Low intensive Anticoagulation ought to be regarded as a trusted concept for treatment of selected Medtronic Open Pivot Mechanical Heart Valves

Guido J. Van Nooten[1] MD, PhD, Thierry Bové[2] MD, PhD, Yves Van Belleghem[2] MD, Katrien François[2] MD, PhD, Frank Caes[2] MD, Michel De Pauw[2] MD, Yves Taeymans[2] MD, PhD.

[1] University Ghent, Belgium [2] Heart Center, University Hospital Ghent, Ghent, Belgium

Background: Since January 1993 the Medtronic Open Pivot Mechanical Heart Valve has been implanted routinely in the aortic position at the authors' institution. The study aim was to analyze, retrospectively, the 20-year clinical results of the prosthesis under a lowered anticoagulation regime.

Patients and Methods: Between January 1993 and December 2012 a total of 1,056 valves was inserted in the aortic position into consecutive patients. Patients in sinus rhythm, with good left ventricular function and without major vascular pathology (n=552) were prospectively kept in a lower INR regime of 1.5-2.5. Mean age of the patients was 58±11.7 years. Preoperatively, 38% of the patients were in NYHA class ≥III. Frequent co-morbidities included: hypertension (n=228), vascular arteriosclerosis (n=157) and coronary disease (n=114). The 99% complete follow-up totaled 5,521 patient-years (range 24-267 months).

Results: 90-day mortality was 0.7% (n=4, none valve-related). Survival at 10-years was 86% and 73% at 20-years. Of the 153 total deaths, 46 were cardiac and 16 valve-related. Multivariable Cox-regression analysis selected age as a continuous variable ($p<0.0001$, HR 0.064/year), emergency operations ($p=0.001$, HR 0.93), hypertension ($p=0.003$, HR 1.8), renal failure ($p=0.004$ HR 0.43), respiratory insufficiency ($p=0.005$, HR 0.55) and poor ventricular function ($p=0.019$, HR 0.02) as risk factors for death. Renal failure ($p<0.0001$) and hypertension ($p=0.003$) were considered risk factors for bleeding. Erratic INR ($p=0.001$) and vascular arteriosclerosis ($p=0.019$) were considered as a risk factor for thromboembolism.

Conclusions: This 22-year experience demonstrated excellent clinical outcomes with no structural valve failure. Odds ratio defined normotensive young patients as the lowest risk for adverse events. By contrast elderly age in combination with co-morbidities and instable anticoagulation yielded the worst long-term results.