Adopting Ultrasound-guided Axillary Vein Access for CIED Lead Implantation

석 사 학 위 논 문

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이 논문을 석사학위 논문으로 제출함

2024년 2월

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감사의 말씀

먼저 바쁘신 가운데 많은 가르침을 주시고 논문의 시작부터 마무리까지 아낌없이 지도해주신 황종민 교수님께 진심으로 감사드립니다.

또한 바쁘신 와중에도 심사위원을 맡아주신 교수님들께 깊은 감사의 말씀을 드립니다.

전공의 수련 과정 중에서 많은 어려움이 있던 과정에서 늘 도와주신 심장내과 교수님들과 모든 내과 교수님들, 함께 수련 생활을 보낸 동산병원의 모든 선생님들께 함께 감사의 말씀 올립니다.

2024년 2월

오 성 택

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1. Introduction

The cardiac implantable electronic device (CIED, mainly pacemaker (PM), implantable cardioverter-defibrillator (ICD), and cardiac resynchronization therapy (CRT)) is one of the cornerstone treatment modalities of contemporary arrhythmia management. With CIEDs, two types of treatment can be provided to patients: cardiac pacing (including resynchronization) and cardiac defibrillation. To achieve these therapies, CIED is primarily composed of two parts: leads and a generator. A generator is inserted into a subcutaneous pocket in the upper pectoral area, while leads are connecting the generator and heart, threaded through a central vein to directly reach the heart, delivering the intended therapy to the patient. Although recent technological advancements have led to the development of leadless PM and subcutaneous ICD, the majority of CIED procedures are still performed with subcutaneous generators and transvenous leads.

Generally, the implantation of CIED is safe, and major complications are rare. However, they do have inherent issues and complications associated with their unique components. In relation to the lead, there are several points where complications may arise: during the assessment of the vein for lead insertion, during the process of advancing the lead to the heart, and finally, during and after fixing the lead in the heart.

Among these topics, we aim to address the venous access for the implantation of CIED leads. Particularly, we sought to evaluate the feasibility of adopting ultrasound-guided axillary vein access (USG-AxA) for the implantation of CIED leads in Korean patients.

2. Materials and Methods

2.1. Study population:

This was a single-center, prospective, observational study. From June 2019 to September 2023, our hospital adopted USG-AxA in all cases of new transvenous CIED lead implantation procedures. During the study period, patients over 18 years of age who understood the purpose of our study and provided informed consent were enrolled. In these patients, USG-AxA was tried, and data were collected. Additionally, to evaluate the effectiveness and safety of USG-AxA, we conducted a comparison with the data of age and sex-matched cohort of FL-AxA (Fluoroscopy-Guided Axillary Venous Access) patients at our institution. The study was approved by the institutional review board of Keimyung University Dongsan Hospital (No. 2021-08-125).

2.2. Description of the procedure:

2.2.1. Baseline procedure setting:

In our center, the baseline patient position for CIED implantation on the angiographic equipment (image-guided therapy system, Azurion 7 M20 (Philips, Amsterdam, Netherlands)) is shown in Figure 1A. Traditionally, the patient's cranial side is positioned towards the image intensifier/X-ray tube. However, we position the patient in the exact opposite way: the patient's caudal side is positioned towards the image intensifier/X-ray tube. Then, we rotate the ceiling-mounted C-arm by 90 degrees. As a result, caudal to the cranial rotation of the C-arm

corresponds to the conventional RAO-LAO view.

After the patient positioning, we performed timeout, and the patient was draped in the usual sterile fashion, including a surgical drape (Ioban; 3M, St. Paul, Minn.) over the left infraclavicular area. The implantation procedures were generally performed with moderate conscious sedation using pethidine, fentanyl, and midazolam. Initial doses of each drug were as follows: pethidine 25mg, fentanyl 25mg, and midazolam 1mg. The pain control and sedation, if not adequately achieved, were managed by administering additional small boluses of each drug, mainly midazolam. Before the procedure, all patients received intravenous antibiotic prophylaxis.

2.2.2. Method of USG-AxA:

1) Ultrasound exploration

After administering local anesthesia, we attempted to visualize the axillary vein using a linear probe from portable ultrasound devices (Vivid q from GE Healthcare, Milwaukee, WI or Zonare Z-One Portable Ultrasound from Zonare Medical Systems, Mountain View, California, USA).

Ultrasound exploration below the clavicle was initially performed, with particular attention to the region where the medial two-thirds and lateral one-third of the clavicle intersect, as well as the medial aspect of the deltopectoral groove. The axillary artery and axillary vein can be readily identified at this location via ultrasound examination. Figure 1B is a photograph of the performing usual USG-AxA procedure in our laboratory.

2) Longitudinal vs. cross-sectional ultrasound images for vessels

Ultrasound can provide both longitudinal and cross-sectional images of vessels. While longitudinal images offer the advantage of clearly depicting the needle's entry into the vessel, they can be confusing in distinguishing the artery and vein. In addition, if the vein's course is tortuous, the only short segment of the vein can be viewed longitudinally. Cross-sectional images, on the other hand, make it easier to distinguish between the artery and vein, although obtaining a real-time image of the needle entering the vein can be challenging. However, by tilting the probe sufficiently, the needle's entry point into the vein (tenting of the vein) can often be clearly visible. Therefore, while scanning and evaluating the axillary vein/artery, we used both views, but for the puncture, we utilized the cross-sectional image (Figure 2). The confirmation of the axillary vein is finalized with compression (the vein is compressible, but the artery is not): color Doppler evaluation is rarely needed.

3) Incision line decision is related to a needle's entry point to the axillary vein

When performing fluoroscopy-guided axillary venous access (FL-AxA), the point where the needle enters the axillary vein should start just before the lateral margin of the 1st rib under the clavicle and be conducted within the shadow of the 1st rib. Care should be taken not to enter too medially or laterally; medially, so as not to exceed the medial margin of the 1st rib to prevent pneumothorax, and laterally, the consensus is to puncture within the confines of the rib cage margin. A far-lateral axillary puncture can lead to significant restrictions in shoulder movement and a higher likelihood of bending stress on the

leads.

As for USG-AxA, there is still no consensus on the ideal needle entry point. During the initial phases of our adoption of ultrasound, we intended to puncture the axillary vein, but checking with contrast venography after the puncture, it was mostly in the lateral part of the axillary vein, especially where the axillary vein receives the cephalic vein. This is probably due to anatomical reasons, therefore, when puncturing above the skin, it's impossible to puncture the subclavian vein, which has almost eliminated the risk of pneumothorax. However, as described above, the cephalic vein was not the vein we intended to access, and the lateral axillary vein was also not a good lead entry point for long-term lead safety as described above.

4) Our current procedural method of axillary vein access and incision line creation for CIED

As our experiences have accumulated, we are currently performing the procedure as follows.

1. We perform a USG-AxA after skin drape and before pocket creation.
2. Initially, we explore the infraclavicular area to identify the axillary vein-cephalic vein and axillary artery using a linear probe of ultrasound.
3. Perform puncture in the cross-sectional US view using a 5-F micropuncture needle (21G needle and a 0.018″ 40cm guidewire, Micropuncture access set, Cook Medical, Bloomington, Indiana, USA).
4. The example of initially punctured wire is shown in Figure 3A. The punctured point is usually located about 1-2 cm inferior and

1-2 cm lateral to the point where the medial 2/3 of the clavicle transitions to the lateral 1/3.

5. Next, referencing the punctured wire, we make an incision. Typically, the incision starts about 1cm superior and 1cm medial to the punctured wire, running parallel to the deltopectoral groove for about 8-10cm (Figure 3B). Then, we make a pocket conventionally.
6. Figure 3C shows the incision site opened with a self-retractor for puncture after creating the pocket, and the initially punctured wire through USG-AxA is observed at the outside of the pocket. Figure 3D shows the course of the punctured wire confirmed with fluoroscopy. As described above, when attempting to puncture above the skin, it results in puncturing the cephalic vein.
7. Then, we perform a second puncture of the axillary vein under venography and fluoroscopy guidance attempting to make a needle entry point at the more proximal axillary vein. In this situation, accessing the proximal axillary vein becomes much easier since the guidewire has already been punctured and retained. Figure 4A shows the attempt of a second puncture using the initially punctured wire and fluoroscopy. Note that the initially punctured wire is retained along the cephalic vein, which is clearly visible in contrast venography. Figure 4B shows a successful second puncture with micropuncture needle under fluoroscopy guidance.
8. In cases where more than two leads are required, we remove the initially punctured wire and perform a third puncture. This third puncture is also very easy because the wire is already well

retained as we intended. Figure 3C is an image of attempting a third puncture along the second punctured wire after removing the initially punctured wire.

9. Once venous access is complete, we insert the leads for the intended CIED using the Seldinger method with a peel-away sheath. Figure 4D is the final anteroposterior fluoroscopy image showing the dual lead of the pacemaker implanted through the axillary vein.

2.3. Statistical analysis:

Continuous variables are expressed as the mean value ± standard deviation or inter-quartile range when the values do not follow a normal distribution. Categorical variables are expressed as numbers and percentages. The independent sample t-test and chi-square test were used for continuous and categorical variables if normality was accepted. If the sample did not meet the normality assumption, the following method was used: the Mann - Whitney test was used to compare within-group continuous variables before and after the intervention, and the Wilcoxon signed-rank test was used to analyze the differences and changes in values between the two groups. Statistical analyses were performed using the MedCalc® Statistical Software version 22.016 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2023). A p-value < 0.05 was considered statistically significant.

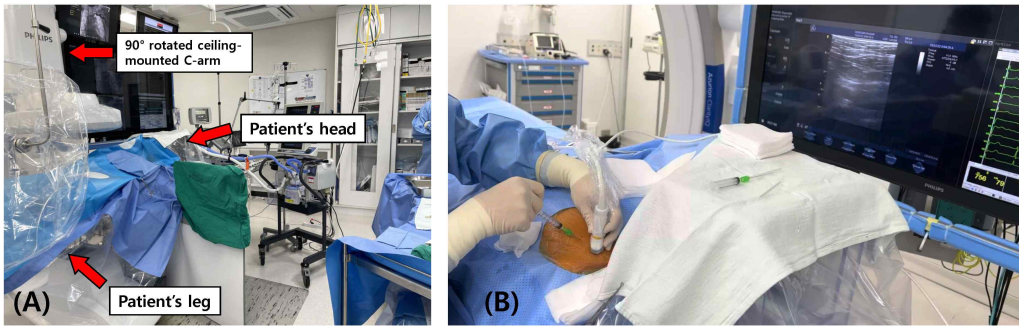

Figure 1. Baseline procedure setting. (A) Baseline patient position on the angiographic equipment (image-guided therapy system, Azurion 7 M20 (Philips, Amsterdam, Netherlands)). We position the patient as follows: the patient's caudal side located at the image intensifier/X-ray tube and patient's cranial side is located at the opposite side. The ceiling-mounted C-arm was rotated by 90 degrees. (B) Performing a ultrasound-guided axillary venous access after skin drape and before pocket creation.

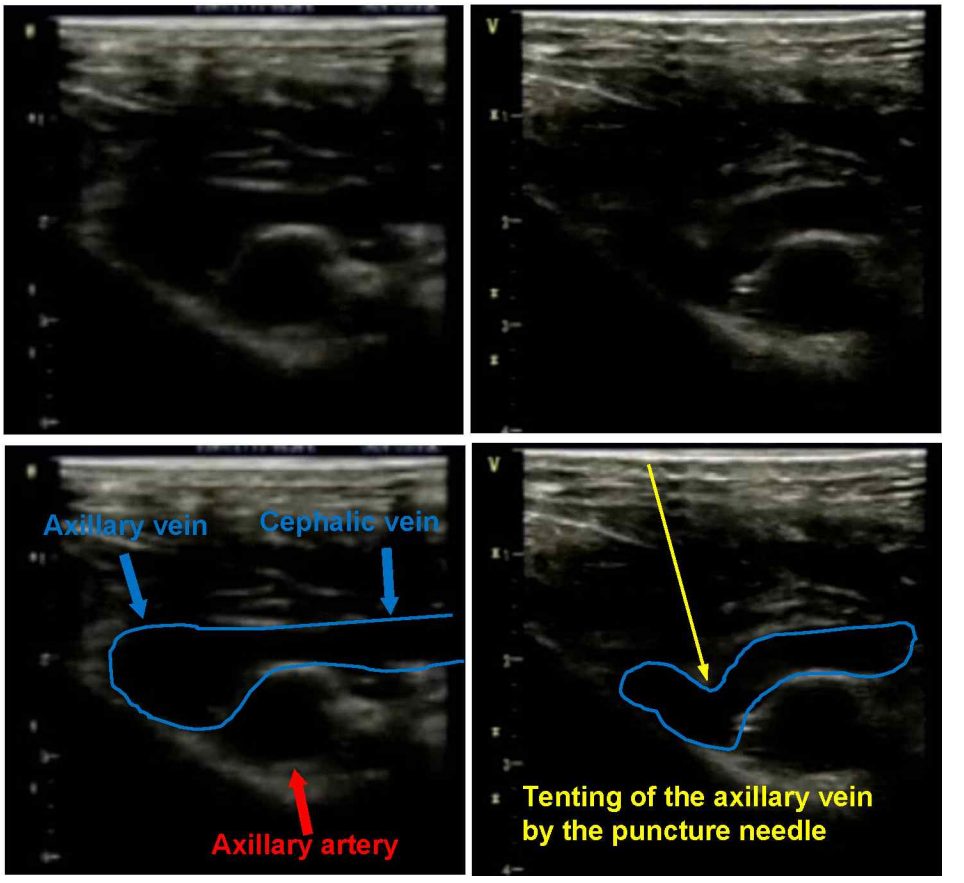

Figure 2. Cross-sectional ultrasound images of the axillary vein. Upper pannel figures are raw ultrasound image and bottom pannel figures are annotated with labels for explanatory purposes in this figures. Note that the tenting of the axillary vein by the puncture needle.

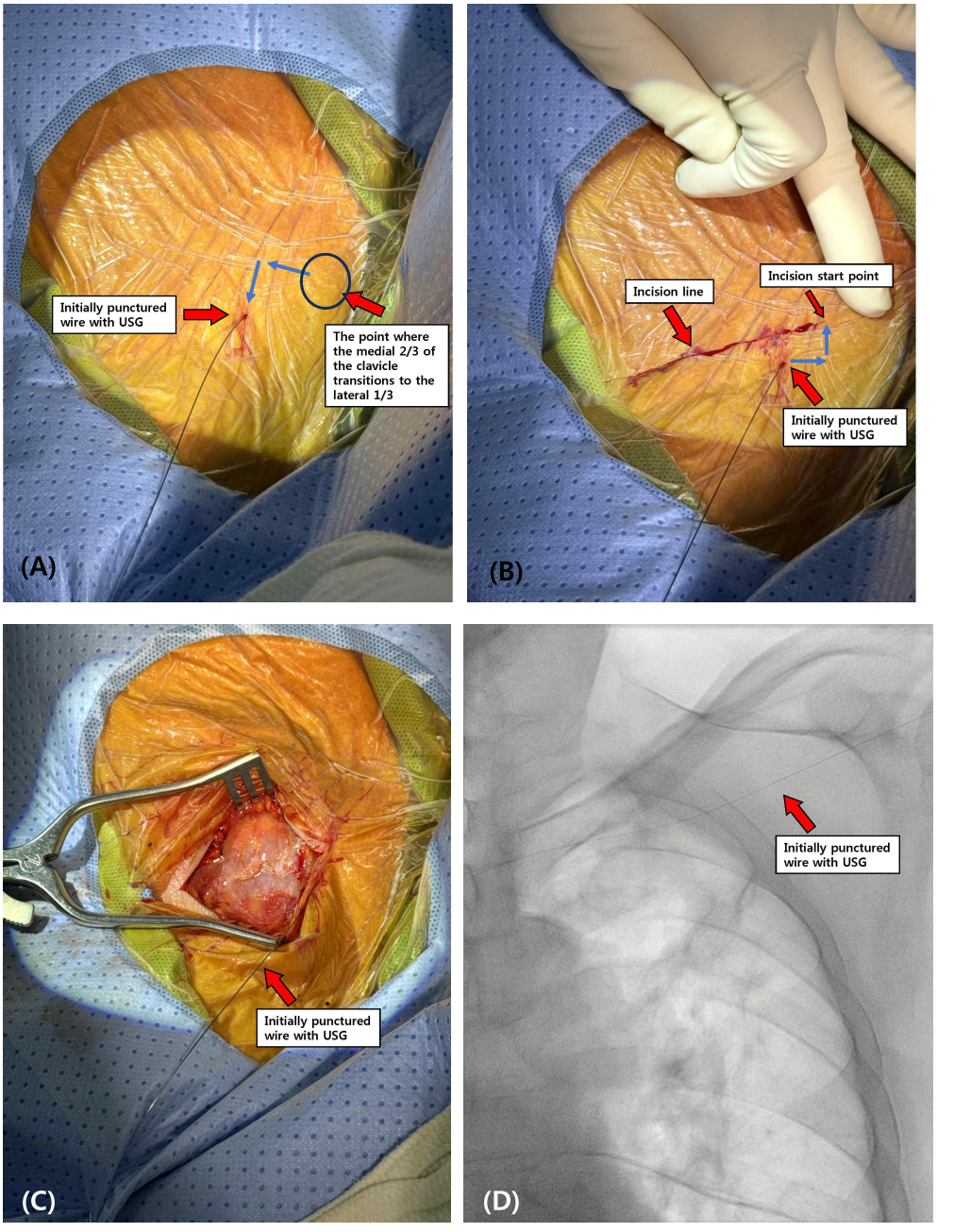

Figure 3. Step-by-step images of the procedure (1). (A) Initially, we perform puncture at the cephalic vein-axillary vein juncture

in the cross-sectional ultrasound view using a linear probe of ultrasound and micropuncture needle. The punctured point at the skin is usually located about 1-2 cm inferior and 1-2 cm lateral to the point where the medial 2/3 of the clavicle transitions to the lateral 1/3. (B) Next, referencing the punctured wire, we made an incision. Typically, the incision starts about 1cm superior and 1cm medial to the punctured wire, running parallel to the deltopectoral groove for about 8-10cm. Then, we make a pocket conventionally. (C) For the next puncture (actually the first axillary vein access used for lead implantation), we set up the operation field as depicted. (D) As shown in this figure, the initially punctured wire is retained along the cephalic vein.

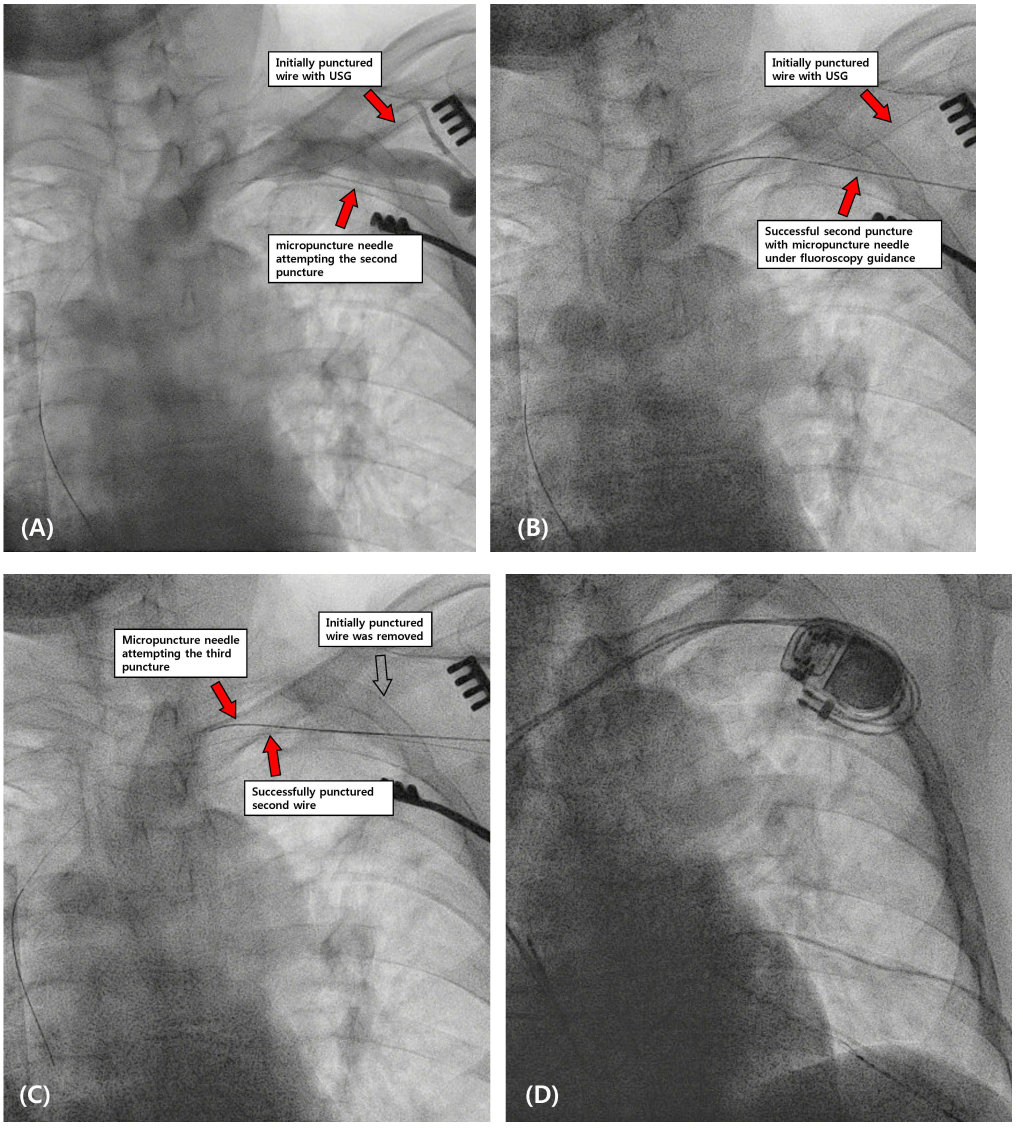

Figure 4. Step-by-step images of the procedure (2). (A) Then, we perform a second puncture of the axillary vein under contrast venography and fluoroscopy. Note that the initially punctured wire is retained along the cephalic vein, which is clearly visible in contrast venography. (B) This figure shows a successful second puncture with micropuncture needle under

fluoroscopy guidance. (C) In cases where more than two leads are required, we remove the initially punctured wire and perform a third puncture. This figure shows attempting a third puncture along the second punctured wire after removing the initially punctured wire. (D) The final anteroposterior fluoroscopy image showing the dual lead of the pacemaker implanted through the axillary vein.

3. Results

3.1. Results of USG-AxA:

3.1.1. Baseline patients' characteristics:

From June 2019 to September 2023, USG-AxA was attempted on a total of 308 patients. The average age of the patients was 72.2 ± 10.6, and the male patients were 144 (46.8%). The median body mass index was 23.8, and the median body surface area was 1.62, which reflects the characteristics of Asians. The pacemaker was implanted in 203 patients, and 67, 38 patients received ICD and CRT implantation. Baseline characteristics of the USG-AxA patients are summarized in Table 1.

3.1.2. Procedural outcome:

The mean procedure time was 57.1 ± 15.4 minutes, and the mean fluoroscopy time was 290.3 ± 154.0 seconds. Radiation doses were as follows: air-kerma 14.3 ± 19.7 mGy, dose-area product 3.2 ± 4.1 $Gycm^2$. The median time from local anesthetic to completion of USG-AxA was 6 min (interquartile range [IQR]: 3 - 11). Procedural outcomes of the USG-AxA patients are also summarized in Table 1.

The USG-AxA was successful in 301 out of 308 patients, with a success rate of 97.7%. Among the 7 patients in whom USG-AxA failed, 5 had a skin thickness of more than 4cm. The remaining 2 had a skin thickness of less than 4cm, but visualization of vessels was poor for unclear reasons. Importantly, in the 301 patients where USG-AxA was successful, there were no occurrences of pneumothorax or inadvertent arterial puncture, nor were there any other significant vascular

access-related complications.

3.2. Comparing the outcomes with FL-AxA:

3.2.1. Baseline patients' characteristics:

To evaluate the effectiveness of US-AxA, we selected age-, sex-matched patients cohorts who underwent FL-AxA at our institution before the adoption of ultrasound. For a more accurate comparison, only patients who received a dual lead pacemaker or ICD were chosen in both group of patients. A comparison of baseline patients' characteristics is shown in Table 2. Data from 187 FL-AxA patients and 191 USG-AxA patients were collected and analyzed for comparison. Demographic and clinical characteristics are not significantly different between the two groups.

3.2.2. Comparison of Procedural Outcome:

The procedure time and fluoroscopy time of the USG-AxA group were significantly shorter. The amount of radiation dose, represented by air-kerma and dose-area product, also tended to decrease in the USG-AxA patients, but it was not statistically significant. This is thought to be because most of the radiation dose occurring during CIED implant procedures comes from the intracardiac positioning of the lead rather than the axillary vein access. In the FL-AxA group, one pneumothorax, one severe hematoma due to superior thoracic artery rupture, and one lead fracture were observed. However, in the USG-AxA group, no complications occurred during the one-year observation period. A comparison of procedural outcomes between the two groups is summarized in Table 3.

Table 1. Baseline Characteristics and Outcomes of USG-AxA Attempted Patients

Characteristic	USG-AxA (N=308)
Male	144 (46.8)
Age (yr)	72.2 ± 10.6
History of HTN	184 (59.7)
History of DM	107 (34.7)
History of AF	125 (40.6)
Height (cm)	159.2 ± 9.8
Weight (kg)	60.5 (53.2 - 67.1)
BMI (kg/m^2)	23.8 (21.9 - 26.0)
BSA (m^2)	1.62 (1.51 - 1.76)
Type of CIED	
Pacemaker	203 (66.0)
SND	143
AVB	60
ICD	67 (21.7)
CRT	38 (12.3)
Lead number	
Single lead	30 (9.7)
Two or more leads	278 (90.3)
USG-AxA time (minutes)	6 (3 - 11)
Procedure time (minutes)	57.1 ± 15.4
Fluoroscopy time (seconds)	290.3 ± 154.0
Air-kerma (mGy)	14.3 ± 19.7
Dose-area product ($Gycm^2$)	3.2 ± 4.1

Values are presented as the n (%) or mean ± SD. Weight/BMI/BSA are presented as median (interquartile range). USG-AxA: ultrasound-guided axillary vein access, HTN; hypertension, DM; diabetes mellitus, AF; atrial fibrillation; BMI: body mass index, BSA; body surface area, CIED; cardiac implantable electronic device, SND; sinus node dysfunction, AVB; atrioventricular block, ICD; implantable cardioverter-defibrillator, CRT: cardiac resynchronization therapy.

Table 2. Baseline Patients' Characteristics Between the Two Groups

Characteristic	FL-AxA (N=187)	USG-AxA (N=191)	P-value
Male	96 (51.3)	84 (44.0)	0.153
Age (yr)	69.2 ± 9.2	70.6 ± 9.1	0.126
History of HTN	106 (56.7)	115 (60.2)	0.487
History of DM	55 (29.4)	62 (32.5)	0.522
Height (cm)	160.1 ± 9.8	158.9 ± 9.5	0.247
Weight (kg)	62.2 ± 11.6	61.3 ± 11.4	0.410
BMI (kg/m^2)	24.2 ± 3.4	24.2 ± 3.5	0.961
BSA (m^2)	1.76 ± 1.37	1.64 ± 0.19	0.238
Procedure			0.961
Pacemaker	157 (84.0)	160 (83.8)	
SND	79 (50.3)	98 (61.2)	0.050
AVB	78 (49.7)	62 (38.7)	
ICD	30 (16.0)	31 (16.2)	

Values are presented as the n (%) or mean ± SD. Weight/BMI/BSA are presented as median (interquartile range). FL-AxA; fluoroscopy-guided axillary vein access, USG-AxA: ultrasound-guided axillary vein access, HTN; hypertension, DM; diabetes mellitus, AF; atrial fibrillation; BMI: body mass index, BSA; body surface area, SND; sinus node dysfunction, AVB; atrioventricular block, ICD: implantable cardioverter-defibrillator.

Table 3. Procedural Results

Characteristic	FL-AxA (N=187)	USG-AxA (N=191)	P-value
Procedure time (minute)	59.8 ± 17.0	55.5 ± 14.7	0.009
Fluoroscopy time (seconds)	410.6 ± 221.3	289.5 ± 153.5	<0.0001
Air-Kerma	16.0 ± 22.1	13.8 ± 15.1	0.279
Dose-Area Product	3.8 ± 8.4	3.2 ± 3.6	0.334

FL-AxA; fluoroscopy-guided axillary vein access, USG-AxA: ultrasound-guided axillary vein access.

4. Discussion

4.1. Main findings:

The main findings of our research are as follows: 1) USG-AxA significantly reduced the incidence of acute procedural complications. 2) Compared to FL-AxA, USG-AxA shortened the procedure/fluoroscopy time and there were no complications. Furthermore, during approximately one year of mid-term follow-up, lead safety was not an issue, and there was one case of lead fracture in the FL-AxA group where the lead was implanted through the cephalic vein. 3) CIED infection did not occur in either group. 4) While there have been many reports on USG-AxA in the West, reports in Asia have been limited. Adopting USG-AxA in Asians, who often have low BMI/BSA, is feasible and it is a very safe and effective method for accessing the axillary vein for the implantation of transvenous leads of CIEDs.

4.2. Using the subclavian vein and the cephalic vein as a route for CIED leads:

The utilization of the antecubital basilic vein to the central vein as the route for electrical stimulation of the heart was first reported in 1959 (1). Despite numerous attempts and incremental changes over the ensuing six decades, the overall approach has continued to rely on the core principles established in the early stages of this practice.

For the insertion of CIED leads, the subclavian, axillary, and cephalic

veins are primarily considered. Although subclavian vein direct puncture, which has been used in clinical practice since the late 1960s (2), is associated with a higher incidence of pneumothorax (1-3%) (3), it is still a popular choice due to its ease of execution, speed, and high success rate. Although safer, this subclavian approach, more medial aspect of the body, results in higher failure rates due to conductor fracture and insulation damage over time (4). This is one of the most serious long-term complications related to the subclavian vein approach. It is postulated that the extreme medial position results in a tight fit, subjecting the lead to compressive forces and causing binding between the first rib and the clavicle (4, 5). Occasionally, this binding can even crush the lead, referred to as the subclavian crush phenomenon (6). During the subclavian vein puncture procedure, catheters pass through the costo-clavicular ligament and/or the subclavius muscle (7). This can result in the leads becoming entrapped in these anatomical structures, leading to frequent fleecing, shearing, and overcharging forces (8). Consequently, the lead structures may be damaged at this site.

In order to mitigate the risk of acute procedural and long-term complications, it was recommended that the operators should implement the CIED leads to the more laterally that are extrathoracic in nature. The use of such techniques can reduce the likelihood of complications and contribute to better patient outcomes. Hence, the use of the cephalic vein in PM implantation has been the gold standard for several decades (9). This approach involves vein dissection through minimally invasive surgery and direct lead insertion into the exposed vein. The cephalic vein provides an access path that avoids subclavian crush syndrome. However, the small size of the cephalic vein, along with its steep and angled entrance into the axillary vein, can make it difficult to handle

leads, particularly when multiple leads are involved (8). Additionally, venous dissection was not a familiar method for internists and cardiologists. As a result, the subclavian vein has been the most widely used venous route for PMs since the late 1970s. However, given the serious complications associated with subclavian vein access, physicians have continually endeavored to identify alternative venous routes that could serve as viable options.

4.3. The Emergence of the Axillary Vein:

The first suggestion for using the axillary vein as a route for implantation of CIED lead was made by Byrd (10). Subsequent to its incorporation into clinical practice, the axillary vein has been acknowledged as an advantageous conduit for venous access in the implantation of CIED leads. This recognition is attributed to the vein's substantial caliber, facile accessibility, and capacity to accommodate multiple leads. Additionally, axillary vein access mitigates issues commonly associated with subclavian vein access, such as pneumothorax and subclavian crush syndrome (11).

4.4. Methods of axillary vein access:

4.4.1. Anatomy:

An in-depth understanding of the anatomical structures of the neck, upper extremities, and thorax is imperative for the implantation of CIED. Accurate identification of the location and orientation of key venous structures, including the internal jugular, innominate, subclavian, and cephalic veins, is crucial for ensuring safe venous access. Especially, a

complete understanding of the superficial and deep venous systems of the upper extremity is inevitable.

The basilic vein, a prominent superficial vein of the upper extremity, emanates from the dorsal venous network of the hand. It progresses along the medial aspect of the upper limb and delves into the deeper regions of the arm at the juncture of the teres major muscle. Here, it converges with the brachial veins of the upper limb's deep venous system, culminating in the formation of the axillary vein. This vein then extends to the outer border of the first rib, transforming into the subclavian vein at the lateral margin of the first rib. Concurrently, the cephalic vein, another superficial vein in the arm, originates at the radial side of the dorsal venous network of the hand and ascends along the arm's lateral aspect. It traverses to the medial aspect of the shoulder, coursing between the deltoid and pectoralis major muscles within the deltopectoral groove, and ultimately drains into the axillary vein (12).

4.4.2. Methods of axillary vein access:

After Byrd had reported successful axillary venous access (10), Magney et al. subsequently reported a new approach to axillary vein using surface landmarks (13). needle insertion is executed at the intersection of the lateral and middle thirds of the line connecting the coracoid process to the sternum angle, subsequently advancing towards the region between the middle and medial thirds of the clavicle. Belott delineated a method for blind axillary venous access, employing a modified approach based on the recommendations of Byrd and Magney (14). Currently, the vast majority of physicians and laboratories use surface landmark methods along with Byrd's first rib/fluoroscopy approach for incision line making and axillary vein puncture as follows

(15).

The dermal incision is optimally positioned at, or marginally inferior to, the coracoid process. This incision should be oriented orthogonally to the deltopectoral groove, situated medially adjacent to the coracoid process, centrally within the deltopectoral groove. Following this, the incision should be extended in an inferomedial trajectory for approximately two inches, maintaining an orientation that is perpendicular to the aforementioned groove.

Following the formation of the pocket, the needle's tip is positioned at the median one third of the first rib, as visualized through fluoroscopy. The syringe and needle's path is progressively fine-tuned to a sharper angle while traversing the pectoralis major muscle. Meticulous management of the percutaneous needle and syringe is essential to maintain the needle tip's fluoroscopic alignment with the central axis of the first rib. This alignment often requires a relatively pronounced angle of insertion. The needle's forward movement is sustained until it makes contact with the first rib. Fundamentally, this technique aims to anchor the axillary vein against the first rib. Upon contact with the first rib, the needle and syringe are gradually withdrawn under aspiration until the vein's penetration is evidenced by the apperance of blood in the syringe.

The implementation of contrast venography played a pivotal role in enhancing the acceptance of the axillary vein approach for the insertion of CIED leads(8). This technique was first reported in 1997 (16). If contrast axillary venography is performed prior to the procedure or during the puncture, it enables real-time visualization of the axillary vein. Therefore, if implemented in conjunction with the aforementioned methods, this approach can significantly enhance the probability of

successful axillary vein access.

4.4.3. Limitations of axillary vein access:

Despite the progress in these techniques, axillary vein access can still be challenging at times, and complications such as pneumothorax or inadvertent arterial puncture have not been completely resolved. In addition, for example, while there is a consensus that the incision site should be two inches from the deltopectoral groove, in practice, there are considerable inter-individual variations in the three-dimensional relationship between skin-clavicle-axillary vein which frequently puts us in a difficult situation, greatly complicating incision line making and axillary vein access. In patients who have very thick subcutaneous fat tissue or wide infraclavicular shoulder area, the incision site is often far from the axillary vein. Also, downward displacement of the clavicle is often found in very elderly patients. As a result, the location of the axillary vein inferred from the fluoroscopic images of the rib and clavicle often differs significantly from its actual position as confirmed by venography. These limitations prompted us to initiate this research.

4.5. Various methods of USG-AxA:

Upon reviewing the literature reported on USG-AxA to date, it consistently reports lower complications, shortened procedure time, and reduced radiation dose compared to FL-AxA (17-20). However, while the goal and premise of accessing the axillary vein through ultrasound are the same, the methods vary slightly across the studies. Specifically, there are groups using linear probes and those using hockey stick probes, as well as those who employ USG-AxA before skin incision and

others after completing both skin incision and pocket creation. Additionally, some groups mainly use longitudinal images for puncture, while others primarily use cross-sectional images. At present, it is difficult to determine the superiority among these methods, and further large-scale prospective research is needed.

The hockey stick probe, due to its smaller size, can be used inside the pocket after skin incision and pocket creation. In this situation, the obstacle of the skin and dermal tissue is removed, making it much easier and clearer to find and view vessels. However, using a linear probe inside the pocket can be challenging unless the incision is made very large. Although the hockey stick probe has these advantages over linear probe, it is more commonly used in vascular surgery clinics than in cardiology, so many cardiac catheterization labs do not typically have it available. Therefore, the role of the linear probe remains important for the immediate adoption of USG-AxA into our daily clinical practice.

4.6. Future perspectives of USG-AxA:

In the long term, most cardiology procedures are expected to move towards zero or near-zero fluoroscopic procedures, which implies an increasingly significant role for USG-AxA. However, as our research indicates, USG-AxA alone still presents challenges in accurately and appropriately implanting leads in the axillary vein. As previously described, USG-AxA attempted before skin incision is likely to access the cephalic vein. Therefore, the current limitation is the need to use fluoroscopy and contrast venography in conjunction with the USG-AxA. While the hockey stick probe may resolve this issue, further research is needed to verify this.

Nevertheless, USG-AxA is highly effective method as it resolves issues of pneumothorax and inadvertent arterial puncture that were not solved by surface anatomy, fluoroscopy, or contrast venography. Moreover, the ability of USG-AxA to facilitate access to the axillary vein and determine the incision line in patients with thick skin/subcutaneous tissue, a narrow infraclavicular area, or downward displacement of the clavicle due to aging, is a clinically meaningful discovery.

4.7. Limitations of our research:

The major limitation of our study is that this was a single-center prospective registry study with a relatively small sample size. Additionally, caution must be given in interpreting the results due to the comparison of outcomes with historical data. As previously mentioned, it should be also noted that our method was limited to the use of a linear probe before skin incision, without attempting various approaches to USG-AxA.

5. Summary

Adopting USG-AxA is feasible in Korean patients and it is a very safe and effective method for the accessing axillary vein for the implantation of transvenous leads of CIEDs.

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Adopting Ultrasound-guided Axillary Vein Access for CIED Lead Implantation

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(Abstract)

Recently, ultrasound-guided axillary venous access (USG-AxA) has emerged as the safe and effective alternative method for accessing axillary vein during the implantation of transvenous leads of cardiac implantable electronic devices (CIED). Nevertheless, USG-AxA has not been adopted, especially in Korea.

From June 2019 to September 2023, our hospital adopted USG-AxA in all cases of new transvenous CIED lead implantation procedures. During the study period, patients over 18 years of age who understood the purpose of our study and provided informed consent were enrolled. Additionally, to evaluate the effectiveness and safety of USG-AxA, we conducted a comparison with the data of age and sex-matched cohort of fluoroscopy-guided axillary venous access (FL-AxA) patients at our

institution.

During the study period, USG-AxA was attempted on a total of 308 patients. The average age of the patients was 72.2 ± 10.6, and the male patients were 144 (46.8%). The pacemaker was implanted in 203 patients, and 67, 38 patients received ICD and CRT implantation. The mean procedure time was 57.1 ± 15.4 minutes, and the mean fluoroscopy time was 290.3 ± 154.0 seconds. Radiation doses were as follows: air-kerma 14.3 ± 19.7 mGy, dose-area product 3.2 ± 4.1 $Gycm^2$. The median time from local anesthetic to completion of USG-AxA was 6 min (interquartile range [IQR]: 3 - 11). The USG-AxA was successful in 301 out of 308 patients, with a success rate of 97.7%. Importantly, in the 301 patients where USG-AxA was successful, there were no occurrences of pneumothorax or inadvertent arterial puncture, nor were there any other significant vascular access-related complications.

To evaluate the effectiveness of US-AxA, we selected age-, sex-matched patients cohorts who underwent FL-AxA at our institution before the adoption of ultrasound. The procedure time and fluoroscopy

time of the USG-AxA group were significantly shorter. The amount of radiation dose, represented by air-kerma and dose-area product, also tended to decrease in the USG-AxA patients, but it was not statistically significant. In the FL-AxA group, one pneumothorax, one severe hematoma due to superior thoracic artery rupture, and one lead fracture were observed. However, in the USG-AxA group, no complications occurred during the one-year observation period.

Adopting USG-AxA is feasible in Korean patients and it is a very safe and effective method for the accessing axillary vein for the implantation of transvenous leads of CIEDs.

심장 이식형 전자기기의 유도전극선 삽입을 위한 초음파 유도 겨드랑이 정맥 접근법 도입

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(초록)

최근 초음파 유도 겨드랑이 정맥 접근법(USG-AxA)이 심장삽입전기장치(CIED)의 정맥 리드 삽입 시 겨드랑이 정맥에 접근하는 안전하고 효과적인 대안으로 떠오르고 있다. 그럼에도 불구하고, 특히 한국에서는 USG-AxA가 여전히 도입되고 있지 않다.

우리 병원은 2019년 6월부터 2023년 9월까지 모든 신규 심장삽입전기장치의 정맥 내 유도전극선 삽입 시술에 USG-AxA를 도입하였다. 연구 기간 동안 연구 목적을 이해하고 사전 동의를 제공한 18세 이상의 환자를 대상으로 연구를 진행하였다. 또한 USG-AxA의 효과와 안전성을 평가하기 위해 우리 기관에서 연령과 성별이 일치하는 fluoroscopy-guide 액와 정맥 접근(FL-AxA) 환자 코호트 데이터와 비교를 실시하였다.

연구 기간 동안 총 308명의 환자에게 USG-AxA가 시도되었다. 환자들의 평균 연령은 72.2±10.6세였고, 남성 환자가 144명(46.8%)이었다. 203명의 환

자에게 심박 조율기를 이식했고, 67명, 38명의 환자에게는 삽입형 제세동기와 심장재동기화치료기를 이식하였다. 평균 시술 시간은 57.1 ± 15.4분, 평균 fluoroscopy 투시 검사 시간은 290.3 ± 154.0초였다. 방사선량은 air-kerma 14.3 ± 19.7 mGy, dose-area product 3.2 ± 4.1 $Gycm^2$ 였다. 국소 마취에서 USG-AxA 완료까지의 시간 중앙값은 6분(사분위수 범위[IQR]: 3~11)이었다. 308명의 환자 중 301명이 USG-AxA에 성공하여 97.7%의 성공률을 보였다. USG-AxA가 성공한 301명의 환자에서 기흉이나 의도치 않은 동맥천자가 발생하지 않았으며, 기타 심각한 혈관 접근 관련 합병증도 발생하지 않았다.

US-AxA의 효과를 평가하기 위해 초음파를 도입하기 전에 우리 기관에서 FL-AxA를 받은 연령과 성별이 일치하는 환자 코호트를 선정하여 비교하였다. 그 결과 USG-AxA 그룹의 시술 시간과 fluoroscopy 투시 검사 시간이 유의미하게 짧았다. 방사선량도 USG-AxA 환자에서 감소하는 경향을 보였지만 통계적으로 유의미하지는 않았다. FL-AxA 그룹에서는 기흉 1건, 상흉동맥 파열로 인한 중증 혈종 1건, 유도전극선 골절 1건이 관찰되었다. 그러나 USG-AxA 그룹에서는 1년간의 관찰 기간 동안 합병증이 발생하지 않았다.

USG-AxA는 한국인 환자에게도 적용이 가능하며, 심장삽입전기장치의 정맥 리드 삽입 시 겨드랑이 정맥에 접근하는 매우 안전하고 효과적인 방법이다.