Balloon Assisted Valsalva Maneuver in the Diagnosis of Saphenofemoral Junction Incompetence

Nuttawut Sermsathanasawadi MD, PhD*,

Kamolrat Pattarakittikul MD*, Kiattisak Hongku MD*, Chumpol Wongwanit MD*, Chanean Ruangsetakit MD*, Khamin Chinsakchai MD*, Pramook Mutirangura MD*

* Division of Vascular Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Background: Conventional Valsalva maneuver (CV) is a standard procedure to exhibit reverse venous flow at saphenofemoral junction (SFJ) by duplex ultrasonography (DUS). However, some patients could not undergo CV during examination. **Objective:** Compare blowing party balloon assisted Valsalva (PBAV) with CV for exhibiting the reverse venous flow at SFJ incompetence.

Material and Method: Forty patients who had symptoms and signs of suspected saphenofemoral junction incompetence were examined for venous reflux by DUS with two techniques of Valsalva maneuver, PBAV, and CV. The design was a 2x2 cross-over study. The patients were randomized to two sequences. The first sequence performed CV before PBAV. The second sequence performed PBAV before CV. The timing for the instruction, reflux time, and total timing of examination were compared between the two sequences.

Results: There was neither period effect nor treatment-period interaction. Both PBAV and CV could equally identify SFJ reflux, but teaching time and total examination time in PBAV was shorter than CV.

Conclusion: PBAV is a new option to exhibit reverse venous flow at SFJ by DUS. PBAV is easier and spend less time than CV.

Keywords: Valsalva, Venous reflux, Ultrasound

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Varicose vein is one of the most common diseases in general population^(1,2). Duplex ultrasonography (DUS) is a sensitive and specific tool for the assessment of most varicose vein for detection of superficial venous reflux⁽³⁾. Valsalva maneuver to increase intra-abdominal pressure is an appropriate method to demonstrate venous reverse flow for diagnosing valvular incompetence⁽⁴⁾. Conventional Valsalva maneuver (CV) is usually used in clinical practice in the assessment of patients with SFJ reflux in many countries⁽⁴⁻⁸⁾. Patients are asked to perform CV teaching by DUS examiner⁽³⁻⁸⁾. Previous studies showed the variation of intra-abdominal pressures generated by CV⁽⁹⁾. Some patients, especially the elderly patients, could not perform CV. This problem made the DUS examiner spend more time to examine the patients.

Blow up the balloon produces a Valsalva effect to increase intra-abdominal pressure^(10,11). In the

Correspondence to:

present study, the authors compared party balloon assisted Valsalva (PBAV) with CV in the diagnosis of SFJ reflux of lower limb.

Material and Method

The present research was carried out in a single tertiary care center, Division of Vascular Surgery, Department of Surgery, Siriraj Hospital. The approval of the Siriraj Institutional Review Board of Ethic Committee was obtained. All patients gave informed consent.

The patients age 18 to 80 years who had the visible varicose vein along great saphenous vein (GSV) and Trendelenburg test positive for saphenofemoral junction (SFJ) and GSV reflux between January and May 2012 were included in the present study. The patients diagnosed as Klippel-Trenaunay Syndrome, deep vein thrombosis, arteriovenous fistula, abnormalities of oral cavity, and could not blow the party balloon were excluded from the study.

The patients' demographic data and venous clinical severity score (VCSS) were recorded.

The design was a 2x2 cross-over study. Forty patients were recruited into this study. Twenty patients

Sermsathanasawadi N, Division of Vascular Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Prannok Road, Siriraj, Bangkoknoi, Bangkok 10700, Thailand. Phone: 0-2419-8021, Fax: 0-2412-9160 E-mail: nuttawut@gmail.com

were randomized by blocked stratified randomization to perform CV before PBAV. The other 20 patients performed PBAV before CV. The standardized verbal instruction was read to each patient before performing CV or PBAV (Fig. 1).

The 9-inch party balloon was connected to 7-mm in diameter of plastic straw, 5-mm in length. It was calibrated with sphygmomanometer to confirm that it could generate standardized pressure to 30 mmHg when blowing (Fig. 2)^(5,6).

The patients were asked to blow the party balloon within 0.5 second and held for at least three seconds to demonstrate the reversed venous flow in duplex $scan^{(5,6)}$.

The timing for the instruction was recorded. The measurement of reflux time from duplex ultrasound was recorded three times for each maneuver in the Reverse Trendelenburg-15-degree (Fig. 3)⁽⁵⁾. Finally, the patients were asked to answer the questionnaires. The color Doppler duplex ultrasonography was performed on GE LOGIC 9, (GE Healthcare, USA) using 9 to 12 MHz linear transducers by an experienced vascular surgeon.

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Statistical analysis

Treatment effect, period effect and interaction between treatment and period in 2x2 cross-over study were tested using a basic principle of comparing three variables (sum of 2 periods, difference between 2 periods and difference between 2 treatments) between two sequences (CV then PBAV vs. PBAV then CV). Since these three variables were skewed, Mann-Whitney U test was employed. Statistical analysis was done using PASW Statistics 18.0 software. A 2-sided *p*-value of less than 0.05 was considered statistically significant.

Results

Twenty-seven female and thirteen male patients participated in the present study. The patient demographic data are presented in Table 1.

The mean age was 56.7 ± 11.31 year old and body mass index was 26.12 ± 6.18 kg/m². All patients had symptomatic varicose vein including pain, leg heaviness, cramping, and edema. There was one patient presented with bleeding varicose vein. The median of VCSS score was 6 (mean 7.43, SD 3.85).

Standardized conventional Valsalva verbal instruction

- Take a deep breath and hold your breath.
- Closed your nose and mouth tightly then push down as if you are on the toilet for as long as you can.
- Stop doing when hear "Please STOP".
- Party balloon assisted Valsalva verbal instructions
- Make a good seal with your mouth around the plastic straw.
- Take a deep breath and blow out the party balloon.
- Blow as hard as you can for as long as you can.
- Stop doing when hear "Please STOP".
- Fig. 1 Standardized conventional Valsalva verbal instruction and party balloon assisted Valsalva verbal instructions.



Fig. 2 The 9-inch party balloon was connected to 7-mm in diameter of plastic straw, 5-mm in length. It was calibrated with sphygmomanometer to confirm that it could generate standardized pressure to 30 mmHg when blowing.



Fig. 3 A patient was examined by duplex ultrasound using party balloon assisted Valsava.

Table 2 and Table 3 showed the results of the average reflux time, the time for patient preparation (teaching the patient before testing) and total timing

	First intervention			
	Conventional Valsalva ($n = 20$)	Party balloon Valsava ($n = 20$)	Total $(n = 40)$	
Sex; n (%)				
Male	7 (35)	6 (30)	13 (32.5)	
Female	13 (65)	14 (70)	27 (67.5)	
Age (years); mean \pm SD	57.30±8.98	56.10±13.47	56.70±11.31	
BMI (kg/m ²); mean \pm SD	24.84±5.23	27.39±6.91	26.12±6.18	
CEAP: clinical classification; n (%)				
Varicose veins (C_2)	7 (35)	3 (15)	10 (25.0)	
Edema (C_3)	8 (40)	6 (30)	14 (35.0)	
Pigmentation/eczema (C_{42})	2 (10)	1 (5)	3 (7.5)	
Lipodermatosclerosis (C_{4b})	1 (5)	7 (35)	8 (20.0)	
Healed venous ulcer (C_5)	2 (10)	1 (5)	3 (7.5)	
Active venous ulcer (C_6)	0 (0)	2 (10)	2 (5.0)	
VCSS score; mean \pm SD	6.70±3.77	8.15±3.88	7.43±3.85	
Median (min, max)	5 (3, 17)	8 (3, 16)	6 (3, 17)	

Table 1.	Demographic	data of 40	patients i	in the	study
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BMI = body mass index; VCSS = venous clinical severity score

Values are presented as mean \pm SD or n (%)

Table 2. Mean ± SD and range of the timing in each step in diagnosis of SFJ reflux of lower limb comparing between partyballoon assisted Valsalva against conventional Valsalva maneuver

Sequence	Average reflux time (sec)		Preparing time (sec)		Total DUS time (sec)	
	CV	PBAV	CV	PBAV	CV	PBAV
CV then PBAV $(n = 20)$	2.67±0.47 (1.74-3.00)	2.85±0.38 (1.42-3.00)	21.50±8.68 (10-40)	11.70±1.42 (9-15)	39.45±22.80 (19-124)	20.70±1.42 (18-24)
PBAV then CV $(n = 20)$	2.67±0.57 (1.20-3.00)	2.65±0.64 (0.95-3.00)	19.85±14.58 (12-78)	12.30±1.63 (10-17)	36.40±20.65 (21-89)	21.50±1.88 (19-26)
Total $(n = 40)$	2.67±0.52	2.75±0.53	20.68±11.88	12.00±1.54	37.93±21.53	21.10±1.69

SFJ = saphenofemoral junction; SD = standard deviation; sec = second; DUS = duplex ultrasound; CV = conventional Valsalva maneuver; PBAV = party balloon assisted Valsalva maneuver

 Table 3. Analysis of cross-over study of the timing in each step in diagnosis of saphenofemoral junction reflux of lower limb

	Period effect	Treatment-period interaction	Treatment effect
Average reflux time	<i>p</i> = 0.084	<i>p</i> = 0.939	<i>p</i> = 0.350
The timing in patient preparation	<i>p</i> = 0.049	<i>p</i> = 0.285	<i>p</i> <0.001
Total timing in DUS examination	<i>p</i> = 0.179	<i>p</i> = 0.615	<i>p</i> <0.001

DUS = duplex ultrasound

in DUS examination for each maneuver, comparing between PBAV and CV.

with the examination using PBAV more than CV. (92.5% vs. 67.5%, p = 0.03).

Using cross-over study analysis, there was neither period effect nor treatment-period interaction. Both PBAV and CV could equally identify SFJ reflux (2.75±0.53 sec vs. 2.67±0.52 sec, p = 0.35) but teaching time and reflux examination time in PBAV was shorter than CV (p<0.001 for both). The patients were satisfied

Discussion

Venous valvular reflux is the most common causes of chronic venous insufficiency^(12,13). Conventional Valsalva maneuver has been used to demonstrate reverse venous flow in superficial vein especially at SFJ by DUS. However, there is no standard Valsalva technique for venous valvular reflux examination. Many elderly patients have problems to comprehend instructions on how to perform Valsalva maneuver. Some investigators developed the criteria to standardize Valsalva maneuver. The standardized pressure to produce Valsalva effect in SFJ reflux examination is 30mmHg established within 0.5 second and holding for at least three seconds^(5,6). In the present study, the authors used PBAV as the Valsalvometer in producing intra-abdominal straining as the Valsalva effect. PBAV could demonstrate the SFJ reflux by DUS as CV did, but PBAV spent less time for patient instruction and DUS examination. From the questionnaire, the patients using PBAV could easily follow the instruction and were satisfied with the reflux examination more than CV.

PBAV is an easy and effective Valsalva method for SFJ reflux examination by duplex scan. It is very cheap and available everywhere. However, the type of party balloon should be checked and calibrated for a blowing pressure of 30 mmHg before using. In addition, the accuracy of PBAV should be compared with another method of reflux examination such as manual calf compression or the other reflux examinations in further study.

Conclusion

PBAV is one of the alternative methods for reflux examination of SFJ by duplex scan. It is easy for patients to perform and spend less time in examination.

What is already known on this topic?

Valsalva maneuver to increase intraabdominal pressure is an appropriate method to demonstrate venous reverse flow for diagnosing valvular incompetence. Conventional Valsalva maneuver is usually used in clinical practice in the assessment of patients with SFJ reflux in many countries.

What this study adds?

Party balloon assisted Valsalva maneuver is a new option to exhibit reverse venous flow at SFJ by DUS. It is easier and spends less time than conventional Valsalva maneuver.

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Potential conflicts of interest

None.

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การตรวจอัลตราซาวด์เลือดดำไหลย้อนบริเวณขาหนีบของขาโดยวัลซาวาแมนนิวเวอร์จากการเป่าลูกโป่ง

ณัฐวุฒิ เสริมสาธนสวัสดิ์, กมลรัตน์ ภัทรกิตติกุล, เกียรติศักดิ์ หงษ์คู, ชุมพล ว่องวานิช, เฉนียน เรื่องเศรษฐกิจ, คามิน ชินศักดิ์ชัย, ประมุข มุทิรางกูร

ภูมิหลัง: การตรวจเลือดดำไหลย้อนที่ขามักให้ผู้ป่วยทำวัลซาวาแมนนิวเวอร์ขณะทำการตรวจอัลตราซาวด์ ซึ่งมีผู้ป่วยบางราย ไม่สามารถทำวัลซาวาแมนนิวเวอร์ได้ ทำให้ไม่สามารถตรวจได้

<mark>วัตถุประสงค์:</mark> เปรียบเทียบการตรวจเลือดดำไหลย้อนที่ขาขณะที่ผู้ป่วยทำวัลซาวาแมนนิวเวอร์แบบดั้งเดิมและวัลซาวาแมนนิวเวอร์ จากการเป่าถูกโป่ง

วัสดุและวิธีการ: ผู้ป่วยหลอดเลือดดำขอดของขา 40 ราย ที่สงสัยว่าจะมีเลือดดำไหลย้อนของขา จะได้รับการตรวจอัลตราซาวด์ โดยที่ผู้ป่วยจะถูกแบ่งเป็นสองกลุ่ม กลุ่มแรกทำวัลซาวาแมนนิวเวอร์แบบดั้งเดิมก่อน แล้วจึงทำวัลซาวาแมนนิวเวอร์จากการเป่า ลูกโป่ง กลุ่มที่สองทำวัลซาวาแมนนิวเวอร์จากการเป่าลูกโป่งก่อน แล้วจึงทำวัลซาวาแมนนิวเวอร์แบบดั้งเดิมตามมา เวลาที่ผู้ป่วย ถูกสอนให้ปฏิบัติ เวลาที่เลือดไหลย้อน และเวลาที่ใช้ตรวจทั้งหมด จะได้รับการบันทึกและเปรียบเทียบ

ผลการศึกษา: การทำวัลซาวาแมนนิวเวอร์แบบดั้งเดิมและจากการเป่าลูกโป่ง สามารถแสดงเลือดดำไหลย้อนได้เหมือนกัน แต่การทำ วัลซาวาแมนนิวเวอร์จากการเป่าลูกโป่งนั้นใช้เวลาในการสอนผู้ป่วย และระยะเวลาตรวจโดยรวมสั้นกว่าการทำวัลซาวาแมนนิวเวอร์ แบบดั้งเดิม ไม่ว่าจะทำวัลซาวาแมนนิวเวอร์ชนิดใดก่อนก็ตาม

สรุป: การทำวัลซาวาแมนนิวเวอร์จากการเป่าลูกโป่ง เป็นทางเลือกใหม่ในการตรวจเลือดไหลย้อนในหลอดเลือดดำของขา สามารถ ปฏิบัติได้ง่าย และใช้เวลาในการตรวจสั้นกว่าการทำวัลซาวาแมนนิวเวอร์แบบดั้งเดิม