycardia (atrial flutter, atrial fibrillation, sinus tachycardia, or broad complex tachycardia) or by agreement of expert ECG reviewer and arbiter that the pre-intervention ECG showed one of these excluded arrhythmias.

The trial had no separate data and safety monitoring committee; however, adverse event data and overall cardioversion rates were monitored by the steering committee to ensure safety and non-futility. We did the statistical analyses with Stata (version 14.0).

The study is registered with Current Controlled Trials, ISRCTN67937027.

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and final responsibility for the decision to submit for publication.

Results

Between Jan 11, 2013, and Dec 29, 2014, 1170 patients attended participating sites with suspected supraventricular tachycardias and of these, 711 patients were screened. We randomly assigned 433 participants, 216 to receive a standard Valsalva manoeuvre and 217 to receive the modified Valsalva manoeuvre (figure). 164 different clinicians delivered the intervention. Data for the second attendance from five patients who were recruited twice in error were omitted from the analyses, leaving 214 in each group. Spontaneous cardioversion after randomisation and before intervention occurred in nine (4%) of 214 participants in the standard group and 12 (6%) of 214 in the modified Valsalva manoeuvre group. Of the 428 participants included in the primary analysis, 205 attempted at least one standard Valsalva manoeuvre and 201 at least one modified Valsalva manoeuvre according to allocation. 179 participants in the standard Valsalva manoeuvre group and 131 in the modified Valsalva manoeuvre group who remained in supraventricular tachycardias attempted a second manoeuvre as allocated.

There was no crossover of treatment and similar numbers of patients in each group achieved the defined study strain with 173 (84%) of 205 participants with strain data in the standard group and 173 (86%) of 202 in the modified group reaching the target pressure and duration of strain. One participant allocated to the modified Valsalva manoeuvre was identified as being in atrial fibrillation before any trial intervention and seven participants in each group withdrew before doing a second Valsalva manoeuvre but all consented to their data

being used. No patients were lost to follow-up and data for all randomised participants, excluding the second attendance data of five patients who had previously been recruited to the trial, were analysed (figure).

Baseline demographic, past medical history, and presenting physiological data were similar in each group (table 1). Potentially eligible patients who were not formally screened had similar demographic features to the recruited population (data not shown).

93 (43%) of 214 participants in the modified Valsalva manoeuvre group versus 37 (17%) of 214 participants in the standard Valsalva manoeuvre group achieved the primary outcome of sinus rhythm at 1 min (odds ratio [OR] 3.7, 95% CI 2.3–5.8; $p < 0.0001$; table 2). The absolute difference was 26.2%; thus, three patients needed the modified Valsalva manoeuvre to avoid one case of further treatment.

This finding was confirmed by analysis of primary source data with expert review of 12-lead post-intervention ECGs in 417 (97%) patients, and by the agreement of the endpoint committee in ten (2%) patients (five in each group). A further patient, for whom there was no post-intervention ECG, was identified as being in atrial fibrillation after enrolment and did not undergo a Valsalva manoeuvre. In both groups, for those who had sinus rhythm restored with a Valsalva manoeuvre, cardioversion occurred mostly at the first manoeuvre. However, nine patients in the standard Valsalva manoeuvre group and 18 in the modified Valsalva manoeuvre group cardioverted at the second attempt.

Use of adenosine was significantly lower in the modified Valsalva manoeuvre group than in the standard Valsalva manoeuvre group (table 2). Only four patients had recurrence of supraventricular tachycardia requiring further treatment in the emergency department. All had initially achieved sinus rhythm with the modified Valsalva manoeuvre. The requirement for any emergency department anti-arrhythmic treatment (appendix) after Valsalva manoeuvre was rarer in the modified Valsalva manoeuvre group than the standard Valsalva manoeuvre group (table 2). Neither time spent in the emergency department nor need for admission differed significantly between groups (table 2).

No serious adverse events were reported. Non-serious adverse events were more common in the modified Valsalva manoeuvre group than in the standard Valsalva manoeuvre group, but not significantly so (table 3). ECG escape events, such as ventricular beats, were occasionally reported during successful cardioversion in the modified Valsalva manoeuvre group (table 3). The five electrocardiograph-captured events were one asystolic pause and four episodes of ventricular escape activity, all of which resolved spontaneously. All adverse events were transient and self-limiting, requiring no additional treatment.

Excluding patients with non-eligible tachycardias (table 4) and those who did not undergo a trial intervention

	Standard VM (n=214)	Modified VM (n=214)
Men	80 (37%)	89 (42%)
Age (years)	54.5 (16.8)	55.1 (16.3)
Previous SVT (undiagnosed)	57 (27%)	63 (29%)
Previous SVT (diagnosed)	103 (48%)	97 (45%)
Previous ablation treatment	15 (7%)	19 (9%)
Ischaemic heart disease	7 (3%)	11 (5%)
Diabetes	18 (8%)	25 (12%)
Hypertension	36 (17%)	47 (22%)
Valvular heart disease	5 (2%)	1 (<1%)
Pneumonia	4 (2%)	2 (1%)
COPD	7 (3%)	2 (1%)
Systolic BP (mm Hg)	124 (22)	125 (23)
Diastolic BP (mm Hg)	82 (18)	83 (19)
Pulse (beats per minute)	179 (29)	172 (29)
O ₂ saturation (%)	97.9 (2.1)	98.0 (1.9)

Data are n (%) or mean (SD). VM=Valsalva manoeuvre. SVT=supraventricular tachycardia. COPD=chronic obstructive pulmonary disease. BP=blood pressure.

Table 1: Baseline characteristics

	Standard VM (n=214)	Modified VM (n=214)	Effect size (95%CI)	p value
Presence of sinus rhythm at 1 min after VM	37 (17%)	93 (43%)	3.7 (2.3–5.8)	<0.0001
Adenosine given	148 (69%)	108 (50%)	0.45 (0.30–0.68)	0.0002
Any emergency anti-arrhythmic treatment	171 (80%)	121 (57%)	0.33 (0.21–0.51)	<0.0001
Discharged home from emergency department	146 (68%)	134 (63%)	0.79 (0.51–1.21)	0.28
Any adverse event	8 (4%)	13 (6%)	1.61 (0.63–4.08)	0.32
Time in emergency department (h; median, IQR)	2.83 (1.95–3.62)	2.82 (1.95–3.77)	0.90 (0.75–1.10)	0.31

Effect sizes are adjusted odds ratios, except for time in emergency department, which is an adjusted hazard ratio. VM=Valsalva manoeuvre.

Table 2: Primary and secondary outcomes

resulted in a greater difference between the groups, with 28 (15%) of 183 participants in the standard Valsalva manoeuvre group achieving sinus rhythm compared with 81 (47%) of 173 in the modified Valsalva manoeuvre group (adjusted OR 4.9, 95% CI 2.9–8.0; $p < 0.0001$).

See Online for appendix

Discussion

We have shown that a simple, cost-free, well-tolerated postural modification to the standard Valsalva manoeuvre is highly effective, returning more than 40% of patients to sinus rhythm compared with 17% with a standard Valsalva manoeuvre. This difference resulted in a substantial reduction in the number of patients needing other emergency treatments, particularly adenosine. Fewer patients treated with the modified Valsalva manoeuvre needed further emergency department treatment, compared with the standard Valsalva manoeuvre.

	Standard VM (n=214)	Modified VM (n=214)
Increased heart rate	4	3
Hypotension or light-headedness	3	3
Nausea	2	3
Electrocardiograph captured events	0	5
Other*	0	4
Musculoskeletal pain†	0	3

Some participants reported more than one adverse event. 30 non-serious adverse events were reported in 21 participants. VM=Valsalva manoeuvre. *Transient headache (n=2), shortness of breath (n=1), and cyanosis (n=1) in different patients. †Transient chest wall pain on straining (n=3).

Table 3: Adverse events

	Standard VM (n=214)	Modified VM (n=214)
Eligible SVT		
Re-entrant, atrial tachycardia, other	184 (86%)	184 (86%)
Undetermined NCT	15 (7%)	12 (6%)
Ineligible rhythms (protocol violations)		
Atrial flutter	13 (6%)	12 (6%)
Atrial fibrillation	0 (0%)	2 (1%)
Broad complex tachycardia	1 (<1%)	4 (2%)
Sinus tachycardia	1 (<1%)	0 (0%)

VM=Valsalva manoeuvre. SVT=supraventricular tachycardia. NCT=narrow complex tachycardia.

Table 4: Presenting rhythm, as assessed retrospectively by electrocardiograph review

We did not detect any time saving or reduced need for hospital admission. Most treatments for supraventricular tachycardia take little time and take up only a small proportion of the total time spent in the emergency department. Likewise, the need for hospital admission is usually determined by the presence of concurrent medical conditions and not for the supraventricular tachycardia per se, which was similar in each group.

A higher proportion of patients had cardioversion in our study than in most observational studies,¹⁹ but the proportion in the control group was similar to that on which we based our sample size and within the range in routine practice. By contrast, the proportion of patients who cardioverted in the modified Valsalva manoeuvre group was substantially higher than that reported in other studies of emergency supraventricular tachycardia vagal treatments, and greater than the 31% reported by Walker and Cutting with a Trendelenberg (supine with head down incline) Valsalva manoeuvre.¹⁴ We believe that there are sound physiological reasons for this difference, with the sequence and timing of the strain and changes to position all important to the success of our particular modification.

We compared a modified Valsalva manoeuvre with the Valsalva manoeuvre most commonly used in routine practice in this setting.^{7,14,16} Although a supine Valsalva

manoeuvre achieves greater vagal tone in healthy patients or those with induced supraventricular tachycardia,^{17,22} patients are routinely assessed in a semirecumbent position and there might be benefits from starting the Valsalva manoeuvre in this position (augmenting the initial fall in venous return on straining) before maximising venous return in the relaxation phase (Valsalva stage 3) through supine position and passive leg lift.

Treating clinicians could not be masked to treatment allocation but we used strict allocation concealment and standardised instructions, and disguised from participants which allocation was the intervention and which was control. Subsequent emergency department treatment was unlikely to be influenced by knowledge of trial allocation because patients would not conceivably have been left in supraventricular tachycardia without treatment or treated with adenosine when in sinus rhythm. Strain data confirmed the equivalence of the Valsalva manoeuvre strain effort in both groups.

We recruited a higher proportion of patients with non-eligible supraventricular tachycardia (mainly atrial flutter) than expected, as a result of the difficulty of distinguishing such rhythms from re-entrant supraventricular tachycardia in an emergency department. Improving the detection and exclusion of these rhythms might further improve the efficacy of the modified Valsalva manoeuvre, as suggested by the per-protocol analysis. We did not assess the relative frequency of re-entrant supraventricular tachycardia subtypes—eg, atrioventricular nodal re-entry tachycardia and atrioventricular re-entry tachycardia. This distinction is not routinely, accurately, or reliably made at presentation and does not affect initial hospital management or preclude use of a Valsalva manoeuvre as first-line treatment.

Future work should assess the implementation and dissemination of this technique and its performance in routine practice. Studies comparing it with the fully supine Valsalva manoeuvre in both patients and healthy volunteers should also be considered.

An improved Valsalva manoeuvre that is successful in 50% of cases has potential benefits for patients with supraventricular tachycardia worldwide. Our study was pragmatic and done in an environment in which these patients are often treated, but used a modification that can be done anywhere, including community and resource-poor settings, without specialist equipment. We used a manometer to ensure a consistent and measurable 40 mm Hg strain, but a 10 mL syringe blown to just move the plunger generates a similar pressure.²¹

We did not identify any disadvantages of using the modified Valsalva manoeuvre technique. As long as individuals can safely undertake a Valsalva strain and be repositioned as described, this manoeuvre can be used as the routine initial treatment for episodes of supraventricular tachycardia regardless of location. The technique could prevent many patients from being

treated with drugs or even seeking health care. Clinicians who encounter this condition should consider learning the technique and teaching it to patients after a first episode of supraventricular tachycardia.

Contributors

AA had the idea for the study and wrote the first draft. AA, AR, and CM initially designed the study, which was refined with PE, AB, JB, and JG. PE provided the statistical plan and did the analyses. JG provided the background information and audit data for the trial. MD assessed the ECGs. TL represented the public and patient views during study development and contributed to publicity and dissemination plans. JV led the clinical trials unit team and oversaw the trial management. All authors critically reviewed successive drafts of the report and approved the final version.

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Declaration of interests

We declare no competing interests.

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