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ORIGINAL SCIENTIFIC PAPER
Arrhythmias

A new fastening system for temporary pacing with active-fixation leads: effectiveness and safety

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Aims Temporary cardiac pacing with active-fixation leads (TPAFL) using a reusable permanent pacemaker generator has been shown to be safer than lead systems without fixation. However, TPAFL requires the off-label use of pacemaker leads and generators. We designed a fastening system to ensure the safety and efficacy of the procedure: the KronoSafe System®. To demonstrate the safety and effectiveness of the KronoSafe System® for temporary pacing in a series of patients receiving TPAFL.

Methods and results A prospective cohort of 20 patients undergoing TPAFL between August 2019 and June 2020 was recruited in a Spanish region. The temporary pacemaker was implanted through jugular access and secured with the KronoSafe System®. R-wave detection, lead impedance, and capture threshold were assessed every 48 h. Complications associated with the procedure or occurring during TPAFL were recorded. There were no complications associated with temporary pacing, and the therapy was effective in all cases. TPAFL was used for a mean of 7.6 days (maximum 25 days), and 84.56% of the time in a cardiology ward.

Conclusion TPAFL secured using the KronoSafe system® provides safe and stable cardiac stimulation for patients requiring temporary cardiac pacing.

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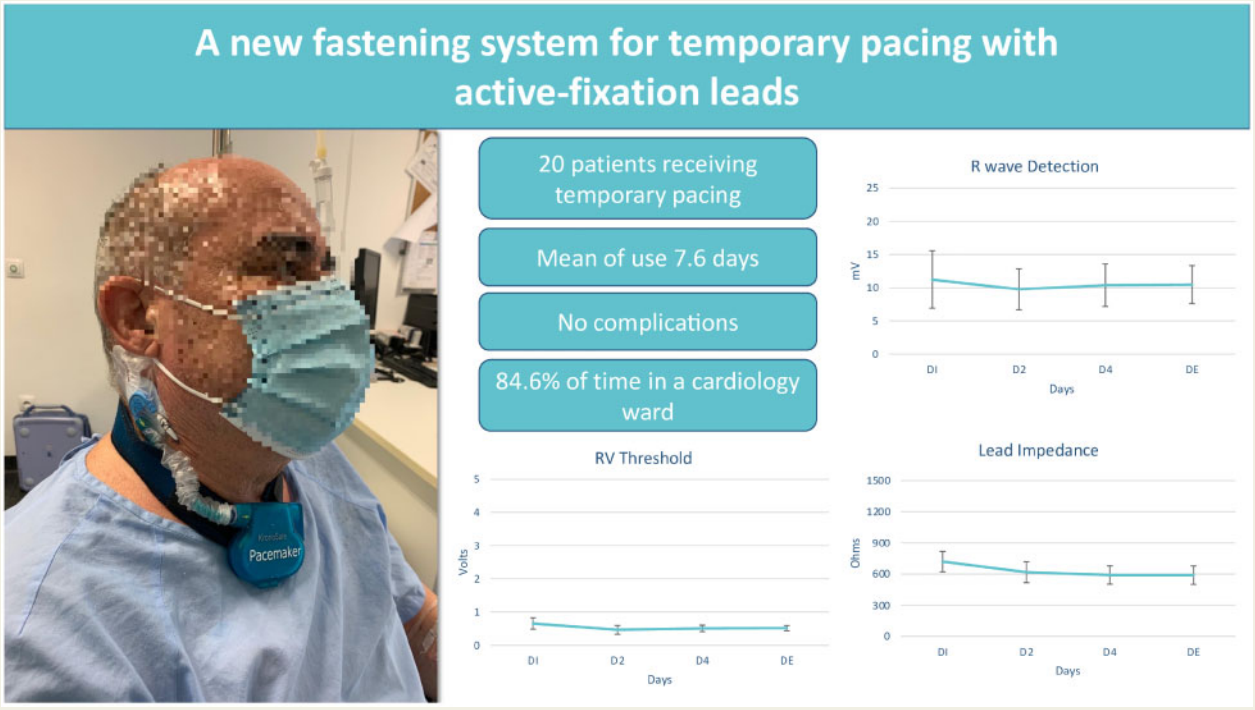
Graphical Abstract



Keywords Pacemaker • Cardiac pacing • Bradycardia • Arrhythmia • Critical care • Treatment outcome

Introduction

Temporary cardiac pacing is a common procedure in patients with acute bradycardia and after cardiac surgery or pacemaker explantation. Between 5.86 and 11.1 cases per 100 000 persons per year are estimated to require this technique.[1,2] The main indications for temporary pacing are symptomatic atrioventricular block (51%), prophylaxis during generator replacement (14.7%), atrioventricular block during acute coronary syndrome (12.6%), and bradyarrhythmia due to drugs (12.2%).[3] Currently, traditional transvenous pacemaker systems including passive-fixation catheters and balloon-tipped pacing catheters are associated with complication rates of up to 35%. The most frequent complications are dysfunction due to electrode displacement (23%) and pericardial effusion (4%).[4] In addition, during cardiac stimulation with passive-fixation leads, patients must be monitored and have limited mobility.[4]

In 2003, a new method of temporary pacing using reusable permanent pacemaker generators and externalized active-fixation leads was described.[5–7] This technique has significantly reduced the number of complications to rates below 5%.[8,9] The high stability allows the patient to be discharged from the intensive care unit (ICU) to the cardiology ward earlier than previously. However, due to the lack of approved material, reusable permanent pacemaker generators and active-fixation leads are used with an off-label indication.[7,9]

In our setting, we have implemented a potential improvement for temporary cardiac pacing with active-fixation leads (TPAFL), which consists of a new fastening system. This new system comprises a case into which the reusable pacemaker generator is placed and is separated from the venous access point. A plastic sheath covers the external portion of the lead to protect it. The lead is fastened to the patient's skin with a fixation device, reducing the risk of accidental dislodgement. This new method to perform TPAFL is anticipated to meet the safety requirements for the procedure. Given the importance of the issue, we assessed the safety and the effectiveness of this new pacemaker fastening system.

Methods

Setting

This study was carried out in the Cardiac Stimulation Unit of Vinalopó Hospital, a 204-bed tertiary public hospital in Elche, Alicante, Spain. Elche is a city with a population of 230 000 inhabitants in the southeast of Spain. Vinalopó Hospital covers 140 000 inhabitants. The health system offers free public health care covering most treatments.

After the diagnosis of bradycardia, the cardiac stimulation unit is consulted to assess the patient. If the patient needs urgent cardiac stimulation, a temporary pacemaker with an active-fixation lead is placed under

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fluoroscopic guidance. The pacemaker is checked to verify correct function, and a chest X-ray is performed to rule out possible complications of the procedure.

The patient is then admitted to the cardiology ward with continuous monitoring, and the pacemaker is reviewed every 48 h, measuring R-wave sensing, lead impedance, and thresholds. Depending on the evolution of the patient, the system is removed if a normal heart rate is recovered. Otherwise, implantation of a permanent pacemaker is required. Neither procedure involves any cost to the patient.

Study design and participants

This prospective observational cohort study included 20 consecutive patients who underwent temporary cardiac pacing from August 2019 to June 2020 at a tertiary public hospital in Elche, Spain (Vinalopó Hospital). The study was conducted in accordance with the Declaration of Helsinki and was approved by the local clinical ethics committee. The study was carried out in a secondary hospital with a cardiac stimulation unit. All patients with an indication for temporary cardiac pacing to treat bradycardia who were aged 18 years or older and were willing to participate and provided written informed consent were included. We excluded patients upon their request. There were no missing data for any of the included patients.

Intervention

A conventional active-fixation pacemaker lead was placed via the internal jugular vein using the standard ultrasound-guided Seldinger technique. A peel-away sheath was inserted over a guidewire. Under fluoroscopic guidance, the lead was inserted through the peel-away sheath and attached to the right ventricle outflow tract, interventricular septum, or right ventricular apex. R-wave detection, lead impedance, and capture threshold were measured before and after extending the screw. The measurements were considered appropriate if R-wave detection was greater than 5 millivolts (mV), impedance was between 200–1200 Ohms, and capture threshold was less than 1 Volt (V) at 0.4 milliseconds (ms). The peel-away introducer was removed, and the lead was sutured to the skin. The entire external portion of the temporary pacemaker was secured with the KronoSafe System® (ICU Medical Technologies S.L., Elche, Spain), and the venous puncture site was covered with a sterile dressing. The lead was covered by a transparent plastic sheath and attached with a fastening device to the neck. Next, the lead was connected to a reusable permanent pacemaker generator, which was introduced into the KronoSafe® case and attached to the neck (*Figure 1*). A chest X-ray was performed after all the procedures to ensure the absence of complications and to record the position of the lead. For added safety, temporary pacemakers were programmed with 5 V at 1 ms output, one-third of the measured R-wave, and the basic frequency was adjusted individually according to the indication and the clinical status of the patient. More information about this device is available at: www.icumedicaltechnologies.com.

Variables and measurements

During hospitalization, the temporary pacemaker was interrogated and measurements recorded on the day of implantation, Day 2, Day 4, and on the day of explantation by physicians in the cardiac stimulation unit (R-wave detection, lead impedance, and capture threshold were measured). After explantation, if normal heart rhythm was not recovered a new permanent pacemaker was implanted, according to current guidelines.[10]

During temporary pacing, associated complications were recorded: lead displacement, capture or sensing failure, generator or lead detachment, and cardiac perforation. When a complication was detected, depending on the complication, the temporary pacemaker was removed or relocated. The clinical characteristics of the patient (gender, age, height, and weight), indication for temporary cardiac stimulation, treatment duration, and both ICU and cardiology ward hospitalization days were recorded at the end of the treatment period, reviewing the patient's electronic medical record.

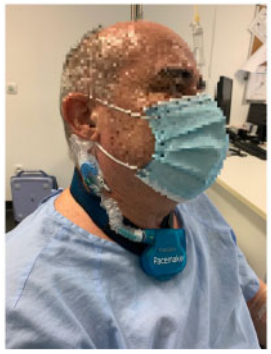

Figure 1 Picture of a patient with the KronoSafe® (ICU Medical Technologies S.L. Elche, Alicante, Spain). The lead is attached to the skin by means of the sleeve, and immediately afterwards the sleeve is covered by the transparent plastic sheath and then introduced into the KronoSafe® case, attached to the patient's neck.

Sample size

This first pilot study included consecutively over a 1-year period all patients who needed temporary cardiac stimulation and received an active-fixation device.

Statistical methods

A Kolmogorov–Smirnov analysis was performed of the continuous variables and when a normal distribution was indicated, they were reported as mean ± standard deviation or median (interquartile range, IQR), as appropriate. Categorical variables were expressed as absolute and relative frequencies (%). Quantitative variables were expressed as means and typical deviations. *P*-values below 0.05 were considered significant. Confidence intervals were calculated when necessary. All statistical analyses were performed with IBM SPSS Statistics v26 (IBM, Armonk, NY, USA) and R 4.0.1 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 20 patients undergoing TPAFL were included in our study. The characteristics of the patients are described in *Table 1*. The mean age was 74.3 ± 6.6 years. Seventeen patients had symptomatic atrioventricular block (85%), one sinus bradycardia (5%), one sick sinus syndrome (5%), and one trifascicular block (5%). The aetiology of the rhythm dysfunction was system fibrosis in 11 cases (55%), early cardiac surgery complications with high epicardial pacing threshold in 6 cases (30%), acute ischaemia in 2 cases (10%), and infective endocarditis in 1 case (5%).

No detection failure was recorded during temporary pacing. The mean right ventricular R-wave values were: 11.23 ± 4.32 mV on the day of implantation, 9.76 ± 3.09 mV on Day 2, 10.38 ± 3.20 mV on

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Table 1 Baseline characteristics of patients who underwent temporary pacing with active-fixations leads in a tertiary hospital in Elche, Spain

Patients	*n* = 20 *n* (%)/x ± s
Demographics	
Gender, female	4 (20)
Age, years	74.3 ± 6.6
Physical	
Height, cm	171.1 ± 8.1
Weight, kg	77.3 ± 14.6
Indication for TPAFL	
Pacemaker or defibrillator infection	7 (35)
Heart failure	4 (20)
Bradycardia	4 (2)
Syncope	3 (15)
Cardiac arrest	2 (10)
Electrocardiogram	
Symptomatic AV block	17 (85)
Sinus bradycardia	1 (5)
Sick sinus syndrome	1 (5)
Trifascicular block	1 (5)
Aetiology	
System fibrosis	11 (55)
Surgical complications	6 (30)
Ischaemic	2 (10)
Infective endocarditis	1 (5)

AV, atrioventricular; *n* (%), absolute frequency (relative frequency); TPAFL, temporary cardiac pacing with active-fixation leads; x ± s, mean ± standard deviation.

Day 4, and 10.47 ± 2.87 mV on the day of explantation. No lead displacements were recorded, and the mean lead impedances were: 718.65 ± 96.72 Ohms on the day of implantation, 616.80 ± 99.80 Ohms on Day 2, 591.17 ± 87.59 Ohms on Day 4, and 589.20 ± 88.44 Ohms on the day of explantation. No capture failure was registered and the mean capture thresholds were: 0.65 ± 0.17 V/0.4 ms on the day of implantation, 0.47 ± 0.13 V/0.4 ms on Day 2, 0.50 ± 0.10 V/0.4 ms on Day 4, and 0.51 ± 0.08 V/0.4 ms on the day of explantation (*Figure 2*). There were no complications associated with TPAFL: no lead displacement or any other complications (cardiac perforation or lead/generator detachment) were detected.

The patients were discharged to the cardiology ward for pacemaker monitoring. Those who remained in the ICU did so for other medical indications. The mean duration of TPAFL in the ICU was 22.50 (IQR 43.75) h, and the total duration of TPAFL was 144.00 (IQR 132) h (6.00, IQR 5.5) (*Table 2*). The difference between ICU stay and TPAFL duration was used as a proxy for reduction of ICU stay, 153.9 h (84.6% reduction). Sixteen patients (80%) needed a permanent pacemaker and four (20%) recovered their normal cardiac rhythm without further intervention.

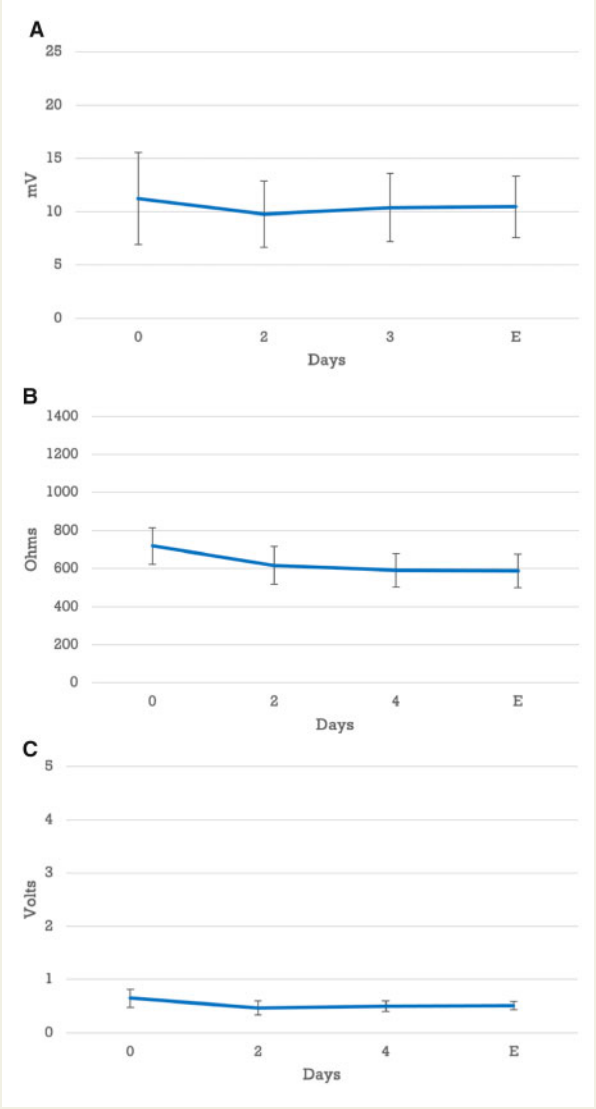

Figure 2 Effectiveness parameters of temporary cardiac pacing. (**A**) Millivolts (mV) R-wave detection; (**B**) ohms lead impedance; and (**C**) volts right ventricle threshold. E, explant day.

Table 2 Duration of temporary pacing with active-fixation leads fastened with KronoSafe® (ICU Medical Technologies S.L. Elche, Alicante, Spain) and length of stay in the intensive care unit and in the ward

	Duration of TPAFL	IQR	Range
ICU stay	22.5 h (0.9 d)	43.7 h (1.8 d)	0–72 h (3 d)
Ward stay	130.0 h (5.4 d)	121.5 h (5.1 d)	0–528 h (22 d)
Total TAPFL	144.5 h (6 d)	132.0 h (5.5 d)	44–600 h (25 d)

d, days; h, hours; ICU, intensive care unit; IQR, interquartile range; TPAFL, temporary cardiac pacing with active-fixation leads.

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Discussion

Summary

In this prospective observational study, we describe a new system to secure the lead and the pacemaker generator in patients receiving a conventional active-fixation pacing lead and external pacemakers for temporary pacing. The safety parameters we recorded (R-wave detection, electrode impedance, and stimulation thresholds) remained within the safe range throughout the TPAFL period, and no complications were documented in any of the patients. These results corroborate the effectiveness of the procedure and demonstrate the safety provided by our fastening system.

Temporary cardiac stimulation with active fixation offers advantages over classic temporary stimulation, although we must consider that it may not be available in all centres for all patients. First of all, it requires training, experience and also equipment for its performance, especially fluoroscopy equipment, whereas classic stimulation can be performed by less trained personnel, and even, although it is less recommended, it can be performed without fluoroscopic control. We advocate the use of this technique in cases where the clinical situation allows it: in case of device infection that can be performed on a scheduled basis, in urgent cases during the usual working day, and provided that adequate personnel and equipment are available, whereas patients with urgent pacing requirements such as those with prolonged pauses, atrioventricular block without stable escape rhythm or cardiac arrest, when trained personnel or adequate equipment are not available, remain candidates for treatment with classic temporary pacing.

Strengths and limitations

The main strength of the study is the demonstration of the safety and effectiveness of KronoSafe®, the first fastening system designed for use with TPAFL. The recording of R-wave detection, electrode impedance and stimulation threshold values throughout the therapy also confirm the stability of the electrode connection to the heart.

We must acknowledge some limitations. As in previous publications, this study was non-randomized, and there was no control group.[1–4] In addition, the sample size was relatively small. The significant increase in safety and effectiveness through the use of this procedure compared to traditional control of cardiac stimulation without fixation makes it difficult from an ethical perspective to carry out a comparative clinical study of both techniques. The specialists who performed the TPAFL procedures in this study are highly trained in cardiac pacing, whereas in clinical practice, physicians with less training perform urgent cardiac pacing.

Comparison with existing literature

Other groups have proven the feasibility of active-fixation leads connected to a pacemaker generator for temporary pacing.[7–9,11] After the proof of concept was published in 2003,[12] several groups have demonstrated the safety of the procedure and, in non-randomized trials, compared them to conventional femoral passive-fixation catheters. In 2006, Zei *et al.*[8] reported no complications in a cohort of 62 patients receiving TPAFL during a mean of 7.5 days. In 2013, Kawata *et al.*[9] reported only one complication after a longer mean TPAFL duration of 19.4 days in a cohort of 23 patients. The complication involved a lead infection in a patient with a pacemaker extraction due to a previous lead infection, which was due to sepsis rather than the procedure. More recently, Cipriano *et al.*[11] published the largest cohort, consisting of 158 cases. The authors describe 13 complications, with a rate of 8.2%. The most frequent complications were lead dislodgement in 8 patients (5%), followed by loss of capture in two cases, one due to a safety switch causing the device to revert to unipolar pacing and another due to a high pacing threshold. The other three complications were vegetations on the temporary lead in two cases and pneumothorax in another. These studies share several limitations.[8,9,11,12] The first is the absence of a double-blind randomized trial comparing the proposed new technology with the standard of care for temporary pacing. The second is the use of off-label material for an indication not approved by both the manufacturer and regulatory agencies. The third limitation is the absence of a protocol or device to secure the system after lead extraction, both to ensure asepsis and to prevent dislodgements.[8,9,11,12]

Our prospective study confirms the very low complication rate shown in previous studies, with no complications after a mean of more than 7 days of TPAFL. We also describe the lead parameter values for sensing, impedance, and capture threshold every 48 h to demonstrate the stability of the therapy, providing additional evidence of the safety and efficacy of this new approach.

This study targets one of the limitations of previous studies, which is the absence of a secure device to ensure asepsis and stability. In addition, the Kronosafe System® provides added comfort to the patient as well as preventing infections and dislodgements. Pathogens from the flora of the patient's skin, such as Coagulase-negative Staphylococci, that adhere to the system are the most common cause of device infection, accounting for more than two-thirds of the bacteria isolated from patients with pacemaker infections.[13,14] Our system reduces contact between the lead and the skin and completely eliminates contact with the reusable generator. Although the small sample size in our study does not allow us to draw strong conclusions with regard to infection prevention, the occurrence of zero infections is encouraging.

Implications to research and clinical practice

Temporary pacing is a procedure performed more than 500 000 times a year worldwide, with a reported complication rate of up to 35% when conducted with systems using no fixation.[1,2] Our study presents the first system designed specifically for TPAFL. The increased safety recorded with this new system could contribute to reducing some of the complications associated with classic temporary pacing, estimated in approximately 150 000 complications each year including 68 000 electrode displacements, 11 900 cardiac perforations, and 4 800 deaths. Another advantage is the possibility of having the patient hospitalized on the cardiology ward, instead of the coronary unit or ICU, which can lead to additional economic savings, in addition to optimizing the consumption of hospital resources. The complication rate associated with TPAFL is closely related to

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operator experience with the technique and the patient profile. Our study was carried out in a cardiac pacing unit, and the procedures were performed by an specialist in pacemaker implants. Future studies should examine the safety results of TPAFL performed by intensive care specialists in patients requiring urgent cardiac stimulation, although this scenario requires a series of additional circumstances, such as the presence of personnel with experience in cardiac pacing and device programming during on-call duty, and especially the availability of fluoroscopy equipment.

Conclusion

TPAFL is a safe procedure for patients requiring short- to medium-duration temporary cardiac pacing. Switching from the currently certified procedure without fixation to active fixation will significantly reduce complications and increase patient safety and comfort. Furthermore, the stability achieved throughout the therapy may allow patients to remain in the hospital ward without the need for admission to the ICU. In addition, the TPAFL procedure was safe for patients who required urgent cardiac pacing. In summary, the KronoSafe® fastening system is the first system designed to perform this procedure and has been used safely and effectively in our patients. To better assess the safety of the procedure, multicentre studies with larger patient samples involving all the departments that perform this procedure are needed.

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Data availability statement

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Conflict of interest: R.V.-M. owns 80% of the patent for the system reported herein (ES 2 804 080 A1; 3 February 2021). None of the other authors has any conflict of interest.

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