Vascular Anastamosis Devices for CABG
Panel Meeting
March 18, 2004

Questions for Panel

Trial Design

1. Please comment on the choice of control in the clinical trial required to evaluate vascular anastomosis devices for CABG. The gold standard of sutured CABG anastomoses has a well documented history of over thirty years:

    a. Can historical data from sutured CABG anastomosis device trials be used as the control in the device studies?

    b. Alternatively, are concurrently performed CABG controls necessary given the multi-factorial causes of CABG failure, e.g. technical construction, extent and progression of native vessel disease, condition of conduit and progression of intima hyperplastic and atheromatous degeneration, and the introduction of drugs for mitigation of arteriosclerotic disease (CAD)?

    c. If these trial designs are inadequate, should randomized controlled clinical trials be performed?

2. With regard to device placement and device design, please address the following:

    a. Given the considerable differences between the proximal and distal CABG anastomoses, what, if any, differences in study criteria should be required?

    b. Are there certain aspects of the clinical study design (e.g. length of follow-up, endpoints) that should be required for all devices irrespective of device form and function? For example, the U-Clip performance closely duplicates that of a suture, whereas the Symmetry has greater similarity to a stent.

    c. It is rarely possible to determine the cause of conduit failure. Can you suggest criteria to determine whether a failure is device related?

3. Do you believe that the significant differences between an arterial conduit and a venous conduit warrant distinct study criteria and assessment for each? If so, please identify these criteria and analyses.

4. Should the primary effectiveness endpoint be graft patency alone, or include both graft patency and myocardial perfusion?

5. With regard to device safety, what criteria (i.e., acceptable adverse event rates as compared to that for suture) should be applied to the evaluation of device safety, as distinguished from device effectiveness, e.g., myocardial infarction, re-operations, neurologic events, incidence of aortic complications?

Endpoint Evaluation

6. With regard to appropriate patient follow-up:

    a. In view of the possible persisting risk of failure of some mechanical anastomosis sites, distinct from progression of native vessel disease, what duration of follow-up is advisable for pre-market evaluation?

    b. Should post-market follow-up be required to assess long term device effectiveness? If so, please define the appropriate length of follow-up after primary patency evaluation.

7. Can non-invasive measuring instruments, e.g., echocardiography, ultrafast spiral CT, MRA, EBT, etc., be used for primary assessment of graph patency or is angiographic follow-up necessary? And at what time points should patency be assessed?