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Pulling heart strings: Quality improvement algorithm for temporary epicardial pacing wire removal post cardiac surgery

Jessica Norman
James Madison University

Pulling Heart Strings: Quality Improvement Algorithm for Temporary Epicardial Pacing Wire Removal Post Cardiac Surgery

Jessica Norman

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FACULTY COMMITTEE:

Committee Chair: Linda Hulton

Committee Members/ Readers:

Megan Rashid

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Abstract

The placement of temporary epicardial pacing wires (TEPW) is considered standard practice post cardiac surgery and is dependent on the patient's cardiac function intra-operatively and their electrophysiologic profile after weaning from cardiopulmonary bypass (Reade, 2007; Elmistekawy et al, 2016). Complications associated with TEPW removal include myocardial damage, infection, perforation, tamponade, disruption of anastomoses, ventricular arrythmias, and death (Bojar, 2009; Carroll et al, 1998;Timothy & Rodeman, 2004). Currently there is no standard practice on the removal of TEPW and there is wide variation in removal practices involving patients who are routinely on medications such as dual antiplatelet therapies and systemic anticoagulation. The utilization of a standardized algorithm would ensure timely review of patient specific lab data, anticoagulation regimen, and use of pacing wires are addressed prior to wire removal in turn mitigating unnecessary risk. Patients were identified using pilot study inclusion criteria and participation in the study was denoted with the placement of a sign over the head of the patient's bed. Adherence data was measured through collection of nursing checklists and the presence of a post-procedure wire removal note completed by the provider removing the wires. Of the pilot study patients (n=10), 7 nursing checklists were appropriately completed and collected, showing 70% adherence. Ten of 10 patients had a post-procedure wire removal note completed in the electronic medical record, equating to 100% adherence. None of the study patients in the pilot study required re-operation or had bleeding complications post-wire removal. Adherence to the use of a standardized algorithm may reduce risk of bleeding or re-operation associated with temporary pacing wire removal (Kiely, O'Brien, & Mooney, 2020).

Key words: *temporary epicardial pacing wires, wire removal, cardiac surgery*

Introduction

Problem Statement

In the contemporary management of cardiac surgery patients there is a lack of a standardized algorithm for the removal of temporary epicardial pacing wires (TEPW) which has the ability to lead to catastrophic complications such as cardiac tamponade, hemorrhage, and death (Suthar et al, 2017; Gal et al, 1998; Mishra et al, 2010; Saidi et al, 2010; Matsushita et al, 2013; Price & Kennan, 1989). According to D'Agostino et al (2018) there were 224,724 cardiac surgery cases reported for 2016, meaning that the number of patients who receive TEPW intra-operatively is likely to be quite high, although no exact statistics are currently available. The incidence of major complications following removal of TEPW is 0.04% as noted by Abu-Omar et al (2005), which equates to 8,988 patients suffering adverse events after wire removal based on statistics from 2016. It is important to note that this complication rate does not include patients who experienced complications after attempts at pulling the TEPW were unsuccessful and may not encompass all patients who experienced complications as it is difficult to discern the timing of wire removal and complications from patient chart review. While overall the use of TEPW is associated with low morbidity and mortality, as described by Abu-Omar (2005), their removal does present circumstances where arrhythmias, hemorrhage, tamponade, lacerations and injury to grafts may occur (Johnson et al, 1993; Del Nido et al, 1989). Despite the comparatively low complication rate, the need for a standardized removal algorithm is necessary to ensure the amount of risk incurred by patients is as minimal as possible. The risk to patients who have undergone redo cardiac surgery and are actively being anticoagulated, which is often the case in this patient population, is higher than that of first time cardiac surgery patients or those not actively being anticoagulated (Abu-Omar et al, 2005).

Available Knowledge

Implantation of temporary epicardial pacing wires is routine after various cardiac surgeries (Elmistekawy et al, 2016; Bougioukas et al, 2017; Donmez et al, 2014). The rates with which these are placed has not been documented well in the literature but is more common than not in post-operative cardiac surgery patients (Mahon et al, 2012). Epicardial pacing wires afford practitioners the ability to manipulate and control

the patient's heart rhythm after cardiac surgery ensuring adequate hemodynamics and preventing arrythmias, such as atrial fibrillation, which can occur in up to 40% of cardiac surgery patients in the post-operative period (Reade, 2007; Batra & Balaji, 2008). According to Batra & Balaji (2008) postoperative arrhythmias, such as atrial fibrillation, third degree heart block, and junctional rhythms, are a major cause of morbidity and mortality following cardiac surgery. In patient specific circumstances, pacing is the quickest and most effective method of managing rhythm disturbances, bradycardia with low cardiac output, nodal or junctional rhythms, or AV block (Reade, 2007). The two types of TEPW placed are atrial and ventricular wires (Reade, 2007). Determining which types of wires a patient receives is left up to the surgeon and can be dependent on whether specific conduction structures were believed to have been stunned or damaged during operative intervention. Current literature supports the selective use of TEPW after coronary artery bypass graft (CABG) surgery, but they are also routinely placed after valve and congenital heart surgeries based on historical evidence demonstrating a need for temporary pacing post-operatively in that patient population (AlWaqfi et al, 2014). According to Bethea et al (2005) and Johnson et al (1993) 48% of patients who underwent CABG and approximately 83% of patients undergoing valve surgery will develop post-operative arrhythmias. As previously mentioned, the use of TEPW to ameliorate hemodynamic compromise is a valuable resource in already critical patients who are likely dependent on vasoactive medications in the immediate post-operative period.

A summary table of the current literature can be found in Appendix A.

Need

There is no standard consensus on which patients receive TEPW versus patients that do not. Donmez et al (2013) only utilized TEPW in 22.4% (n= 498 adult patients, 112 received TEPW) of their adult cardiac surgery patients compared to Elmistekawy et al (2016) which had a sample size of 1582 patients, of which 1368 (86.5%) received ventricular pacing wires and 580 (36.7%) received atrial pacing wires intra-operatively. According to AlWaqfi et al (2014) temporary cardiac pacing was only needed in 23.9% of their valve surgery patients compared to just 16.9% of patients in Donmez et al (2013). This begs the question as to whether the placement of TEPW is necessary for most patients (as is the current practice) or if there are specific parameters and criteria that could be used to determine potential need of TEPW intra-operatively

and post-operatively. Bethea et al (2005) conducted a study of patients undergoing CABG who had TEPW placed and found that only 19 of the 222, or 9%, patients used in the sample required pacing post-operatively which supports the argument that selective placement of TEPW for CABG only surgeries is appropriate.

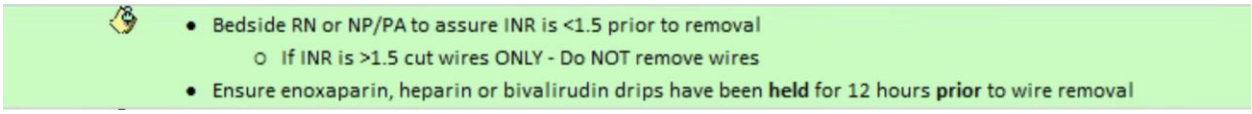
Considerations

An important consideration in the removal of TEPW is the patient's anticoagulation status. The patient's INR and aPTT should be checked prior to removal of TEPW to ensure adequate clotting ability. Currently there is very little literature to support specific INR or aPTT levels, but the available literature does recommend that TEPW are removed prior to initiation of oral anticoagulants, especially new oral anticoagulants, and when the INR is <2 (Elmistekawy, 2019). Reade (2007) only mentions that pacing wires should be removed after therapeutic anticoagulation has been discontinued and before initiation of heparin therapy, which can be difficult in this patient population as they are often bridged from intravenous anticoagulation to oral anticoagulants for mechanical valve anticoagulation or atrial fibrillation. Both Elmistekawy et al (2016) and Bougioukas et al (2017) note that a significant number of their patients were on aspirin therapy the day of their TEPW removal. Thirty-nine perecent of Elmistekawy et al's (2016) patients were on Coumadin anticoagulation at the time of their TEPW removal with an average INR of 2.1 and Bougioukas et al (2017) reports that three patients were on dual antiplatelet therapy when their TEPW were removed in addition to vitamin K antagonist, low molecular weight heparin or heparin infusion for bridging. The INR in Bougioukas et al (2017) ranged from 1.2-2.2 with aPTT values of 28-99, showing that even patients with normal coagulation profiles are still at risk for hemorrhage after TEPW removal. Elmistekawy et al (2016) had similar findings and stated there were no issues after TEPW removal in the presence of a moderately elevated INR, even when the patient was also taking aspirin.

Rationale

Despite the frequent use of TEPW after cardiac surgery across the world, a standardized algorithm for their removal has not yet been developed or agreed upon. There is currently no consensus in the cardiac surgery community on what criteria must be met prior to the removal of TEPW and the purview is left up to

the surgeon and intensive care unit team. Currently at a tertiary care center in a mid-Atlantic state the only order that is related to TEPW removal is as follows:



This institution utilizes powerplans, which are collections of relevant and frequently used patient care orders or medications for specific patient populations within the health system. The aforementioned directive is outlined in the powerplan orders, but it is only visible when in the editing phase of the powerplan and is not displayed with active orders that are frequently reviewed by bedside nursing staff as well as housestaff. This is concerning for several reasons: being an academic institution means the intensive care unit has new rotations of residents every month who are unfamiliar with the patient population and cardiac surgery specific procedures. The lack of an easily visualized algorithm means that new residents may perform TEPW removal without consideration of a patient's anticoagulation status, need for pacing wires, or need to hold systemic anticoagulation prior to removal. A second concern is the lack of clarity in the order. Both the bedside nurse and the provider performing wire removal should be responsible for ensuring that the patient meets the appropriate criteria for removal to minimize risk to the patient. Additionally, the suggestion about cutting the wires in patients with INR >1.5 is inaccurate. This standard is rarely, if ever, followed in the cardiothoracic surgery department and cutting wires without discussion with a surgeon is unacceptable. Complications secondary to retrained wires is well documented by Shaikhrezai et al (2012). They found 105 papers related to complications after cutting TEPW and were able to analyze 13 papers to determine the best evidence available to answer the question: Is it safe to cut pacing wires flush with the skin instead of removing them? They strongly recommend removing wires if possible, in order to minimize risk of later complication to the patient. The current recommendation in the powerplan would lead to a disproportionate number of patients having their pacing wires cut instead of pulled, potentially leading to even greater risk of complication than is associated with wire pulling as noted by Shaikhrezai et al (2012).

Specific Aims

This quality improvement project aimed to improve the standardization of the removal of temporary epicardial pacing wires post coronary artery bypass graft surgeries. The purpose of this project was to design, develop, implement and evaluate a standardized algorithm for the removal of temporary epicardial pacing wires in patients post cardiac surgery. Analysis of patient medication regimens as well as their anticoagulation profile was conducted to determine if those factors contributed to the complication. The second, and most substantial purpose, was the implementation of a quality improvement epicardial pacing wire removal algorithm (Figure 1) to provide guidance for safe removal of epicardial pacing wires and a reduction in risk of potential complications post pacing wire removal.

Methods

Context

The use of TEPW is commonplace in patients who have undergone cardiac surgery. This patient population is frequently high risk at baseline, with multiple comorbidities, making any surgical intervention higher risk than that of their healthier counterparts. These patients are routinely placed on dual antiplatelet therapy (DAPT) post-operatively to ensure graft patency and that replaced valves do not thrombose post-operatively. The 2017 EACTS Guidelines on perioperative medication in adult cardiac surgery have a class IB recommendations for resuming aspirin as soon as there is no concern for bleeding, but within 24 hours after surgery. For patients undergoing non-coronary cardiac surgery there is a class IC recommendation to resume aspirin therapy as soon as there is no concern for bleeding, but within 24 hours of surgery. For the second antiplatelet therapy, a P2Y12 inhibitor, there is a IC recommendation to resume P2Y12 inhibitor as soon as there is no concern for bleeding, but within 48 hours of surgery for patients who have received a coronary stent one month prior to surgery. For patients who received a stent greater than 1 month prior to surgery, the IC recommendation states that P2Y12 inhibitor therapy should be resumed as soon as there is no concern for bleeding, but within 96 hours of surgery (Sousa-Uva et al., 2017).

For patients who receive mechanical versus biological valves the antithrombotics recommendations include vitamin K antagonists and oral anticoagulants with INR goals specific to the type of valve received. For mechanical mitral valve replacements and aortic valve replacements with risk factors (including atrial

fibrillation, previous thromboembolic events, left ventricular dysfunction or older generation mechanical aortic valve replacement) the use of a vitamin K antagonist with an INR goal of at least 3 with concurrent use of aspirin 75-100mg is a level IC recommendation. For patients who received an aortic valve replacement, the IC recommendation is a vitamin K antagonist with an INR goal of at least 2.5 (Sousa-Uva et al., 2017). Patients who received a biological aortic valve replacement/repair or biological mitral valve replacement/repair should receive oral anticoagulation for the first 3 months after surgery in the Level IIa recommendation followed by single antiplatelet therapy as level Iia evidence (Sousa-Uva et al., 2017).

These distinctions are important to the removal of TEPW as the use of these agents predisposes patients to a higher risk of bleeding during procedures such as TEPW removal or central line removal, which are common in the intensive care unit. Considering what agents patients are actively taking prior to TEPW removal is imperative in minimizing patient complications post TEPW removal.

Population and Setting

This project was conducted in the 14 bed cardiac surgery intensive care unit at a level one trauma center in a mid-Atlantic state. Average cardiac case volume ranges from 500-600 annually. The patient population included adults 18 years of age and above who underwent coronary artery bypass graft surgery and were cared for in the cardiac surgery intensive care unit post-operatively. Inclusion criteria for patients included in the pilot study were those with an ejection fraction greater than 30%, those on less than 3 vasoactive medications, and those on less than .05mg/kg/min of Epinephrine or Norepinephrine, either individually or concurrently.

Framework

A Rapid Cycle Quality Improvement (RCQI) model was utilized in the formation of this project. This allowed for use of the plan, do, study, act method (Figure 6) which permitted for revisions and adjustments to protocols or algorithms allowing for improvements that would facilitate positive clinical results and outcomes in the patient population. This model allowed for collection of retrospective data on the current reoperation rate (School of Public Health, 2016). Once the data on reoperations was obtained, a chart review was conducted to determine whether reoperation was associated with epicardial wire removal. This

enhanced the review of current literature and data on TEPW removal associated morbidity and mortality. The "Do" portion of the framework took place when the algorithm (Figure 1) was implemented in the cardiac surgery intensive care unit and was applied to every patient who fit the inclusion criteria. Once the tool was introduced to the unit, percent compliance with the tool was analyzed using a nursing checklist (Figure 2) and wire removal procedure note (Figure 3).

Havelock's Theory of Planned Change (1976) was utilized as the theoretical framework for this pilot study. This model took Lewin's theory of change and broke it into six distinct phases:

- Building a relationship: in this stage the need for a change to current wire removal practices was identified
- Diagnosing a problem: identified specific interventions and changes that needed to be implemented relative to temporary epicardial pacing wire removal
- Acquire resources for change: in this stage data was gathered via a literature review, retrospective reoperation data was obtained and reviewed
- Selecting a pathway for resolution: this phase was where the algorithm was created based on literature review and current practices and where the algorithm was revised after review with stakeholders
- Accept and establish change: in this stage education was given to unit staff (intensivists, advanced practice providers (APPs), bedside nurses, supplemental staff and surgeons) and the algorithm was implemented in the unit with consistent supervision by the principal investigator
- Maintenance and separation: this stage also involved the monitoring of implementation by the principal investigator as it was in the beginning phases of implementation until it was a normalized and accepted practice within the unit (Willcox et al, 2018).

Interventions

Phase 1- Literature Review and Team Development: A thorough literature review of current best practice for removal of temporary epicardial pacing wires was conducted. Data pulled from articles and current standards were reviewed and utilized in the creation of a standardized algorithm for use in a cardiac

surgery intensive care unit. Review of the literature lead to recommendations based on current practices in the field of cardiac surgery and were made on several areas relating to epicardial wire removal: anticoagulation (both oral and intravenous routes) and length of time held prior to wire removal, length of time anticoagulation held post wire removal, and acceptable ranges of aPTT, INR, and platelet counts prior to wire removal. Key stakeholders were identified as: surgeons, intensivists, APPs, bedside nurses, unit secretaries and care partners.

Phase 2- Process Development: Using the best evidence based practices the algorithm was created, reviewed and approved by the chair of the cardiothoracic surgery department. Isolated CABG patients were selected after discussion with both surgeons and intensivists who requested we limited the initial pilot to a less complex patient population. A total of 8 algorithm versions were created before the final version was approved and implemented. APPs and residents were expected to identify patients meeting inclusion criteria (isolated CABG patient, EF≥ 30%, less than 3 pressors or inotropes, and Norepinephrine/Epinephrine <.05mcg/kg/min concurrently or individually) who have temporary epicardial pacing wires upon arrival to the intensive care unit post-operatively and instruct nursing staff to place a laminated sign at the head of the bed identifying the patient as part of the pilot study. Each day both the provider and bedside nurse were expected to review the need for pacing wires and utilize the algorithm to determine if the patient meets criteria for wire removal. The operative surgeon had the ability to delay wire removal if they had any clinical concerns. A total of four of six cardiac surgeons agreed to allow the protocol to be implemented in their coronary artery bypass graft patients.

A nursing checklist was created as part of the pilot study to ensure both nursing staff and providers were reviewing the key components of the algorithm together prior to wire removal. The checklist (Figure 2) requires the signature of the bedside nurse as well as the provider executing the wire removal. In conjunction with the use of the wire removal algorithm, a wire removal procedure note (Figure 3) was completed by the APP or resident removing the wires. A template for the note was created and automatically populated using a note template. This allowed for the standardization of documentation related to wire removal and allowed for easy collection of data, which was used to determine the adherence and effectiveness of the algorithm. The note template included the time and date of wire removal, current in-patient medications, up to date lab

values, the provider performing the removal, the supervising provider, the type of surgery the patient underwent and what post-op day they were in their hospitalization, the type of epicardial wires (atrial, ventricular or both), the indication for removal, the unit on which the wires are being removed, the standard technique in which the wires should be removed, and any post-procedure complications or comments.

Phase 3- Education: The residents rotating through the intensive care unit each month were taught by either the APPs or the intensivists as to how to remove pacing wires, utilize the algorithm and where to locate additional resources. The algorithm, nursing checklist, provider procedure note and an instructional PowerPoint were presented to all staff in the week leading up to algorithm initiation and were uploaded to the unit's intranet site, allowing for quick and easy reference should a laminated copy not be available. As new nursing and APP staff is hired, the algorithm will be integrated in their onboarding education to ensure familiarity and appropriate application. A laminated version of the algorithm was placed in each patient bedside book for review by the nurse and the provider removing the wires immediately prior to wire removal with a reminder of the expectation of vital sign and chest tube output monitoring by nursing staff for one hour post removal. The use of this algorithm will ensure that all residents rotating through the cardiac surgery intensive care unit have a reference tool and a competency prior to temporary pacing wire removal reducing the level of unnecessary risk to patients.

Phase 4- Implementation: In order to determine the effectiveness of this quality improvement project several measures were utilized. First and foremost the implementation of the new algorithm required education as described in Phase 3. Next a two-sided laminated copy of the algorithm and nursing checklist (Figures 1 & 2) was created and placed in each patient bedside book. Nursing already utilized a rounding tool and performed a FASTHUG (an acronym used to identify key areas that should be addressed in rounds) at the end of rounds to summarize key elements of patient care. During use of the FASTHUGS rounding tool, there is a section that addresses "unnecessary wires and lines" which was identified as an ideal time to review whether temporary epicardial pacing wires were still needed. At this point the bedside nurse would have the backside of the algorithm sheet filled out to address the following checklist: patient post-operative day, type of surgical procedure, type of epicardial wire (atrial vs ventricular or both), use of epicardial wires in the last 24 hours and rationale, current antiplatelet or anticoagulation profile (this must be updated daily), most recent

INR, platelet count and PTT. The team collectively reviewed the information on the checklist during rounds and determined if wire removal was appropriate for that patient based on the most up to date lab values and medications. For the purposes of the pilot study, a paper copy of the nursing checklist was utilized allowing the principal investigator the ability to collect the checklist after each use and determine adherence during the initial implementation phase of the algorithm. As part of the algorithm the provider removing the wires was to complete a post-procedure note in the electronic medical record allowing for the measurement of provider adherence to the algorithm.

Measures

Retrospective data collection of all adult, ages 18 and above, cardiac surgery patients from January 2019 to December 2019 and those who underwent re-operation, during the same time frame, due to any cause was completed in September 2020. Stratification of patients who underwent reoperation secondary to bleeding categorized as cardiac versus patients who underwent reoperation due to causes not cardiac in nature was completed in September 2020. Chart review was completed for each patient who underwent reoperation secondary to bleeding to determine whether the patient had epicardial wires removed prior to the need for reoperation and to analyze the patient's coagulation status, current list of medications and anticoagulation values immediately prior to reoperation. Lab data, primarily coagulation profiles including INR, aPTT, and platelet counts, for each case was reviewed and analyzed. This retrospective data collection informed the creation of the evidence-based algorithm.

A post-algorithm implementation evaluation was completed in November 2020. In order to evaluate the effectiveness of the algorithm the study collected data on patients post wire removal via a wire removal procedure note. Use of this note allowed for the collection of coagulation lab data, real time antiplatelet and/or anticoagulation regimens, whether the algorithm was followed prior to wire removal and whether the patient suffered any adverse events after wire removal. The removal note allowed for efficient tracking of patients who had epicardial wires removed post-cardiac surgery and of patients who required reoperation post wire removal to be easily flagged.

Data Analysis

Results of Retrospective Chart Review

Retrospective data was collected from January 1, 2019 to December 31, 2019 for all cardiac surgery patients (n=394). Of these, 81 patients underwent re-operation due to any cause. These patients were further stratified based on indication for re-operation: bleeding related (n=34) versus not-bleeding related (n=47). Approximately 20% of patients who underwent cardiac surgery at this institution in 2019 underwent re-operation secondary to any cause and 8.6% of cardiac surgery patients underwent re-operation secondary to bleeding complications. Men accounted for 74% of patients who underwent reoperation secondary to bleeding (Table 1). The most common types of surgeries to require reoperation were orthotopic heart transplant (29.4%), left ventricular assist device implantation (17.6%), and CABG + valve surgery (14.7%) (Figure 4). Approximately 64% of re-operations due to bleeding were categorized as acute bleeding, bleeding that occurred within 24 hours of index surgery, and 35.3% were considered late, any bleeding later than the first 24 hours post index surgery (Figure 5). Retrospective data analysis revealed that approximately 8.8% of re-operations secondary to bleeding occurred in patients who underwent isolated CABG. The average INR of this group was approximately 1.6 with an average PTT of approximately 50 seconds. Average platelet count in this group was 124 with an average length of stay of 38 days. Data on the timing of wire removal, lab values prior to removal and type of temporary pacing wires for this group was not available secondary to the lack of documentation required prior to algorithm initiation.

Results of Pilot Study

Data collection for the standardized algorithm occurred from October 5, 2020 to November 23, 2020. A total of 23 patients underwent CABG during this time frame, with 11 of those patients meeting inclusion criteria for algorithm application. There was 1 patient who had the algorithm inappropriately applied, a valve replacement patient, without adverse outcomes or complications. One patient, who did meet inclusion criteria initially, was ruled out after having to return to the operating room secondary to bypass graft failure within 24 hours of index surgery and as such the surgeon chose to remove the pacing wires herself. The 12 patients who underwent isolated CABG and were not enrolled in the study were patients of

the two surgeons who opted out of having their patients included due to preferential practices. The types of wires present in the pilot study group were 50% atrial, 20% ventricular and 30% of patients arrived in the ICU with both sets of wires. Review of the most recent lab values prior to wire removal demonstrated that all ten patients met criteria for wire removal as illustrated in the algorithm. The average age in the re-operative for bleeding group was ten years younger than the pilot group (58.8 years, 68.6 years respectively) (Table 1). Average INR in the re-operative group was higher than that of the pilot group, 1.59 and 1.29 respectively. Average platelet count between the two groups was 124 and 173. None of the 10 patients who were part of the pilot group required re-operation for any cause. Seven of the 10 nursing checklists were filled out to completion and collected after wire removal, demonstrating 70% adherence. All ten of the pilot patients had post-procedure wire removal notes completed in the electronic medical record, equating to 100% adherence (Table 2). Due to the small pilot study size it cannot be determined if the differences between the groups are statistically significant at this time.

Discussion

The purpose of this pilot study was to determine compliance and adherence to the wire removal algorithm. A secondary purpose was to mitigate risk in patients undergoing wire removal and prevent adverse outcomes and costly reoperations. Cote et al (2020) acknowledged, while rare, bleeding complications after epicardial wire removal have significant financial impacts as a result of prolonged hospitalization, morbidity, and utilization of resources. Mehaffey et al. (2017) conducted a retrospective review of data from 18 hospitals in Virginia on CABG complications between January 2006 to December 2015 and found the cost for reoperations to be $7.6 million. Expanding the application of this algorithm across multiple cardiac surgeries, including those who undergo valve repair or replacement, has the ability to reduce re-operation costs secondary to bleeding after wire removal. The review of wire removal practices at this institution should also trigger discussions around intra-operative indications for placement of temporary epicardial pacing wires. Bethea et al (2005) found that only 2.6% of CABG patients required pacing after surgery, if patients with significant predictors of pacing post-operatively were excluded, which begets the question: which patients truly need temporary epicardial wires placed intra-operatively? What standards and indications are used by surgeons to determine which patients receive wires and which do not? Does the utilization of a specific type

of wire and the method with which it is placed predispose patients to increased risk of complications or adverse outcomes than another type of wire and method?

The surgeons who agreed to enroll their patients were strong advocates for the use of the algorithm and helped to ensure its application and use regularly. The bedside nursing staff felt that the use of the algorithm lead to more timely removal of pacing wires and added an additional layer of surveillance, which required them and the provider to review lab data together to ensure each were up to date on the most recent values. Nursing staff did inquire as to whether there was a plan to move the nursing checklist to an electronic form for ease of use and tracking, which is an anticipated improvement for the next cycle of the study.

Limitations

A unique limitation of this pilot study was COVID-19. The pandemic put a significant strain on hospital resources, greatly limiting the investigator's ability to acquire retrospective data and to request additional data during the pilot study. The pandemic also halted surgeries that were non-emergent in nature for several months, leading to a later than anticipated start date for algorithm implementation. Additional limitations of this pilot study were its retrospective nature and its implementation at a single academic medical center. The development of a prospective study of this nature presents a challenge when post-operative bleeding requiring reoperation is a rare occurrence and is difficult to predict. Collection of the retrospective data was limited as much of the information being sought out required the principal investigator to conduct an in-depth chart review for each patient, which was time consuming and impractical for future studies with larger study populations. Retrospective data was also limited to what was documented in the patient electronic medical record without the ability to determine context. This pilot study had a small sample size with very specific inclusion criteria rendering the investigator unable to generalize findings to other cardiac surgery patients at this time. Validity and quality of data analysis was dependent on the information added to the database and reliant on the information documented in the electronic medical record. Data acquisition and documentation practices severely limited the investigator's ability to collect data, both retrospectively and prospectively.

Implications

The continuation of this pilot study among CABG patients will allow the investigator to perform additional data analysis and potentially expand the study to patients having undergone other cardiac

procedures if proven efficacious and safe based on outcomes. Having a standardized wire removal protocol will reduce chance for error with residents rotating through a busy cardiac surgery intensive care unit and will eliminate the need for redundant communication between surgeons and the ICU team. The use of a standardized protocol has the ability to reduce length of time TEPW are in situ and thereby reduce the likelihood for complications associated with removal. Ideally this algorithm would be applied across the cardiac surgery department in both the intensive care unit and the stepdown units. Additional research on complications after TEPW removal should be continued as it can have a significant impact on morbidity, mortality, and cost. With the continued improvement of electronic medical record documentation and the ability to capture more inclusive data further analysis and recommendations for the removal of epicardial wire removal can be expected. The ability to accurately interpret and analyze objective and subjective data across multiple institutions has the potential to lead to a widely accepted and standardized method for wire removal, ideally leading to reduced incidences of hemorrhage, tamponade, prolonged hospitalization and death.

Table 1: Summary of Studies Evidence Table

Author, Title, Journal	Year	Purpose of Study (Describe intervention if there is one)	Variables (Independent and Dependent)	Subjects (population/ sample/sample methods)	Methods (instruments with reliability and validity & analysis & level of evidence)	Findings/Results (Statistical Evidence)	Limitations/Gaps/ Conclusions
Alwaqfi, N. R., Ibrahim, K. S., Khader, Y. S., & Baker, A. A. (2014). Predictors of temporary epicardial pacing wires use after valve surgery. *Journal of cardiothoracic surgery*, *9*, 33. https://doi.org/10.1186/1	2014	Determine the predictors of temporary cardiac pacing in valve surgery with the potential to regulate pacing wire insertion	Retrospective data analysis	400 consecutive valve surgery patients between May 2002 and December 2012	Patients were grouped according to avoidance or insertion of temporary pacing wires, and were further subdivided according to temporary cardiac pacing need. Multiple logistic regression was used to determine the predictors of temporary cardiac pacing.	• 170 (42.5%) patients did not have insertion of temporary pacing wires and none of them needed temporary pacing. • 230 (57.5%) patients had insertion of temporary pacing wires and among these, only 55 (23.9%) required temporary pacing who were compared with the remaining 175 (76.1%) patients in the main analysis.	• Retrospective data analysis

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Bougioukas, I., Jebran, A.F., Grossmann, M. *et al.* Is there a correlation between late re-exploration after cardiac surgery and removal of epicardial pacemaker wires?. *J Cardiothorac Surg* **12,** 3 (2017). https://doi.org/10.1186/s13019-017-0569-5	2017	Gather all confirmed and suspicious cases of pericardial tamponade after removal of EPW and to estimate the frequency of this complication. Study the patient's medications, in order to find a possible correlation, trying to avoid or minimize this risk.	Single center retrospective study	4244 patients who underwent major cardiac procedure with placement of epicardial pacing wires -	Jan 2011 to Dec 2015 a total of 4244 major cardiac procedures. Temporary epicardial pacemaker wires in all cases. Collected data on re-explorations for bleeding and pericardial tamponade from surgical database and focused on the late re-explorations, meaning on the 4th postoperative day and thereafter, trying to identify the removal of the temporary pacemaker wires as the definite cause of bleeding.	• A late re-exploration was necessary in 39 patients (0.92%), varying from the 4th till the 30th POD. • Late procedures accounted for 17.4% of all re-explorations for bleeding (39 out of a total of 223 re-explorations) • Resternotomy was performed in 20 cases, thoracotomy in five, and subxiphoid pericardial drainage insertion in 14 cases • Defining the exact cause of bleeding in the late re-explorations seemed to be complicated, as in many cases no active bleeding	• single center retrospective study

						could be found. The removal of the epicardial pacemaker wires could be recognized as the definite cause of bleeding in only 8 cases of the total of 4244 patients (0.2%), accounting for 3.6% of all re-explorations for bleeding (2 CABG, 3 valve patients, myectomy, and 2 combined) • 2 deaths, 2 repeat sternotomy, 4 perc drains • none of 8 patients had chest tubes at time of EPW removal • delayed EPW removal 7-16th post-op day • modified the standard procedure of removal of the EPW at our department. In order to minimize the risk of serious bleeding, we initiate the oral anticoagulation regimen –	

						VKA or NOAC – after the EPW have been taken out	
Dönmez, Arzu & taş, Serpil & Tuncer, Eylem & Adademir, Taylan & Yazıcı, Süleyman & Köksal, Cengiz & Alp, Hızır. (2013). Temporary Epicardial Pacing After Adult Cardiac Surgery. Kosuyolu Kalp Dergisi. 16. 133-138.	2013	Determine predictors for need of TEPW and to document complications of wires	Prospective study	12 patients operated at single institution from April 2010 to October 2010 who received TEPW	Preop, intraop, and postoperative data was collected. Surgical team not aware of study and placed TEPW according to normal practices for that institution. Data analysis performed with SPSS and evaluated for descriptive statistical methods, and chi-squared test with statistical significance of $p<0.05$	• 22.4% of cardiac surgery patients received TEPW • 83.1% of patients never required pacing. • No complications were observed related to use of removal of TEPW • 16.9% needed pacing during weaning from CPB • 52.6% of patients who required pacing during CPB weaning required pacing in the ICU	Single center study with limited sample size

10.5578/kkd.5361.							
Elmistekawy, E., Gee, YY., Une, D. *et al.* Clinical and mechanical factors associated with the removal of temporary epicardial pacemaker wires after cardiac surgery. *J Cardiothorac Surg* **11,** 8 (2016). https://doi.org/10.1186/s13019-016-0414-2	2016	• Sought to assess the tension required for the routine removal of temporary epicardial pacemaker wires after cardiac surgery as well as factors related to resistance of removal. • Sought to evaluate factors related to routine use including their need during weaning from cardiopulmonary bypass (CPB) and complications related to their removal.	Retrospective analysis of data	We retrospectively analyzed prospectively collected data from the University of Ottawa Peri-Operative Database Unit to identify patients undergoing cardiac surgery between 02/01/2014 and 31/12/2014 ($n = 1582$).	Volunteers from the attending surgical staff (senior housestaff and staff surgeons) as well as nursing staff experienced in temporary wire removal were asked to apply tension to a loop of wire attached to the hand-held portable electronic scale to document the maximal weight tension at which they would cease further pulling. Pacer wires were removed at discharge or at a maximum of 4–6 weeks if the patient was still in hospital. Removal of wires of patients on Coumadin was only completed when the	• Ventricular wires were placed in 1368 patients (86.5 %) whereas atrial wires were used in 580 patients (36.7 %). • Atrial and ventricular wires and sequential wires were used in weaning from CPB in 47 (3.0 %), 61(3.9 %) and 131(8.3 %) respectively (total 15.2 %). • Pacer dependence during CPB weaning was demonstrated in 33 patients (2.1 %). These cases included 27 % post CABG/AVR, 24 % post CABG, 12 % post transplant, 12 % post AVR Maze procedure and 24 % other. • Wires were clipped in 104 cases (6.6 %) due to excessive resistance (56	• Inability to have duplicate measurements if patient had only single chamber wires • Not all patients had both atrial and ventricular wires h • More late complications may have occurred in the larger population such as sub-clinical pericardial effusions and these were not determined as patients did not undergo routine echocardiographic followup

					INR was less than 2.5. At the time of wire removal, a loop was fashioned with the exterior end of the wire.	[53.9 %]) or due to caution related to documented suturing of the wire to the epicardium (48 [46.2 %]).	
Kiely, N., O'Brien, F., & Mooney, M. (2020). Epicardial pacing wires after cardiac surgery: an Irish cross-sectional study. *British Journal of Nursing*, *29*(8), 476–480. https://doi.org/10.12968/bjon.2020.29.8.476	2020	Aim of this study was to evaluate the insertion, use, duration and complications of epicardial pacing wires following cardiac surgery in a cohort of patients in Ireland	Non-experimental cross sectional study	Patients following cardiopulmonary bypass and analyzed in terms of use, duration of use and complications of pacing wires after surgery	Measured the number of patients in whom pacing wires were inserted and their associated surgery, together with their postoperative pacing requirements, the duration of pacing wire placement and length of hospitalization for each patient. The authors also measured whether there were complications associated with wire removal.	• Wires were inserted in 164 of the 167 patients. • Most (74%) did not require pacing. • Patients were categorized into those who had aortic valve replacement (AVR) (n=42) and those who did not (n=122). • Of the AVR group, 26% (n=11) were pacemaker dependent after surgery and 10% (n=4) required permanent pacemakers. • Most pacing wires were removed by day 4. The only noted complication was delayed discharge	• Single center study • Small sample size

Mahon, L., Bena, J. F., Morrison, S. M., & Albert, N. M. (2012). Cardiac tamponade after removal of temporary pacer wires. *American journal of critical care : an official publication, American Association of Critical-Care Nurses*, *21*(6), 432–440. https://doi.org/10.4037/ajcc2012585	2012	New knowledge might pro- vide the basis for a more appropriate assessment of patients that will improve patient safety and provide the best use of nurses' time.	Descriptive, correlational, cross sectional study and review	Cardiothoracic surgeons perform between 12 and 25 cardiac surgery procedures each weekday. The study's sample consisted of consecutive CABG and/or valve surgery cases that met the requirements of the Society of Thoracic Surgeons. The only other inclusion criteria were that the incision was a mini or full open chest midline incision and that cases were carried out from January 1999 through December 2008.	This descriptive, correlational, cross-sectional study used review of medical records and a cardiovascular surgery database that has been active since 1972. Data were obtained retrospectively from a cardiothoracic surgery database after being separated into the 4 groups previously identified. The data included 31 variables involving patients' characteristics, medical history, surgery type, complications, and length of stay.	• No research studies were focused on the incidence of cardiac tamponade after TPWR. • only 23 patients had further surgery for cardiac tamponade after TPWR, an incidence of less than 1% or 9.7 cases/10,000. • Of the total sample, more patients were male (69%), most were white (87%), and 59% had a history of smoking. By medical history, 73% of patients had hypertension, 47% had peripheral artery disease, and 44% had a history of myocardial infarction. • TPWR. This study is the first to report more than 1 case per center and provides analytical results regarding clinical outcomes of patients in	• It is difficult to perform a prospective study of cardiac tamponade after TPWR because of its rarity • The sample size was sufficient; however, all patients are from 1 large academic, quaternary-care medical center. • Other cardiac surgical centers may implant TPW differently than our site or have different procedures for when and how such wires are removed, which could affect the incidence of cardiac tamponade after removal.

						whom cardiac tamponade develops after TPWR. • In conclusion, hypotension, bleeding, and dyspnea are important markers of cardiac tamponade after TPWR.	
Matsushita, T., Fuse, H., Takeuchi, K., Masuda, S., & Inoue, T. (2013). Aortic bleeding one week after removal of an intraoperative epicardial temporary pacing wire. *Annals of thoracic and cardiovascular surgery : official*	2013	• Discuss safety of TEPW and potential complications	Case Report	56 yo M who underwent nephrectomy and resection of cavoatrial tumor thrombus on cardiopulmonary bypass and required bipolar TEPW, which were removed on POD 8.	Case Report	• TEPW routintely used in patients undergoing cardiac surgery • Complications reportedly occur in .09% patients • Delayed tamponade may be underreported due to difficulty in capturing data • TEPW should be cut at helical portion so tip does not hit aortic wall during implantation	• Case report involving one patient

journal of the Association of Thoracic and Cardiovascular Surgeons of Asia, *19*(3), 231–233. https://doi.org/10.5761/atcs.cr.12.01886							
Mishra, P. K., Lengyel, E., Lakshmanan, S., & Luckraz, H. (2010). Temporary epicardial pacing wire removal: is it an innocuous	2010	Facilitate discussion regarding removal of epicardial pacing wires and complications post removal	Case Report	76-year-old female underwent aortic valve replacement (AVR) (21 mm St Jude Medical Epic, SJM MN, USA) with coronary artery bypass grafting (CABG)	Case Report	• Pacing wires during should be removed during the day and not on the day of discharge to ensure that any complication can be dealt with more efficiently • Pacing wires should be placed behind rather than in front of the SVG to avoid the potential complications relating to	• Case report involving one patient

procedure?. *Interactive cardiovascular and thoracic surgery*, *11*(6), 854–855. https://doi.org/10.1510/icvts.2010.240978						graft compression and/or injury	
Mukaihara, K., Yotsumoto, G., Matsumoto, K., & Imoto, Y. (2015). Migration of a retained temporary epicardial pacing wire into an abdominal aortic aneurysm. *E*	2015	Facilitate discussion and raise awareness regarding migration of retained temporary epicardial pacing wires	Case Report	69-year old male previously visited the hospital for dyspnoea and leg oedema. Coronary angiography and left ventriculography revealed three-vessel disease with old anteroseptal myocardial infarction. He was admitted to our hospital and preoperative computed tomography (CT) revealed an infrarenal abdominal	Case study review of patients electronic medical record	• Migration of TEPW can occur years after index operation and can have deleterious impacts • TEPW should be removed whenever possible • Close follow up of patients with retained TEPWs is necessary	Case report, not a study

uropean journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery, *48*(1), 169–170. https://doi.org/10.1093/ejcts/ezu334				aortic aneurysm (AAA) and a giant tumour of the left kidney.			
Shaikhrezai, K., Khorsandi, M., Patronis, M., & Prasad, S. (2012). Is it safe to cut pacing wires	2012	To perform a literature review to determine whether cutting temporary epicardial pacing wires a the skin is safe and to determine what recommendation	Literature search and review of best evidence	105 total papers on the topic identified; 13 of which were selected as best evidence	Medline from 1948 to week 1 July 2012 using the OVID SP interface was searched utilizing the following strategy: (epicardial OR temporary OR epicardial wire) and	• The range of complications associated with retained TEPWs varied from minor complications, e.g. localized cutaneous abscess and fistula formation to major complications, e.g. the distant migration of the	• Review of literature, not a study

flush with the skin instead of removing them?. *Interactive cardiovascular and thoracic surgery*, *15*(6), 1047–1051. https://doi.org/10.1093/icvts/ivs397		s should be made.			(Postoperative complications).	TEPWs and the development of infective endocarditis requiring reoperation leading to significant morbidity and often mortality • Retained TEPWs can present with various and often vague signs and symptoms that may present decades postoperatively and may lead to significant morbidity and further surgery • recommend that any retained TEPWs should be documented in the patients' notes prior to their discharge and the surgeon should be mindful of retained TEPWs when patients present with any postoperative complication • The routine retention of TEPWs by cutting them	

						flush with the skin is not recommended.	

Table 2: Demographics of Retrospective Group (n = 34) and Pilot Group (n = 10)

	Gender	Race	Mean Age (SD)	Primary Insurance	Length of Stay (SD)
Retrospective Group (n =34)	74% male 27% female	58.8% Caucasian 41.2% Black	58.8 (14.9%)	44% Medicare 35% Private 14.7% Medicaid 5.9% Uninsured	38.8 (35)
Pilot Group (n = 10)	90% male 10% female	70% Caucasian 30% Black	67.5 (8.4)	40% Private 40% Medicare 10% Medicaid 10% Department of Corrections	12.8 (9.6)

Note: Data on patient demographics was obtained via chart review and is subject to accuracy based on data availability at time of collection.

Table 3: Case Summaries of Outcomes

	Age	LOS (days)	Types of wires	INR	PTT	Platelet Count	Post-Removal Note	Nursing Checklist	Post-Op Day of wire removal
Case 1	63	22	Atrial	1.4	36	207	Yes	No	6
Case 2	73	5	Ventricular	1.2	35	189	Yes	Yes	1
Case 3	61	9	Both	1.2	31	143	Yes	Yes	1
Case 4	78	7	Atrial	1.3	50	85	Yes	No	3
Case 5	68	5	Atrial	1.5	35	133	Yes	No	2
Case 6	72	3	Ventricular	1.3	39	159	Yes	Yes	1
Case 7	76	32	Atrial	1.4	52	252	Yes	Yes	2
Case 8	49	15	Both	1.2	37	110	Yes	Yes	2
Case 9	69	18	Atrial	1.2	31	322	Yes	Yes	1
Case 10	77	5	Both	1.2	41	130	Yes	Yes	3

Note: Lab values were collected via chart review and were the most recent values reported immediately prior to wire removal; length of stay encompasses the patient's entire hospitalization and is not specific to the time post cardiac surgery.

Figure 1: CABG Temporary Epicardial Wire Removal Algorithm

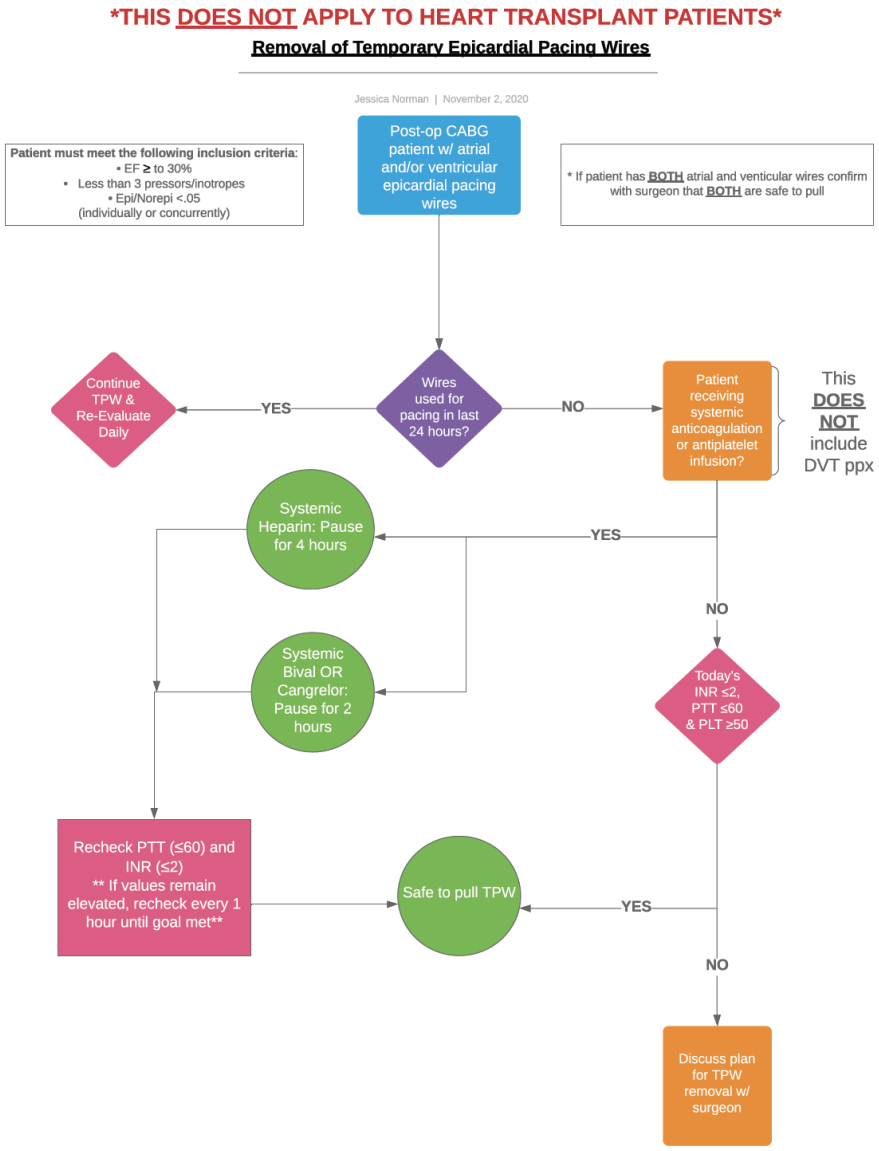


Figure 2: Wire Removal Nursing Checklist

Nursing Algorithm Checklist

*****This does NOT apply to orthotopic heart transplants*****

Type of Surgery:

Post-Operative Day:

Surgeon Approval (name):

Criteria	**Yes**	**No**
Does patient meet the following inclusion criteria: • EF≥ to 30% • Less than 3 pressors/inotropes • Epi/Norepi < .05 mg/kg/min (individually or concurrently)	Proceed to next step.	Re-evaluate as patient clinically improves & meets criteria.
Wires used for pacing in last 24 hours?	Continue TPW & re-evaluate need daily.	Proceed to next step.
Today's INR <2, PTT <60, **AND** PLT >50?	Proceed to next step.	Discuss plan for removal vs cutting wires with surgeon.
Patient receiving systemic anticoagulation or antiplatelet infusion? (DOES **NOT** INCLUDE DVT PPX)	Pause systemic anticoagulation/antiplatelet medication. For Heparin: pause for 4 hours, Bival and Cangrelor: pause for 2 hours. Infusions can be resumed 4 hours post removal.	Safe to remove TPW. Ensure provider writes procedure note.

*****Reminder**: Vital signs to be monitored by nursing q15 minutes for 1 hour post wire removal. Patient may ambulate after 1 hour.***

Signatures:

Nurse:

Provider:

Figure 3: Wire Removal Post Procedure Note

Temporary Epicardial Pacing Wire Removal Note

Procedure Name
Temporary Epicardial Pacing Wire Removal

Date/Time

Provider Performing

Supervising Provider

Type of Surgery & Post-op Day

Type of Wires: Atrial, Ventricular or Both

Indication
Patient has not required pacing via temporary epicardial pacing wires in the last 24 hours.

Coagulation Status
.lab24hrs

Antiplatelet/anticoagulants
.med_inpt

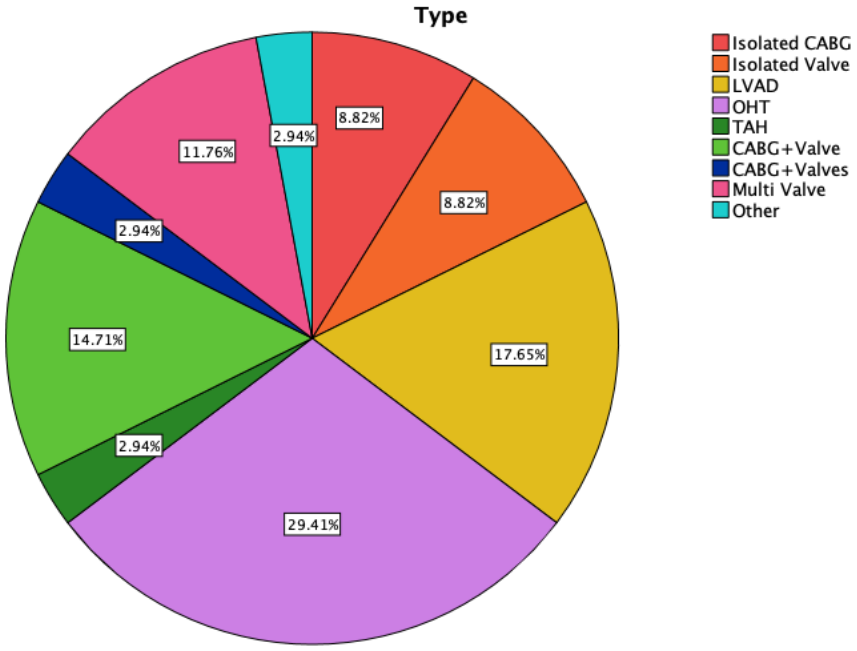
Location

Pre-Procedure Exam
Technique: Temporary epicardial pacing wires disconnected from pacing box. Dressing removed to expose sutures and insertion site. Chlorhexidine prep stick used to clean insertion site and surrounding skin. Using a suture removal kit: sutures cut and removed. Temporary epicardial pacing wires grasped and wrapped around index and middle finger of provider's dominant hand. Gentle, but constant, traction used to pull wires inferiorly from the insertion site until completely removed. Wire ends inspected for residual tissue. Gauze placed over insertion site and secured with either silk tape or Medipore tape. Bedside nurse to monitor patient vitals q15 minutes for 1 hour and the patient is to remain on bedrest for 1 hour.

Post-Procedure Exam
Complications

Comments

Figure 4: Retrospective Data: Type of Surgery in Reoperations Due To Bleeding



*LVAD= Left Ventricular Assist Device, OHT = Orthotopic Heart Transplant, TAH = Total Artificial Heart

Figure 5: Retrospective Data: Rebleed Timing

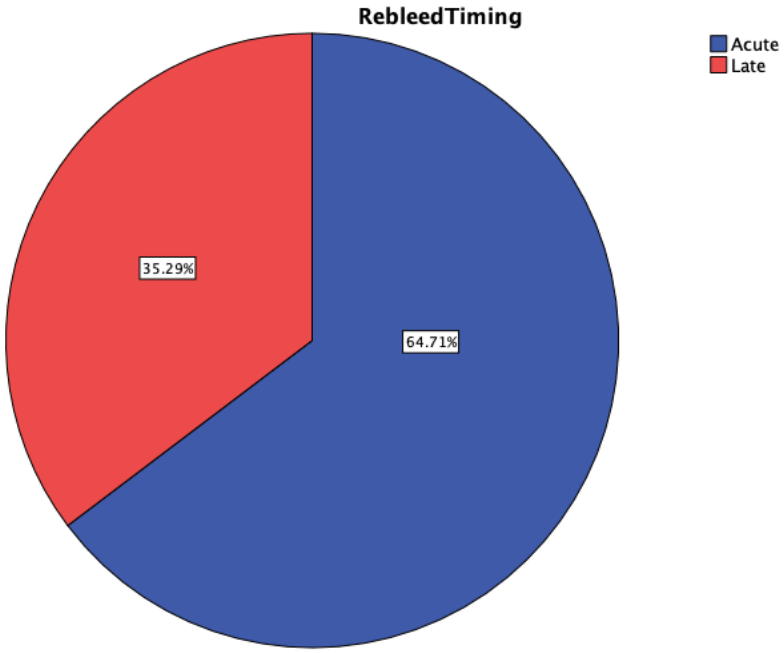
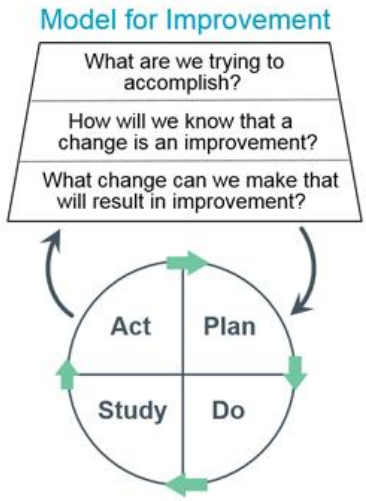


Figure 6: PDSA Cycle Flowchart



Note: Plan Do Study Act Model for Improvement (School of Public Health, 2016)

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