Original Article

Comparison of two techniques of administering the Valsalva manoeuvre in patients under general anaesthesia: A randomised controlled study

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ABSTRACT

Background and Aims: Surgeons often request a Valsalva manoeuvre (VM) at the end of surgery (head–neck surgery, craniotomy) to check haemostasis and to unmask covert venous bleeders. We aimed to compare an anaesthesia machine-generated objective technique for delivering VM under pressure-control (PC) mode with the traditional subjective technique of delivering VM in manual mode**. Methods:** This randomised controlled study included 60 adult patients randomised to manual (Group M) and controlled ventilation (Group C) groups. Our primary outcome measure was internal jugular vein (IJV) diameter at pre-determined time points (T_0 = baseline, T_1 = VM initiation, T_2 = 20 s after VM initiation, T_3 = immediately after VM release, and T_4 = 1 min, T_5 = 2 min and T_6 = 5 min post-VM release). Secondary outcome measures included mean arterial pressure (MAP), heart rate, time to desired plateau airway pressure, number of patients with bleeders unmasked and surgeon satisfaction. Independent/paired sample *t*-tests were applied. Results are expressed as mean (standard deviation), mean difference (95% confidence interval), dotted box–whisker plots and trendlines. P <0.05 is considered statistically significant. **Results:** Mean differences in diameter changes in IJV (in centimetres) in the mediolateral and anteroposterior directions between Group C and Group M were -0.136 (-0.227, -0.044) and -0.073 (-0.143, -0.002), respectively. VM in the PC mode produced more significant IJV dilatation (P = 0.004, P = 0.044). MAP at T_0 and T_1 was comparable. At T_2 and T_3, there was a more significant fall in MAP in Group C versus Group M (P = 0.018 and P = 0.021, respectively). At T_4, T_5 and T_6, MAP was comparable. **Conclusion:** Performing VM in PC mode is a better technique based on IJV diameter, haemodynamics, bleeder unmasking and surgeon satisfaction.

Keywords: Anaesthesia, haemostasis, jugular veins, Valsalva manoeuvre, ventilation

INTRODUCTION

Intraoperative utility of Valsalva manoeuvre (VM) spans across unmasking covert venous bleeders during haemostasis in head–neck and thyroid surgery, cerebrospinal fluid (CSF) leak in neurosurgery, evaluation of autonomic neuropathy, localising the site of venous air embolism in posterior fossa surgery and facilitating internal jugular vein (IJV) cannulation and pain attenuation during skin puncture before neuraxial block/venous cannulation.[1-5] A rise in intrathoracic pressure, mean arterial pressure (MAP) and bradycardia occurs during phase I of VM (increased intrathoracic pressure raises internal jugular venous

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pressure by producing reflux of venous blood and aids haemostasis). Intracranial pressure increases in phase II, accompanied by a fall in MAP and tachycardia.[1] Traditional VM administration utilises the 'intermittent positive pressure technique' comprising partially closing the adjustable pressure limiting (APL) valve to 40 cmH_2O, gentle manual squeezing of the reservoir bag, maintaining the compression for 15–20 s and keeping the fresh gas flow in the circle system at 2 l/min while observing the airway pressure graph and numerical values on the anaesthesia workstation monitor screen.[1,5,6] Observing the airway pressure values on the monitor during traditional VM administration revealed delivery of a highly variable airway pressure, which seldom reached the set 40 cmH_2O mark with this subjective technique.

We aimed to compare an anaesthesia machine-generated objective technique for delivering VM under pressure-controlled (PC) mode and the traditional subjective technique of delivering VM in manual mode. Our primary objective was to measure the IJV diameter (IJVD), and secondary objectives were to measure heart rate (HR) and MAP at specific time points, the number of patients in whom bleeders were unmasked and surgeon satisfaction. We hypothesised that the PC mode technique of delivering VM was superior to the traditional manual technique.

METHODS

This interventional, two-arm, single-centric, randomised controlled study was conducted at a tertiary care oncology setup from March 2023 to August 2023 in accordance with the Declaration of Helsinki (2013) and Good Clinical Practice. Written informed consent was obtained from all patients for participation in the study and to use the patient data for research and educational purposes. The approvals were obtained from the ethics committee (vide approval number RGCIRC/IRB-BHR/27 2022; dated 6 April 2022). The study was prospectively registered with the Clinical Trials Registry- India (vide registration number CTRI/2023/03/050686; https://ctri.nic.in/). The study included 60 adult American Society of Anesthesiologists physical status I/II patients undergoing head and neck cancer surgery with free flap reconstruction. Patients with hypertension, aortic stenosis, hypertrophic obstructive cardiomyopathy, recent myocardial infarction, supraventricular tachycardia with haemodynamic instability, chronic obstructive airway disease and positive history of stroke, glaucoma and retinopathy were excluded from the study.

The patients were randomly allocated into two groups: manual VM group (Group M; $n = 30$) and PC ventilation VM group (Group C; $n = 30$) by computer-generated block randomisation (15 blocks of block size 4). Group allocation was concealed in sequentially numbered, opaque, sealed envelopes, and the allocation ratio was 1:1.

All patients were adequately hydrated (Carboload, Hexagon Nutrition; 100 mg the night before surgery and 50 mg 2 h before surgery) as per the institutional 'Enhanced Recovery After Surgery' protocol for elective head and neck surgery. After applying standard monitors, face mask ventilation was instituted using a fresh gas flow of 6–8 l/min. Anaesthetic induction was carried out with intravenous (IV) fentanyl 2 μg/kg and bispectral index (BIS)-guided IV propofol (1 mg/kg bolus followed by 10 mg every 30 s after 1 min of initial bolus, till BIS 40–60 was achieved) in both the groups. IV atracurium 0.5 mg/kg bolus was administered. After 3 min, IV atracurium 5 mg was given every 30 s till loss of single second twitch on peripheral nerve stimulation. A 7-mm internal diameter flexometallic cuffed endotracheal tube (ETT) was nasotracheally introduced in both groups 4–4.5 min after the initial atracurium dose. After capnographic and auscultatory confirmation of correct ETT placement, the patient was put on volume control-AutoFlow mode of ventilation, sevoflurane was turned on, and fresh gas flow was reduced to 2 l/min after inspiratory sevoflurane matched the set dial concentration of 2% sevoflurane. An invasive arterial line was placed immediately after endotracheal intubation. In all the patients, VM was instituted using our anaesthesia workstation (Perseus A-500; Drägerwerk AG, Lübeck, Germany), and the corresponding measurements were taken only after the haemodynamics were stabilised to within 20% of baseline values or after waiting for 5 min post-intubation, whichever was longer. Fresh gas flow was fixed at 2 l/min in both groups. In Group M, the ventilator was put on manual/spontaneous mode and the APL valve was partially closed to 40 cmH_2O.[7] The reservoir bag was manually compressed to an extent expected to deliver an average tidal breath (8 ml/kg), and the compression was maintained for 20 s. A test tidal breath was manually given, and the expiratory tidal volume (VTe) was noted on the monitor. In the next breath, the reservoir bag was compressed to an extent guided by the VTe in the previous breath, but this time, the compression was maintained for 20 s. If the VTe in the previous breath was higher than 8 ml/kg, the reservoir bag was compressed with lesser force and if the VTe was <8 ml/kg, the reservoir bag was compressed with greater force, accordingly. Group C patients were placed on PC mode with 40 cmH_2O pressure setting, positive end-expiratory pressure 35 cmH_2O and respiratory rate (RR) 3 breaths/min to deliver 20 s of 35–40 cmH_2O airway pressure (40 cmH_2O during inspiration and 35 cmH_2O during expiration).[8] Invasive MAP and HR were measured at seven time points: T_0 = baseline (30 s before the initiation of VM), T_1 = initiation of VM, T_2 = 20 s after VM initiation, T_3 = immediately after VM release, and T_4 = 1 min, T_5 = 2 min and T_6 = 5 min post-VM release. IJVD was measured in two perpendicular directions in the same plane using point-of-care ultrasonography with 7.5 MHz linear ultrasound (USG) probe (Sonosite Edge II Ultrasound System; Fujifilm SonoSite Inc., Bothell, WA, USA) at three time points: baseline IJVD before initiation of VM (T_0), at T_2 and T_6. The patient's neck was rotated 30° to the contralateral side to visualise IJV during sonography better, and measurements were taken at the base of the triangle formed by two heads of the sternocleidomastoid muscle. The principal investigator (PI) administered VM, while an assistant took a snapshot of the monitor screen (displaying HR and MAP) at the required time points as directed by the PI. The second investigator handled the USG probe and froze the USG screen image at T_0, T_2 and T_6. A snapshot was taken and measurements (using virtual callipers in the USG machine) were completed for the IJVD readings. An assistant, stably and lightly holding the USG probe *in situ* throughout the 6 min of measurement, repeated the VM after tumour resection for unmasking covert bleeders, and surgeon satisfaction was also noted in both groups. The study was participant blinded, and the patients were unaware of the study group to which they were allocated. It was clarified to them earlier that, once under anaesthesia, they could fall in either of the two groups.

Our primary outcome measure was IJVD, measured at predetermined time points (T_0 = baseline, T_2 = 20 s after VM initiation and T_6 = 5 min post-VM release) in the mediolateral and anteroposterior diameters in the cross-sectional view of IJV. Our secondary outcome measures were MAP and HR measured at pre-determined time points (T_0 = baseline, T_1 = VM initiation, T_2 = 20s after VM initiation, T_3 = immediately after VM release, and T_4 = 1 min, T_5 = 2 min and T_6 = 5 min post-VM release), time taken to attain the desired plateau airway pressure, number of patients in whom bleeders were unmasked and surgeon satisfaction.

Sample size calculation and statistical analysis were done using MedCalc statistical software (version 18.9.1, released 2018; MedCalc Software Ltd, Ostend, Belgium). Taking the difference of IJVD between groups as 0.2 cm after induction of anaesthesia and institution of mechanical positive pressure ventilation, the standard deviation (SD) being 0.21 and 0.26, respectively, the ratio of sample sizes as 1:1, with a power of 80% and Type I alpha error of 0.1,[9] a sample size of 25 patients in each group was arrived. Allowing for dropouts, we enroled 30 patients per group. A descriptive summary was used for both categorical (gender, bleeders unmasked and surgeon satisfaction, expressed as numbers and percentages) and continuous variables. Independent sample *t*-tests for intergroup comparison of normally distributed, quantitative variables (age, weight, height, IJVD, HR, MAP and time to plateau) and paired sample *t*-tests for intragroup comparison of IJVD, HR and MAP were performed. Results were expressed as mean (SD) [95% confidence interval (CI)], dotted box–whisker plots and trendlines. A correlogram calculated by Pearson's correlation coefficient was created for change in IJVD (δIJVD), HR (δHR) and MAP (δMAP). P <0.05 was considered statistically significant.

RESULTS

The Consolidated Standards of Reporting Trials Diagram [Figure 1] depicts participants' flow across both groups. Demographic parameters (age, weight, height, gender) were comparable in both groups [Table 1].

The mean difference in mediolateral diameter [0.36 (SD: 0.21) (95% CI: 0.28, 0.44) cm in Group C versus 0.23 (SD: 0.15) (95% CI: 0.17, 0.28) cm in Group M], as well as the anteroposterior diameters [0.26 (SD: 0.13) (95% CI: 0.21, 0.31) cm in Group C versus 0.19 (SD: 0.15) (95% CI: 0.13, 0.24) cm in Group M] on sonographic cross-sectional view of the IJV were statistically significant (P = 0.004 and P = 0.044, respectively) [Table 1; Figures 2 and 3].

On categorising the patients undergoing head and neck surgery with free flap reconstruction, carcinoma buccal mucosa was found to be the most common indication

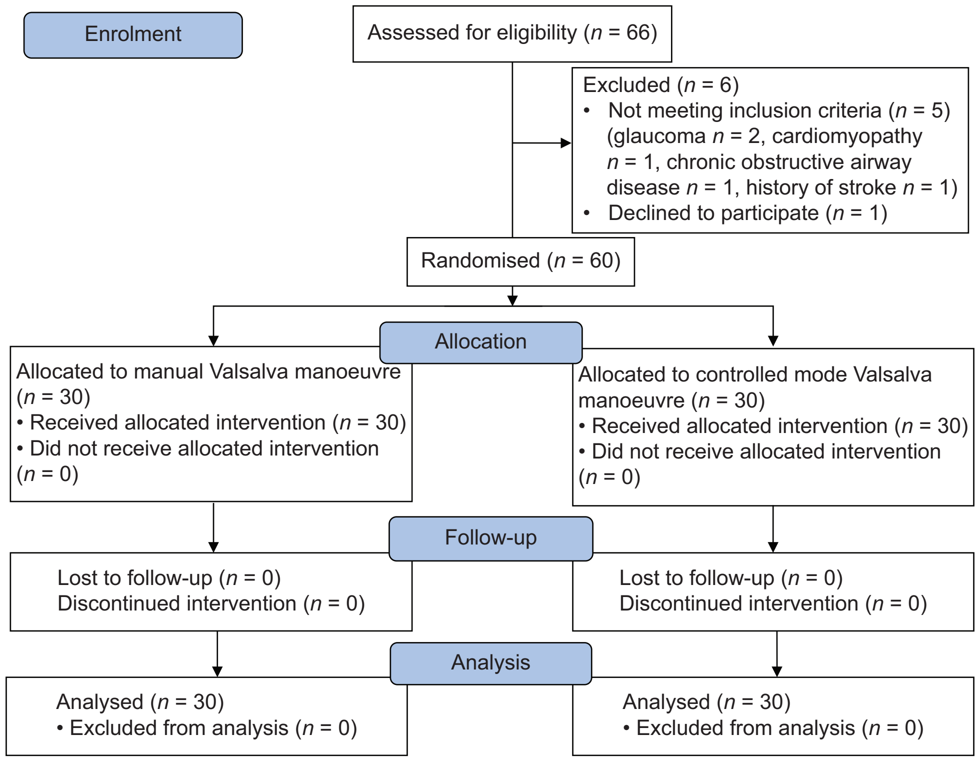

Figure 1: Consolidated system of reporting trials flow diagram

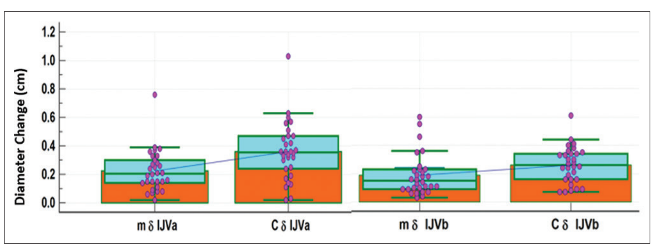

Figure 2: Dotted box–whisker plots with bars comparing the dilatation of IJV as a result of VM in Group M or manual mode VM and Group C or controlled mode VM (brown bar = mean; blue box–whisker = median, first and third quartiles, upper and lower adjacent values to the upper and lower inner fence; green error bars = 95% CI for mean; pink dots = dot plot displaying all data/individual patient values). CδIJVa = change in mediolateral IJV diameter after 20 s of VM in Group C, CδIJVb = change in anteroposterior IJV diameter after 20 s of VM in Group C, CI = confidence interval, IJV = internal jugular vein, mδIJVa = change in mediolateral IJV diameter after 20 s of VM in Group M, mδIJVb = change in anteroposterior IJV diameter after 20 s of VM in Group M, VM = Valsalva manoeuvre

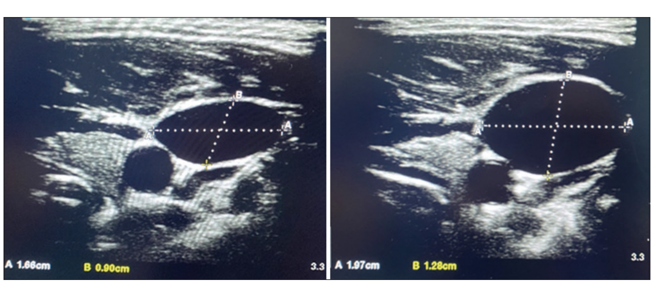

Figure 3: Sonographic image comparing internal jugular vein diameter before (left) and 20 s after (right) application of Valsalva manoeuvre

for surgery (18/30 Group M versus 15/30 Group C). In 4/30 patients in Group M and 3/30 patients in Group C, 6 mg of IV ephedrine was administered when MAP fell below 65 mmHg post-induction of anaesthesia. In 2/30 patients in Group M and 3/30 patients in Group C, 5 mg of IV diltiazem was required when a 20% above baseline rise in MAP was observed post-endotracheal intubation.

Statistically significant changes in MAP were observed at the initiation of VM, 20 s after VM initiation and immediately after VM release in Group C ($P < 0.001$, <0.001 and <0.001, respectively) and at 20 s after VM initiation and immediately after VM release in Group M ($P < 0.001$ and <0.001, respectively) compared to baseline values in each group [Figure 4].

The correlogram depicts the Pearson coefficient for correlation between change in HR (δHR), change in MAP (δMAP) and change in IJVD (δIJVD) [Table 2]. A negative correlation between δMAP and δIJVD was seen in Group M and Group C (Pearson correlation coefficient = -0.49 and -0.45, respectively).

The incidence of unmasking of covert bleeders and surgeon satisfaction were higher in Group C. The time to achieve the required plateau airway pressure

Table 1: Demographic and study parameters

Parameter	Group M (*n*=30)	Group C (*n*=30)	*P*
Age (years), mean (SD)	55.8 (10.79)	52.8 (9.13)	-
Weight (kg), mean (SD)	69.1 (12.05)	69.5 (13.54)	-
Height (cm), mean (SD)	165.2 (6.28)	166.0 (9.07)	-
Gender: male/female	27:3	24:6	-
Bleeder unmasked (yes/no)	12/18	9/21	0.630
δIJVa (cm), mean (SD) (95% CI)	0.23 (0.15) (0.17, 0.28)	0.36 (0.21) (0.28, 0.44)	0.004
δIJVb (cm), mean (SD) (95% CI)	0.19 (0.15) (0.13, 0.24)	0.26 (0.13) (0.21, 0.31)	0.044
Time to plateau airway pressure (s), mean (SD) (95% CI)	15 (2.07) (14.23, 15.77)	3.5 (0.51) (3.31, 3.69)	<0.001
Surgeon satisfaction (yes/no)	25/5	21/9	0.229
Type of surgery			
• Ca buccal mucosa	18	15	
• Ca lower alveolus	4	5	
• Ca tongue	4	5	
• Ca maxilla	1	2	
• Osteoradionecrosis	1	1	
• Ca retromolar trigone	1	1	
• Unknown primary	1	1	

Data expressed as mean (standard deviation) (95% confidence interval) or numbers. δIJVa=change in mediolateral internal jugular vein diameter, δIJVb=change in anteroposterior internal jugular vein diameter, Ca=carcinoma, CI=confidence interval, *n*=number of patients, SD=standard deviation

Table 2: Correlogram where 1.0 (red) is the maximum positive correlation, 0 (green) is no correlation, -1.0 (blue) = maximum negative correlation

Correlogram 1.0 -1.0

	cδIJVb	cδIJVa	mδIJVb	mδHR	mδIJVa	cδHR	cδMAP	mδMAP
cδIJVb		0.76	0.11	-0.03	0.12	0.23	-0.28	-0.19
cδIJVa	0.76		-0.08	-0.14	0.10	0.29	-0.45	-0.16
mδIJVb	0.11	-0.08		-0.10	0.51	-0.03	0.02	-0.38
mδHR	-0.03	-0.14	-0.10		-0.21	-0.23	-0.12	0.40
mδIJVa	0.12	0.10	0.51	-0.21		-0.03	-0.02	-0.49
cδHR	0.23	0.29	-0.03	-0.23	-0.03		-0.03	-0.29
cδMAP	-0.28	-0.45	0.02	-0.12	-0.02	-0.03		0.03
mδMAP	-0.19	-0.16	-0.38	0.40	-0.49	-0.29	0.03	

Pearson correlation coefficient for change in internal jugular vein diameter, heart rate and mean arterial pressure in both the groups.

HR=Heart Rate; IJV=Internal Jugular Vein; MAP=Mean Arterial Pressure; VM=Valsalva Manoeuvre; mδIJVa=Change in mediolateral IJV diameter after 20s of VM in Group M; cδIJVa=Change in mediolateral IJV diameter after 20s of VM in Group C; mδIJVb=Change in anteroposterior IJV diameter after 20s of VM in Group M; cδIJVb=Change in anteroposterior IJV diameter after 20s of VM in Group C; mδHR=Change in HR after 20s of VM in Group M; cδHR=Change in HR after 20s of VM in Group C; mδMAP=Change in MAP after 20s of VM in Group M; cδMAP=Change in MAP after 20s of VM in Group C

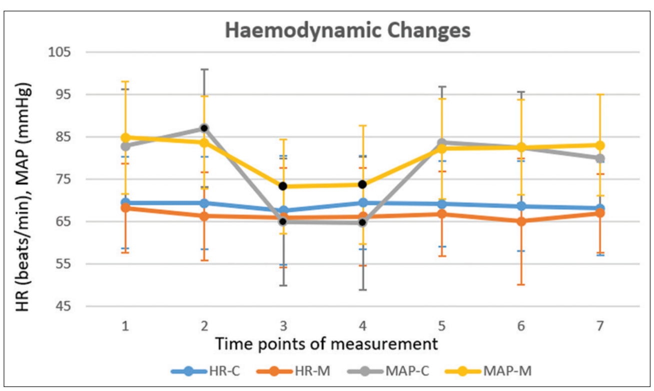

Figure 4: Line diagram with error bars for the standard deviation, with black asterisks representing points of significant variation. HR-C = heart rate in Group C, HR-M = heart rate in Group M, MAP-C = mean arterial pressure in Group C, MAP-M = mean arterial pressure in Group M

was higher in Group M than in Group C [Table 1]. No complications attributable to VM were observed.

Results showed that 7/30 patients in Group M and 6/30 patients in Group C experienced postoperative bleeding of varying degrees. All seven patients in Group M required re-exploration in the major operation theatre, and one patient had a chyle leak. In Group C, three patients with neck oedema required resuturing in the minor OT under local anaesthesia, while the remaining three required re-exploration in the major OT under general endotracheal anaesthesia.

DISCUSSION

As hypothesised, VM performed in the PC mode produced greater IJV dilatation than manual VM as measured by the increase in anteroposterior and mediolateral diameters on the sonographic cross-sectional view of IJV. This is attributable to a more predictable and constant plateau airway pressure obtained in the PC mode.

The traditional VM administration is subjective and delivers a highly variable airway pressure, seldom reaching the set 40 cmH_2O mark. The increase in IJVD at T_2 (20 s after VM initiation, before VM release) owing to a rise in intrathoracic pressure and rise in venous pressure is the intended outcome of VM, which is beneficial by exposing any covert bleeders at the surgical site during haemostasis towards the end of surgery. An increase in venous pressure causes reflux of venous blood, leading to the identification of covert bleeders.[6] These bleeders, if left unattended, may result in complications like haematoma formation, compromise of free flaps employed for reconstructive surgery warranting an emergency re-exploration, airway compromise in case of thyroid surgery, wound infection and patient discomfort.

We rotated the patient's head 30° contralaterally and performed all measurements at the base of the triangle formed by the two heads of sternocleidomastoid muscle to maintain uniformity. The importance of this step is highlighted by a study that reported variation in IJVD at the apex, middle and base of the triangle, with IJVD being greatest at the base of the triangle.[10] As per Dincyurek *et al*.,[9] who performed VM to facilitate IJV cannulation in 100 paediatric patients, VM increased IJVD by 0.2 cm in the VM group. Although the percentage increase was similar, the absolute IJVD was greater in our patients. The cross-sectional area of the right IJV in the supine position in adult male volunteers was 3.20 cm^2, which increased to 3.45 cm^2 during VM, as per Kalkan and Kavak,[11] which is comparable to our results.

Brown *et al*.[12] found VM to be effective in identifying dermal bleeders after paramedian forehead flap elevation under local anaesthesia. As per a study by Tokaç *et al*.[6] on 100 patients undergoing total thyroidectomy, intraoperative VM identified bleeding points in 32% of the patients, which is comparable to our study. Similarly, Pacilli *et al*.[13] studied whether intraoperative VM detected occult bleeders in thyroidectomy patients and reported that revision of haemostasis after VM was performed in 34.15% of 86 patients who received VM, and the VM group displayed significantly less postoperative drainage volumes (56.7 vs. 79.4 ml).

The increase in diameter of IJV correlates with the fall in MAP at 20 s post-initiation of VM. A negative correlation between δMAP and δIJVD in Group M and Group C is explained by the mean MAP falling from 84.7 to 76.2 mmHg in the manual VM group, while IJVD increased from 1.29 to 1.51 cm. Similarly, the mean MAP fell from 82.9 to 64.9 mmHg in the controlled mode VM group, while IJVD increased from 1.28 to 1.64 cm. The greater the expansion in IJVD, the greater the fall in MAP. Without USG IJVD monitoring, a fall in MAP can be a surrogate for IJV dilation when the neck is open intraoperatively.

Although the surgeon-satisfaction quotient was high in both groups, surgeons were better satisfied with VM delivered by the PC mode technique, attributable to the greater number of bleeders unmasked and reduced degrees of postoperative bleeding.

The major strength of our study is that, although VM is a universally accepted practice to detect bleeders at surgical sites during haemostasis and closure, the literature review reveals no studies with quantification of MAP and IJVD changes during intraoperative VM by manual and PC modes for head and neck surgery. Our study fills this knowledge gap, which is methodologically sound. In addition, no study compared the above two techniques of delivering VM, concerning the identification of covert bleeders. A limitation of our study is that we did not include spine surgery/craniotomy patients to detect CSF leaks, nor did we note frailty preoperatively. Our study is generalisable to all patients undergoing head and neck surgery.

CONCLUSION

Performing the Valsalva manoeuvre in the pressure-controlled mode is a better technique based on internal jugular vein diameter, haemodynamics, unmasking of bleeders and surgeon satisfaction.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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