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Trauma victims requiring dabigatran reversal with idarucizumab in RE-VERSE AD

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Background: Idarucizumab is licensed for dabigatran reversal based on the results of the RE-VERSE AD study, which showed rapid and complete reversal of dabigatran anticoagulation in patients presenting with severe bleeding (Group A), or in those requiring urgent surgery (Group B). Enrollment was based solely on the clinical decision to reverse anticoagulation. This analysis focuses on the outcomes in the cohort of trauma patients.
Methods: Trauma patients on dabigatran could be enrolled in either group in RE-VERSE-AD, whether for serious bleeding or for reversal prior to urgent surgery. All patients were given 5 grams of idarucizumab intravenously and the primary endpoint was maximum reversal of dabigatran anticoagulation in the first 4 hours, as measured by ecarin clot time or diluted thrombin time.
Results: Of the 503 patients enrolled in RE-VERSE AD, there were 114 trauma victims, 80 enrolled in Group A and 34 in Group B (Table). The most commonly documented mechanism of injury was fall from standing height, resulting in open or closed head injury or pelvic or hip fractures; 6 patients sustained high-impact polytrauma. Other injuries included fractured ribs, broken nose, and severed fingers. No trauma patient received more than one dose of idarucizumab, all patients had 100% reversal, and no drug-related adverse events were reported. Thrombotic events rates were low and consistent with the entire study cohort.

	Entered as Group A	Entered as Group B	Head trauma	Pelvic/hip fracture	Polytrauma	Other injuries
N	80	34	48	39	6	21
Median age (yrs)	80	81	82	82	72	76
Creatinine Clearance (mL/min)	54 (40-84)	64 (44-86)	55 (43-81)	57 (40-80)	82 (66-111)	49 (30-88)
% with CV comorbidity	96.3	88.2	95.8	92.3	83.3	95.2
Concomitant antiplatelet therapy (%)	16.3	8.8	14.6	5.1	33.3	23.8
Hemodynamic instability on presentation (%)	23.8	N/A*	2.1	62.5*	75.0*	47.6
Time since last dabigatran dose (hrs)*	15 (9-22)	21 (16-30)	14 (8-19)	20 (13-30)	15 (11-17)	21 (15-30)
Median dabigatran level at presentation (ng/mL)	74 (36-124)	61 (23-96)	70 (27-117)	74 (38-106)	52 (41-100)	74 (44-162)
Median hospital length of stay (days)	8 (5-20)	15 (7-35)	8 (5-15)	20 (8-36)	9 (7-15)	6 (4-10)
In-hospital mortality n (%)	9 (11.3)	2 (5.9)	7 (14.6)	3 (10.3)	1 (16.7)	0 (0.0)
Thrombotic events at 30 days, n (%)	5 (6.3)	1 (2.9)	4 (8.3)	1 (2.6)	0 (0.0)	1 (4.8)

All values are given as median (25-75% quartiles) unless otherwise stated, *patient reported, *only recorded in Group A patients, N/A not available, CI confidence interval

Conclusions: Regardless of mechanism of injury, age, comorbidity, renal status, hemodynamic stability, or group assignment, idarucizumab provided prompt, complete, and safe reversal of dabigatran-mediated anticoagulation, allowing treating clinicians to manage the complications of trauma without concern for iatrogenic coagulopathy.
Funding Acknowledgements: The study was funded by Boehringer Ingelheim

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Surgical left atrial appendage occlusion for stroke prevention compared with long-term warfarin therapy in patients with nonvalvular atrial fibrillation

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Background: Both left atrial appendage (LAA) transcatheter occlusion and surgical LAA occlusion are the alternative treatments for long-term warfarin therapy in the matter of stroke prevention in patients with nonvalvular atrial fibrillation. At present, several non-inferiority clinical trials have provided sufficient evidence for the comparison of LAA transcatheter occlusion and warfarin therapy. However, profound evidence through large-scale prospective studycomparing surgical LAA occlusion and warfarin therapy is still lacking.
Objectives: The goal of this study was to assess the safety and efficacy of surgical LAA occlusion for stroke prevention in patients with nonvalvular atrial fibrillation (NVAF) compared with long-term warfarin therapy.
Methods: This prospective cohort study assessed the efficacy and safety of surgical LAA occlusion compared with long-term warfarin therapy. 492 NVAF Patients with a CHADS2 (congestive heart failure, hypertension, age >75 years, diabetes mellitus, and previous stroke/ transient ischemic attack) score ≥1 were enrolled. Of these, 257 (52.2%) patients treated by surgical LAA occlusion (17 were lost to follow-up) and 235 (47.8%) patients treated by long-term warfarin therapy (14 were lost to follow-up) were clinically followed up for 2 years. A total of 31 people were lost, and the follow-up rate was 461/492 (93.699%).Two efficacy and two safety coprimary endpoints were assessed.
Results: The baseline data between the two groups were comparable [age 67.69±9.87, 67.68±9.84 years (P=0.992); CHADS2score2.05±1.05, 1.99±1.01 (P=0.525); CHA2DS2-VASc score3.02±1.38, 3.02±1.43 (P=0.991); HAS-BLED score1.84±0.831.88±0.86 (P=0.631)]. At 24 months, the rate of the first efficacy endpoint (composite of stroke, systemic embolism [SE], and cardiovascular/unexplained death) was 0.018 in the surgical group versus 0.043 in the warfarin group (HR 0.42 [95% credible interval (CrI): 0.19 to 0.93] p=0.033). The rate for the second efficacy endpoint (composite of stroke or SE >7 days' post-procedure) was 0.010 versus 0.032 (HR 0.30 [95% credible interval (CrI): 0.11 to 0.82] p=0.019). The rate of the first safety endpoint (surgery-related and surgery-irrelated hemorrhage)was 0.016 in the surgical group versus 0.044 in the warfarin group (HR:0.38; 95% credible interval (CrI): 0.17 to 0.87; p=0.022). The incidence of surgical complications in the surgical group was 1.167%.
Conclusions: This cohort study showed that surgical LAA occlusion was superior to warfarin in the matters of preventing stroke, systemic embolism [SE], and cardiovascular/unexplained death. The surgical group also had significantly lower bleeding risk. The incidence of surgical complications associated with LAA removal (pericardial effusion/chest wall hematoma/ surgery-related embolism) was low, and all of them occurred in the hospital without causing serious outcomes.

LEADLESS PACING

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Transformation in rotational atrial activity before and after PVI in patients with persistent AF

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Introduction: Pulmonary vein isolation (PVI) is an established treatment strategy to reduce the initiation of atrial fibrillation (AF). Recent advances in noninvasive mapping have allowed for the identification of patient specific bi-atrial AF drivers responsible for the perpetuation of persistent AF. The aim of this study was to evaluate the transformation of rotational atrial activity (RAA) before and after pulmonary vein isolation (PVI) in patients with persistent AF using a non-invasive panoramic mapping system.
Methods: Noninvasive mapping will be performed pre- and post-PVI to map and identify AF drivers in 13 patients with persistent symptomatic AF and resistant to at least one antiarrhythmic drug. Pulmonary veins will be isolated with the cryoballoon. Bi-atrial AF detections identified by CardioInsight will be targeted for contact-force controlled irrigated radiofrequency catheter ablation, but without any additional RF applications near the PV's. Local endpoints for AF detection ablation are, increasing local cycle length and transformation of fractionated, highly complex signals into simple, discrete signals. The Primary Clinical Endpoint of this study is termination of AF during the ablation procedure, after targeting bi-atrial AF detections identified by the non-invasive mapping system. All Patients will be followed for a total of 12 months, with the first 3 months considered the blanking period. Patients will receive 7-day Holter ECG monitoring every 3 months.
Results: To date, 13 patients with persistent AF (age 63 years, median uninterrupted AF duration before PVI 11 months, LA area 25 cm^2, RA area 19 cm^2), resistant to antiarrhythmic drugs (2±1) and to electrical cardioversion have been enrolled. In all patients RAA's could be observed nearby or inside the pulmonary veins but also in the left and right atrium. RAA's were eliminated inside and nearby the pulmonary veins after isolation with the cryoballoon. However, the RAA's outside the pulmonary veins were only slightly transformed. AF could be terminated during ablation in 12 out of 13 patients. RAA's at the posterior and inferior left atrium were the most common locations for termination of AF.
Conclusions: The study potentially shows insights in transformation of rotational atrial activity before and after pulmonary vein isolation in patients with uninterrupted atrial fibrillation >6 months before intervention. The impact of acute AF termination by ablation of rotational activities needs to be evaluated during the ongoing clinical follow-up.

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Transmural activation delay to predict fibrosis architecture with whole heart histology in patients with NICM and VT

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Background: Ventricular tachycardias (VT) in non-ischemic cardiomyopathy (NICM) are related to the amount and architecture of fibrosis. Transmural acti-