Official Title: **Pleth variability index (PVI) as a measure of volume status during transcatheter mitral valve repair**

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Study Protocol

The study aims (1) To measure the intraprocedural change in pleth variability index (PVI) during transcatheter mitral valve repair (TMVR) and 2. To compare PVI with left atrial pressure (LAP) prior to and after mitral clip deployment

The purpose of the study is to determine if pleth variability index (PVI) can be used during transcatheter mitral valve repair as a monitor of volume status and understand its importance as a noninvasive hemodynamic monitor by comparing it to invasive indices including left atrial pressure.

Transcatheter mitral valve repair in the form of MitraClip® is a safe and effective alternative to surgical mitral valve repair/replacement in patients with high operative morbidity and mortality risk. Successful MitraClip application depends on intraprocedural quantification of mitral regurgitation and left atrial pressure (LAP) monitoring. Large volumes of intravenous fluids administered during TMVR may result in significant changes in LAP and hemodynamics. Studies indicate that LAP measured immediately after transseptal puncture would be significantly different than LAP measured immediately prior to MitraClip leaflet grasping. The pleth variability index (PVI) is a noninvasive, dynamic index based on analysis of the respiratory variations in the plethysmographic waveform recorded transcutaneously by the pulse oximeter. Studies demonstrate that PVI is accurate in predicting fluid responsiveness in mechanically ventilated adult patients. In this study, we wish to measure PVI during TMVR and correlate with invasive indices such as left atrial pressure (LAP) and stroke volume variation. Our study hopes to provide a real-time non-invasive alternative to invasive indices to better guide fluid management and improve hemodynamics.

Transcatheter mitral valve replacement is becoming increasingly popular in the management of mitral regurgitation in patients with high operative morbidity and mortality. Accurate fluid management is key in hemodynamics in these patients. Current practice is to rely on invasive indices such as left atrial pressure which cannot practically be measured in real-time. Based on the principles of PVI, using this noninvasive modality can potentially change current practice during TMVR and improve patient outcomes with minimal risk.

Inclusion Criteria: Male and female patients with mitral regurgitation undergoing transcatheter mitral valve repair (TMVR) with Mitra-Clip at Henry Ford Hospital - Main Campus.

Exclusion Criteria: MitraClip procedure unsuccessful (defined as no clip deployment and/or procedural interruption due to complication), or patients in whom PVI monitoring was not performed due to technical issues.

Statistical Analysis Plan

Study design – Prospective cohort

Sample size – 30

The sample size was calculated based the on the correlation of delta PVI and delta LAP: the null hypothesis correlation of 0 and the alternative hypothesis correlation of 0.6 using a two-sided hypothesis test with a significance level of 0.05. The power was set at 0.8 and 0.95 to determine a possibly sufficient range for sample size. The results indicated that a minimum of 19 and a maximum of 30 were warranted. Thus, we plan to include a total of 30 patients for this study.

Masimo Radical-7® probe to be attached to patient's finger along with standard ASA monitors at the start of procedure. Intraprocedure LAP (v-wave and mean) to be recorded prior to and after MitraClip deployment. Data to be analyzed - age, sex, BMI; Preprocedure EF, PAP, rhythm, MR severity; HR, SBP, DBP, MAP every 5 minutes; SPV, PPV, PVI every 5 minutes; LAP prior to mitraclip deployment; LAP after mitraclip deployment

Patients baseline characteristic and clinical data will be summarized with mean, SD or median and interquartile range (IQR) for continuous variables, and frequency and proportion for categorical variables. The change for PVI, and LAP between pre and post will be calculated as delta PVI, delta and delta LAP, respectively. Spearman correlation coefficient will be used to study the correlation between delta PVI and delta LAP. A p-value<0.05 will be considered statistically significant.