Ultrasound versus fluoroscopy-guided axillary vein access for cardiac device implantation

Ecografía frente a punción venosa axilar guiada por fluoroscopia para el implante de dispositivos cardiacos

To the Editor,

According to the European guidelines, the cephalic vein cut-down technique and axillary vein (AV) access are recommended as the first-line approach for transvenous cardiac implantable electronic device (CIED) implantation.[1] AV catheterization can be performed using surface landmarks, fluoroscopic guidance (FG), with or without venography, or ultrasound imaging.[2] Compared with ultrasound guidance, FG may increase the risk of collateral damage (inadvertent arterial puncture or pneumothorax). In a recent single-center retrospective trial comparing ultrasound-guidance with FG-AV access for single or dual chamber CIED first implant, performance was similar, but with higher radiation exposure in the FG group.[3] We conducted a multicenter randomized controlled study to compare the performance, safety, and radiation exposure of ultrasound-guided vs FG-AV access for CIED implantation.

From November 2020 to November 2021, we included all consecutive patients eligible for transvenous CIED implantation (by 4 operators) in 3 participating centers (patients were excluded if younger than 18 years, or required battery revision only). We analyzed single, dual chamber, cardiac resynchronization therapy pacemakers and defibrillators, and upgrade procedures. Of 4 operators, 3 were electrophysiologists practicing CIED implantation for more than 10 years (> 200 cases with ultrasound for the first; > 200 cases with FG for the second; > 100 cases with ultrasound for the third), and 1 was a less experienced electrophysiology fellow (> 50 procedures with ultrasound, and < 20 cases with FG). A time limit for AV catheterization attempts was set to 15 minutes after which a crossover could be performed for the other arm. If both the ultrasound and FG techniques failed, the cephalic vein technique was used as a second option, and subclavian vein access as the last option. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the human research committee of participating institutions. All patients provided written consent for enrollment in the registry and the study.

After the roll-in period (5 patients), 102 patients (n = 51 patients per group) were included (table 1). A total of 99 leads were implanted in the ultrasound group and 96 in the FG group. AV catheterization was successfully performed in 50/51 patients (98%) in the ultrasound group and in 49/51 patients in the FG group (96%; *P* = .56). The mean number of access attempts was 1.17 per lead in the ultrasound group vs 1.14 per implanted lead in the FG group (*P* = .96). Of note, the overall percentage of patients requiring the 2 x 1 technique (single access for 2 leads) was 20% in the ultrasound group vs 17% in the FG group (*P* = .54). In the ultrasound group, AV access time and procedure time were shorter than in the FG group, but without reaching significance, respectively: 60 seconds (interquartile range [IQR], 41-120) vs 90 seconds (IQR, 42-168); *P* = .33; 50 minutes (IQR, 40-70) vs 55 min (IQR, 49-68 min); *P* = .37. Total fluoroscopy time and total dose area product (DAP) were lower in the ultrasound group, but without reaching significance (table 2). In the subgroup of patients with single or dual chamber CIED, this difference became statistically significant in favor of the ultrasound group. DAP was also lower in the ultrasound group than the FG group. There were 2 major complications in each group during the 16 ± 6 months of follow-up: 1 pocket hematoma and 1 pocket infection in each group. All patients were alive at the 12-month follow-up visit.

This is the first randomized clinical trial comparing AV puncture techniques using either ultrasound or FG for CIED implantation. In agreement with results reported by Tagliari et al.[4] (97%), our study confirms the high success rate of the ultrasound technique (98%). The radiation dose using ultrasound-guided catheterization was decreased by 57% in our global population, although this result was not statistically significant.

Table 1
Patient characteristics

	Total (n = 102)	Ultrasound (n = 51)	Fluoroscopy (n = 51)	*P*
Age, y	79 ± 13	78 ± 14	79 ± 10	.55
Male sex	63 (61)	33 (64)	30 (59)	.54
Body mass index, kg/m²	26.3 ± 4.8	26.1 ± 5.2	26.5 ± 4.3	.73
Hypertension	60 (59)	33 (68)	27 (53)	.23
Diabetes	27 (26)	14 (27)	13 (25)	.82
Structural heart disease	57 (56)	29 (57)	28 (55)	.84
Pacemaker indication	76 (75)	38 (75)	38 (75)	1
Atrioventricular block	44 (43)	24 (47)	20 (39)	.42
Sick Sinus Syndrome	28 (27)	12 (23)	16 (30)	.37
Others	4 (4)	2 (4)	2 (4)	1
ICD indication	26 (25)	13 (25)	13 (25)	1
Primary prevention	16 (16)	7 (14)	9 (18)	.59
Secondary prevention	10 (9)	6 (12)	4 (8)	.51
Left-sided implant	93 (91)	47 (92)	46 (90)	.73
Type of device				
Single-chamber	15 (15)	11 (21)	4 (8)	.06
Dual chamber	72 (71)	34 (67)	38 (75)	.38
CRT	14 (14)	6 (12)	8 (15)	.56
HBP	1 (1)	0 (0)	1 (2)	.32
Upgrade	7 (7)	2 (4)	5 (10)	.24

CRT, cardiac resynchronization therapy; HBP, His-bundle pacing; ICD, implantable cardioverter defibrillator.
Values are expressed as No. (%) or mean ± standard deviation.

Table 2
Radiation exposure data and implantation procedure time

	Ultrasound (n = 51)	Fluoroscopy (n = 51)	*P*
Total procedure time, min	50 (40-70)	55 (49-68)	.37
Total puncture time, s	60 (41-120)	90 (42-168)	.33
Total fluoroscopy time, s	104 (60-270)	166 (57-289)	.47
Fluoroscopy time (single/dual chamber, s)	84 (54-118)	110 (50-98)	.02
Dedicated fluoroscopy time for AV access, s	0	51 ± 55	< .01
Dedicated dose area product for AV access, mGy.m²	0	0.075 ± 0.13	< .01
Total dose area product, mGy.m²	0.09 (0.04-0.4)	0.21 (0.08-0.5)	.25
Dose area product (single/dual chamber, mGy.m²)	0.06 (0.03-0.17)	0.13 (0.07-0.39)	.04

AV, axillary vein.
The data are expressed as mean ± standard deviation, or median [Q1-Q3].

When considering single or dual chamber CIED implantations with ultrasound-guided AV access, DAP was divided by 2 in our study compared with the FG group ($P = .04$). Our results on fluoroscopy time confirm those published by Migliore et al., with a significant decrease using ultrasound vs FG.[3]

Our study demonstrates that, in a population referred for CIED first implant or upgrade procedure, ultrasound guidance and FG have similar performance, with a high success rate (> 95%) and a similar complication rate (2%). Compared with FG, ultrasound guidance reduces the radiation exposure required for AV access to 0, and decreases total radiation exposure, although this result was not significant.

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AUTHORS' CONTRIBUTIONS

Conceptualization, methodology, validation, formal analysis, writing-review and editing: S.S. Bun. Investigation: P. Taghji, F. Squara and P. L. Massoure. Writing-original draft preparation: P. T Taghji, S.S. Bun. Visualization: F. Squara and P. Taghji. Supervision: J.C. Deharo and E. Ferrari.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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Feasibility and safety of early discharge after transcatheter aortic valve implantation

Factibilidad y seguridad del alta precoz tras el implante percutáneo de válvula aórtica

To the Editor,

The introduction of the latest generation of bioprosthetic aortic valves has allowed specialist centers experienced in transcatheter aortic valve implantation (TAVI) to use minimally invasive approaches, which reduce hospitalization times. Early hospital discharge after TAVI with balloon-expandable valve prostheses has been shown to be safe,[1–3] but there is less evidence for TAVI with self-expanding valves,[4,5] raising concerns about the risk of conduction disorders. In this context, immediate assessment of the conduction system through rapid atrial pacing (RAP) is useful to evaluate the integrity of the conduction system and predict the need for pacemaker implantation during follow-up.[6]

In the present study, we retrospectively analyzed the outcomes of a protocol for early post-TAVI discharge (APRETAVI) introduced in response to the COVID-19 pandemic. This patient-care protocol included all elective TAVI procedures conducted with ultrasound-guided transfemoral access and conscious sedation. We excluded hospitalized patients, those undergoing by more invasive procedures, and severely frail patients lacking adequate family support. The Medical Research Ethics Committee granted an exemption for informed patient consent.

After elective admission, patients received appropriate preparation for the intervention (including assessment of their familial and social situation and frailty status) and gave informed consent. After the TAVI procedure, the conduction system was assessed by RAP.[6] Pacing was discontinued in the catheterization laboratory in patients in sinus rhythm who did not develop Wenckebach atrioventricular (AV) block at RAP rates up to 120 bpm, as well as in those in atrial fibrillation with a post-TAVI His-ventricular interval < 55 ms. Otherwise, pacing was continued for at least 24 hours. Patients were monitored for a minimum of 12 hours after the TAVI procedure and underwent physical examination, electrocardiography, complete blood count, and transthoracic echocardiography.

Patients without complications were considered for very early discharge (< 24 hours) according to the scheme depicted in figure 1A. Those meeting all the early discharge criteria were given a "rapid rehabilitation" guide (figure 1B) and a pulse heart rate monitor together with written instructions detailing abnormal readings requiring prompt consultation with the medical team after discharge. Each patient's status was also monitored via telephone within 48 hours of discharge. As per the protocol, all patients discharged early (< 72 hours) attended a clinical follow-up consultation 1 week after TAVI, including assessment of the femoral puncture site and a follow-up electrocardiogram). A further in-depth consultation took place after 1 month.

A total of 169 patients underwent transfemoral TAVI at our center between June 2020 and January 2022. The mean age of the patients was 80.2 ± 44.5 years, and 45% of the patients were women. The mean EuroSCORE II was 3.5 ± 2.6%. Baseline patient characteristics are summarized in table 1. Transfemoral access with local anesthesia was achieved in all patients, and secondary radial access was achieved in 164 patients (97%). The incidence of severe complications (VARC-2) was low (table 1). The pacing protocol permitted immediate removal of the temporary pacemaker in 62.9%