STUDY PROTOCOL

Project title

Early Diagnosis of Right Ventricular Dysfunction in High-Risk Cardiac Surgery Patients – A Pilot Study

Investigators

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Introduction

Right ventricular (RV) dysfunction or acute RV failure in perioperative and postoperative cardiac surgical care is associated with high morbidity and mortality [1]. Patients at particular risk include those with pre-existing RV dysfunction, pulmonary hypertension, procedures requiring prolonged cardiopulmonary bypass, and patients undergoing tricuspid valve surgery [2].

Accurate monitoring and therapeutic intervention algorithms for deterioration of pre-existing RV dysfunction or acute RV failure during surgery or in the early postoperative period remain limited, and relevant information in the international literature is relatively scarce [3]. In the preoperative period, some risk-scoring systems, such as the Parsonnet score or EuroSCORE II, include elevated pulmonary artery pressures as a perioperative risk factor. Perioperative diagnosis of RV dysfunction can be performed using transoesophageal echocardiography, including fractional area change (FAC), tricuspid annular plane systolic excursion (TAPSE), and three-dimensional measurement of RV ejection fraction. However, interpretation requires specific training and, even then, does not provide a complete assessment of RV function [4].

A standard Swan-Ganz catheter (also referred to as a pulmonary artery catheter) enables measurement of systolic and diastolic pulmonary artery pressures and calculation of mean pulmonary artery pressure. These measurements may provide information about RV afterload (pulmonary vascular resistance), but the standard catheter cannot simultaneously measure pressures within the right ventricle [5].

The new Swan-Ganz IQ™ pulmonary artery catheter (SGIQ), using an additional port positioned in the right ventricle and connected to the HemoSphere Alta monitor, enables sophisticated assessment of a broad range of RV performance parameters [6]. Measured parameters include systolic, diastolic, and mean RV pressure, cardiac output and RV cardiac index, as well as RV stroke volume (Figure 1). In addition, the slope of the RV pressure waveform during the diastolic phase of the cardiac cycle and its relationship to the pulmonary artery pressure waveform (Figure 2) may enable detection of RV failure at an early stage [7].



Figure 1. The HemoSphere Alta monitor

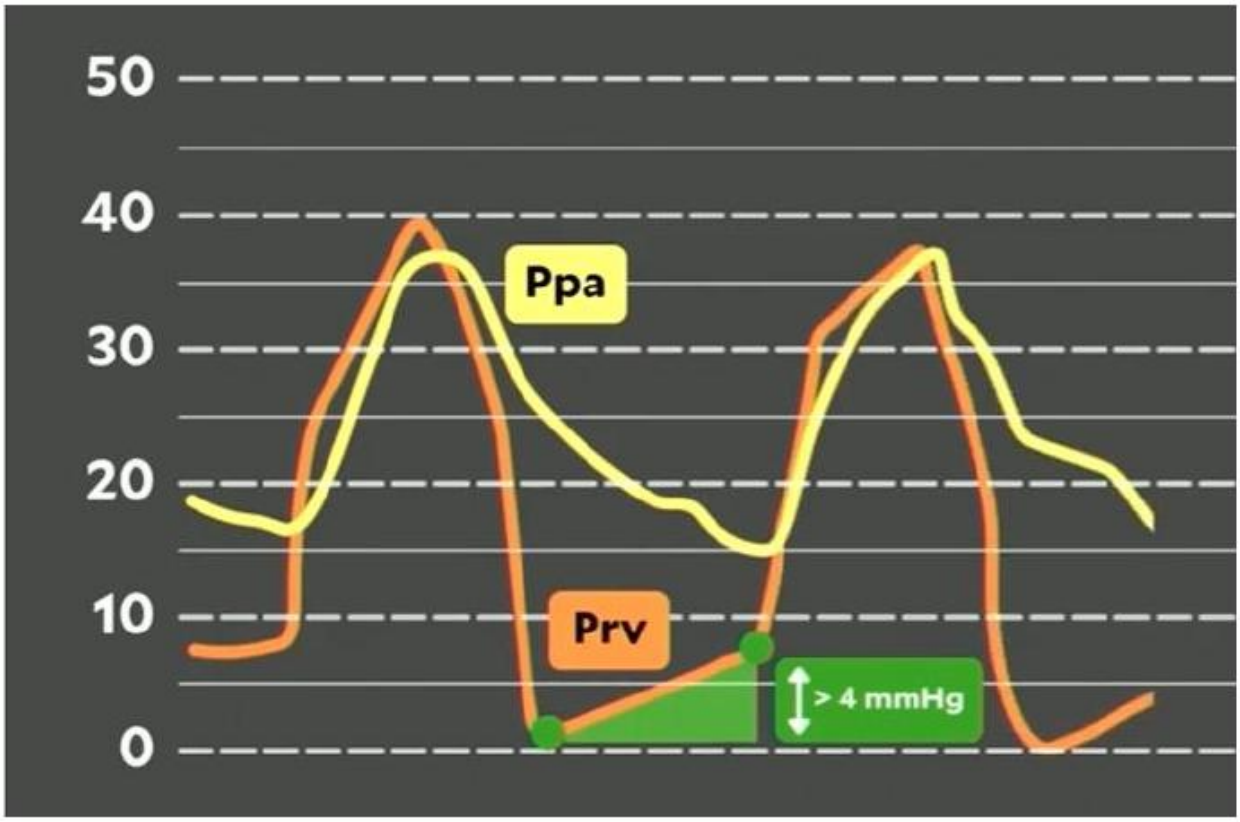


Figure 2. Alterations in the diastolic segment of RV pressure waveform in relation to RV dysfunction.

The technology is registered in the European Union; nevertheless, only limited data on its use in clinical medicine are currently available.

Wozolek et al. reported their experience in a cohort of 149 patients undergoing cardiac surgery, liver transplantation, or pulmonary endarterectomy (only four patients) [7]. The primary objective of that study was to determine whether technical acquisition of an RV pressure waveform was feasible. Failure occurred in only three patients (2%): in one patient because the catheter could not be advanced across the tricuspid valve, in another because of technical failure to position it in the pulmonary artery, and in the third because of difficult central venous access. Overall, detailed analysis of RV pressure waveforms was possible in 98% of patients.

The aim of the present study is to analyse changes in RV pressures in relation to pulmonary artery pressures and other haemodynamic parameters in cardiac surgery patients with predicted preoperative RV dysfunction or at risk of perioperative or postoperative RV dysfunction.

Figure 1. HemoSphere Alta monitor for comprehensive monitoring of right-sided cardiac parameters.

Figure 2. Changes in the shape of the diastolic portion of the right ventricular pressure waveform associated with right ventricular dysfunction.

Methodology

A total of 25 patients hospitalised at the 2nd Department of Surgery and the Department of Anaesthesiology, Resuscitation and Intensive Medicine, First Faculty of Medicine, Charles University and General University Hospital in Prague, will be enrolled in this prospective pilot study. Eligible patients will have confirmed RV dysfunction and an indication for cardiac surgery. These will include patients with pulmonary hypertension, patients scheduled for tricuspid valve surgery, and other patients with impaired RV function demonstrated by echocardiography or cardiac catheterisation. Only patients in whom comprehensive haemodynamic monitoring using a Swan-Ganz catheter is clinically indicated according to the standard decision of the attending anaesthesiologist, independently of participation in this study, will be enrolled.

Participation in the study entails no additional risk to the patient. The SGIQ is a CE-certified medical device registered for use in the Czech Republic. It is inserted in the same manner as a standard Swan-Ganz catheter, which is routinely used at our institution in all patients with the above indications. The only difference is the presence of an additional sensor positioned in the right ventricle. The study therefore involves no additional invasive procedure beyond standard care.

Following induction of general anaesthesia, a Swan-Ganz IQ catheter will be inserted through an introducer sheath into the pulmonary artery using the standard technique. In patients undergoing pulmonary endarterectomy, the catheter will be positioned in a pulmonary artery branch while maintaining an interpretable RV pressure waveform; in other patients, it will be advanced to the pulmonary artery occlusion (wedge) position.

The following parameters will be monitored continuously as numerical values and waveforms and subsequently stored as time-series graphs:

- Systolic, diastolic, and mean right ventricular pressure (RVP)
- Difference between early and late diastolic right ventricular pressure
- Right ventricular cardiac output (CORV) and right ventricular cardiac index (CIRV)

- Right ventricular end-diastolic pressure (EDPRV)
- Systolic, diastolic, and mean pulmonary artery pressure (PAP)
- Mixed venous oxygen saturation (SvO_2)
- Global hypoperfusion index (GHI)

Study objectives

The primary objective will be the technical success of catheter placement in the required position, allowing simultaneous interpretation of pressure waveforms from the right ventricle and pulmonary artery.

Secondary objectives will include correlation of RV dysfunction identified from changes in the RV pressure waveform with other parameters, including a decrease in mixed venous oxygen saturation (SvO_2) and an increase in lactate. Additional secondary objectives will include the incidence of technical and clinical complications, specifically:

- Failure of catheter insertion
- Serious cardiac arrhythmias
- Perforation of the superior vena cava or cardiac chambers
- Cardiac tamponade
- Dislodgement of the SGIQ catheter

Inclusion criteria

- Age >18 years
- Signed informed consent
- Planned cardiac surgical procedure
- Clinical indication for Swan-Ganz catheter insertion
- Right ventricular dysfunction confirmed by echocardiography or cardiac catheterisation

Exclusion criteria

- Contraindication to Swan-Ganz catheter insertion
- Thrombus in the right ventricle or right atrium
- Active tricuspid valve endocarditis
- Inability to obtain informed consent

Expected study timeline

Submission to the Ethics Committee of the General University Hospital in Prague – September 2026

Start of patient recruitment – October–November 2026

Completion of patient recruitment – May–June 2027

Data processing – July–September 2027

Statistical analysis

Given the cohort design of the study, demographic data and graphical time-series representations of changes in the monitored parameters will be recorded. Basic statistical methods will also be used to assess correlations between changes in right ventricular pressure waveforms and other parameters (Pearson correlation coefficient).

References

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