

Temporary-Permanent Pacemakers are Associated with Better Clinical and Safety Outcomes Compared to Balloon-Tipped Temporary Pacemakers

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Abstract

Background Balloon Tipped Temporary Pacemakers (BTTP) are the most used temporary pacemakers; however, they are associated with a risk of dislodgement and thromboembolism. Recently, Temporary Permanent Pacemakers (TPPM) have become increasingly used. Evidence of better outcomes with TPPM compared to BTTP is still scarce. **Materials and methods** Retrospective, chart review study evaluating all patients who underwent temporary pacemaker placement between 2014 and 2022 (N=126) in the cardiac catheterization laboratory (CCL) at a level 1 trauma center. Primary outcome of this study is to evaluate the safety profile of TPPM vs BTTP. Secondary objectives include patient ambulation and healthcare utilization in patients with temporary pacemakers. **Results** Both groups had similar baseline characteristics distribution including gender, race and age at temporary pacemaker insertion ($p>0.05$). Subclavian vein was the most common site of access for the TPPM cohort (89.0%) vs the femoral vein in the BTTP group (65.1%). Ambulation was only possible in the TPPM group (55.6%, $p<0.001$). Lead dislodgement, venous thromboembolism, local hematoma, and access site infections were less frequently encountered in the TPPM group (OR = 0.23 [95% CI (0.10-0.67), $P<0.001$]). Within the subgroup of patients with TPPM, 36.6% of the patients were monitored outside the ICU setting. There was no significant difference in the pacemaker related adverse events among patients with TPPM based on their in-hospital setting. **Conclusion** TPPM are associated with more favorable safety profile compared to BTTP. They are also associated with earlier patient ambulation and reduced healthcare utilization.

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Materials and methods

Retrospective, chart review study evaluating all patients who underwent temporary pacemaker placement between 2014 and 2022 (N=126) in the cardiac catheterization laboratory (CCL) at a level 1 trauma center. Primary outcome of this study is to evaluate the safety profile of TPPM vs BTTP. Secondary objectives include patient ambulation and healthcare utilization in patients with temporary pacemakers.

Results

Both groups had similar baseline characteristics distribution including gender, race and age at temporary pacemaker insertion ($p>0.05$). Subclavian vein was the most common site of access for the TPPM cohort (89.0%) vs the femoral vein in the BTTP group (65.1%). Ambulation was only possible in the TPPM group (55.6%, $p<0.001$). Lead dislodgement, venous thromboembolism, local hematoma, and access site infections were less frequently encountered in the TPPM group (OR = 0.23 [95% CI (0.10-0.67), $P<0.001$]). Within the subgroup of patients with TPPM, 36.6% of the patients were monitored outside the ICU setting. There was no significant difference in the pacemaker related adverse events among patients with TPPM based on their in-hospital setting.

Conclusion

TPPM are associated with more favorable safety profile compared to BTTP. They are also associated with earlier patient ambulation and reduced healthcare utilization.

Keywords : temporary pacemaker, active fixation, passive fixation, safety, ambulation, intensive care unit

Abbreviations and Acronyms

TPM: Temporary Pacemaker

BTTP: Balloon tipped temporary pacemaker

TPPM: Temporary permanent pacemaker

ICU: Intensive care unit

CCL: cardiac catheterization lab

AV: Atrioventricular

VTE: Venous thromboembolism

DVT: Deep venous thrombosis

SD: Standard deviation

Introduction

Temporary transvenous cardiac pacing is a well-established treatment procedure performed emergently in cases of life threatening bradyarrhythmia, such as complete (3rd degree) heart block, prolonged symptomatic sinus pause or to prevent fatal ventricular arrhythmia refractory to medical treatment.⁽¹⁻³⁾ The ultimate purpose of temporary pacemakers is to stabilize the hemodynamic status and electrical conduction until the underlying condition (e.g., myocardial infarction, heart failure, drug intoxication, Lyme disease, etc.) is treated, or a permanent pacemaker is implanted.^(4,5)

A conventional Balloon-Tipped Temporary Pacemaker (BTTP) consists of a pulse generator box connected to the myocardium with a balloon-tipped lead with passive or no active fixation mechanism.⁽⁶⁾ It is commonly placed by femoral or internal jugular vein access.⁽⁷⁾ While BTTP is the most common type of temporary pacemaker used in clinical practice, it may be associated with multiple complications, including lead dislodgement (due to passive fixation) leading to loss of capture, access site infection, and venous thromboembolism.^(6,8-10) BTTP can be placed via jugular, femoral, or subclavian access, balloon tipped catheters remain in a stable position in the right ventricular apex. Patients with BTTP typically need to be admitted to the intensive care unit (ICU) for continuous monitoring and maintained on strict bedrest because of the risk of lead dislodgement and loss of capture.^(8,11) Use of BTTP also requires a higher skill of nursing and other medical personnel who are well-educated and well-versed in the management and troubleshooting for any of the above complications.

On the other hand, Temporary Permanent Pacemakers (TPPM) are placed using active fixation leads, where the tip of the lead is “screwed into” the myocardial septum, giving it significantly more stability.⁽⁶⁾ Venous access can be obtained from the internal jugular or the subclavian vein but not usually via the femoral vein. This provides ease of mobility to the patient and decreases the requirement of ICU level nursing and monitoring. Typically, a permanent pacemaker pulse generator is connected to the lead and secured to the skin on the chest or neck, depending on the site of access (**Figure 1**). TPPM is being used more frequently recently due to its potential benefits compared to BTTP. Two prior studies in 2003 and 2006 compared TPPM and BTTP in relatively small numbers of patients and found that TPPM is associated with a smaller risk of dislodgement and loss of capture.^(8,11) However, these studies did not have sufficient statistical power to evaluate other clinically important outcomes such as a potential reduction in the incidence of venous thromboembolism associated with patient mobility or utilization of hospital resources. Available data on the use of TPPM outside the ICU is scarce. Considering the importance of temporary pacing, understanding the risks and benefits of each technique is crucial for optimal patient care. For this reason, we conducted this observational study, evaluating the clinical and safety profile of TPPM compared to the BTTP. In addition to that, we also assessed the safety of TPPM outside the ICU setting.

Materials and Methods

Patient Selection and Data Collection

This is a retrospective cohort study evaluating all patients who underwent temporary pacemaker placement between 2014 and 2022 (N=126) in the cardiac catheterization laboratory (CCL) at the Hennepin Healthcare (Hennepin County Medical Center; Minneapolis, MN) by either interventional cardiologists or cardiac electrophysiologists. Hennepin Healthcare is a level 1 trauma center and a safety net hospital for the state of Minnesota. This retrospective cohort study was conducted in accordance with the recommendations of the Hennepin Healthcare Institutional Review Board.

Pacemakers placed outside the CCL were not included in our study due to limited procedure-related information, procedural variation and missing data. Patients with temporary pacing from epicardial leads were not included as this constitutes a unique and prophylactic modality that is only applicable to post cardiac surgery patients.

We used the Medtronic model 5076 CapSureFix active fixation lead (Medtronic, Minneapolis, MN, USA) in the TPPM group, and the Pacer Flow Directed Pacing Catheter (Right Heart Curve; Abbott Cardiovascular, Plymouth, MN) in the BTTP group. All patients had a complete procedure note in their electronic health record. Baseline characteristics, procedure related data, and post procedure outcomes and complications

were obtained from a thorough chart review. Temporary pacemaker indications were summarized into three major categories: i) Atrioventricular (AV) node dysfunction (including Mobitz II second degree AV block and complete heart block), ii) Sinus node dysfunction, iii) Prevent recurrent ventricular tachycardia/fibrillation and Torsades de pointes in patients with long QT interval.

Study Outcomes

Our study's primary objective aimed to evaluate the safety of temporary permanent pacemakers through the assessment of temporary pacing-related adverse events compared to balloon-tipped temporary pacemakers. Secondary clinical outcomes included: i) Comparison of healthcare utilization between the 2 pacing modalities and ii) patient ambulation.

The pacemaker related adverse events were defined as the composite of venous thromboembolic events (VTE), pneumothorax/ hemothorax, lead access site hematoma or infection, and lead dislodgement or/and loss of capture. A standardized approach was applied for the care of all patients with temporary pacemaker at our institution, including hygiene protocols for infection prevention, VTE prophylaxis (unless contraindicated for specified reasons), and a routine post procedure chest x-ray to identify any possible mechanical complication and to evaluate lead position. Deep venous thromboses were diagnosed by Duplex Ultrasonography as clinically indicated.

As a standard practice, patients with BTTP are admitted to ICU setting. At our institution, patients with TPPM are monitored on telemetry or step-down unit if their clinical status otherwise does not warrant an ICU stay. This allowed us to further assess healthcare utilization in terms of total number of days pacing was required, as well as number of days spent in ICU versus outside of ICU. To assess safety of TPPM outside of ICU setting, we also compared pacemaker related adverse events between the subsets of this group who did not require ICU level of care to those requiring ICU admission.

Statistical Analysis

Patients who crossed over from BTTP to TPPM were included in their initial treatment group, and the analysis was performed based on the intention-to-treat principle.

Data were reported as mean $\pm$ standard deviation (SD) for continuous variables or percentage for categorical variables. Pacing duration was reported as median (range) for better representation of non-normal distribution. Variables were compared between the two groups using t-tests for continuous variables and Chi-square (χ^2) test for categorical variables. A multivariable logistic regression analysis was performed to obtain the Odds Ratios (OR) and 95% Confidence Interval (95% CI) for pre-defined outcomes, adjusting for age, gender, and indication for a temporary pacemaker. A sensitivity analysis was also performed to evaluate the incidence of temporary pacemaker related adverse events in patients with TPPM based on their in-hospital setting location. A two-tailed P value < 0.05 was considered statistically significant. All statistical analyses were conducted using the JMP Pro software version 14.1.0 (SAS Institute, Inc, Cary, NC) and GraphPad Prism version 9.2.0 (GraphPad Software, San Diego, CA).

Results

Baseline Characteristics

Among the 126 patients with a temporary pacemaker, 63 (50%) had a TPPM, and others (n=63) had a BTTP. Baseline demographics and cardiac history are summarized in **Table 1**. The mean age was 66.6 ± 16.5 years in the TPPM group compared to 70.1 ± 12.6 years in the BTTP group ($P= 0.183$). Both groups had similar baseline characteristics, including female gender and racial minorities representation. Fifty-two percent of the TPPM group were males compared to 54% of BTTP group. African Americans constituted more than 25% of each group ($P= 0.672$). The prevalence of hypertension was similar in both groups. There was no statistically significant difference in the prevalence of coronary artery disease and congestive heart failure between the two groups at time of pacemaker insertion. None of the patients in both groups had a history of DVT/PE prior to admission.

The most common indication for temporary pacemaker placement in both groups was AV node dysfunction (50.8% vs 52.4%), followed by sinus node dysfunction and ventricular arrhythmia overriding ($p=0.911$, **Table 2**). For the TPPM cohort, subclavian vein was the site of access in 89.0% of cases, followed by internal jugular vein (11.0%). The femoral vein was not used as access site in this group. However, the femoral vein was most used for access in the BTTP group (65.1%) followed by internal jugular vein (31.7%) and subclavian vein (3.2%) ($P<0.001$).

Patient ambulation and healthcare utilization amongst patients with temporary pacemakers

Patient ambulation was only possible in the TPPM group, with more than half of the patients ($n=35$, 55.6% vs 0 in the BTTP group, $P<0.001$) being able to ambulate while having a temporary pacemaker in place (**Table 3**).

In general, TPPM patients were paced for a longer duration than BTTP patients (median of 4 days vs 2 days in the BTTP group, $P<0.001$) (**Table 3**). Most importantly, pacing outside the intensive care unit was only observed in the TPPM group (median of 2 days, range between 0 and 10 days maximum). In the TPPM group, 23 patients (36.5%) were paced exclusively outside the ICU. The cumulative total number of days paced outside the ICU was 160 days out of 422 total days paced for the TPPM cohort, representing almost 38% of the cumulative total pacing duration (with a mean duration of 2.5 ± 2.8 days per patient).

Temporary Pacemakers Related Adverse Events

The different complications related to pacing are found in **Table 4**, **Figure 2**. In our study population, complications were encountered more frequently in the BTTP group. Venous thromboembolism events were encountered in zero patients with TPPM compared to 4 (6.3%) in the BTTP group ($P=0.042$). Lead dislodgment/loss of capture occurred in 7.9% and 22.2% of patients with TPPM and BTTP, respectively ($P=0.025$). No patients in both groups developed tamponade as a complication of pacemaker insertion. In total, 4 patients who initially had a BTTP placed were later switched to a TPPM because of lead dislodgment. No patients were switched from a TPPM to a BTTP. Local (access site) hematoma and infection were only encountered in BTTP group, in 3.2% and 1.5% of the patients respectively. No Pneumothorax or hemothorax were found after the procedure in either group. Serious cardiovascular events happened in one patient (1.5%) with a TPPM, compared to 6 (9.5%) with BTTP ($P=0.075$).

The Odds Ratio of developing any of the studied adverse events for the TPPM group compared to the BTTP group was 0.23 [95% CI (0.10-0.67), $P<0.001$]. This association remained consistent after adjusting for: age, gender, and temporary pacemaker indication [OR= 0.24, 95% CI (0.07-0.91), $P=0.030$].

In the TPPM group, we compared the incidence of pacemaker related adverse events for the subgroups of those who were monitored exclusively outside the ICU setting, exclusively within the ICU setting, and those who required pacing both in ICU and outside of ICU setting. There was no significant difference in the pacemaker related adverse events between those subgroups (**Table 5**).

Discussion

In our study cohort, patients with temporary permanent pacemakers had better clinical and safety outcomes compared to patients with balloon-tipped temporary pacemakers (**central illustration**). Temporary permanent pacemakers were associated with a decreased risk of complications, including lead dislodgment and loss of capture, venous thromboembolism, and access site hematoma and infection. This reduced incidence of such complications was not affected by age, gender, and the indication for temporary pacing. Ambulation and temporary pacing outside the intensive care unit were only possible in the TPPM group. Additionally, our data also demonstrates safety of monitoring such patients outside of ICU setting.

Clinical implications of temporary permanent pacemakers

Balloon-tipped temporary pacemakers (BTTP) are associated with an increased risk of dislodgement due to lead instability in the right ventricle.^(6,9) This increases the risk of loss of capture, requiring lead repositioning or replacement.^(6,9,12) For this reason, in current clinical practice, most patients undergoing

balloon-tipped temporary pacemaker placement are admitted to the intensive care unit for close and frequent monitoring.^(10,13) This was reflected in our study, where none of our BTTP subjects were placed outside the intensive care unit while having the temporary pacemaker inserted. On the other hand, active fixation of the lead into the myocardium provides more stability, less risk of dislodgement and eventual loss of capture. Our data shows it is safe to monitor patients with TPPM outside the ICU setting, unless patient's condition otherwise necessitates ICU admission.

On average, patients with TPPM were paced for a longer duration than patients with BTTP. One possible explanation of this observation is that active fixation offers greater stability and safety, permitting a longer observation duration before inserting a permanent pacemaker, or until the underlying reversible condition is resolved. Importantly, patients with TPPM were paced for up to 10 days on the general medical ward outside the ICU. Using TPPM instead of BTTP helped save 160 total ICU days in our cohort of patients, resulting in salutary implications for the patient as well as reduced utilization of healthcare resources and resultant cost savings. Temporary pacing with active leads may save hospitals more ICU bed-days, resulting in decreasing cost of hospitalization and giving opportunity to better care for patients with several conditions requiring ICU admissions. For example, this can be crucial in scenarios similar to the COVID 19 pandemic, with historic difficulties in bed availability and staffing. In addition, prolonged ICU stay can be associated with significant morbidity and mortality,^(12,14-16) including increased risk of hospital acquired infections (pneumonia,⁽¹⁷⁾ urinary tract infections⁽¹⁸⁾), deep venous thrombosis, stress ulcers, and death.^(19,20) ICU associated delirium and severe deconditioning are also frequently seen among patients hospitalized in the ICU.^(21,22)

On the contrary, BTTP lead instability renders ambulation extremely risky, and thus patients with a BTTP remain bedridden with close monitoring until the pacemaker is safely replaced or removed. Prior studies related to temporary pacemakers with active fixation leads (TPPM) have reported increased ambulation among patients with TPPM.^(8,23,24) Our study showed similar results regarding patient ambulation. Almost half of our TPPM cohort were ambulating while being paced, whereas none of the BTTP patients were ambulatory while needing the temporary pacemaker. A significant contributor to this observation was the vascular access site, the majority of BTTP patients had femoral access, which renders mobility impractical, compared to subclavian or jugular access. The ability of mobilizing patients early on gives TPPM a significant advantage over BTTP since early mobility is associated with many benefits among hospitalized adults.⁽²⁵⁾ Immobility is associated with increased risk of venous thromboembolism, deconditioning, increased hospital length of stay, and higher in-hospital mortality rates.⁽²⁶⁾

Safety profile of temporary permanent pacemakers

In this study, TPPM were associated with lower incidence of complications, reflected by an adjusted odds ratio (OR) of 0.20 ($P < 0.001$).

Temporary pacemaker insertion, although considered a routine and safe procedure, is associated with significant complications. These complications can be immediate (or procedure related) such as local hematoma, pneumothorax, or access site infection. All patients with a BTTP who developed access site infection or hematoma had femoral access. Femoral venous catheterization is associated with increased risk of infections compared to other catheterization access sites,⁽²⁷⁾ especially the subclavian vein, which was used predominantly in the TPPM group. Utilizing the subclavian and jugular veins as access sites may have reduced the incidence of these complications in the TPPM cohort.

Delayed complications may be more life threatening than procedure related complications, such as VTE, loss of capture and lead dislodgment. All three complications happened significantly more frequently in the BTTP group compared to the TPPM group.

We believe that a reduced ICU stay and patient mobility in the TPPM cohort are the main reasons behind the lower incidence of VTE compared to the control group. Early ambulation plays a major role in reducing the incidence of deep vein thrombosis (DVT) during hospitalization.⁽²⁸⁾ One prior study has also demonstrated a lower risk of DVT in mobile patients with TPPM.⁽²⁹⁾

As mentioned earlier, active fixation of pacemaker leads significantly decreases the risk of dislocation compared to passive fixation.⁽⁶⁾ In our study, we only reported clinically significant lead dislodgement leading to loss of capture requiring repositioning or replacement. Our finding that lead dislodgement was significantly more common in the BTTP group (21.3% vs 8.2%) is similar to the results from prior studies. De Cock et. al showed a 5.5% prevalence of lead dislodgement with TPPM (compared to 36.4% in BTTP).⁽⁸⁾ This specific study used the Medtronic Temporary Pacing Lead System Model 6416 that was recalled later in 2016, since these leads were not compliant with standards set by the FDA and the International Electrotechnical Commission (IEC) (U.S Food & Drug, 2016).⁽³⁰⁾ Braun et. al reported only one case of dislodgement in their TPPM cohort compared to 24 in the control group. In cases of pacemaker dependency such as unstable complete heart block, loss of capture can lead to profound hemodynamic instability and possible death.⁽³¹⁾ Lead replacement or repositioning requires catheterization lab activation, exhausting both financial and personnel resources.

Importantly, patients with TPPM who were exclusively paced outside the ICU did not have significantly different rates of complications compared to the TPPM patients who were paced in the ICU setting. Hence, temporary pacing with a TPPM can be safely executed outside an intensive care setting.

Study Limitations

This is a retrospective cohort study looking back at patients with a temporary pacemaker between 2014 and 2022. An inherent limitation to retrospective analyses is the reliability on available clinical data and predisposition to uncontrolled selection bias. Secondly, our TPM outcomes examination was performed over a several-year timeframe in which practice patterns may have changed. Our study lacked post-hospitalization outcomes analysis; our results do not reflect long term improved outcomes with TPPM over BTTP. Utilization of fixation leads for temporary pacing is an “off-label use” of this device and not yet FDA approved, thus a large prospective controlled study comparing both techniques is necessary to assess short- and long-term outcomes between the two different temporary pacing modalities. On the other hand, we included the largest number of subjects to date for any study looking at TPM outcomes. Our study includes demographic characteristics that are usually under-represented in other studies, including female gender, and non-white racial minorities, allowing for greater generalizability of our results

Conclusion

Temporary cardiac pacing is commonly used in settings of life-threatening arrhythmia. Patients with BTTP are paced exclusively in the ICU and are generally non-ambulatory. BTTPs are associated with major complications including lead dislodgement, thromboembolism, and access site related adverse events. On the other hand, temporary permanent pacemakers with active fixation leads provide more stability leading to lower likelihood of lead dislodgement, and VTE. This allows early patient mobility. These findings make TPPM superior to BTTP in the management of critically ill patients, both from the standpoint of patient outcomes as well as metrics of healthcare utilization. Additional prospective and randomized controlled trials are required to validate our findings and assess long term outcomes between the two modalities.

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Figure legends

Figure 1: Example of a TPPM with subclavian access. External pacemaker generator taped to the skin of the patient.

Figure 2: Summary of the different temporary pacemakers related complications. All pacemaker related complications, including lead dislodgement and venous thromboembolism, were more frequently encountered in the BTTP group than the TPPM group. BTTP: Balloon tipped temporary pacemaker, TPPM: Temporary permanent pacemaker

Central Illustration: TPPM are associated with better safety and healthcare utilization outcomes compared to BTTP. BTTP: Balloon tipped temporary pacemakers, TPPM: Temporary permanent pacemakers.

Table 1: Characteristics of the patients at time of temporary pacemaker insertion

	BTTP (N=63)	TPPM (N=63)	P Value
Age at TPM insertion in years, mean + SD	70.1 + 12.6	66.6 + 16.5	P=0.183
Males, n (%)	34 (54.0%)	33 (52.4%)	P=0.858
Race Caucasian, n (%)	39 (61.9%)	39 (61.9%)	P=0.672
African American, n (%)	18 (28.6%) 2 (3.2%)	16 (25.4%) 5 (7.9%)	
Hispanic, n (%) Asian, n (%)	4 (6.3%)	3 (4.8%)	
History of smoking, n (%)	35 (55.6%)	45 (71.4%)	P=0.064
History of HTN, n (%)	36 (57.4%)	37 (58.7%)	P=0.857
History of CAD, n (%)	18 (28.5%)	23 (36.5%)	P=0.341

	BTTP (N=63)	TPPM (N=63)	P Value
History of CHF, n (%)	12 (19.0%)	15 (23.8%)	P=0.515
CAD- Coronary artery disease, CHF- Congestive heart failure, HTN- Hypertension, SD- Standard deviation, TPM- Temporary pacemaker	CAD- Coronary artery disease, CHF- Congestive heart failure, HTN- Hypertension, SD- Standard deviation, TPM- Temporary pacemaker	CAD- Coronary artery disease, CHF- Congestive heart failure, HTN- Hypertension, SD- Standard deviation, TPM- Temporary pacemaker	CAD- Coronary artery disease, CHF- Congestive heart failure, HTN- Hypertension, SD- Standard deviation, TPM- Temporary pacemaker

Table 2: Summary of different temporary pacemaker related characteristics

	BTTP (N=63)	TPPM (N=63)	P Value
Indications for TPM insertion	33 (52.4%) 24 (38.1%) 6 (9.5%)	32 (50.8%) 26 (41.3%) 5 (7.9%)	P=0.911
AV node dysfunction, n (%)			
Sinus Node Dysfunction, n (%)			
Ventricular arrhythmia, n (%)			
Vein Access	2 (3.2%) 20 (31.7%) 41 (65.1%)	56 (89.0%) 7 (11.1%) 0 (0%)	P<0.001
Subclavian, n (%)			
Internal jugular, n (%)			
Femoral, n (%)			
Permanent pacemaker, n (%)	36 (57.1%)	35 (55.5%)	P=0.857
Serious cardiovascular events* after TPM insertion, n (%)	6 (9.5%)	1 (1.5%)	P= 0.075
* Including cardiogenic shock, new myocardial infarction, and new fatal ventricular arrhythmia AV- Atrioventricular, TPM- Temporary pacemaker	* Including cardiogenic shock, new myocardial infarction, and new fatal ventricular arrhythmia AV- Atrioventricular, TPM- Temporary pacemaker	* Including cardiogenic shock, new myocardial infarction, and new fatal ventricular arrhythmia AV- Atrioventricular, TPM- Temporary pacemaker	* Including cardiogenic shock, new myocardial infarction, and new fatal ventricular arrhythmia AV- Atrioventricular, TPM- Temporary pacemaker

Table 3: Patient ambulation and healthcare utilization amongst different temporary pacing modalities

	BTTP (N=63)	TPPM (N=63)	P Value
Ambulation with TPM, n (%)	0 (0%)	35 (55.6%)	P<0.001

	BTTP (N=63)	TPPM (N=63)	P Value
Total pacing duration in days, median (range)	2 (1-14)	4 (1-38)	P<0.001
Days paced in the ICU, median (range)	2 (1-14)	1 (0-38)	P=0.149
Days paced outside the ICU, median (range)	0 (0)	2 (0-10)	P<0.001
Days Paced outside ICU/total days paced, n (%)	0/155 (0%)	160/422 (38.0%)	P<0.001
ICU- Intensive care unit, TPM- Temporary pacemaker	ICU- Intensive care unit, TPM- Temporary pacemaker	ICU- Intensive care unit, TPM- Temporary pacemaker	ICU- Intensive care unit, TPM- Temporary pacemaker

Table 4: Pacing related adverse events in the TPPM group compared to the CTPM group

	BTTP (N=63)	TPPM (N=63)	P Value
Venous thromboembolism, n (%)	4 (6.3%)	0 (0%)	P= 0.042
Lead dislodgement or loss of capture, n (%)	14 (22.2%)	5 (7.9%)	P= 0.025
Local hematoma, n (%)	2 (3.2%)	0 (0%)	P= 0.154
Local infection, n (%)	1 (1.5%)	0 (0%)	P= 0.315
Haemothorax/Pneumothorax, n (%)	0 (0%)	0 (0%)	P= 1.000
Composite adverse events, n (%)	17 (27%)	5 (7.9%)	P<0.001

Table 5: adverse events related to TPPM based on the in-hospital setting

	Paced exclusively outside the ICU (N= 23)	Paced exclusively in the ICU (N= 22)	Paced inside and outside the ICU (N=18)	P Value
Venous thromboembolism, n (%)	0 (0%)	0 (0%)	0 (0%)	-
Lead dislodgement or loss of capture, n (%)	2 (8.7%)	3 (13.6%)	0 (0%)	P=0.279

	Paced exclusively outside the ICU (N= 23)	Paced exclusively in the ICU (N= 22)	Paced inside and outside the ICU (N=18)	P Value
Local hematoma, n (%)	0 (0%)	0 (0%)	0 (0%)	-
Local infection, n (%)	0 (0%)	0 (0%)	0 (0%)	-
Haemothorax/Pneumothorax, n (%)	0 (0%)	0 (0%)	0 (0%)	-

ICU- Intensive
care unit

Figure 1

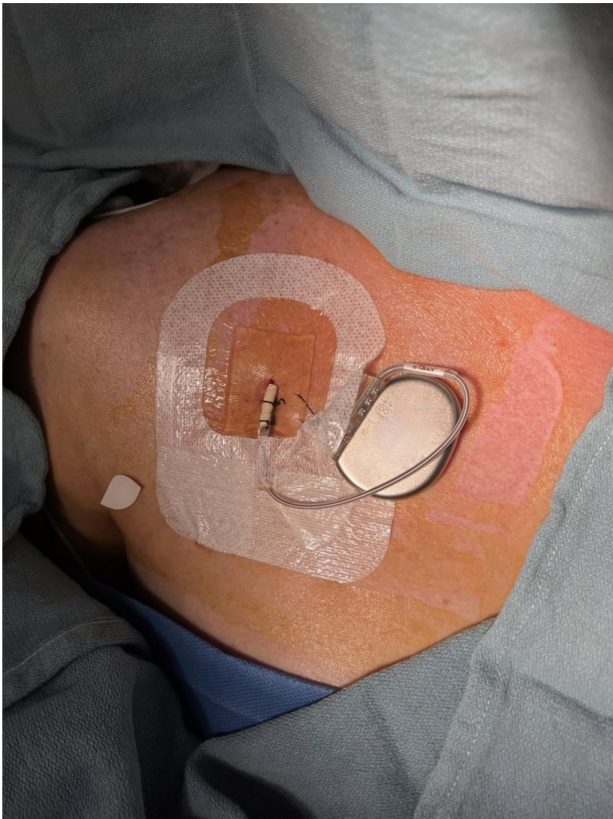


Figure 2

