Zero-fluoroscopy permanent pacemaker Implantation using Ensite NavX system: clinical viability or fanciful technique?

Running Title: Zero-fluoroscopy Implantation of Permanent Pacemakers.

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Units and abbreviations:

ESC= European Society of Cardiology; AHA= American Heart Association; SVA= superior vena cava, RA= right atrium, RAA= right atrial appendage; AV= atrioventricular; ECG= Electrocardiograph; SD= standard deviation; F= Fluoroscopy; ZF= Zero-Fluoroscopy.
Abstract

**Background**: Fluoroscopy is the imaging modality routinely used for cardiac device implantation and electrophysiological procedures. Due to the rising concern regarding the harmful effects of radiation exposure to both the patients and operation staffs, novel 3D mapping systems have been developed and implemented in electrophysiological procedure for the navigation of catheters inside the heart chambers. Their applicability in cardiac device implantation has been rarely reported. Our aim is to evaluate the feasibility and safety of permanent pacemaker implantation without fluoroscopy.

**Methods and Results**: From January 2012 to June 2016, six patients (50±15 years, four of six were female, one of which was at the 25th week of gestation) that underwent permanent pacemaker implantation were included (zero-fluoroscopy group). Data from twenty consecutive cases of implantation performed under fluoroscopy guidance were chosen as a control group (fluoroscopy group). Total implantation procedure time for single chamber pacemaker was 51.3± 13.1 min in zero-fluoroscopy group and 42.6± 7.4 min in fluoroscopy group (p=0.155), The implantation procedural time for a dual chamber pacemaker was 88.3± 19.6 min and 67.3± 7.6 min in the zero-fluoroscopy and fluoroscopy group (p=0.013), respectively. No complications were observed during the procedure and the follow-up in the two groups, and all pacemakers worked with satisfactory parameters.
Conclusion: Ensite NavX system can be used as a reliable and safe zero-fluoroscopy approach for the implantation of single- or dual-chamber permanent pacemakers in specific patients, such as pregnant women or in extreme situation when the X-ray machine is not available.

Key words: Permanent pacemaker; implantation; Ensite NavX system; zero-fluoroscopy.

Introduction

Implantation of permanent cardiac pacemaker has been a well-established therapy for patients with heart rhythm disorders. This approach is traditionally performed under fluoroscopic guidance. Besides other peri-interventional risks, radiation exposure should be considered for its stochastic and deterministic effects on health \(^1\). As the number of cardiac pacemakers implanted around the world are rising rapidly, careful attention to limit radiation exposure to the staffs and patients is of paramount importance.\(^2\). Therefore, the measures taken to reduce radiation exposure in every medical practice and facility are necessary and meaningful.

Novel three-dimensional(3D) mapping systems, such as Ensite NavX, CARTO, Localisa, have been developed and implemented in electrophysiological procedure to guide the navigation of catheters inside the heart and to reduce radiation exposure \(^3\)-\(^4\). However, to date there have been few reports on the use of 3D mapping systems for the implantation of
cardiac pacemakers, only described in single case reports or in case series for reducing radiation exposure\textsuperscript{5-10}. Recently, Colella A. \textit{et al.} have reported their experience of the zero-fluoroscopy approach for cardiac resynchronization therapy and during the procedure, they manoeuvred magnetic traceable guide wires to identify and map the coronary sinus, guided only by the Ensite NavX system\textsuperscript{9}.

Here, we present a case series of 6 patients who underwent permanent pacemaker implantation with zero-fluoroscopy approach guided by Ensite NavX system. To assess the feasibility and safety of this technique, results are compared to a group of patients who underwent pacemaker implantation with traditional fluoroscopy technique.

\textbf{Methods}

\textbf{Patients Inclusion}

We enrolled 6 consecutive patients in our institution undergoing implantation of a cardiac pacemaker with zero-fluoroscopy between January 2012 and June 2016. Patients enrolled were in the following situations: (1) an extremely emergent implantation was required while the X-ray machine in catheter laboratory was not available; (2) special populations (i.e. pregnant women) who were extremely sensitive to fluoroscopy (zero-fluoroscopy group). Ensite NavX was the only navigation system during the process of permanent cardiac pacemaker implantation. In addition, 21 consecutive cases who underwent traditional pacemaker implantation (performed under fluoroscopic guidance) by the same operator were
chosen as a control group. (fluoroscopy group). All the patients were evaluated according to
the current European Society of Cardiology (ESC)/ American Heart Association (AHA)
guideline(10). Informed consents were required in all patients before the procedure. Our
study was censored and approved by the electrophysiological quality control team under the
supervision of Institutional Human Research Ethics Board.

**Procedure Preparation**

A standby echocardiography was performed for each patient at bedside. All procedures were
performed under the guidance by Ensite NavX system (St Jude Medical, MN, USA) in
zero-fluoroscopy group. Three orthogonal pairs of electrode patches were placed on the skin
of the patient, in order to create the required three-dimensional electrical navigation field.
Surface patches were used as reference. The system permitted the accurate position of any
electrode placed and the construction of a geometric contour of the patient’s cardiac chamber
within the navigation field. Two sets of alligator cable were used for implantation. Under
local anesthesia, left or right subclavian and/or right femoral vein were punctured. As for
single-chamber pacemaker, only the subclavian vein was punctured unless the situation
which required temporary pacing. Correct venous puncture was always judged by the
following methods: (1) the characteristic dark color of venous blood; (2) the presence of
venous pressure; (3) the obvious movement of electrode, which was placed at the middle part
of right atrium via femoral vein, by rotating the J-shaped wire placed via subclavian vein. A
special designed unipolar guide-wire was used when only the subclavian vein was punctured for the procedure.

**Ventricular Lead Implantation**

The ventricular lead was connected to the Ensite NavX system with an alligator cable, and the inter-electrode distance was set according the type of ventricular lead used. The geometry of the superior vena cava (SVA), right atrium (RA), and right ventricular apex were roughly created by wagging the pacing lead inside the cavity. Usually, the ventricular lead was further advanced at a length about 3 to 5 centimeters after it just reached the ideal place; the length depended on the patients’ statue and the test of pacing stability mentioned below.

**Atrial lead Implantation**

In the patients undergoing a dual-chamber pacemaker using the Ensite NavX system without fluoroscopy, it needed atrial lead implantation in addition to the above steps. Right femoral vein was punctured, and then a steerable ten-polar electrode (St Jude Medical, MN, USA) was advanced to the right atrium with an alligator cable being connected to the three-dimensional system. The geometry of right atrium and right atrial appendage (RAA) was constructed. The J-shaped guide wires were usually replaced with six-French sheath before the geometry reconstruction. The tip of atrial lead, which was used for permanent pacing, was manipulated to an ideal site in RAA under the guidance of NavX system.
Measurement of Parameters

The second set of alligator cable was collected to the program analyzer to assess lead characteristics, including sensing, pacing, and impedance measurements. Unipolar or bipolar parameters were measured routinely.

Confirmation and Lead Collection

After initial satisfactory parameters were acquired, the pacing stability of the electrodes was further confirmed if the following tests had no influence on the pacing parameters: (1) Gently advancing, withdrawing, and rotating the leads several times; (2) making the patient breathe deeply and cough strenuously. The leads were finally connected to a permanent pacemaker, and then the apparatus was placed into the prepared -subcutaneous pouch. The pouch was sewed by absorbable suture material after checking the system.

All procedures were successfully performed by the same electrophysiologist experienced in pacemaker implantations.

Variables and Follow-up

All medical data, including demographics, procedure time, pacing parameters, complications, average duration of stay and outcomes, were recorded. Patients were usually discharged two or three days after operation. Each patient was followed with a scheduled clinic visit in 1, 2,
3, and 6 month. At each follow-up examination, pacing parameters were tested. The results were compared with that obtained in 20 consecutive patients who were implanted with fluoroscopy and were retrospectively analyzed.

Statistical analysis

Data was expressed as mean ± standard deviation (SD) and as percentage. The differences between groups were compared using an independent Standard t-test. Statistical significance was defined as P<0.05 for all analyses. All analyses were performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA).

Results

The mean age of the patients was 50±15 (range: 24–66) years, and four of six were female. One patient presented with symptomatic complete atrioventricular (AV) block was at the 25th week of gestation, with a high risk of cardiac arrest. Single-chamber pacemakers were implanted in 3 patients (50%) and dual-chamber pacemakers were implanted in others(50%), respectively. Clinical characteristics of the patients were shown in Table 1.

All patients underwent successful pacemaker implantation without fluoroscopic guidance. All leads were successfully placed (three atrial leads, six ventricular leads) without fluoroscopy.
Total implantation procedure time of the single chamber pacemaker was 51.3±13.1 min (42.6±7.4 min in the fluoroscopy group; P=0.155), and of the dual chamber pacemaker was 88.3±19.6 min (67.3±7.6 min in the fluoroscopy group; P=0.013). Manufacturers of the pacemakers were as follows: Biotronik (GMBh & Co. KG, Berlin, Germany) (n=2), St. Jude (St Jude Medical, MN, USA) (n=4). The results of the zero-fluoroscopy and fluoroscopy group were analyzed and shown in Table 2.

All patients were followed up in the outpatient pacemaker clinic for 1, 2, 3, and 6 month after implantation. No complications were observed during the procedure and the follow-up in two groups, and all pacemakers worked properly with satisfactory parameters (Table 3).

Discussion

To our knowledge, prior reports have described the feasibility of cardiac device implantation utilizing a minimal radiation exposure technique, which combining 3D mapping systems and fluoroscopy\textsuperscript{11-14}. Seldom single cases have described the feasibility of pacemaker implantation without fluoroscopy\textsuperscript{5-9,15}. In our study, all permanent pacemakers were successfully implanted with satisfactory parameters and without any complications using Ensite NavX system. Other imaging systems, such as transthoracic echocardiography or trans-esophageal echocardiography, were not used in our procedures. Based on our data, we
believed that the Ensite NavX system was a safe and feasible navigation system to guide lead deployment in patients (including pregnant patient).

Traditionally, during the process of trans-venous implantation of permanent pacemaker, fluoroscopy has acted as the critical imaging tool for tracking lead insertion and placement. However, the cumulative radiation may significantly increase the risk of cancer or genetic abnormality in patients or medical staff, and induce transient or permanent adverse reactions, such as skin injury or cataracts\textsuperscript{16}. Furthermore, radiation exposure has been considered to be associated with birth defects, such as neurologic disorders, growth retardation, congenital malformations, childhood cancer and embryonic death\textsuperscript{17}. Nowadays, fluoroscopy has been widely used in medication, such as chest X-Ray, cardiac computer tomography, catheter ablation of arrhythmia, and fixation of bone fractures. Though radiation shielding equipments such as lead aprons and collars have been shown to reduce the rate of exposure in radial catheterization procedures, the electrophysiologists’s hands are exposed to radiation inevitably\textsuperscript{16}. Besides, some studies have reported that the prevalence of cervical and lumbar spondylosis increased significantly among interventional electrophysiologists due to the heavy lead equipments\textsuperscript{18}. Hence, it is urgent to take measures to reduce radiation exposure and minimize time spent wearing lead as much as possible.

Recently, some novel systems have been developed in the placement and navigation of catheters during electrophysiological procedures. The Biosense CARTO\textsuperscript{®} system, which is
mainly relied on magnetic field for navigation, has been used in ablation and pacemaker implantation\textsuperscript{7,19,20}. Zero-fluoroscopy approach through the 3D navigation systems may represent a new strategy in the field of cardiac device implantation. Besides the potential benefit of reducing radiation exposure, the Ensite NavX system has many other advantages. Detailed 3D reconstruction of the cardiac chambers with Ensite NavX system, especially the right atrium and right atrial appendage, could be helpful to locate the atrial lead accurately. Another advantage is that Ensite NavX system clearly shows the 3D tracking catheter and lead movement in the vein and cardiac chamber models, revealing the relationship between leads and complex cardiac anatomy, while conventional method using fluoroscopy can only provide two-dimensional intracardiac orientation.

Although it is rare during pregnancy, heart block will bring serious health problems for the patient. Special populations (such as pregnant women and children) are more vulnerable to radiation, so it should be meaningful to avoid the exposure of radiation in such cases. Studies have already reported some cases of device implantations with zero or very small amount of fluoroscopy. In those reports, they have applied transesophageal echocardiography and transthoracic echocardiography combined Electrocardiograph (ECG) to confirm the satisfactory position of the permanent pacemaker and cardioverter defibrillator in pregnant patients\textsuperscript{21-24}. However, transthoracic echocardiography is difficult to visualize all leads in fact\textsuperscript{25}. The aspiration pneumonia or suffocation will be likely to occur during the process of transesophageal echocardiography navigation, especially for pregnant patients. As a result,
Echocardiography has not been widely used in the cardiac device implantation by the electrophysiologists. Due to the limitations of echocardiography in the pacemaker implantation, 3D navigation systems may be considered for pregnant patients. With the development of 3D navigation systems, Ensite NavX system has been introduced to guide the implantation of a cardioverter defibrillator for pregnant patients\textsuperscript{6,8}. The Ensite NavX system combined the transthoracic echocardiography or minimal fluoroscopy has already been reported for the permanent pacemaker implantation in pregnant patients\textsuperscript{15,26}.

In consideration of the likelihood of cardiac perforation, transthoracic echocardiography is required to be standby and bedside, although the incidence of this complication is very low (≤1%)\textsuperscript{27}. To some extent, we believe that detailed 3D model is beneficial to monitor lead movement and avoid the presence of cardiac perforation. Anyway, gently manipulation of the catheter is the critical point for reducing relevant complications; whereas real time image system is helpful for immediately confirmation.

**Limitations**

This study has its limitations. The sample size is small. Power randomized controlled trials with a broader patient population are required to confirm our findings. The time consuming are another additional limitation, and the procedure time in zero-fluoroscopy group is
significantly longer than the control group, hence, we believe the procedure time in this study within practicing gradually will be shorter in the next future.

Conclusions

In our study, we demonstrate that zero-fluoroscopy approach implantations of single- or dual-chamber permanent pacemakers using Ensite NavX system are safe and feasible. This technique is particular suitable for pregnant patients. Our method offer an additional choice for some special population who need to avoid radiation or in the rare occasion when the X-ray machine is not available.

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**Figure Legends**

**Figure 1** Final position of the pacemaker lead in the right atrium appendage is shown in the Ensite electroanatomic mapping in the RAO (right) and LAO (left) views. Abbreviations:

RAO = right anterior oblique; LAO = left anterior oblique; SVC = superior vena cava; IVC = inferior vena cava; RAA = right atrium appendage.
**Figure 2** Final position of the pacemaker lead in the right ventricular apex is shown in the Ensite electroanatomic mapping in the RAO (right) and LAO (left) views. Abbreviations:

RAO = right anterior oblique; LAO = left anterior oblique; SVC = superior vena cava; IVC = inferior vena cava; RV = right ventricular.
Table 1. Baseline characteristics of the patients undergoing zero-fluoroscopy implantation (n=6)

| Case no. | Age (years) | Gender   | Diagnosis                                      |
|----------|-------------|----------|------------------------------------------------|
| 1        | 54          | Male     | Paroxysmal Atrial fibrillation with sinus pause greater than 6.5 seconds |
| 2        | 41          | Female   | Third-degree atrioventricular block            |
| 3        | 66          | Female   | Third-degree atrioventricular block            |
| 4        | 58          | Male     | Third-degree atrioventricular block            |
| 5        | 57          | Female   | Sick sinus syndrome                            |
| 6        | 24          | Female in pregnancy | Third-degree atrioventricular block |

Table 2. Procedural variables and outcomes

| Pacemaker | VVI | DDD |
|-----------|-----|-----|
|           |     |     |

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| Procedure | 42.6± 7.4 | 51.3± 13.1 | 0.155 | 67.3± 7.6 | 88.3± 19.6 | 0.013 |
|-----------|-----------|------------|-------|-----------|-----------|-------|
| time (min)|           |            |       |           |           |       |
| Fluoroscopy | 3.1± 1.1 | 0          | -     | 5.0± 2.4  | 0         | -     |
| time (min)|           |            |       |           |           |       |
| Complication | 0       | 0          | -     | 0         | 0         | -     |
| s (n)     |           |            |       |           |           |       |

F, Fluoroscopy; ZF, Zero-Fluoroscopy

Table 3. Parameters of pacemakers during follow-up.
Table 3.1 Parameters of pacemakers at the 1 month after implantation.

| Case | Lead | Unipolar | Bipolar |
|------|------|----------|---------|
|      |      | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) |
| 1    | V    | 0.8       | 1620     | 8         | 0.7       | 1580     | 8.5         |
| 2    | V    | 0.7       | 1800     | 9         | 0.6       | 1320     | 9           |
| 3    | A    | 0.7       | 540      | 3.6       | 0.7       | 680      | 3.4         |
|      | V    | 0.8       | 680      | 7         | 0.6       | 720      | 8.6         |
| 4    | A    | 0.8       | 660      | 7         | 0.6       | 760      | 8           |
| 5    | A    | 0.8       | 580      | 4         | 0.7       | 760      | 4           |
|      | V    | 0.6       | 660      | 10        | 0.6       | 800      | 9           |
| 6    | A    | 0.8       | 800      | 3.5       | 0.8       | 580      | 3           |
|      | V    | 0.6       | 640      | 10        | 0.6       | 470      | 8           |

Table 3.2 Parameters of pacemakers at the 2 month after implantation.

| Case | Lead | Unipolar | Bipolar |
|------|------|----------|---------|
|      |      | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) |

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| Case | Lead | Unipolar | Bipolar |
|------|------|----------|---------|
|      |      | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) |
| 1    | V    | 0.7       | 1540     | 8         | 0.6       | 1460     | 9         |
| 2    | V    | 0.6       | 1640     | 9         | 0.5       | 1280     | 10        |
| 3    | A    | 0.7       | 540      | 3.6       | 0.6       | 640      | 3.4       |
|      | V    | 0.7       | 690      | 8         | 0.5       | 710      | 9         |
| 4    | A    | 0.8       | 660      | 7         | 0.6       | 750      | 8         |

Table 3.3 Parameters of pacemakers at the 3 month after implantation.
| Case | Lead | Unipolar | Bipolar |
|------|------|----------|---------|
|      |      | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) | Threshold (Volt) | Impedance (Ohm) | Sensed Amplitude (Volt) |
| 1    | V    | 0.6 | 1560 | 8 | 0.6 | 1480 | 9 |
| 2    | V    | 0.6 | 1660 | 10 | 0.5 | 1260 | 10 |
| 3    | A    | 0.7 | 550 | 3.6 | 0.6 | 600 | 3.4 |
|      | V    | 0.6 | 700 | 8 | 0.5 | 720 | 9 |
| 4    | A    | 0.7 | 650 | 7 | 0.6 | 730 | 8 |
| 5    | A    | 0.7 | 580 | 4 | 0.7 | 640 | 4 |
|      | V    | 0.6 | 670 | 10 | 0.5 | 740 | 9 |
| 6    | A    | 0.8 | 820 | 3.4 | 0.8 | 580 | 3 |
|      | V    | 0.6 | 600 | 11 | 0.5 | 500 | 10 |

Table 3.4 Parameters of pacemakers at the 6 month after implantation.