In age-adjusted Cox regression analyses, mrPRA levels (both classes or at least class I or II) were significantly associated with all-cause mortality (hazard ratio [HR], 95% confidence interval [CI] per 10% increase in PRA level: class I HR 1.03, 1.02–1.05, P<0.001; class II HR 1.02, 1.0–1.04, P=0.028), graft failure (class I HR 1.03, 1.00–1.05, P=0.042) and acute rejection (class II HR 1.07, 1.02–1.13, P=0.011) in the whole sample. pPRA levels were associated with all-cause mortality (class I HR 1.03, 1.01–1.05, P=0.0078) and CAV (class II HR 1.04, 1.01–1.07, P=0.0037) in the whole sample.
Significant sex interactions were seen for the association of class I and II pPRA with graft failure (P interaction 0.034 and 0.036, respectively) with a higher risk in women, and for class I pPRA with CAV (P interaction 0.016) with a higher risk in men.
Conclusions: Women had higher levels of mrPRA and pPRA at time of heart transplantation than men. Sex interactions were seen for the association of pPRA with graft failure and CAV. Whether sex-specific immunosuppression or closer surveillance may improve transplant-related outcomes needs to be shown.
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DRUG THERAPY IN CONGENITAL HEART DISEASE – WHAT ARE THE OPTIONS AND THE NEEDS?

6010
Thromboembolic prevention in adolescents and adults with Fontan circulation: Is ASS a therapeutical option in long-standing Fontan circulation?

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Background: The risk of thromboembolism increases with the duration of Fontan circulation. However, it is still discussed controversially, when to start preventive medication and which drug should be chosen.
Purpose: The aim was to characterize thromboembolism in long-standing Fontan circulation and to analyse whether in adolescents and adults Acetylsalicylic acid (ASS) is equipotential to Vitamin K Antagonists (VKA) to prevent this complication.
Methods: We analysed the data of 78 adolescents and adults (20.7±5.7 years; 51 male). Last medication and duration of therapy were documented, either prior to thromboembolism or up to the end of observation time. Perioperative events were excluded.
Results: 44 patients were on VKA, 15 on ASS, 19 remained without treatment. During a mean observation time of 8.1±5.6 years, 15 (19.2%) patients experienced thromboembolism. Nine patients had deep venous thromboses with resulting pulmonary embolism in five cases. Supraventricular tachycardia occurred in four cases, two presented with cerebral embolism, two with a thrombus within the Fontan tunnel. Isolated thrombus in the Fontan tunnel was diagnosed in two cases.
Time of Fontan circulation was significantly longer in patients with thromboembolism (25.6±8.3 years vs. 20.0±5.2 years). NYHA-class was worse (p=0.03). The risk of thrombotic events was significantly higher without treatment [OR 10.2 (95% CI 1.5–66.3)] and with ASS [OR 2.8 (95% CI 0.9–8.12)] than with VKA [OR 0.17 (95% CI 0.09–0.33)]. Kaplan-Meier analysis with Log-Rank test did not differ in lacking treatment versus ASS (p=0.2). Therapy with VKA was superior to lacking treatment (p<0.001) and ASS (p<0.001). VKA treatment was associated with three severe bleeding complications.
Conclusions: In adolescents and adults with Long-standin Fontan circulation, only anticoagulation provides sufficient protection against the frequent complication of thromboembolism. The observed small impact of ASS points to its known inability to prevent deep vein thrombosis and intracardiac thrombus formation in atrial fibrillation.

6011
Thromboembolism and bleeding in adults with congenital heart disease using non-vitamin K antagonist oral anticoagulants for thromboembolic prevention: a prospective worldwide observational study

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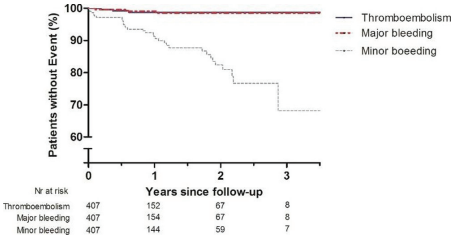
Background: Adults with congenital heart disease (ACHD) and atrial arrhythmias (AA) have high annual incidence of bleeding (4.4%) under the use of vitamin K antagonists (VKA). Non-vitamin K antagonist oral anticoagulants (NOACs) may be attractive alternatives, however, data on safety are lacking and adherence is of great concern due to lack of monitoring.
Purpose: The NOTE registry was designed to evaluate safety and adherence of NOACs in ACHD patients.
Methods: This is an international multicenter prospective study of ACHD using NOACs. Primary endpoints were thromboembolic events and major bleeding. Secondary endpoints were minor bleeding and sufficient adherence, measured with pharmacy interrogation (≥80% medication refill rate) and Morisky-8 questionnaire (≥6 out of 8).
Results: In total, 407 ACHD patients (mean age 45±16 years; 55% male; 11% complex; 43% moderate) using NOACs (34% apixaban; 5% edoxaban; 11% dabigatran; 44% rivaroxaban) were included. Indications of NOACs were mostly AA (88%). During 1.3±0.8years, three thromboembolic events (annual incidence 0.8% [95% CI 0.2–2.2]), all in complex defects (mean CHA_2DS_2-VASc 2 [range 0–3]) and three major bleedings (annual incidence 0.8% [95% CI 0.2–2.1]) in moderate/complex defects (mean HASBLED 0.6 [range0–1]) occurred. Annual incidence of minor bleeding was 10.1% [95% CI 7.1–13.8] (n=35), mostly occurring in complex defects (mean HASBLED 0.4 [range 0–3]). Adherence was sufficient at 1- and 2-year follow-up in 95% (n=41) and 93% (n=28) of patients by pharmacy interrogation and in 80% (n=69) and 91% (n=49) of patients by Morisky-8.



Event free Kaplan-Meier survival curves.

Conclusions: Annual incidence of thromboembolism and major bleeding were lower under NOACs than previously reported in ACHD using VKA. Adherence to NOACs was good and similar to previously reported VKA adherence. Risk of thromboembolism and bleeding seemed to be mostly related to defect severity.
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6012
Combination of fenestrated atrial septal occluder with targeted medical therapy in patients with secundum atrial septal defect and severe pulmonary arterial hypertension

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Background: In patients with secundum atrial septal defect (ASD) and severe pulmonary arterial hypertension (PAH), complete closure is generally contraindicated. Though targeted medical therapy has demonstrated efficacy on exercise capacity, the reduction of pulmonary vascular resistance (PVR) induces a further increase in left-to-right shunt, which leads to the worsening of right ventricular volume overload and progression of pulmonary vascular disease. The combination of fenestrated atrial septal occluder (F-ASO) and targeted medical therapy might have the complementary advantages, however, the related data are scarce.
Purpose: The study was carried out to investigate the combined use of F-ASO and targeted medical therapy in patients with ASD and severe PAH.
Methods: 27 consecutive ASD patients (5M/22F; age, 44.2±15.9 years) with severe PAH (resting PVR: 5–12 Wood units, the ratio of pulmonary to systemic blood flow ≥1.5 after targeted medical therapy) were referred for attempted transcatheter closure with F-ASO (the size of communication was 10 mm). Transcatheter closure of ASD was performed after the initiation of targeted medical therapy (ambrisentan+tadalafil for more than 3 months), which was continued postoperatively together with dual antiplatelet therapy (clopidogrel+aspirin for 6 months). The hemodynamic changes were compared between baseline, preoperative targeted medical therapy and partial closure of ASD with F-ASO. Follow-up was performed to evaluate the patency of communication, morphologic and hemodynamic outcomes.
Results: The size of ASD was 25.8±4.2 mm, resting systolic pulmonary arte-

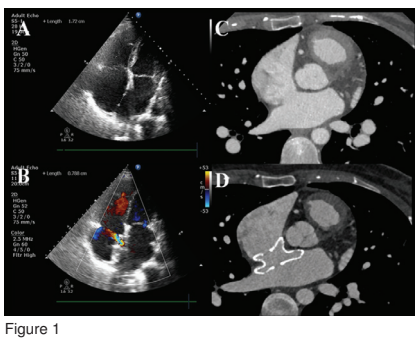

Figure 1