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Randomized, prospective assessment of bioprosthetic valve durability. Hancock versus Carpentier-Edwards valves.

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BACKGROUND. Although the major limitation of porcine valves is their finite durability, no controlled clinical data exist regarding the relative durability of the two porcine bioprostheses implanted most commonly today, the Carpentier-Edwards (C-E) and Medtronic Hancock I (H) valves. METHODS AND RESULTS. To assess this question, 174 patients undergoing aortic (AVR) or mitral (MVR) valve replacement with a bioprosthesis between March 1980 and March 1982 were randomized to receive either a C-E or a H valve. There were 102 AVRs (54 C-E and 48 H) and 74 MVRs (39 C-E and 35 H). For both the AVR and MVR cohorts, the average patient age was 58 +/- 14 years (+/- SD). The male/female ratio was 2.2:1 for AVR and 0.57:1 for MVR. Clinical follow-up was undertaken periodically; the most recent follow-up closing interval was July through October 1992, and current follow-up was 96% complete. Cumulative follow-up totaled 1369 patientyears (mean, 7.7 +/- 3.6 years; median, 9.1 years; maximum, 12.0 years). The main focus of this analysis was bioprosthetic durability, using the AATS/STS guidelines defining "Structural Valve Deterioration" (SVD). Multivariate analysis revealed that (younger) age was the only significant (P = .024) independent predictor of SVD. Valve manufacturer (C-E versus H) and valve site (aortic versus mitral) did not emerge as significant independent risk factors for SVD. Actuarial rates (Cutler-Ederer) expressed as percent free of SVD (+/- SEM) at 10 years (n = number of patients remaining at risk) were 71 +/- 7% and 59 +/- 9% for the C-E (n = 26) and H (n = 17) groups, respectively, for the AVR cohort; for the MVR cohort, these estimates were 60 +/- 10% (n = 12) and 72 +/- 10% (n = 11), respectively, but these differences were not statistically significant (P = NS, Lee-Desu). CONCLUSIONS. After 10 years, there was no statistically significant difference in durability or other valve-related complications between the H and C-E aortic or mitral valves. Based on current information, the choice of a porcine bioprosthesis should be based on factors other than durability, including ease of implantation, hemodynamic performance, and cost.

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