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Predictors of Successful Ultrasound Guided Femoral Vein Cannulation in Electrophysiological Procedures

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Abstract

Background: Vascular complications are frequently reported after electrophysiological (EP) procedures. Ultrasound (US) guidance during femoral vein cannulation has shown to reduce vascular damage related to unsuccessful attempts.The aim of our study is to define, under ultrasound guidance,anatomical and technical predictors of successful femoral vein cannulation in a cohort of patients undergoing EP procedures.

Material and Methods: From December 2015 to January 2018, 192 patients (mean age 63,1±15,9 years, M:F=118:74) undergoing EP procedures were enrolled in the study. US-guided approach to femoral vessels cannulation was used in all subjects by four untrained operators. Femoral vein and artery depths and diameters were measured in all patients. Unsuccessful attempts (UA) and time to successful cannulation (TSC) were also calculated.

Results: Vein and artery depths correlated with body weight (r=0.38 and 0.39, p=0.00), body mass index (r=0.53 and 0.50, p=0.00), and body surface area (r=0.25 and 0.28, p=0.00). Interestingly, the number of UA positively correlated with vein depth (r=0.23, p=0.01 for the right side and r=0.33, p=0.00 for the left side). Linear regression analysis showed that both vein depth (ß=0.42, p=0.001) andoperator training (ß= -0.75,p=0.00) were independently associated with UA.

Conclusions: Anthropometric features, namely BMI and BSA, may provide information about femoral vein/artery anatomy in patients undergoing EP procedures. Patients with high BMI have deeper and larger veins, however only vein depth is a determinant of successful cannulation. Numbers of UA and TSC significantly decrease with operators training.

Introduction

Vascular damages are frequent but underestimated complications in patients undergoing electrophysiological (EP) procedures[1]. In the recent FIRE and ICE trial patients undergoing ablation for atrial fibrillation had a high rate (4.3% in the radiofrequency group and 1.9% in the cryoablation group) of groin-site vascular complications, namely vascular pseudoaneurysm, arteriovenous fistulas, hematomas,puncture-site hemorrhages, and groin pain[2]. Many factors concur to the increased risk of vascular complications in patients undergoing EP procedures. These include - but are not limited to - the increasing use of peri-procedural anticoagulant therapy[3], introduction of several wide sheaths within the same vein as well as vein cannulation technique used[4].The procedure of vein cannulation usually fore sees the palpation of the laterally positioned common femoral artery to guide the insertion of the needle into the vessel ("so called" blinded approach). However,this procedure is highly dependent both on patient anatomyand operator skills. These variables significantly reduce the chances of first pass success, leading in many cases to undesirable arterial or nerve punctures. Ultrasound (US) guidance during EP procedures has shown to be a valuable tool for the visualization of femoral vessels trajectory,and its use has shown to dramatically decrease vascular complications[5-7].

The aim of the present study is to identify clinical predictors of femoral vessel anatomy and unsuccessful vein cannulationin patients undergoing EP procedures with US-guided cannulation. We also investigate how operator performance and training may impact on successful vein cannulation.

Key Words

Ultrasound Guided Cannulation, Femoral Vein Puncture, Vascular Complications, Electrophysiological Procedures

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Material and Methods

Patient population

From December 2015 to January 2018 all patients undergoing EP procedures among the Electrophysiology Laboratory of Misericordia Hospital, Grosseto, Italy, were consecutively enrolled in the study. Clinical history and laboratory parameters were collected for each subject. At the time of the procedure, all patients provided written informed consent to data storage and analysis. After the procedure patients were evaluated on daily basis until discharge,and underwent a follow-up visit at 30-days.

Ultrasound guided femoral cannulation and anatomical measures

An US-guided approach was used by four untrained electrophysiologists in all patients. Right and/or left femoral veins were selective cannulated based on procedural needs.

An ultrasound system (MyLab™SevenHD CrystalLine, ESAOTE s.p.a., Genoa, Italy) equipped with a 7.5 MHz AL2442 linear probe was used for all the exams. Briefly,the probe was inserted in a sterile sleeve and positioned on the groins. Basal frames were recorded at the level of desired puncture site (about 1-1,5 cm under the inguinal ligament)in the short axis view. Femoral vein and artery depths and diameters were measured, as shown in [Figure 1]. During real time visualization of the femoral vasculature (both artery and vein) in short axis scanning, local anesthetic was injected into the subcutaneous tissue. Thereafter,an 18-gauge, 7-cm length needle was advanced below the US probe toward the vein while watching for needle tip or tissue movement on the US screen. Once the vein was entered(Seldinger technique),a metallic guide was introduced into the needle that was removed. An unsuccessful attempt (UA) was defined in case of failure to reach the vessel leading to remove the needle from the skin; inability to introduce the wire once the vessel was tip with needto move away the needle, or in case of arterial or nerve puncture.A maximum of two sheaths (from 5F to 15F) were placed into each femoral vein. Instead of using fluoroscopy, the operator checked the effective route of the guidewire inside the vein using US short and long axis view. When a retrograde approach was desired the right or left femoral artery was also cannulated in the same manner. Time to successful cannulation (TSC) was considered the time to complete insertion of the needed sheats "per side" and not "per single vein" including: visualization of the vessels, needle advancing with vessel puncture, insertion of the wires, check of the wires in long axis view, insertion of the sheats.

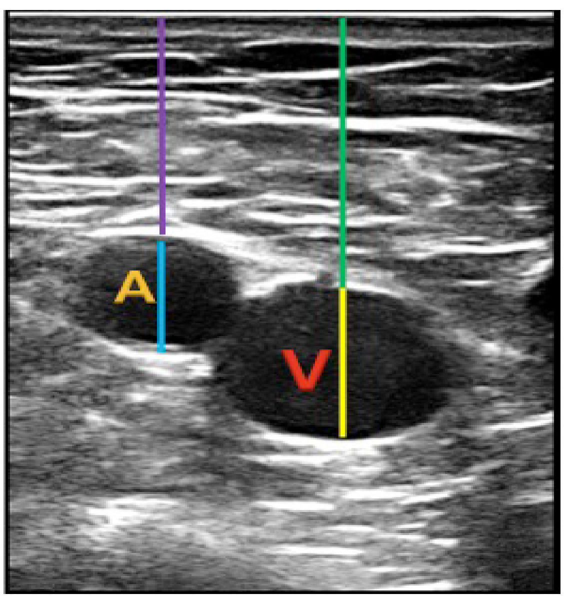

Figure 1: **Short axis view and anatomical measurements at puncture site. To be noted femoral vein lying below and medial to the ipsilateral artery. V=vein, A=artery, green bar=vein depth, yellow bar=vein diameter, violet bar=artery depth, light blue bar=artery diameter.**

Electrophysiological study and ablation

Procedures were performed following the standard of care for each indication using appropriate tools and systems.Traditional fluoroscopy-guided simple electrophysiological studies and ablations such as intra-nodal reentry tachycardias, cavo-tricuspid isthmus dependent atrial flutters, accessory pathways-related tachycardias were performed. CARTO®3 mapping system (Biosense Webster, Johnson and Johnson, Diamond Bar, USA) was used for complex ablations like Pulmonary Veins Isolation (PVI), atypical atrial flutters, ventricular tachycardias, premature ventricular contractions (PVCs) ablation and for redo procedures. Almost half of PVI procedures (21/49) were performed using Crioballoon technology (Artic FrontAdvanceTM, Medtronic, Minneapolis, USA).Warfarin was uninterrupted during the procedures. During the first year direct oral anticoagulants (DOACs) were suspended according to international guidelines[8,9]whereas DOACs were left uninterrupted during the second year based on recent evidence[3,10,11,12]. During catheterization of left side chambers intravenous nonfractionated heparin was administered reaching target ACT values of 300 to 400 sec[13]. Protamine Solphate was administered at the end of the procedure to reverse anticoagulation.

Postprocedural follow up

Patients were discharged the next day of the procedure in case of simple electrophysiological studies and ablation or the second day after in case of complex ablations. If the patient needed therapy other than ablation hospitalization was prolonged according to the specific treatment. We routinely checked groins with inspection, palpation and auscultation the evening of the procedure, the next morning, and the day of discharging. In case of presence of any complication we checked the groin every day until discharge. If indicated a groin ultrasound was performed. Patients were reevaluated at 30 days after the procedure with clinical examination and were carefully asked for any complication during the time spent at home.

Statystical Analysis

Continuous variables are expressed as mean ± SD. Categorical variables are expressed as percentages. Pearson correlation was employed to evaluate a possible relationship between femoral vein depth and anthropometric and clinical characteristics. Several multivariate linear regression model (with a stepwise forward procedure) adjusted for relevant confounders were built to identify predictors of unsuccessful attempts. The statistical package SPSS 17.0 was used for the analysis. A $p < 0.05$ was considered as significant.

Results

Baseline Population characteristics

From December 2015 to January 2018, 192 consecutive Caucasian patients (mean age 63,1±15,9 years, M:F=118:74) were consecutively enrolled. [Table 1]resumes baseline anthropometric and laboratory characteristics of the study population. [Table 2] depicts clinical information (i.e. underlying heart disease, antithrombotic therapy, indication to the EP procedure). 61.5% of patients were males while 54.7% displayed overt heart disease. Half of patients underwent

Table 1: Anthropometric and laboratory characteristics of study population

Number of patients	192
Age (years)	63.1±15.1
M:F (%)	61.5:38.5
Weight (Kg)	77.1±14.6
Height (m)	1.7±0.1
BMI (Kg/m2)	26.4±4.1
BSA (m2)	1.9±0.2
Creatinine (mg/dl)	1.1±0.5
Haemoglobin (gr/dl)	13.6±1.6
Platelets (x 10 3 /mL)	217.5± 8.5

BMI: Body mass index, BSA: Body surface area

Table 2: Clinical characteristics of study population.

		N (%)
Cardiomyopathy	Hypertensive	60 (31.3)
	Ischaemic	15 (7.8)
	Valvular	14 (7.3)
	Idiopathic	11 (5.7)
	Other (i.e. congenital, tachycardiomiopathy)	5 (2.6)
Antithrombotic Therapy	None	85 (44.3)
	DOACs	41 (21.3)
	Vitamin K antagonists	34 (17.7)
	Antiplatelets	29 (15.1)
	LMWH	3 (1.6)
Indications to EP procedure	PSVT	54 (28.1)
	AF/Atypical AFL	52 (27.1)
	Typical AFL	37 (19.3)
	Syncope	30 (15.6)
	VAs	19 (9.9)

DOACs=Direct Oral Anticoagulants; LMWH=Low Molecular Weight Heparin, EP=Electrophysiological, PSVT=Paroxysmal SupraVentricular Tachycardia, AF=Atrial Fibrillation, AFL=Atrial Flutter, VAs = Ventricular Arrhythmias

procedures under antiplatelet or anticoagulant therapy (up to 55,7% including DOACs, vitamin K antagonists, aspirin, clopidogrel, low molecular weight heparins). Only 15 out of 34 (44,1%) patients, assuming warfarin uninterruptedly, had INR 2<3 on the day of the procedure.The high rate of prescribed antithrombotic therapy reflects the fact that half of the indications to the EP procedure were represented by atrial flutter/atrial fibrillations (46,4%, [Table 2]).

Anatomical features of femoral vessels

Mean femoral vein depth was 2.2±0.6 cm,higher than artery depth (1.8±0.6 cm). Vein and artery diameters were respectively 0.9±0.3 cm and 0.8±0.2 cm. Interestingly enough,we observed that both vein and artery depths significantly and positively correlated with body weight (r=0.38 and 0.39, p=0.00), BMI (r=0.53 and 0.50, p=0.00) and BSA (r=0.25 and 0.28, p=0.00). The same anthropometric factors also correlated with veins (r=0.44, p=0.00 for weight; r=0.32, p=0.00 for BMI; r=0.44, p=0.00 for BSA) and arteries diameter (r=0.33, p=0.00 for weight; r=0.16, p=0.02 for BMI; r=0.36, p=0.00 for BSA). [Figure 2] shows linear correlation between right femoral vein depth and BMI.

Unsuccessful attempts (UA) and time to successful cannulation (TSC)

Among 192 procedures, 62 were performed by operator 1 (27 during the first year and 35 during the second year), 57 were

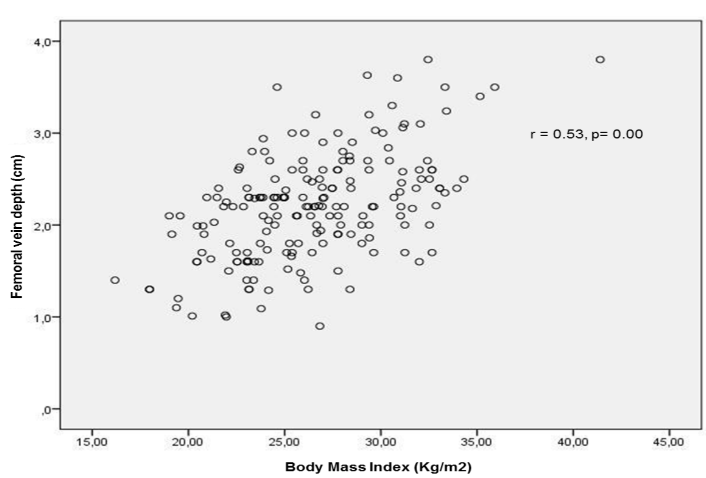

Figure 2: Linear correlation between femoral vein depth andbody mass index.

performed by operator 4 (22 in the first year and 35 in the second year). Operator 2 and operator 3 performed respectively 38 (15 and 23) and 35 (10 and 25) cases. The four operators showed comparable rates of unsuccessful attempts (UA ≥ 1), ranging between 21,3% to 38% on the right side and from 20.7 to 27.8% on the left side([Figure 3], upper panels). Interestingly, the number of UAfor each operator positively correlated with vein depth (r=0.23, p=0.01 for the right side and r=0.33, p=0.00 for the left side).

The mean time to successful cannulation (TSC) was <2 minutes in 65,8% of cases on the right side and 64.7% on the left side with no significant differences between operators ([Figure 3], lower panels).

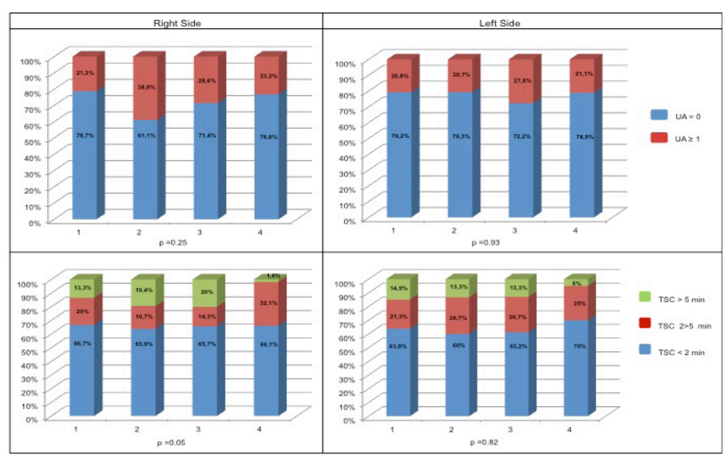

Figure 3: Upper Panels: global rate of unsuccessful attempts (UA) for cannulation divided across operators (1,2,3,4). Lower Panels: global time to successful cannulation (TSC) divided among operators (1,2,3,4).

When analyzing the number of UA and TSC along the study period, they significantly decreased during the second year as compared to the first one[Figure 4]. Time-dependent reduction of UA and TSC was comparable among the 4 operators [Figure 5].

Linear regression analysis found an independent correlation between vein depth(ß=0.42, p=0.001), operators training time during the study (second year vs first year)(ß= -0.75, p=0.00), and unsuccessful attempts after adjusting for all variables (Table 3).

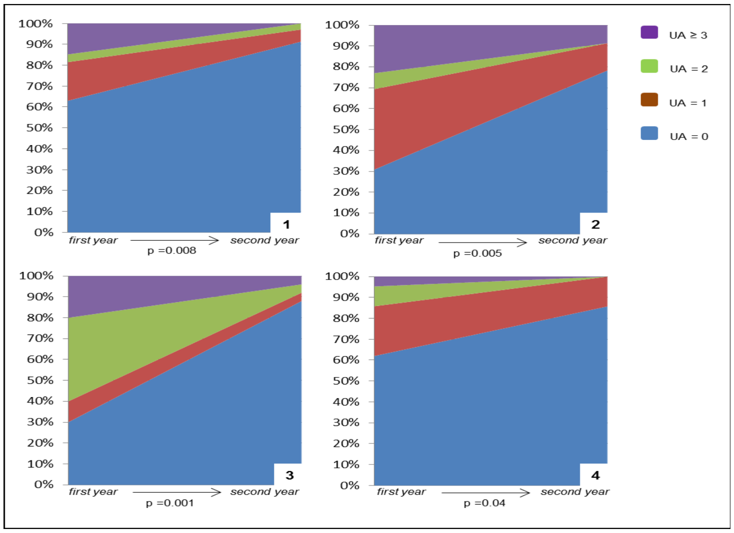

Figure 4: Rate of unsuccessful attempts (UA) for cannulation counted for each operator (1,2,3,4) during the first and during the second year of the study.

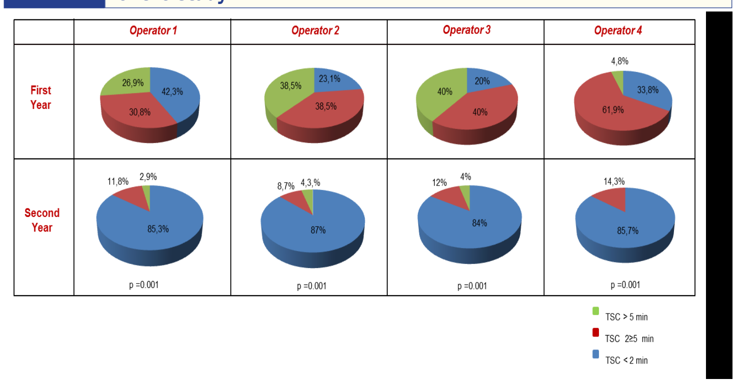

Figure 5: Time to successful cannulation (TSC) counted for each operator during the first and during the second year of the study.

Vascular complications

Over a 30-day follow-up we observed 4(2,08%) superficial groin ecchymosis, but no clinical hematoma, arterio-venous fistulas or pseudoaneurysms necessitating interruption of anticoagulant therapy, surgery or blood transfusion. All the ecchymosis spontaneously regressed in a few days, in the absence of symptoms.Interestingly only anticoagulated patients (2 on warfarin, 1 on rivaroxaban, 1 on apixaban) developed complications.

Table 3: Linear Regression Analysis showing the association between unsuccessful attempts (UA) and anatomical or technical variables.

	Linear Regression Analysis	
Variables	Unstandardized Coefficients	P-value
Vein depth (cm)	0.43	0.001
Operators training time (second year vs first year)	-0.75	0.000

Dependent variable: unsuccessful attempts during cannulation. The model is created after adjusting for age, gender, BMI, BSA, height, weight, vein and artery depths, vein and artery diameters, operators training time: defined as difference in operators performance between the second (2017) and the first (2016) year of the study.

Discussion

Ultrasound-guided vascular access has been shown to shorten time of the procedure, reduce the number of failed puncture attempts, and minimize complications during central venous catheterization [14]. In the setting of EP procedures an US guidance to femoral cannulation is related to a 60% reduction in the likelihood of major vascular complications and a 66% reduction in the likelihood of major vascular complications[6]. This is probably due to the visualization of the exact course of the vessels along the femoral triangle of the anterior thigh. In fact, there is a clinical relevant percentage of patients in whom the femoral artery overlaps the vein, making the perforation of the artery a real possibility. Reviewing the inguinal region of 100 computed tomographic scans of the pelvis (200 vessel pairs), Baum et al. found a portion of the common femoral artery overlapping the vein on the anterior-posterior plane in 65% of cases. In addition, more than 25% of the artery overlapped the vein in 8% of the vessel pairs [15]. In the pediatric population this percentage drops to 17% [16]. But the femoral vein can also split or double, encircling the femoral artery or be separated from the artery in its course [17].

We investigated with ultrasound the principal anatomical parameters of the femoral vessels (i.e. depth and diameter). Moreover, we investigated independent predictors of unsuccessful vein cannulation in patients undergoing US-guided EP procedures. In our study a complete (100%) of overlapping between artery and vein was present only in 3 cases (1,5%) and it did not rise the rate of unsuccessful attempts, probably for the help of the ultrasound guidance.

Our first result was that femoral vein depth is linearly correlated with anthropometric variables, especially BMI. Namely the higher the BMI the deeper is the vein. Consistently, vein diameter was also larger in patients with higher body weight, BMI and BSA values. Univariate analysis showed that only vein depth (and not diameter) was related to unsuccessful attempts. This is confirmed by linear regression models (ß=0.42, p=0.001) showing that for every 2 cm increase in vein depth a new UA was observed. Our results can be explained by the fact that the deeper is the vein the more difficult is to visualize the needle tip advancing under the probe. However, in obese patients an US-guided approach would certainly prevent a large number of UA and accidental arterial punctures and it should be always used.The impact of reducing major vascular complications in overweight patients is outlined by the recent estimates from the international diabetes federation stating that more than 600 million people are expected to develop obesity by the year 2040[18].

An important finding of our study is that, despite slight differences among the four operators, the rates of unsuccessful attempts, arterial puncture and time to cannulation using the US-guided approach are rather low. Errhamouni and coauthors published their preliminary experience in 2014 showing an extremely low complications rates and setting the learning curve of the technique on six cases, after which the puncture time reaches a plateau [19]. As compared with the latter study, we observed a significantly lower rate of unsuccessful attempt during the second year of training after a least of 11 procedures. Globally the medium time to cannulation was reasonably low for all the operators (< 5 min in most of cases) since the beginning of the study, although none of them had been previously trained. It confirms that the technique, even as self-taught, can be easily learned and performed. Furthermore, in a previous elegant study, Rodriguez Munoz et al, using US-guided technique during EP procedures, calculated their average time to successful cannulation (87,3±94,3 sec), medium number of unsuccessful attempts (0,26±0,8 attempts per cannulation) and rate of accidental arterial puncture (0,02±0,1 arterial punctures per cannulation)[20]. We performed in a very similar manner collecting a medium of 0,51±1,05 UA and an average of 0,07±0,32 accidental artery punctures. TSC was < 120 sec in 65,8% of cases and totally <320 sec in almost 86,3% of cases. This homogeneity of results confirms the technique is highly reproducible.

Finally, the very low rate of vascular complications, exclusively minor in terms of clinical relevance (i.e. modest ecchymosis not requiring any diagnostic or therapeutic approach) confirms the technique is safe.

Limitations

This is a single center, not randomized, study aimed to characterize femoral vessels anatomy and clinical predictors of successful cannulation in a cohort of consecutive patients undergoing EP procedures. Thus, our results cannot be extrapolated to the general population. Although the retrospective nature of the study, we attempted to minimize selection bias by collecting data on consecutive patients who underwent EP procedures in our lab. Finally, according to our cannulation protocol we inserted no more than two sheats per vein when needed. Thus it's possible the results could be different when three sheats are inserted in the same vessel.

Conclusion

Anthropometric features may provide information about femoral vein and artery an atomyas assessed with US-guided femoral cannulation, in patients undergoing EP procedures. Patients with high BMI have deeper and larger veins but only vein depth seems to be related to unsuccessful cannulation. In US-guided femoral vein cannulation numbers of unsuccessful attempts and time to successful cannulation significantly decrease with operator training.

Disclosures

All the authors report they have no relationships relevant to the contents of this paper to disclose.

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