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Sex-related differences regarding cephalic vein lead access for CIEDs implantation

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Abstract

Background: Minimally invasive and safe central venous access is imperative for lead insertion of cardiac implantable electronic devices (CIEDs). The purpose of this trial was to explore and compare the usability of the cephalic vein (CV) between both sexes.

Methods and results: This single-center prospective study included 102 consecutive patients in a period of six months. Pre-procedural contrast-enhanced venographic images of the upper arm were performed in all included patients. Our attention was focused on comparing several morpho-anatomical CV characteristics such as venous diameter, presence of valves and angle of entrance of the CV into the subclavian vein (SV). Study results concerning the CV morpho-anatomical differences were more favorable regarding the female patient group, with significant differences in CV diameter (p-0.030). There was also a difference in favor of the female group regarding the favorable CV angle of entrance into the SV, found in the 61.7% versus 54.4% in the male patient group. The comparison of usability of the CV and CVC technique was explored by comparing the number of leads inserted through the CV in both sexes. Two leads were implanted in 11.7% in the female group versus 5.8% in the male group, and 0 leads through the CV in 38.2% of the female patients versus 50% of male group.

Conclusion: Female patients have more favorable cephalic vein morpho-anatomical futures and better usability for lead placement than male patients.

Keywords: Sex differences, Cephalic vein, Axillary vein, Subclavian vein, Device implantation

Background

The number of cardiac implantable electronic devices (CIED) implantation procedures has been increasing exponentially in the past few decades [1].

Central venous access that is minimally invasive and safe is imperative for lead insertion of cardiac implantable electronic devices (CIEDs) such as permanent pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy [2]. Numerous reports

have explained modification of CIED implantation techniques [3–5]. Needless to say that no account can totally cover all the implant techniques and their variations used by different operators. As any practical skill, written descriptions cannot replace the practical experience of a skilled implanter [3].

CIED implantation technique can be divided in several stages. The first stage begins by gaining central venous access for lead insertion. This fundamental step can be broadly divided into techniques involving direct visualization of the target vein by a cut-down technique (most commonly the cephalic vein), or those involving needle puncture of the vein [6]. Cephalic vein cut-down (CVC) followed by subclavian vein puncture (SVP) and recently added fluoroscopy-guided axillary

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vein puncture (AVP) techniques are widely used for lead insertion in clinical practice. However, the use of one technique over the other is largely limited by operator experience and local working strategies [7, 8].

Subclavian vein access was associated with increased rates of early and late complications. On the other hand, CVC technique requires longer learning curve and can have lower success rates. Numerous operators consider AVP technique to be suitable alternative in terms of safety and efficacy [8]. The subclavian/axillary vein approach can be used as a first or alternative choice, especially because of a more rapid learning curve. Less-experienced implanters are usually more confident with SVP technique, particularly if an extrathoracic approach is used [9]. In both techniques, it is highly recommended to have fluoroscopic guidance especially for axillary and intrathoracic subclavian vein puncture [5]. These approaches can result in complications like pneumothorax, hemopneumothorax, inadvertent subclavian artery puncture, brachial nerve plexus injury, thoracic duct injury and mechanical damage to the lead(s) [10].

Many centers, especially academic, prefer to use the cephalic vein cut-down (CVC) technique as their first choice. The cephalic vein's usual location is in deltopectoral groove, penetrating the clavipectoral fascia to join the axillary vein medial to the pectoralis minor muscle and together continuing as the subclavian vein [2]. Naturally, there can be different variations and anomalies of the cephalic vein and the tissues around it. These variations and anomalies may prolong the procedure time, and result in unsuccessful cephalic access in 40% of cases, especially pronounced in less-experienced operators. Improvements of this technique have been described, like the use of a hydrophilic guidewire when direct lead insertion failed and cannulation of retro-pectoral veins in cases of insufficient caliper of the cephalic vein. Also, two additional techniques were introduced, namely the simultaneous use of two guidewires and the use of stiff angiography guidewires. These techniques can reduce failure rates up to 10–20% [11, 12].

The purpose of this study was to explore and compare the usability of the cephalic vein (CV) between both sexes. First by comparing several morpho-anatomical parameters, like CV diameter, the presence of valves and the angle of entry into the SV and secondly by determining the number of leads placed through the CV or through an alternative venous access site (SVP/AVP techniques). With this trial, we tried to answer the question of sex-related differences in cephalic vein usability as a central venous access site for pacing leads.

Methods

This single-center prospective study included 102 consecutive patients referred for CIED implantation in the period between March and September 2015.

Pre-procedural contrast-enhanced venographic images (in PA, posterior–anterior projection) of the upper arm were made in all included patients, and they were interpreted directly after each procedure. Our attention was focused on comparing several morpho-anatomical CV characteristics such as venous diameter, presence of valves and angle of entrance of the CV into the SV.

Procedure

All CIED implantation procedures were made in a sterile electrophysiology laboratory. Anticoagulated patients with low thromboembolic risk were operated after suspension of anticoagulant treatment to minimize bleeding risk. Those with moderate-to-high thromboembolic risk were operated under anticoagulant treatment, avoiding bridge therapy with heparin. Antibiotic prophylaxis was administered to all patients. Procedures were performed from both left and right side under local anesthesia (Lidocaine injection bp 2%). Once the cutaneous incision was created and the subcutaneous tissue dissected, the appointed venous access site was used. Afterward, CIED implantation procedures were identical in all included patients and were performed in the standard way. The preferred and first choice for central venous access was cephalic vein cut-down technique (CVC) for one or two leads. In those cases where we were unable to do so, we tried advancing with hydrophilic wire before switching to subclavian/axillary vein puncture access techniques (SVP/AVP), guided by pre-procedural venographic images. As an alternative, if needed we performed extrathoracic fluoroscopic-guided SV puncture or AV puncture guided by contrast venography.

The study included implantation of single/dual-chamber permanent pacemakers (PPM), dual-chamber implantable cardioverter defibrillator (ICD) and one cardiac resynchronization therapy device (CRT-p). All procedures were performed by experienced operators (> 100 CIED per year and center complication rate 1.8% per year).

Pre-procedural venography

Images were made before the application of local anesthesia, with 10 ml of undiluted contrast (Ultravist 370—Bayer AG, Leverkusen, Germany) which was injected, through the left/right cubital vein. The pre-procedural venography images gave a clear morpho-anatomical

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picture of the CV, AV/SV and their mutual connections, just before the beginning of the implantation procedure.

At the end of every procedure, we stored fluoroscopic images of the deltopectoral groove to assess the position of the pacing generator and pacing leads.

Definitions

Cephalic vein diameter—After the procedure, we used DSA (digital subtraction angiography) to perform measurements of the diameter of the cephalic vein used for implantation of the leads. The diameter was measured at the narrowest part of the vein, parallel to the head and neck of the humerus (Fig. 1). Cases with CV constriction were measured on the narrowest measurable part of the vein.

Angle of entrance—This variable represents angle of entrance of the CV into the SV. We considered an angle between 0 and 90 degrees pointing medially as favorable for CV usage and lead placement [Fig. 2].

Valves—We counted the number of valves in the part of CV that we use for lead placement, and in this trial results, 1 or less valves in both sexes were considered as favorable [Fig. 3].

Procedural time—In all included patients, we measured the time of the first stage of every procedure, starting from injecting the local anesthesia until we introduced the leads, regardless of which vein we use to obtain central venous access.
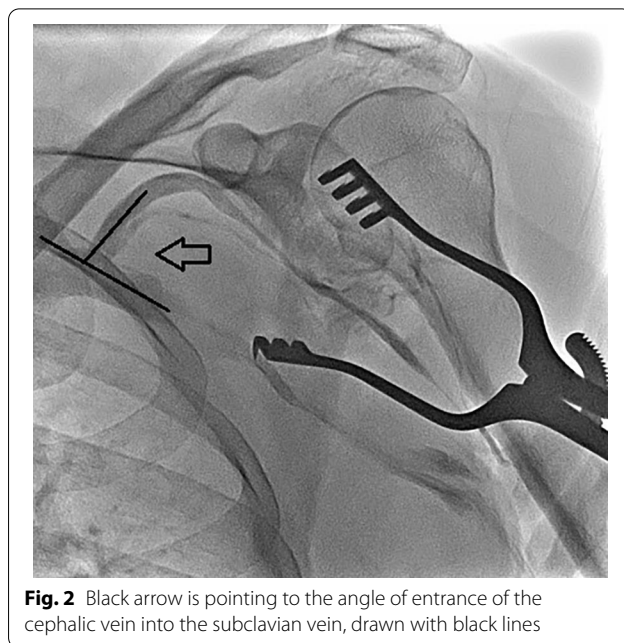

Fig. 2 Black arrow is pointing to the angle of entrance of the cephalic vein into the subclavian vein, drawn with black lines

Statistical analysis

Categorical variables are expressed as numbers and percentages and continuous variables are expressed as the mean ± standard deviation or median (interquartile range). To assess the role of sex, age, CV diameter, angle of entrance, and number of valves ≤ 1, hierarchical multiple regression model was tested for number of leads through CV. Sex and age were entered in the first step, while CV diameter, angle of entrance, and number
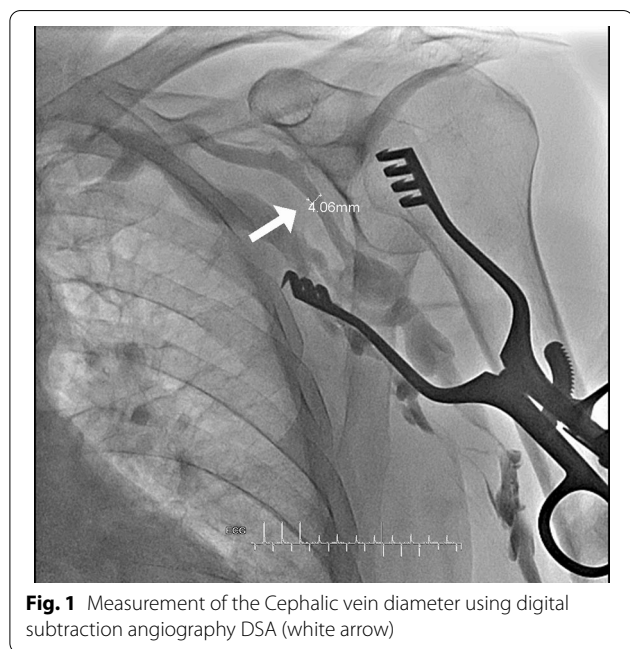

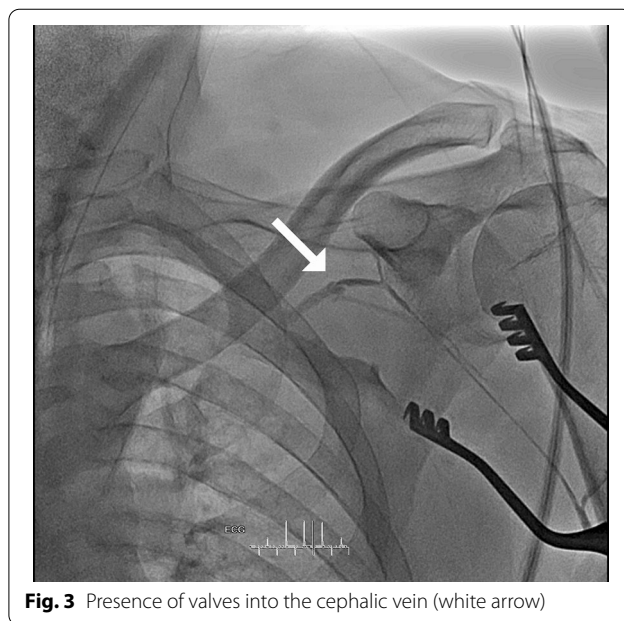**Fig. 1** Measurement of the Cephalic vein diameter using digital subtraction angiography DSA (white arrow)

Fig. 3 Presence of valves into the cephalic vein (white arrow)

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of valves ≤ 1 were entered in the second step. Statistical analysis was performed using the Statistical Package for Social Sciences software version 17.0 for Windows (IBM Corp., Armonk, NY, USA).

Results

During a period of one year, we evaluated (102) venography-guided CIED implantation procedures. Sixty-eight (66.6%) patients were male and 34 (33.3%) were female. The mean age of the female group of patients was 73.9 years old, and in male group 70.5 years old ($p < 0.0001$). Ninety-eight (96%) CIED were implanted from the left side and only four (3.9%) of CIED from the right (deltopectoral) side.

During this period of time 98 (96%) of the CIEDs implanted were permanent pacemakers (PPM). This group included 41 dual-chamber pacemakers (DDD), seven single-chamber pacemakers with atrial sensing coil (VDD) and 48 single-chamber pacemakers (VVI). This trial also included three (2.9%) dual-chamber implantable cardioverter defibrillators (ICD) and one (0.9%) cardiac resynchronization therapy device (CRT). Ninety-seven (95%) of all implanted pacing/defibrillation leads were with active fixation and only five (4.9%) with passive fixation.

In the majority of patients, 55 (53.9%), CV was used as central venous access site for pacing leads, and in 46 (45%), at least one lead was introduced by using CVC technique. Regarding the sex-related differences in the utilization CVC technique and the number of implanted leads through this venous access, we obtained the following results.

We can see the main difference in usability of the CV in both sexes regarding the number of implanted leads, especially with the fact that two leads were implanted in 11.7% in the female group versus 5.8% in the male group, and zero leads through the CV in 38.2% of the female patient's versus 50% of male.

One of the main goals of this trial was to explore the morpho-anatomical differences of the CV in both sexes. Several variables were explored and compared. We found a significant difference (p-0.030) regarding the CV diameter. The mean diameter value in the female group was 3.5 versus 2.9 in the male group. There was also a difference in favor of the female group regarding the CV angle of entrance into the SV. Favorable angle of entrance was found in the 61.7% of the female patients versus 54.4% of the male patients. Regarding the last variable, there were some differences in favor of the male group of patients. A total of 34.3% of the female patients had one or less valves in the CV versus 50% in the male group (Tables 1 and 2).

It is also important to note that factors that could negatively influence vein diameter, such as CKD and diabetes

Table 1 Patient characteristics

Variable	Female ($n = 34$)	Male ($n = 68$)
Age (years)	73.9(35–85)	70.5 (56–86)
BMI (kg/m²)	27 (17–41)	30 (17–37)
Hypertension	29 (85%)	60 (88%)
Diabetes	11 (32%)	12 (17%)
CKD[a]	1 (2.9%)	1 (1.4%)
CAD[b]	4 (11.7%)	17 (25%)
CIED[c] indication		
AV block gr III	17 (16.6%)	19 (18.6%)
Mobitz II	10 (9.8%) 19(18.6%)	19 (18.6%)
Mobitz I	0	1 (0.9%)
AFib[d]	4 (3,9%)	13 (12.7%)
SSSy[e]	2 (1.9%)	9 (8.8%)
VT[f]	0	3 (2.9%)
PM[g] upgrade to CRT[h]	0	1 (0.9%)

[a] Chronic kidney disease
[b] Coronary artery disease
[c] Cardiac implantable electronic devices
[d] Atrial fibrillation
[e] Sick sinus syndrome
[f] Ventricular tachycardia
[g] Pacemaker
[h] Cardiac resynchronization therapy

Table 2 Anatomical and functional cephalic vein (CV) differences between sexes

Variable	Female	Male	$P < 0.03$
Number of leads through CV			
0 leads	38%	50%	NS
1 lead	50%	44.1%	NS
2 leads	11.7%	5.8%	NS
CV diameter	3.5	2.9	0.030
Angle of entrance	61.7%	54.4%	0.054
Valves ≤ 1	34.3%	50%	0.531

were more prevalent in the female group of patients with 2.9% versus 1.4% and 32% versus 17% accordingly.

Regarding the procedural complication rates, there were no significant differences in both sexes. Procedural time for both groups, where CVC technique was used, was between 8 ± 1 min, and for SVP/AVP techniques 6 ± 2 min. However, in some patients, we were forced to switch to SVP/AVP techniques due to long procedural time (> 20 min) spent on CVC technique.

Standardized beta coefficients for the independent predictors of number of leads through CV in the study sample are shown in Table 3. Angle of entrance ($\beta = 0.61$,

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Table 3 Hierarchical multiple regression model for number of leads through CV in the study sample

Number of leads through CV		B	SE	95% CI for B		Beta	R^2
				Lower	Upper		
Step 1	Male sex	− 0.07	0.15	− 0.37	0.23	− .05	0.006
	Age	− 0.004	0.01	− 0.02	0.01	− .06	
	Constant	1.08	0.57	− 0.05	2.2		
Step 2	Male sex	− 0.16	0.11	− 0.39	0.07	− .13	0.482
	Age	− 0.004	0.01	− 0.02	0.01	− .06	
	CV diameter	0.04	0.04	−0.04	0.11	.09	
	Angle of entrance	0.83	0.12	0.6	1.06	.61**	
	Number of valves ≤ 1	0.34	0.11	0.12	0.55	.27*	
	Constant	0.25	0.44	−0.63	1.12		

$R2 = .006$ for Step 1; $\Delta R2 = .476$ for Step 2 ($P < 0.001$) *$p < 0.01$, **$p < 0.001$

$p < 0.001$) and number of valves ≤ 1 ($\beta = 0.27$, $p < 0.01$) positively predicted number of leads through CV. Preferable angle of entrance and low number of valves (valves ≤ 1) were associated with a higher number of leads through CV. Transition from male to female patient group also predicted higher number of leads through CV, but this association ($\beta = −0.13$, $p > 0.05$) was not significant.

Discussion

Study results showed an important difference regarding the CV morpho-anatomical characteristics and CVC technique usability, between sexes. There was a significant difference in CV diameter in favor of the female patient group, also there was difference in favor of the same group regarding the angle of entrance as well. Regarding the usability of the CV and CVC technique, we explored the number of implanted leads, and again there was difference in favor of the female patient group. Clearly, there is a directly proportional relation between morpho-anatomical characteristics of the CV and the CVC technique usability, where this trial showed an advantage of the female patient group. These results were confirmed with multivariable analysis, which showed that CV usability increases as we move from male to female patients. It also showed that CV angle of entrance and low or no valves are significant factors for increased CV usability. Our high failure rate shows that the CVC technique is technically more complex approach, and it needs a longer learning curve to reach higher success rate [2, 4]. However, as study results showed, learning curve for CVC technique is not the only parameter that influences its success, sex-related morpho-anatomical differences can be crucial for successful lead passage also.

Cephalic vein cut-down (CVC), subclavian vein puncture (SVP) and axillary vein puncture (AVP) are the three most commonly used techniques for transvenous access. CVC was found to be the venous access of choice in 60% of the centers in Europe in a survey [13]. This technique has its advantages and disadvantages over SV/AV puncture techniques [4, 14]. In a meta-analysis, CVC technique was associated with a lower risk of pneumothorax and lead failure compared with SVP; however, there was no significant difference in the risk of pocket hematoma/bleeding or device infection with CVC compared with SVP. The same meta-analysis showed that the acute procedural success was higher with AVP and SVP compared with CVC, and total procedure time was significantly longer with CVC compared with AVP but not SVP [2].

Successful lead passage through the CV or CVC technique usability depends on the morpho-anatomical parameters of the vessel and other factors like size and structure of the leads introduced via the CV, vessel wall elasticity and operator's experience [1, 10, 15]. Morpho-anatomical characteristics of the CV were analyzed and associated with successful lead passage in one prior clinical trial. In that same trial, contrast venography results, obtained during first-time lead placement were analyzed. Venography was indicated only in cases of problematic lead introduction (15%) with either the CVC or AVP/SVP techniques. This clinical trial results showed that most common unfavorable morpho-anatomical parameters were CV diameter of ≤ 1 mm (18%), sharp curvature of the terminal CV segment as it joined the axillary vein (14%) and terminal CV bifurcation (9%) [1].

In one study, peri-procedural scoring system was presented for morpho-anatomical evaluation of the cephalic vein, which should facilitate the choice between the CVC and SVP/AVP techniques. Results from this trial were very encouraging regarding peri-procedural score safety and efficacy and should allow less-experienced implanters to gain more confidence during the procedure [16].

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Another prospective study showed 17% of failure rate in lead placement through CV approach, associated with the small vessel diameter [15]. In addition to this morpho-anatomical parameter of the CV, a different study described a technique where pre-procedural ultrasonography was used for the vessel assessment, to minimize the failure rate [17]. Various studies have described alterations to the classical CV cut-down technique, including the use of a hydrophilic guidewire, cannulation of retropectoral veins, simultaneous use of two guidewires and the use of stiff angiography guidewires. These so-called "no puncture" techniques were successful in over 95% of implantations, without any major complications [11, 12, 18].

Most common short-term complications related with central venous access and lead insertions are pneumothorax, lead dislodgement, and pocket hematoma/bleeding, reportedly range from 8 to 12% [19, 20]. In a Danish pacemaker register, Kirkfeldt et al. reported that the risk of pneumothorax was almost 8 times higher with SVP in contrast with CVC technique [21]. In addition, SVP is known to be linked with higher risk of lead failure and fractures due to the phenomenon of "subclavian crush," where the lead is mechanically ensnared between the costo-clavicular ligament and subclavius muscle [22]. One clinical trial reported that lead failures occurred mainly with ICD leads, a lesser age, the puncture method, lead model, and diagnosis of idiopathic ventricular fibrillation and Brugada syndrome [23].

However, CVC is the safest venous access obtainable for lead insertion. This access site avoids all the complications linked to SVP such as pneumothorax and subclavian crush syndrome and all at a reduced cost. Nevertheless, because it is a cut-down technique, CVC requires surgical experience with a steep learning curve, often associated with lower success rate and higher blood loss [9, 10]. In addition, AVP remains a suitable alternative with similar safety and efficacy as CVC technique, with shorter learning curve. In the same meta-analysis, they confirmed the need for continuous widespread dispersion and adoption of CVC technique [2].

In this retrospective study, we compared several important morpho-anatomical features of the CV and CVC technique in male and female patients scheduled for CIED implantation procedure, and at the same time, we demonstrated the advantage of this approach in the female population of patients.

Limitations of the study

This was a retrospective single-center study with limited number of patients. More prospective, randomized multi-center studies are needed to explore our results.

Conclusion

Cephalic vein should be the first choice for CIED lead(s) implantation. Female patients have more favorable cephalic vein morpho-anatomical features and better usability for lead placement than male patients. Understanding these CV features will lead to its more efficient and safer utilization.

Abbreviations
CIED: Cardiac implantable electronic devices; CVC: Cephalic vein cut-down technique.; AVP: Axillary vein puncture; SVP: Subclavian vein puncture; CV: Cephalic vein; SV: Subclavian vein; PPM: Permanent pacemaker; ICD: Implantable cardioverter defibrillator; CRT: Cardiac resynchronization therapy; DSA: Digital subtraction angiography; CKD: Chronic kidney disease; CAD: Coronary artery disease; AFib: Atrial fibrillation; VT: Ventricular tachycardia; PM: Pacemaker; SSSy: Sick sinus syndrome.

Authors' contributions
JT analyzed and interpreted the patient data and a major contributor in writing the manuscript. LP interpreted the data and contributed in writing the manuscript. DR, FJ and BP analyzed the patient data. SS and ZZ supervised the interpretation of the data and the manuscript. All authors read and approved the final manuscript.

Availability of supporting data
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate
The study protocol adhered to the Declaration of Helsinki and was approved by the institutional review board.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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