Edwards Lifesciences

Initial Experience in Mitral Valve Repair using the Physio II Annuloplasty Ring

Steven Livesey
Consultant Cardiac Surgeon, Southampton General Hospital, Southampton, UK

The number of mitral valve repairs performed each year has more than doubled in the last decade. [1] There are many reasons for this, not least improvements in surgical education, but alongside greater awareness is the benefit of improved technologies. Prosthetic rings as adjuncts to mitral valve repair have evolved in many since the introduction of the original devices. The Physio II annuloplasty ring was introduced into the UK in March 2009. It has been developed primarily to accommodate the range of pathologies seen in degenerative mitral valve disease – in particular, the ratio of antero-posterior to transverse diameter is increased in the larger sizes to accommodate the larger anterior leaflet seen in Barlow valves.

The Physio II ring has four significant changes from the original Physio ring:

- the three anterior-posterior diameters (A1, A2, A3) increase progressively from size 36mm whereas in the original Physio ring the antero-posterior/transverse ratio was constant
- the saddle shape of the anterior part of the ring has been markedly increased; the posterior part of the ring has also been given a saddle shape, though this is not as pronounced
- the sewing cuff has been improved to facilitate suture placement (and also to avoid the occasional problem of suture fraying when inadvertently placed through the core)
- the retainer has been redesigned so the valve can be easily visualised through it and only one knife cut is needed to release it

In the year prior to the introduction of the Physio II ring I implanted either the original Physio ring or the Cosgrove Edwards Annuloplasty ring. My choice was largely determined by the degree of anterior leaflet pathology. Although my primary philosophy favoured using the complete, semi-flexible ring to aid the stability and longevity of the repair, I found that in some patients, the original Physio ring would not accommodate the enlarged anterior leaflet seen particularly in Barlow valves. So in patients who had excess tissue in the anterior leaflet, and hence a longer anterior leaflet height, I favoured the Cosgrove Edwards ring, which, because it is an incomplete ring, does not constrain the anterior leaflet and so avoided the potential for SAM.

In the year prior to the introduction of the Physio II, I performed 86 mitral valve repairs; I used 50 Cosgrove Edwards rings and 36 Physio. Since the Physio II was introduced I have performed 29 mitral repairs and implanted the Physio II ring in all of them. I have found that the diameters of the new ring accommodate the range of anterior leaflet pathologies – 10 of these repairs required neo-chordae for anterior leaflet prolapse. One patient had mild regurgitation post-operatively; the rest had either trivial or no MR. There were no incidences of SAM. However, surgeons used to the original ring should guard against oversizing the Physio II ring, particularly in larger valves.

So, in my practice, the Physio II does seem to provide a "one ring fits all" solution for the repair of degenerative mitral valves. If your philosophy is to favour a complete ring which re-shapes the annulus, believing that this provides the best chance of giving your patient a long-lasting mitral repair; then my initial experience with the Physio II is very encouraging.

Reference
1. Sixth National Adult Cardiac Surgical Database Report (2008). Demonstrating Quality. Ben Bridgewater and Bruce Keogh for the Society for Cardiothoracic Surgery in Great Britain & Ireland. Robin Kinsman and Peter Walton for Dendrite Clinical Systems

Subject specialty: Location **Time**

The risk of postoperative bleeding in patients receiving clopidogrel can be predicted using modified bed-side thromboelastography

Sergey Preisman, M.D,
Director of Cardiothoracic Anesthesia Unit, Sheba Medical Center, Tel Hashomer, Israel

Antiplatelet therapy with aspirin and clopidogrel is an integral part of cardiac surgery perioperative management, due mainly to the extensive use of implantable intravascular devices, and the proven efficacy of antiplatelet therapy in patients with unstable coronary syndromes. However, the use of these drugs in perioperative period carries certain risk. It is associated with a substantial increase in re-exploration rates, chest drain blood loss and blood product usage. Increase of postoperative bleeding caused by platelet dysfunction may have significant impact on morbidity, mortality and utilization of healthcare resources in cardiac surgery. This is why current clinical guidelines call for the cessation of clopidogrel therapy 5–7 days prior to surgery even in urgent cases, and the withdrawal of aspirin administration 2–10 days prior to elective surgery, even though it may constitute an increased risk of myocardial infarction in patients waiting for surgical myocardial revascularization.

Although it is widely known that in general population the response to antiplatelet drugs varies, and some patients exhibit resistance to their standard doses, no data were available regarding the prevalence of aspirin and clopidogrel resistance in patients undergoing coronary artery bypass. We hypothesized that the use of modified thromboelastography, point-of-care test designed for the assessment of the degree of inhibition of platelets' aggregation caused by aspirin and clopidogrel, may help in prediction of bleeding tendency in patients undergoing coronary surgery who have received antiplatelet therapy in preoperative period. We prospectively studied 59 patients undergoing coronary artery bypass treated with aspirin and clopidogrel before the surgery. 25 of these patients received aspirin alone. Modified thromboelastography with platelet mapping was performed immediately before the operation. Its results were concealed from the operating room staff, the intensive care unit team, and investigator collecting postoperative information.

After statistical analysis we were able to isolate 9 patients with excessive post-operative blood loss. These patients also used more blood products and had to stay more time in Intensive Care Unit. 8 out of them were treated by clopidogrel before surgery. However, remaining 26 of 34 patients receiving clopidogrel did not have bleeding tendency. Inhibition of platelet aggregation caused by clopidogrel and diagnosed by modified thromboelastography with platelet mapping discerned between bleeders and non-bleeders with sensitivity of 78% and specificity of 84%. Aspirin-induced platelet dysfunction did not reflect any bleeding tendency. 85% of all patients in our study were non-responders to standard dose of clopidogrel, and 44% to aspirin.

The results of our study suggest that quantification of patient response to antiplatelet therapy by means of this point-of-care test may help to individualize the surgical approach, facilitating more precise timing of the operation and prediction of the risk of microvascular bleeding. The prevalence of non-responsiveness to antiplatelet therapy including clopidogrel in patients undergoing coronary surgery is higher than in general population.

Sergey Preisman

Platelet mapping device