

Bleeding in patients with severe Aortic STenosis: Methodology of a pilot prospective cohort study (BLAST)

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Background: Patients with severe aortic stenosis (AS) can develop acquired von Willebrand syndrome (AVWS). Patients with AVWS undergoing surgical aortic valve replacement (AVR) are at a higher risk of perioperative bleeding complications. Unfortunately, diagnosing AVWS is difficult as even specialized coagulation laboratory tests are poorly sensitive. Recent evidence suggests that a pre-operative bleeding history may be predictive of post-operative blood loss. We hypothesize that the self-administered bleeding assessment tool (self-BAT), a validated bleeding questionnaire in congenital von Willebrand disease, may be predictive of hemorrhagic complications peri-AVR.

Methods: We propose a pilot prospective cohort study to evaluate the feasibility of conducting a definitive, larger study of the predictive value of the self-BAT score for perioperative bleeding among patients undergoing AVR for severe AS. All patients with severe AS pending surgical AVR at St. Michael's Hospital (Toronto, Canada) will be evaluated for study eligibility. Participants will complete a modified self-BAT questionnaire pre-operatively. Analysis of coagulation parameters (VWF antigen, VWF:RCo, VWF:GP1bM, VWF collagen binding, VWF propeptide, VWF multimer analysis with densitometry, factor VIII, PFA-100) will be completed pre-operatively, and intra-operatively distal to the aortic valve. The primary feasibility outcomes are: number of identified eligible patients, recruitment rates, number of self-BAT questionnaires filled correctly, and number of patients who successfully completed the protocol. The secondary clinical outcomes include blood loss in the 24-hour post-operative period, measured as follows: i) major bleeding events, ii) cumulative chest tube losses, iii) total quantity of RBC units transfused, iv) total quantity of blood products, and v) amount of hemostatic medications. The self-BAT score will be correlated with secondary clinical outcomes.

Results: *In progress*

Conclusion: In patients with severe AS, AVWS can lead to increased peri-operative blood loss with surgical AVR. The self-BAT may be able to risk-stratify patients into high and low risk of peri-operative bleeding complications, which may allow for improved outcomes using targeted therapy.