

Trombosi ed emostasi in età pediatrica

LONG TERM TREATMENT WITH VITAMIN K ANTAGONIST IN PEDIATRIC PATIENTS WITH PROSTHETIC HEART VALVE: THE BERGAMO EXPERIENCE

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Background and aims. Children with mechanical heart valve (MV) replacement require lifelong vitamin K antagonist (VKA) treatment in order to prevent systemic embolism; however the anticoagulation treatment predisposes patients to a substantial risk of bleeding. Clinical data on long term follow up in pediatric setting are lacking. The aim of this study is to retrospectively analyze the safety of long term VKA treatment in MV implanted children, from infancy to adolescence, at our centre.

Methods. We describe the characteristics and outcome, in terms of major bleeding and thromboembolic events, of our cohort of 8 pediatric patients with mechanical prosthetic heart valve. All patients used a point-of-care device for the determination of INR (International Normalized Ratio). INR levels were tested weekly or every two weeks. The Rosendaal method was used to calculate the Time in Therapeutic Range (TTR).

Results. Eight children (2 female and 6 male) underwent MV implantation from 2013 to 2024; the median age at the time of data collection was 9 (2-14) and the median follow up was 5 years (2-12). In 4 patients the valvular heart disease is part of a systemic syndrome (Down, Mucopolysaccharidosis, Myhre, VACTERL syndrome); the valve replacement involved the mitral valve in 5 cases, the aortic valve alone in 2 patients, and double replacement (aortic and pulmonary) in 1 patient. The mechanical valve implanted were all bileaflet valves made in pyrolytic carbon: the valves placed in the aortic position were all St.Jude Medical (SJM), whereas the prostheses implanted in the mitral position were the SJM in one case (the surgical intervention performed in 2013) and Sorin CarboMedics in the other ones. Warfarin was the VKA anticoagulant used by all patients; 6 of them used tablets and 2 the galenic preparation. Therapeutic range INR differed according to the valve position, between 2.5 and 3.5 for the mitral valves (except for 1 patient, between 2.5 and 3), between 2.5 and 3 for 1 aortic valve and the double valve replacement; and between 2 and 3 for the last aortic valve. The width of the range was 0.5 for 3 patients and 1 for the other 5; the narrow width is associated with worse TTR. The median TTR was 54.5% (0-89.2%), and in 50% of cases was >65%, which shows good compliance for the anticoagulant therapy. One exception was a patient in early childhood who reported the worst TTR. A total of 5 hemorrhagic events occurred during follow-up in half of the patients: 3 minor bleeds and 2 major gastrointestinal bleedings: these 2 events occurred in patients with mitral valve replacement and INR range 2.5-3.5. Temporary stop of oral anticoagulation was done. Both patients were less than 10 years old when the event occurred. With a total follow up of 47 person-years the incidence rate of major bleeding was 4,2% per year, while described warfarin-related major bleeding rates in pediatrics are from 0,5% to 1,7% per year. No patient had thromboembolic complications.

Conclusions. Anticoagulant treatment in pediatric patients with mechanical heart valve replacement is effective in preventing thromboembolic events but some concerns remains about safety. Improvement in surgical tecniques and materials and a constant interest in pediatric care are desirable.