ORIGINAL ARTICLE

Ultrasound-guided venous access facilitated by the Valsalva maneuver during invasive electrophysiological procedures

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KEY WORDS
complications, femoral venipuncture, Valsalva maneuver

ABSTRACT

BACKGROUND Data on the feasibility of an ultrasound-guided venous access (USGVA) for catheter ablation (CA) and electrophysiological studies (EPS) in large cohorts are scarce. The impact of the Valsalva maneuver (VM), which can increase the diameter of the femoral vein (FV), on the USGVA is unknown.

AIMS The study aimed to determine the impact of the VM on FV diameters during establishing the USGVA and overall safety and effectiveness profile of the USGVA in a large cohort.

METHODS Consecutive patients undergoing CA and / or EPS with the USGVA were included, and those with anatomical landmark–guided VA were recruited as controls. In a subgroup of USGVA patients, a VM-facilitated FV puncture was performed. The measurements obtained before and during the VM were used to calculate the estimated access area (EAA) of the FV.

RESULTS A total of 1564 ultrasound-guided FV accesses in 876 patients and 172 FV accesses in 105 patients in the anatomical-VA group were performed. We observed no major complications associated with the USGVA. Minor adverse events related with VA were less common in the USGVA group than in controls (1.5% vs 6.7%, respectively; $P = 0.001$), resulting in a 4-fold decrease in VA-related complications. In 204 consecutive patients who underwent the VM-facilitated USGVA, the FV diameters increased during VM in both vertical (mean [SD], 10.1 [3] mm vs 14.4 [3.2] mm; $P < 0.001$) and horizontal axes (10.6 [2.9] mm vs 14.5 [3.2] mm; $P < 0.001$). This led to the mean (SD) increase in EAA of 38%: from 0.8 (0.2) cm^2 at baseline to 1.1 (0.2) cm^2 during VM ($P < 0.001$).

CONCLUSIONS The USGVA for EPS and / or CA is feasible. Complication rates for the USGVA are low and result in minor events. The Valsalva maneuver is a simple way to remarkably increase the femoral vein EAA and it can be helpful in performing the USGVA in difficult cases.

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INTRODUCTION Catheter ablation (CA) and electrophysiological studies (EPS) are widely performed and their applicability is constantly growing.[1] Both procedures are invasive and venous access (VA)–related complications remain substantial.[2] Moreover, the widespread use of noninterrupted oral anticoagulation during CA and EPS may increase bleeding-related adverse events associated with the VA.[3] Recent studies showed that the ultrasound-guided VA (USGVA) can minimize the risk of VA-related complications;[4] however, data regarding large cohorts are missing. Additionally, in some patients, due to the small diameter of the femoral vein (FV) or specific anatomy limiting optimal vessel visualization, the USGVA can still pose a challenge. The Valsalva maneuver (VM) increases peripheral venous pressure[5] and the diameter of the FV, but it has not been investigated yet whether performing USGVA with the VM is feasible. Thus, the purpose of this study was to determine the safety and effectiveness of the USGVA in a large cohort, as well as to assess the feasibility of supporting the USGVA with the VM and its impact on the FV diameter.

WHAT'S NEW?

The study outlines the safety and efficacy of ultrasound-guided vascular access during electrophysiological procedures in the largest population studied so far. We present a novel approach using the Valsalva maneuver to facilitate venous puncture. The results of the study may significantly influence everyday clinical practice.

METHODS Consecutive patients who underwent CA and/or EPS between November 2016 and April 2019, supported with the USGVA, were included in the study to determine feasibility and complication rates associated with the USGVA. Patients in whom the VA was obtained using anatomical landmark palpation, recruited between November 2016 and September 2018, were used as controls (the anatomical-VA group). Additionally, from the USGVA cohort, a group of consecutive patients was enrolled between October 2017 and April 2018 to have the USGVA performed in combination with the VM. In these patients, the right FV was measured at baseline and during the VM, both in horizontal and vertical axes.

The USGVA was performed using the Esaote Biomedica 7050 AU3 ultrasound device (Genoa, Italy). In 5 patients, a portable ultrasound device (Lumify, Phillips, Best, the Netherlands) was used to store still images for the purposes of the study. The linear ultrasound probe (LA13A, Esaote Biomedica, Genoa, Italy) was placed inside a sterile sleeve (Dina-Hitex, Bielsko-Biała, Poland) with a small amount (approximately 1 cm^3) of ultrasound gel (Zelpol USG, Centrum Medicum, Łódź, Poland). Next, the probe was placed at the groin, 1 cm below the inguinal ligament, of a patient in supine position. The FV was identified using ultrasound compression test as described elsewhere.[6] Baseline vertical and horizontal measurements were obtained using ultrasound device calipers. During measurements, we attempted to minimize the venous compression of the ultrasound probe. Next, the VM was performed: the patient was asked to take a deep breath, hold air, and push on the abdomen. The ultrasound screen was frozen and the FV measurements were repeated.

After that, the VM was repeated and, using the Seldinger technique, an USGVA was obtained above the saphenofemoral junction. If more than 1 VA was necessary, the VM was repeated each time a new puncture was performed. An estimated access area (EAA), using the horizontal (x) and vertical (y) measurements of each FV, was calculated from the modified side surface area of an elliptical base cylinder:

$$EAA = [\frac{1}{4}\pi(\frac{3}{2}(a+b) - \sqrt{ab})] \times 1\ cm$$

where "a" and "b" correspond with the half axis of the ellipse (half x and half y, respectively) (FIGURE 1).

Minor complications were defined as an incidental arterial puncture, failure to achieve femoral vein cannulation, and groin hematoma not requiring any intervention. Major complications included hematoma requiring blood transfusion or prolonged hospitalization, an arteriovenous fistula, and femoral artery pseudoaneurysm. These minor and major complications were used as a composite safety endpoint.

Statistical analysis The results of the study are presented as mean (SD) or numbers and percentages. A 2-tailed, paired *t* test was used to compare horizontal, vertical, and EAA measurements at baseline and during the VM. A χ^2 test was used to compare qualitative variables. A *P* value less than 0.05 was considered significant.

The study was approved by the institutional review board, and all patients provided written consent to undergo the procedure and to use their clinical and demographic data for scientific purposes.

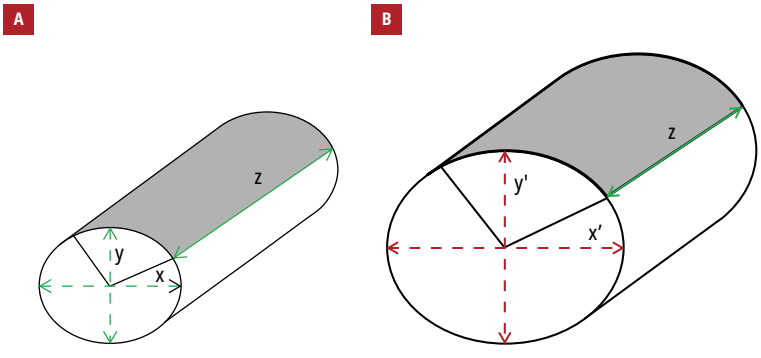

FIGURE 1 Schematic presentation of the effects of the Valsalva maneuver on the vein diameter: **A** – baseline horizontal (x), vertical (y), and longitudinal (z) dimensions; **B** – the Valsalva maneuver increases the horizontal (x') and vertical (y') dimensions, whereas the longitudinal (z) value remains of the same length. Approximately one-fourth of the femoral vein surface is accessible for puncture. The estimated access area is marked in grey.

RESULTS A total of 1564 FV accesses under ultrasound guidance in 876 patients and 172 FV accesses in 105 patients in the anatomical-VA group (mean [SD] number of procedures, 1.8 [0.5] and 1.6 [0.8], respectively; $P = 0.51$) were performed. Demographic and clinical characteristics of the study groups are presented in TABLE 1. The same operators performed procedures in the USGVA and control groups. There were no major complications associated with the VA. Minor adverse events related with the VA were less common in the USGVA group than in controls (1.5% vs 6.7%; $P = 0.001$), resulting in a 4-fold decrease in the VA-related minor complication rate when ultrasound guidance was used (TABLE 1). None of these events required interventional management.

The FV cannulation was successful in the subgroup of patients in whom the USGVA was

TABLE 1 Demographic, clinical, and periprocedural characteristics of patients undergoing catheter ablation with ultrasound- vs anatomical landmark–guided venous access

Variable	USG (n = 876)	Anatomical (n = 105)	*P* value
Female sex	485 (55)	53 (50)	0.34
Age, y, mean (SD)	56 (16)	51 (17)	0.43
BMI, kg/m^2, mean (SD)	28 (5)	28 (6)	0.55
AVNRT	193 (22)	22 (21)	0.8
WPW	71 (8.1)	17 (16)	0.28
AFL	237 (27)	28 (27)	0.93
PVI	45 (5)	7 (7)	0.51
PVC / VT	242 (27.6)	28 (27)	0.84
AT	46 (5.2)	4 (4)	0.53
PAC	45 (5.1)	0	0.011
VA, total n	1564	172	–
VA per patient, mean (SD)	1.8 (0.5)	1.6 (0.8)	0.51
VA-related complications	15 (1.7)	7 (6.7)	0.001
Failure to achieve an access	7 (0.8)	4 (4)	0.006
Hematoma	1 (0.1)	1 (1)	0.07
Incidental arterial puncture	7 (0.8)	7 (6.7)	<0.001

Data are presented as number (percentage) unless otherwise indicated.

Abbreviations: AFL, atrial flutter; AT, atrial tachycardia; AVNRT, atrioventricular nodal reentrant tachycardia; BMI, body mass index; PAC, premature atrial contraction; PVC, premature ventricular contraction; PVI, pulmonary vein isolation; USG, ultrasound-guided; WPW, Wolff–Parkinson–White; VA, venous access; VT, ventricular tachycardia

TABLE 2 Demographic, clinical, and periprocedural characteristics of patients undergoing catheter ablation with the ultrasound-guided venous access with and without the Valsalva maneuver

Variable	With VM (n = 204)	Without VM (n = 672)	*P* value
Female sex	109 (53)	376 (56)	0.53
Age, y, mean (SD)	55 (16)	56 (16)	0.43
BMI, kg/m^2, mean (SD)	28 (5)	28 (5)	0.55
AVNRT	50 (24.5)	143 (21)	0.33
WPW	14 (6.9)	57 (8.5)	0.46
AFL	52 (25.5)	185 (27.5)	0.57
PVI	4 (2)	41 (6)	0.02
PVC / VT	58 (28.4)	184 (27.4)	0.77
AT	9 (4.4)	37 (5.5)	0.54
PAC	13 (6.4)	32 (4.8)	0.36
VA, total n	362	1202	–
VA per patient, mean (SD)	1.8 (0.4)	1.8 (0.5)	0.94
VA-related complications	4 (2)	11 (1.6)	0.75
Failure to achieve access	0	7 (1)	0.36
Hematoma	0	1 (0.2)	1
Incidental arterial puncture	3 (1.5)	4 (0.6)	0.22

Data are presented as number (percentage) unless otherwise indicated.

Abbreviations: VM, Valsalva maneuver; others, see TABLE 1

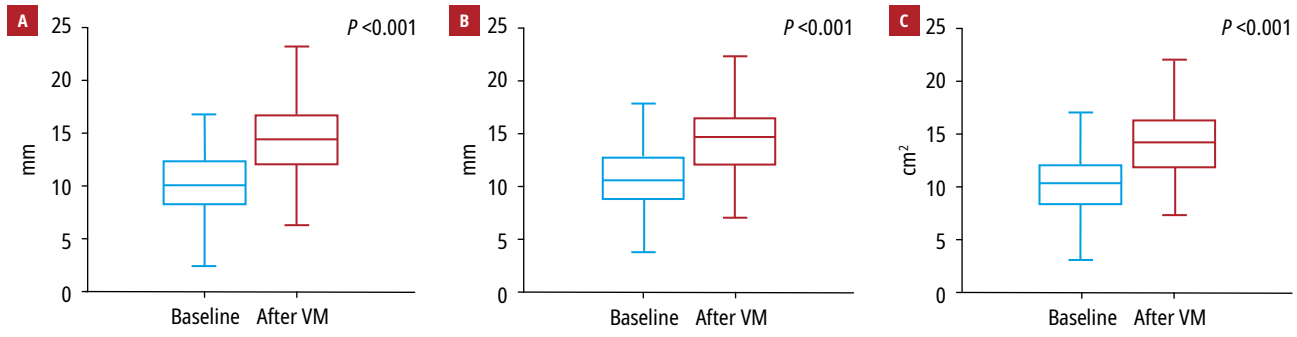

FIGURE 2 Impact of the Valsalva maneuver (VM) on the vertical (**A**) and horizontal (**B**) diameters of the femoral vein and the estimated access area (**C**) during the femoral venous access. Boxes indicate ranges from the first to the third quartile. Vertical lines denote median values. Whiskers represent ranges from the minimum to the maximum value.

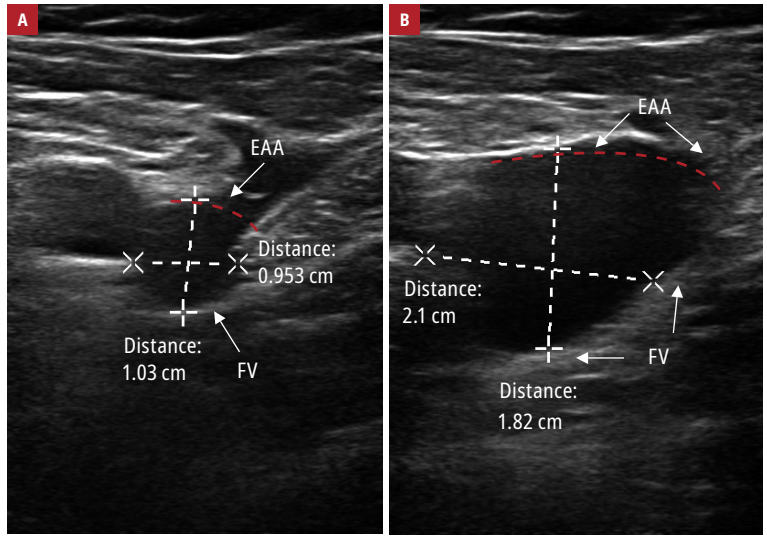

FIGURE 3 Diameters of the femoral vein (FV) at baseline (**A**) and during the Valsalva maneuver (**B**). During the Valsalva maneuver, the diameters become longer in both horizontal and vertical planes, which leads to an increase in the effective access area (EAA).

supported with the VM. Patients with or without the VM support during establishing the USGVA did not differ with regard to demographic and clinical characteristics (TABLE 2). During the VM, the FV diameter increased in both vertical (mean [SD], 10.1 [3] mm vs 14.4 [3.2] mm; P <0.001) and horizontal axes (mean [SD], 10.7 [2.9] mm vs 14.5 [3.2] mm; P <0.001) (FIGURE 2). An example of an increased FV diameter during the VM is depicted in FIGURE 3 and in the Supplementary material, *Video S1*. An increase in the FV diameters led to a 38% increase in the mean (SD) estimated access area (EAA) of the FV: from 0.8 (0.2) cm^2 at baseline to 1.1 (0.2) cm^2 during the VM (P <0.001). No significant differences in the rate of minor adverse events between the VM-supported and standard USGVA were observed (TABLE 2). Of note, 2 out of 3 inadvertent femoral artery punctures occurred in the 2 first patients from the VM-arm, thus this complication was mainly associated with the learning curve of the VM-supported VA.

DISCUSSION The main finding of this study is that the USGVA is feasible and safer than the standard anatomical landmark–guided approach. In addition, the VM significantly increases the FV diameter and further facilitates achieving a venous access.

Of note, in our study, which included a large cohort of patients undergoing USGVA, no major VA-related complications were observed. Moreover, the incidence of minor complications was very low when the VA was supported with ultrasound. Those minor events did not require any specific treatment other than prolonged manual compression. This suggests that performing the USGVA has a very good safety profile, which is of importance considering the constantly increasing number of CA.[7,8]

Vascular complications are usually nonfatal. However, if these occur, they are associated with bleeding, the need for transfusions, surgical interventions, prolonged hospital stay, and increased morbidity; they may also increase mortality.[9] Thus, new methods are sought to prevent such outcomes. In a meta-analysis of 4 trials, establishing the USGVA was associated with a 60% decrease in complication rates when compared with the anatomical landmark–guided puncture.[10] In our study, we achieved a 4-fold decrease in minor adverse events. This suggests that the benefits of the USGVA approach can be even larger than those reported so far.

The USGVA approach can be particularly desirable in patients undergoing CA for atrial fibrillation (AF). In a randomized trial that included patients undergoing this procedure, performing the USGVA was associated with improved intraprocedural outcomes; however, the difference in the composite primary endpoint (vascular complications requiring surgical treatment, retroperitoneal hematoma requiring blood transfusion or hemoglobin drop of >3 g/dl, strong pain at the groin, prolonged hospital stay or necessary readmission) between the USGVA group and controls did not meet statistical significance.[4] In order to prevent possibly

devastating embolic events associated with ablation for AF, uninterrupted anticoagulation has been recommended.[10,11] This, however, may lead to an increased risk of bleeding.[9] Any possible periprocedural VA-related events may require withholding anticoagulation, and this may increase the risk of stroke in the vulnerable post-CA period.[12] Thus, further improvement of performing the USGVA in the AF subgroups, such as using the VM or figure-of-8 sutures, would be welcomed.[13]

Not surprisingly, the VM resulted in a significant increase in the FV diameter and EAA. Although there were no differences between the VM- and the non-VM–supported USGVA, a trend towards lower incidence of local complications was noted. The lack of difference may be due to the low overall number of local complications. Perhaps larger studies might show more remarkable differences. The nonsignificant higher incidence of incidental femoral artery punctures when using ultrasound guidance can be explained by an early period on the learning curve of this novel VA method.

The VM can be especially beneficial in patients who have small FV diameters, such as women and those with low weight or anatomical abnormalities. The VM-supported VA can be helpful not only for those physicians who perform the USGVA but also for those who use anatomical landmarks for puncture or when ultrasound is not available.

Limitations Our study has several limitations. First of all, it was not a randomized controlled trial; however, the groups were well balanced regarding demographic and clinical characteristics. Second, despite a large study sample, the cohort was heterogenous and, for example, only 7% of patients underwent ablation for AF. Third, our study does not specify which CA subgroups may particularly benefit from the VM-supported VA (ie, patients undergoing cryoablation for AF requiring large 12F sheaths). Fourth, patients under general anesthesia were not eligible for the VM-supported access.

Conclusions The USGVA for EPS and/or CA is feasible and associated with low complication rates, which results in only minor VA-related adverse effects. Furthermore, the VM can be considered an easy way to remarkably increase the EAA of the FV. Additionally, it can be helpful in performing the USGVA in complicated cases.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

NOTE This study was presented in part at the 2019 European Heart Rhythm Association Congress; March 17, 2019; Lisbon, Portugal; and at the 2019 Heart Rhythm Society Congress; May 9, 2019; San Francisco, California, United States.

CONFLICT OF INTEREST None declared.

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