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ORIGINAL INVESTIGATION

Feasibility and safety of exclusive echocardiography-guided intravenous temporary pacemaker implantation

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Abstract

Background The standard approach for urgent trans-venous temporary cardiac pacemaker (TVTP) implantation is fluoroscopy guidance. The delay in activation of the fluoroscopy-room and the transfer of unstable patients may be life-threatening. Echocardiography-guided TP implantation may increase the safety of the patients by obviating the need for in-hospital transfer. We examined the feasibility and safety of echocardiography-guided vs. fluoroscopy-guided TVTP implantation.

Methods From January 2015 to September 2017 data for consecutive patients who needed emergent TVTP implantation were retrospectively reviewed. Ultrasound-guided TVTP protocol that was introduced in our center in January 2015 involved ultrasound guidance for both central venous access and pacing lead positioning. Access sites included femoral, subclavian, or jugular veins. Electrodes were placed in the right ventricular apex by means of echocardiographic monitoring in intensive care unit or by fluoroscopic guidance. Endpoints were achievement of successful ventricular pacing and procedural complications.

Results Sixty-six patients (17 echocardiography-guided and 49 fluoroscopy-guided) were included. There were no differences in pacing threshold between the echocardiography-guided group and the fluoroscopy-guided group (0.75 ± 0.58 mA vs. 0.57 ± 0.35 mA, $p = 0.24$). The access site for implantation was femoral vein in 27% for the fluoroscopy-guided vs. none for the echocardiography-guided approach ($p = 0.015$). One hematoma and one related infection occurred in the fluoroscopy-guided group. The need for electrode repositioning was observed in 1 patient in each group. There were no procedural-related deaths in either group.

Conclusions Echocardiography-guided temporary cardiac pacing is a feasible and safe alternative to fluoroscopy-guided approach and significantly lowers the need for in-hospital transfer.

Keywords Heart block · Echocardiography · Fluoroscopy · Temporary pacemaker · Point-of-care ultrasound

Abbreviations

POCUS Point-of-care ultrasound
TVTP Trans-venous temporary cardiac pacemaker

Introduction

Trans-venous temporary cardiac pacemaker (TVTP) implantation is a life-saving procedure in patients with severely symptomatic bradycardia and can be used as a bridge to permanent pacemaker implantation or resolution of a transient or reversible cause for the bradycardia [1, 2]. Nevertheless, TVTP implantation can be associated with potentially fatal complications such as cardiac perforation and tamponade, puncture site bleeding, pneumothorax, as well as lead malfunction and a need for repositioning. Fluoroscopic guidance which is very commonly used to guide TVTP implantation may improve procedural safety and reduce complication rate; yet, the delay in activation of the fluoroscopy room team and the need for in-hospital transfer may expose an already unstable patient to unnecessary life-threatening risks [3–6]. Since in hospital transfer of critically ill patients is

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well recognized as a process prone to complications, there is an urgent need for a safe, quick and a reliable method for TVTP implantation which will obviate the need for patient transfer [7–10].

The use of point-of-care ultrasound (POCUS) in critical care is rapidly increasing in various medical specialties and care situations (e.g., for vascular access, thoracentesis, paracentesis, focused cardiac and lung ultrasound) [11]. This technology provides real-time images which can be directly correlated with the patient's clinical condition at the bedside, which is particularly important in unstable patients. Therefore, POCUS is uniquely suitable to address focused clinical questions in critically ill patients. POCUS may, therefore, increase the safety of procedures, shorten the procedural time and obviate the need for in-hospital patient transfer but fluoroscopy still remains the most commonly used modality for the purpose of TVTP. Therefore, we examined the feasibility and safety of echocardiography-guided vs. fluoroscopy-guided TVTP implantation.

Methods

We reviewed retrospective data on all consecutive patients who needed emergent TVTP implantation at our institution between January 2015 and September 2017. Previously, all emergent TVTP implementations at our center had been performed in the catheterization laboratory under fluoroscopic guidance. Echocardiography-guided TVTP was introduced in our center in January 2015. The choice of echocardiographic or fluoroscopic guidance for TVTP remained at the discretion of the operator.

Ultrasound-guided TVTP protocol involved ultrasound guidance for both central venous access and pacing lead positioning. When performed, this protocol was accomplished by 2 physicians who were well-trained in POCUS and TVTP implantation. The procedure was performed at the bedside, either in the cardiac care unit or the emergency department. A brief echocardiographic assessment of the acoustic window for the cardiac chambers using the apical or subcostal views was initially performed to confirm the procedure's feasibly in the patient examined. Using an aseptic technique including prepping and covering the puncture site with a large sterile drape and covering the ultrasound probe. As a first step, we used US in short-axis and long-axis view of the vessels to identify the anatomy of the insertion site and the localization of the target vein. The US probe was placed at approximately 45° with respect to the target vessel and the puncture of the vein using the Seldinger technique (6-F sheath) was performed in real-time US guidance (Fig. 1), at the time we confirmed the needle and wire position in the vein, respectively.

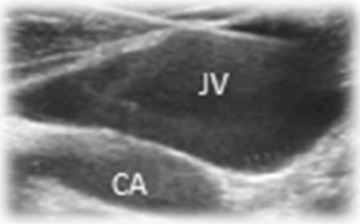

Fig. 1 Ultrasound images during real-time to confirm needle position in the right internal jugular vein. Short-axis view of the internal jugular vein (JV) and its anatomic relation to the carotid artery (CA)

A 5F balloon-flotation pacing electrode was advanced by a primary operator toward the right ventricular apex under continuous echocardiography monitoring from the subcostal or 4-chamber views (Fig. 2). In real-time US guidance, the cardiac probe was placed under the patient's drape by a second operator. All ultrasound-guided procedures were performed using GE Vivid S6 portable machine (GE, Milwaukee, WI, USA) with appropriate software for vascular and cardiac ultrasound. We used linear (GE, L9) and cardiac (GE, M4S) transducers.

In patients in whom fluoroscopic (Philips Healthcare/Philips Medical System, Amsterdam, The Netherlands) guidance was chosen it was performed in the catheterization laboratory in the standard fashion using the femoral, subclavian or jugular approaches. This required the activation of a catheterization team (including a physician, nurse and a technician).

Following TVTP implantation sensing and pacing thresholds were documented and a chest radiograph was obtained to confirm a satisfactory wire position and to rule out complications. Daily care in the intensive care unit included threshold testing, inspection of the venous access site for infection, and a full clinical assessment. Relevant demographic, clinical, angiographic, echocardiographic, treatment data and the reason for TVTP implementation were extracted from our computerized records. Study endpoints were the achievement of successful ventricular pacing (defined as a pacing threshold of < 2.0 mA) and peri-procedural complications. The study protocol was approved by the Institutional Ethical Committee. The need to obtain an informed consent was waived due to the retrospective nature of the study.

Categorical variables were expressed as proportions and compared by Pearson's Chi-square test or Fisher's exact test where appropriate. Independent two-tailed Student's *t* test was used to compare continuous variables which were expressed as mean ± SD. A p value < 0.05 was considered statistically significant. Statistical analyses were conducted with the SPSS 18.0 package (SPSS Inc.; PASW Statistics for Windows, Chicago, IL, USA).

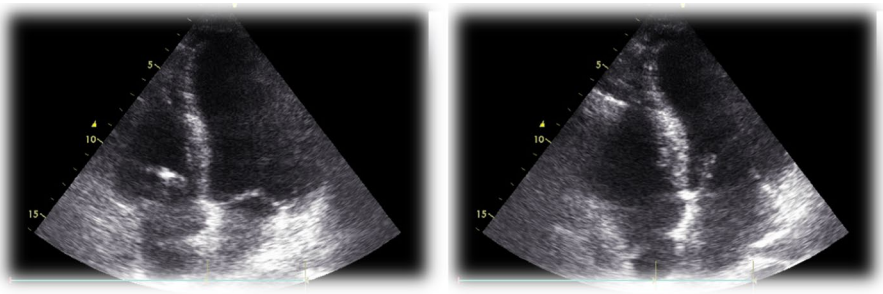

Fig. 2 Apical 4-chamber view showed the pacing electrode after crossing the tricuspid valve (left) with final position in the free wall of the right ventricle (right)

Table 1 Baseline characteristics of the patient population

	Echocardiography-guided ($n=17$)	Fluoroscopy-guided ($n=49$)	p value
Age (years)	73.35 ± 13.2	75.35 ± 13.8	0.607
Female (n, %)	5 (29)	27 (55)	0.068
OAC (n, %)	2 (12)	9 (18)	0.714
Clinical manifestations			
AMI (n, %)	2 (12)	13 (27)	0.318
Heart failure (n, %)	2 (12)	5 (10)	1
Cardiac arrest (n, %)	1 (6)	7 (14)	0.669
Syncope (n, %)	11 (65)	19 (39)	0.064
Drugs overdose (BB, CCB, DIGOXIN) (n, %)	1 (6)	1 (2)	0.452
Indications			
Advanced AVB (n, %)	13 (76)	34 (69)	0.759
SSS (n, %)	1 (6)	7 (14)	0.669
VT (TdP) (n, %)	2 (12)	1 (2)	0.16
Asystole (n, %)	1 (6)	8 (16)	0.427

AMI acute myocardial infarction, *AVB* atrioventricular block, *BB* beta blocker, *CCB* calcium channel blocker, *OAC* oral anticoagulation, *SSS* sick sinus syndrome, TdP torsade de pointes

Results

A total of 66 patients (17 in the echocardiography-guided group and 49 in the fluoroscopy-guided group) were included in the study. Baseline characteristics of the patient population, clinical manifestations and indications for pacing are listed in Table 1. The two groups showed no statistically significant differences in terms of clinical manifestation and the indications for TVTP implantation. The majority of patients presented with syncope in the setting of advanced heart block.

All fluoroscopy-guided TVTP implantations took place in the catheterization laboratory, whereas the echocardiography-guided TVTP implantation took place at the bedside. Among the echocardiography-guided group, 14 implantations were performed in the Intensive cardiac care unit, 2 in the emergency department and one in the medical intensive care unit. Most of the fluoroscopy-guided TVTP implantations were placed through the subclavian vein, whereas in the echocardiography-guided group the most common site was the jugular vein (Table 2). The efficacy and safety of the two approaches are compared in Table 2. No statistically significant difference between the two groups was observed in the initial pacing threshold measured after lead positioning and during the following days (data not shown) until pacing was no longer needed or when permanent pacemaker was implanted. Eventually, a total of 40 patients in the study (61%) required permanent pacemaker with no statistically significant differences between groups. There was 1 failure to pace and cross-over from the echocardiography-guided to fluoroscopy-guided in a patient who had a previous implantable pacemaker. One patient in each group had lead dislodgement and required reposition. There were no complications related to echocardiography-guided pacing vs. one hematoma and one related infection occurred in the fluoroscopy-guided group. There were no procedural-related deaths in either group (Table 2).

Discussion

The main finding of this study is that emergent TVTP implantation can be safely and effectively performed by ultrasound guidance at the bedside. In line with scarce data, we were able to show that in patients with a reasonable transthoracic acoustic window, an echocardiography-guided TVTP implantation is a practical and well-tolerated alternative to the classical fluoroscopy-guided approach [12]. The use of POCUS to aid diagnosis and guide management and procedures especially among critically ill patients has expanded rapidly [13]. It provides relevant bedside information while reducing the need for radiation exposure and in-hospital transfer. Robust data from multiple studies have shown that POCUS has significantly impacted patient management and its use for procedures such as intravenous access has been incorporated in several guidelines [14, 15].

Table 2 Procedural characteristics and complications

	Echocardiography-guided ($n=17$)	Fluoroscopy-guided ($n=49$)	p value
Pacing threshold basal (mV)	0.75 ± 0.58	0.57 ± 0.35	0.24
Access (vein)			
Jugular (n, %)	9 (60)	12 (24)	**0.014**
Subclavian (n, %)	6 (40)	24 (49)	0.4
Femoral (n, %)	0 (0)	13 (27)	**0.015**
Permanent pacemaker insertion (n, %)	(76) 13	(55) 27	0.12
Complications			
Lead dislodgement requiring reposition (n, %)	1 (6)	1 (2)	0.45
Hematoma	0	1 (2)	1
Myocardial perforation	0	0	
Pneumothorax	0	0	
Arrhythmias (VT/VF)	0	0	
Infection (n, %)	0	1 (2)	1
Procedural related deaths	0	0	

VF ventricular fibrillation, *VT* ventricular tachycardia

When the internal jugular access was chosen in our study, POCUS was used. We avoided the transfemoral venous access as much as possible (and did not use it at all in the echocardiography-guided group) because it is associated with a higher risk for deep venous thrombosis and infection than are the internal jugular or subclavian catheters [16–20]. A review of temporary cardiac pacing wires concluded that the right-side internal jugular veins are associated with the lowest complication rates and highest access success [21]. Although its safety and effectiveness are clear, the use of POCUS especially in emergency situations requires adequate training. Implementation of educational programs and continuous training by professional organizations is obligatory to ensure high success rates and a low complication rate.

Echocardiography is currently used only rarely to guide TVTP implantation, yet this modality of imaging has some advantages over the traditional fluoroscopic guidance [13]. Small portable echocardiography machines are readily available nowadays not just in cardiology departments and ICCUs. Clinical staffs in disciplines such as cardiology, intensive care and emergency medicine, frequently have the skills and accreditation to perform POCUS study [22]. The skillful use of echocardiography eliminates exposure to ionizing radiation and significantly obviates the need for in-hospital transfer to the fluoroscopy suite. In hospitals where fluoroscopy is not available, POCUS use is justified. Similarly, it may be a suitable alternative in cases of pregnant patients and patients undergoing cardio-pulmonary resuscitation, a situation in which the use of fluoroscopy is difficult. Therefore, it is plausible that the echocardiography-guided approach may become the standard approach particularly in patients who do not need emergent transfer to the catheterization laboratory for primary coronary revascularization.

We think that the procedural characteristics and comparator are different to some extent in our study, thus we believe our paper provides an additional piece of information to the literature. In Ferri's paper, the temporary pacemakers in the fluoro-guided approach were all placed through the femoral vein as compared to only 27% in our study. Thus, not only the guiding approach is different in 100% but also the placing site (femoral vs. jugular). The reported rates of infection and puncture-related hematomas in Ferri's paper in the fluoro-guided group may be attributed to the fact that procedures in that group were performed through the femoral vein. We think that our comparison reflects a real-world standard approach with less bias of the placing site to the final results.

Our study has several limitations. Unfortunately, time to pacing and procedural time were not collected. However, we may assume that the echocardiography-guided procedure is an overall faster approach since it obviates the need for intra-hospital transfer and activation of the fluoroscopy suite. Second, the sample size has an unequal distribution between the groups. It would take a few more years to collect not much larger data since the rate of temporary pacing is quite low. Although our data is quite small we think it gives a good signal for a safe and reasonable alternative to the current approaches. Physicians were allowed to choose their preferred favorite approach based on their skills and since the echocardiography-guided approach is relatively novel, fewer physicians had the knowledge and skills to perform echocardiography-guided TVTP implantation. This might have caused selection bias. Nevertheless, the baseline

characteristics of the groups were quite similar and those chosen for the echocardiography approach were not healthier. It should be noted that the echocardiography-guided TVTP implantation may be an inappropriate approach in cases with unsuitable acoustic window or a previously implantable pacemaker.

In summary, in patients requiring emergent TVTP implantation POCUS provides results similar to those obtained by fluoroscopy while obviating the need for in-hospital transfer of critically ill patients. As a user-dependent technology, it requires appropriate training and quality assurance. If these findings are confirmed by larger cohorts, POCUS-guided pacemaker implantation may become the preferred approach in unstable patients requiring temporary cardiac pacing.

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Compliance with ethical standards

Conflict of interest Author Aref El Nasasra declares that he has no conflict of interest. Author Hilmi Alnsasra declares that he has no conflict of interest. Author Doron Zahger declares that he has no conflict of interest. Author Tsahi T Lerman declares that he has no conflict of interest. Author Sergio Kobal declares that he has no conflict of interest. Author Carlos Cafri declares that he has no conflict of interest. Author Moti Haim declares that he has no conflict of interest. Author Lior Fuchs declares that he has no conflict of interest. Author Avi Shimony declares that he has no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent The need to obtain an informed consent was waived due to the retrospective nature of the study.

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