Implementation of Direct Oral Anticoagulant (DOAC) Perioperative Interruption and Interval evaluation of the DOASENSE Dipstick performance

Background and Objective
As the use of DOACS increases, so does the need for interruption in patients requiring procedures, reaching up to 20%. We have addressed this with a standardized institutional interruption policy anchored on emerging data. The urine-based DOAC Dipstick is a novel testing option designed to deliver a real-time qualitative estimate of the presence of DOACs. We designed a trial testing the safety of a standardized interruption protocol and the accuracy of the DOAC Urine Dipstick for determination of DOACs' presence. We present our interim data safety and performance results.

Methods
A prospective, single cohort study currently undergoing recruitment of patients requiring DOAC interruption. Before-surgery DOAC level was tested with plasma Factor Xa inhibitor assay and urine was tested by DOAC Dipstick to correlate results in the interim analysis. We present continuous variables as median (SD) and categorical as percentages. Independent T-test, Cohen's Kappa, Chi-Square and Fisher exact test used as indicated.

Results
Thus far, a total of 79 patients have been recruited, 60.8% male and predominantly Caucasian (87.3%). Indication for anticoagulation was mostly atrial fibrillation (83.5%), followed by VTE 24.1%. Other comorbidities were hypertension 53.2%, cancer 34.2%, hyperlipidemia 24.1%, obstructive sleep apnea 22.8%, diabetes 19%, prior bleeding 19%, coronary artery disease 15.2% and cardiomyopathy 6.3%. Anticoagulants used were mostly Apixaban 72.2%, followed by Rivaroxaban 22.8% and Dabigatran 2.5%. Peri-procedural arterial events (stroke) occurred in 1 patient (1.3%), and VTE (pulmonary embolism) in 1 patient (1.3%) at 3 month follow-up. Two patients (2.5%) had major bleeding outcomes as defined by ISTH. Urine samples from 35 patients (44.3%) were analyzed using DOASENSE. Anti-Xa inhibition for patients with DOASENSE positive urine was significantly higher than those with negative DOASENSE dipstick results (10.90 ± 9.2 vs. 5.05 ± 5.36, p= 0.025) with fair correlation (kappa=0.342, p= 0.04).

Conclusion
Standardized periprocedural interruption of DOACs appears safe, simple to implement and was widely accepted institutionally. In interim analysis, DOASENSE results significantly associate with percentages of anti-Xa inhibition, with fair correlation between effective anticoagulation and dipstick results. Larger numbers are needed to validate this promising strategy.