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Identification of new-onset atrial fibrillation after cardiac surgery in Vietnam. A feasibility study of a novel screening strategy in a limited-resource setting: study protocol

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ABSTRACT

Introduction Atrial fibrillation (AF) developing after cardiac surgery is the most common postoperative complication with an incidence up to 50%. The presence of postoperative AF is associated with significant morbidity, mortality and economic burden. However, in Vietnam, data on AF postcardiac surgery are limited, in part due to a shortage of screening equipment. This project aims to identify the incidence, risk factors and postoperative complications of new-onset postoperative AF after cardiac surgery, and the feasibility of introducing a novel screening strategy using the combination of two portable devices to detect AF.

Methods and analysis This is a feasibility study examining patients who are (1) ≥18 years old; (2) undergoing coronary artery bypass graft and/or valve surgery and (3) in normal sinus rhythm prior to their operation. Patients with congenital heart disease, a prior history of AF or those who require a pacemaker after surgery will be excluded. All patients will be followed up for the duration of their hospitalisation. The screening strategy will include monitoring the continuous ECG tracing in the intensive care unit, and if AF is suspected, a 30 s lead-1 ECG will be recorded using the smartphone-based AliveCor Kardia Mobile. On the postoperative wards, blood pressure will be measured three times daily using a modified blood pressure device (Microlife BP200 Afib): and if AF is suspected a 30 s ECG will be recorded using the AliveCor Kardia Mobile. A 12-lead ECG may be ordered subsequently if clinically indicated. The primary outcome is the incidence of postoperative AF. Secondary outcomes include establishing the risk factors and complications associated with postoperative AF; and the barriers and facilitators of the screening strategy.

Ethics and dissemination Ethics approval was granted by Scientific Board of Cardiovascular Centre, E Hospital on 28 September, 2017. Study results will be disseminated through local and international conferences and peer-reviewed publications.

Strengths and limitations of this study

- This is the first known study to examine the incidence of postoperative atrial fibrillation in a Vietnamese population.
- The study is unique as it explores the feasibility of introducing a simple screening strategy for atrial fibrillation in a limited-resource setting in Vietnam. If the screening strategy is determined to be easy to implement, time-effective and cost-effective, it could be implemented widely in similar low-resource settings.
- The study design involves a large proportion of hospital staff in the development and implementation of the screening strategy, including management, nurses, doctors and trainees. This will provide a full understanding of the feasibility, challenges and implications of the study, including changes in staff practice.
- A limitation in the study design is that the incidence of postoperative atrial fibrillation may be underestimated, due to the large number of staff responsible for monitoring the patients, and the high variation in the educational background and skills of the staff.
- This study will assess the true and false positive rates for each of the screening devices used in this protocol (ie, the AliveCor Kardia Mobile and Microlife BP200 Afib) compared with the 12-lead ECG. However, due to the limited available resources in Vietnam, it is not possible to assess the sensitivity and specificity of these devices in this setting.

INTRODUCTION

Atrial fibrillation (AF) developed postoperatively among patients undergoing cardiac surgery is also the most common complication, occurring in up to 50% of patients.[1 2] Postoperative AF (POAF) frequently occurs within 5 days after surgery with the peak incidence on postoperative day 2.[3] The majority of AF episodes are asymptomatic, with

Figure 1 Phillips IntelliVue Patients MP20 Monitor.

palpitations reported in only 1/3 of all AF episode,[4] and many other symptoms such as fatigue, dizziness or shortness of breath are non-specific and easily confused with what might be expected during recovery from surgery. Therefore, the incidence of POAF may be underestimated if patients are not routinely monitored.

Once POAF has occurred, it is associated with worse surgical outcomes, substantial morbidity, mortality and economic burden.[5 6] The 30-day postoperative mortality after coronary artery bypass graft (CABG) or aortic valve replacement is seven times higher among patients developing POAF compared with normal sinus rhythm group (5% vs 0.7%, respectively; p=0.001).[7] Additionally, median length of hospital stay is almost 5 days longer and length of intensive care unit (ICU) stay is double the length of patients with normal sinus rhythm.[7] Patients experiencing POAF also have a fourfold higher frequency of major infections including endocarditis and mediastinitis (0.9% vs 0.2%, p=0.03), and higher rates of minor infections (pneumonia, superficial wound infection and urinary tract infection).[7] Creswell *et al* have shown that the incidence of stroke associated with POAF is threefold higher.[1] POAF is also associated with a significantly higher long-term mortality.[7–9] In a meta-analysis about new-onset AF following coronary bypass surgery, the pooled HR significantly favoured higher survival rate in patients without POAF (HR 1.28; 95% CI 1.19 to 1.37, p<0.0001).[9] Better understanding of the pathology of this arrhythmia would lead to better prevention, management and postoperative outcomes.

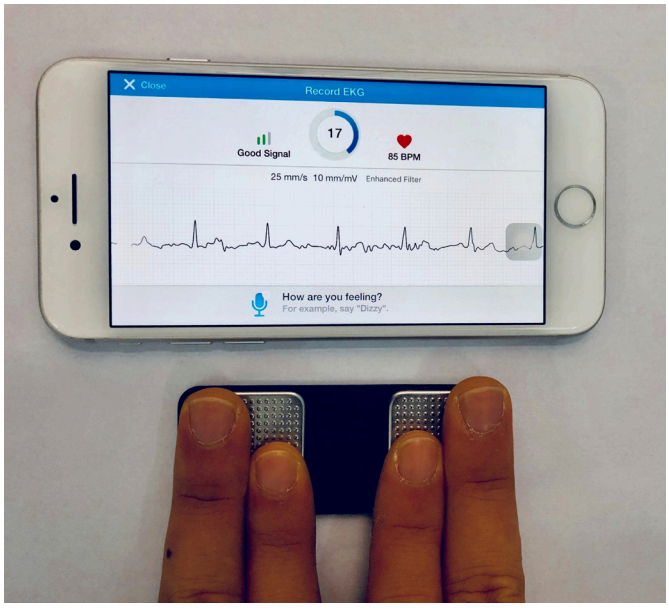

Figure 2 Single-lead ECG being recorded using AliveCor device with Kardia Mobile app on iPhone.

The mechanisms for development of AF after cardiac surgery are not fully understood, and it is believed that POAF is a multifactorial disorder. POAF shares similar risk factors to medical AF including advanced age, cardiovascular disease (hypertension, coronary artery disease, diabetes mellitus, obesity, obstructive sleep apnoea. A variety of causative factors have been described for POAF, including pericardial inflammation, excessive production of catecholamines, autonomic imbalance during the postoperative period and interstitial mobilisation of fluid with resultant changes in volume, pressure and neurohormonal environment.[3]

Several strategies have been proposed to prevent the complications of POAF. Beta blockers, given preoperatively, have been shown to be the most effective preventive medication: carvedilol is associated with significant reduction in incidence of POAF (RR 0.49, 95% CI 0.37 to 0.64, p<0.001).[10] However, beta blockers have the risk of negative inotropic effects and cannot be used for patients with obstructive pulmonary disease. Other options such as corticosteroid,[11 12] amiodarone,[13] colchicine,[14 15] vitamin C[16] are of modest value, and evidence is inconsistent for statins[17 18] and ACE inhibitor.[19] Despite evidence for prevention medications, these strategies are not routinely implemented, and therefore, POAF is still complicating cardiac surgery, resulting in poorer clinical outcomes for patients.

In Vietnam, there are only a few small studies on AF. One study has investigated the prevalence of AF in 461 elderly patients admitted to National Geriatric Hospital, and identified the prevalence of 3.9% in patients with a mean age of 76±9 years,[20] which is comparable to prevalence in people ≥60 years old in other Asian countries but is much lower than that of Caucasian population (8%).[21] This study also identified a treatment gap, as only 22.2% of eligible patients were prescribed anticoagulation according to guideline-based treatment recommendations.[20] There are only two studies on AF in a surgical setting in Vietnam, both with small sample sizes <100: one about the prophylactic use of amiodarone intraoperatively in patients with known AF[22] and the other about the use of Cox-maze procedure by high-frequency ablation to treat AF.[23] The former study showed the single use of intravenous amiodarone during cardiac surgery was effective at increasing the rate of conversion to sinus rhythm

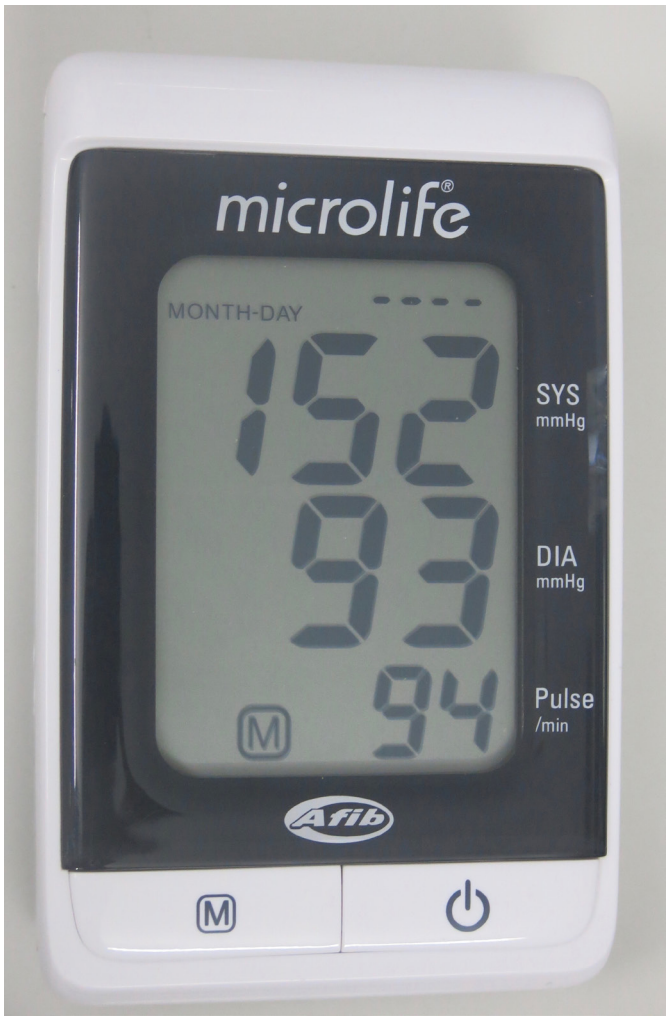

Figure 3 Microlife BP200 Afib.

compared with normal saline (65% vs 15%, respectively). The latter reported the rate of conversion to sinus rhythm by using Cox-maze procedure was approximately 84% until 1 year after surgery.

Little is known about the incidence of POAF in Vietnam, the risk factors for developing POAF or the associated complications. In other countries, these data have largely been collected through interrogation of electronic medical record databases,[24] however, electronic medical records do not exist in Vietnam, and heart rhythm is not routinely monitored outside of the ICU. Establishing a baseline for POAF incidence and outcomes is critical for defining the current problem in Vietnam. This data will then be available to inform future research investigating POAF treatment and preventative interventions.

SPECIFIC OBJECTIVES

The aims of this study are to:

1. Test the feasibility of establishing a sustainable system of monitoring cardiac surgery patients for POAF during their inpatient stay, in a Vietnamese setting.
2. Document the incidence of new-onset POAF after cardiac surgery in a Vietnamese population.
3. Investigate the risk factors for developing POAF.
4. Investigate the postsurgical complications associated with POAF during hospitalisation.

METHODS AND ANALYSIS

Study design

This feasibility study will use a single-centre, prospective cohort design to examine a novel strategy for screening for POAF and the incidence of POAF among adult patients undergoing cardiac surgery. The study will be conducted over 1 year at the Cardiovascular Centre, E Hospital, Hanoi, Vietnam from December 2017 to December 2018.

Description of the participating hospital

The Cardiovascular Centre of E Hospital is a 150-bed centre which was founded to provide high-quality cardiovascular care for both children and adults from all parts of Vietnam. Nearly 1000 operations are performed each year at this centre, including valve surgeries, coronary artery bypass surgeries, repair or palliative surgeries for various types of congenital heart diseases with the implementation of modern techniques (minimally invasive cardiac surgery, aortic valve reconstruction), all of which have made the centre one of the leading facilities for cardiovascular surgery in Vietnam.

Routine practice and currently available screening resources

In current practice, after cardiac surgery, all patients are transferred to the ICU and once they are stable, they are transferred to the postoperative wards in the department of cardiovascular and thoracic surgery.

In the ICU setting

All patients have continuous ECG tracing using a bedside patient monitor (Phillips IntelliVue Patients M30 Monitor) (figure 1), but the tracing is not recorded in any way and cannot be printed out. However, the patient's heart rate is recorded hourly by the nurses, using data provided by the bedside patient monitor.

In the postoperative wards

No ECG tracing is available. Holter ECG is not a feasible option since it records the ECG in only 24 hours while the hospitalisation length of stay may be days, weeks or even months. On the other hands, patients have their blood pressure (BP) and heart rate measured routinely by the nursing staff three times per day.

Preintervention training

All doctors and nurses from the ICU department, and the cardiovascular and thoracic surgery department will receive education regarding POAF; the study aims and protocol; correct interpretation of an ECG to recognise AF; how to record a smartphone single-lead ECG (AliveCor Kardia Mobile) (figure 2) and how to complete the data collection form. Nurses on the cardiothoracic wards will also be trained in the correct use of the modified BP measuring device with the capacity to detect AF

(Microlife BP200 Afib) (figure 3) and the smartphone single-lead ECG.

AliveCor Kardia Mobile

The AliveCor Kardia Mobile is a smartphone-based single-lead ECG. Hand-held electrodes attach to the smartphone, and when the Kardia 'app' is opened on the phone, a 30 s lead-I ECG is recorded on the phone, and the ECG recording is automatically synchronised to a secure internet server. An on-device algorithm automatically detects the possibility of AF based on an irregularity index and the presence of P-waves. The device and algorithm has been validated with a sensitivity of 98% and specificity of 97% for the detection of AF and has received Food and Drug Administration Class II Medical Device clearance.

Microlife BP200 Afib

The Microlife BP200 Afib is an electronic sphygmomanometer, which is equipped with an algorithm to automatically detect irregular beats. The device automatically records three consecutive measurements to provide the most accurate BP results. In AF mode, an algorithm is used to calculate the irregularity index based on interval between heartbeats and indicates an irregular pulse if the threshold is exceeded. If an irregular pulse is detected in at least two out of three measurements, the icon 'AFib' on the display starts blinking. The Microlife BP200 Afib device has high sensitivity and specificity for detecting AF (100% and 92%, respectively).[25] The National Institute for Health and Care Excellence guideline advocates the use of automated AF detection sphygmomanometer for the detection of AF.[26]

Participants

All patients admitted for cardiac surgery at the cardiovascular and thoracic surgery department will be screened for their eligibility using the following criteria:

Inclusion criteria

- ≥18 years old.
- CABG and/or valve surgery.
- In sinus rhythm prior to surgery.

Exclusion criteria

- Congenital heart diseases.
- Known AF prior to surgery.
- Patients with third degree atrioventricular nodal block requiring pacemaker.

Intervention

Consecutive patients undergoing cardiac surgery will be identified by the cardiothoracic surgical list, and they will be screened by the principal investigator. A research data collection form (online supplementary 1) will be attached to the routine medical record and will be completed by the treating doctors in the ICU, and cardiovascular and thoracic surgery department. Figure 4 illustrates the study flow and patient pathway from screening through to prospective treatment and discharge.

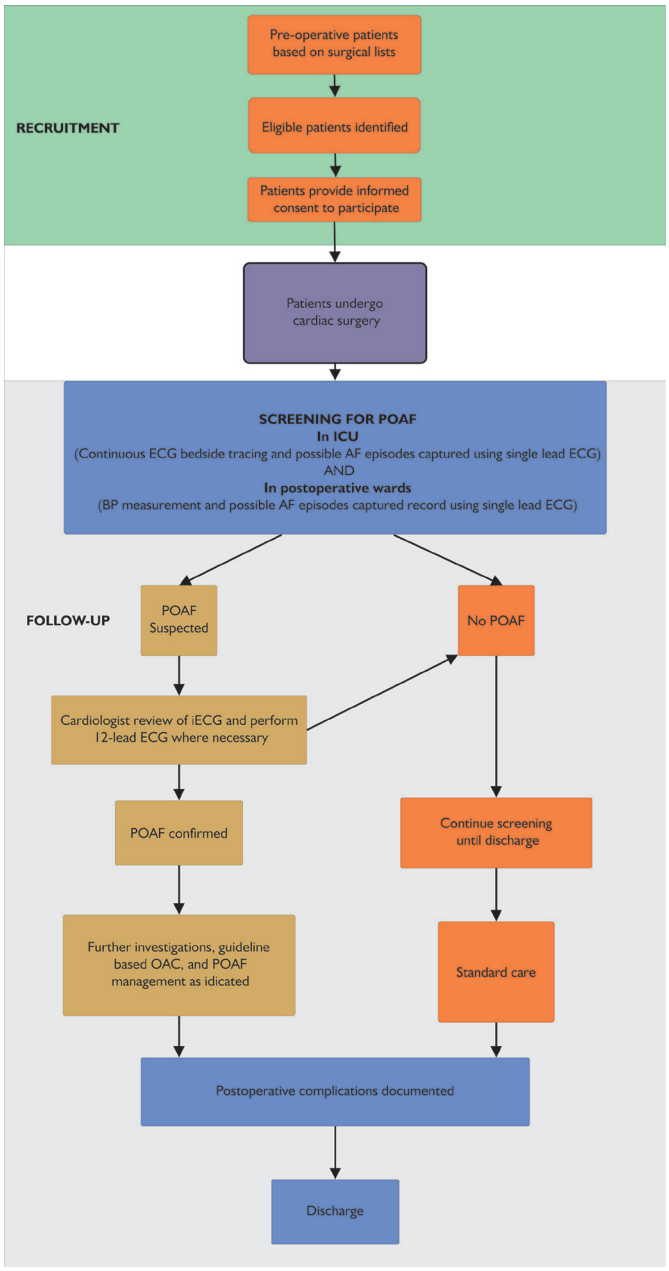

Figure 4 Study flow and patient pathway. AF, atrial fibrillation; BP, blood pressure; ICU, intensive care unit; OAC, oral anticoagulant; POAF, postoperative atrial fibrillation.

AF screening strategy

As there is no current method by which patients are screened for POAF after surgery, a novel screening strategy was developed to fit within the current workflow and limit additional work for the staff.

Enrolled patients will be reviewed daily until discharge. As standard care, patients are continuously monitored during their ICU stay, using a bedside patient monitor (Philips IntelliVue Patients M30 Monitor) (figure 1), which the nursing staff monitor. Episodes of POAF will

be identified by nursing staff inspecting the ECG tracing on the monitor while they are recording the patients' hourly heart rate observation from the monitor. If AF is suspected, nursing staff will document the suspected episode by recording a 30 s ECG trace on the smartphone single-lead ECG, as no facility exists to print the trace from the bedside monitor. The treating physicians will be notified and will review the patient and the single-lead ECG trace, ordering a 12-lead ECG where necessary. All AF episodes ≥30 s will be classified as POAF.

Once patients are discharged from ICU to the cardiovascular and thoracic surgery department, continuous bedside monitoring is no longer routinely performed on the ward. Therefore, the nursing staff will screen all patients three times per day (morning, early afternoon and early evening) using the modified BP measuring device (Microlife BP200 Afib), instead of the standard-care BP monitor. If AF is suspected, either by observation, symptoms or on the modified BP device, the nursing staff will document the suspected episode by recording a 30 s ECG rhythm strip using the smartphone single-lead ECG. As per the protocol in the ICU department, the treating physicians will be notified and if required a 12-lead ECG will be performed.

Data collection

Once an eligible patient consents to participate into the research project, a data collection form (online supplementary 1) will be attached to their routine medical record. Baseline data will be collected preoperatively by the primary investigator. Intraoperative parameters including operation time, cardiopulmonary bypass duration, aortic cross-clamp time will be recorded by the anaesthetist. In the postoperative period, physicians and nurses will record data daily until discharge, regarding any episodes of POAF and any postoperative complications. The detailed definitions of the medical conditions of interest are provided in online supplementary 2.

Process evaluation

Evaluation of benefits, challenges and factors influencing sustainability beyond the trial setting using semistructured interviews with a selection of participants, health professionals and key stakeholders within the hospital management team.

Outcomes

Primary outcomes

Coprimary outcomes:

- Feasibility of monitoring cardiac surgery patients for POAF during their inpatient stay, in Cardiovascular Centre, E Hospital (evaluated by compliance to protocol and qualitative process evaluation data).
- The incidence of POAF: the percentage of patients with new-onset AF after cardiac surgery out of the total number of patients undergoing cardiac surgery (measured with the AliveCor Kardia Mobile and confirmed with a 12-lead ECG).

Secondary outcomes

- Thromboembolic and bleeding risk profile of patients with POAF. (measured using the **CHA2DS2VASCs thrombo-embolic-risk score** [calculated based on the presence of: **C**ongestive heart failure/left ventricular dysfuction, **H**ypertension, **A**ge {65-74 years old or >=75 years old} , **D**iabetes mellitus, **S**troke/Transient ischeamia attack, **Vasc**ular disease, and female **S**ex with total score ranges from 0 to 9]and **HASBLED bleeding-risk score** [calculated based on the presence of: **H**ypertension, **A**bnormal liver/renal function, **S**troke, **B**leeding tendency/predipostion, **L**abile international normalized ratio, Age, and use of that predispose to bleeding **D**rugs or alcohol with total score ranges from 0 to 9][27]).
- Risk factors associated with development of POAF: including demographic data, types of heart disease, comorbidities, clinical laboratory tests and intraoperative parameters.
- Postoperative complications associated with POAF: including infections, ICU length of stay, postoperative hospital length of stay, reoperation and bleeding events (online supplementary 1).
- Accuracy of the possible AF diagnosis made by the AliveCor Kardia Mobile compared with the 12-lead ECG diagnosis (reported as rate of true positives and false positives).
- Accuracy of the possible AF diagnosis made by the Microlife BP200 Afib device compared with the 12-lead ECG diagnosis (reported as rate of true positives and false positives).

Sample size calculation

The anticipated number of patients undergoing cardiac surgery per year at cardiovascular centre is estimated to be 450. Assuming that 50% may not be eligible, and 5% of eligible patients may refuse to participate, the expected number of enrolled patients will be approximately 210. A sample size of 210 with a conservative assumed incidence of POAF being 30%[1 2] will give a 95% CI of 23.9% to 36.7% for the proportion of patients undergoing cardiac surgery who experience POAF (calculated on http://statpages.info/confint.html). This study is primarily focused on assessing the feasibility of the screening strategy, and as such the study is insufficiently powered for the secondary outcomes of risk factors and postsurgical complications associated with POAF, however, the results will provide exploratory data for these outcomes.

Statistical analysis

Primary analyses will be conducted using SPSS software V.24. Data are expressed as mean±SD for continuous variables and number and percentage for categorical variables. T-tests will be used for comparison of continuous variables and for categorical variables, Pearson's χ^2 test will be used (or Fisher's exact test wherever Pearson's χ^2 test is not acceptable). All tests will be two tailed and a $p \leq 0.05$ is considered statistically significant.

The incidence of POAF will be calculated by the percentage of patients developing AF after cardiac surgery divided by the total number of enrolled patients. For POAF risk factor analysis: study subjects will be divided into subgroups based on the presence of possible risk factors and Fisher's exact test will be used to compare the rate of POAF between subgroups by calculating OR. Multivariate regression will also be used to adjust for all other characteristics other than the risk factor of interest. To analyse postoperative complications, the percentages of each postoperative complication of patients with POAF will be compared with that of patients without POAF using Fisher's exact test. A relative risk will be calculated between subgroups (the rates of complications between patients with POAF and withoutPOAF).

Significance and outlook

This study is conducted to establish the baseline incidence of POAF in Vietnam and to assess the feasibility of implementing a simple POAF screening strategy in a low-resource setting. If deemed feasible, it could lead to large-scale multicentre studies investigating implementation and cost-effectiveness of the screening strategy in Vietnam. Ultimately, this screening strategy could be widely implemented in other similar low-resource settings.

Knowledge of baseline POAF incidence, and a feasible screening strategy could provide a platform to be able to repeat intervention studies aimed at POAF prevention in Vietnam, and potentially to trial novel interventions. In addition to its research focus, this study is expected to raise the awareness of clinicians and nurses about AF in general and POAF in particular.

Patient and public involvement

Patients and public were not involved in the design of the study. The results of the study will be made available to study participants through an information sheet that will be publicly available at the Cardiovascular Centre, E Hospital. This information sheet will summarise the results in lay language, written in Vietnamese.

ETHICS AND DISSEMINATION

Patients will be aware of the possible benefits and risks of participating into the study and that they can withdraw from the study at any stage without any changes to his or her usual care. All data will be extracted by the principal investigator. De-identified and stored data in an excel file which is password protected. Paper data forms will be kept in locked cabinet in the hospital by the principal investigator. All information about the patients will not be disclosed, except in case required by law. Study results will be widely disseminated via the usual forums including, but not limited to, peer-reviewed publications and presentation at local and international conferences.

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Contributors NTHL conceptualised the study, wrote the protocol and drafted the manuscript. VVB and NL assisted with the development of the study protocol and the manuscript. LTD and NCH: vice directors of the ICU and department of cardiovascular and thoracic surgery, respectively, contributed to the manuscript and provided great support with the training sessions and the conduction of this research. HTK facilitated me with the training sessions and he will help me with the data extraction and analysis after finishing data collection. BF critically revised the protocol, as well as the manuscript. All authors approved the final version of the manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Ethical approval was provided by the Scientific and Technological Board of Cardiovascular Centre, E Hospital on 28 September 2017.

Provenance and peer review Not commissioned; externally peer reviewed.

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