both echocardiography and MRI assessment) are promising signs. Furthermore, follow-up data collected beyond 12 months (range 14–36 months between ABPP and alternative xenograft materials) support the durability of the ABPP. Although direct comparisons should be treated with caution, our follow-up period is relatively close to the reported follow-up with other currently available xenografts yet we are still to observe intimal peel formation or stenosis, as seen in studies of those materials [17, 18]. Ongoing follow-up will continue in our cohort of patients to assess long-term durability of the ABPP.

This study was a non-randomized, single-centre experience with relatively small patient numbers, and the results should be interpreted in the light of this limitation. The device was tested without a control group and follow-up was incomplete over 12 months. There is the possibility that incomplete follow-up may add selection bias, which could have influenced the total outcome in graft calcification during that period. With regard to the characteristics of the ABPP, we also acknowledge that handling characteristics and surgeon-related quality are subjective measures and susceptible to operator bias. Nevertheless, in this initial experience, the ABPP consistently demonstrated appropriate characteristics, including thickness, flexibility and elasticity. The ADAPT™-treated bovine pericardium (CardioCel®) is currently under consideration for regulatory approval in a number of global markets. CardioCel is currently being used in Australia as part of a Therapeutic Goods Administration (TGA) authorized prescriber scheme for repair of congenital heart defects. The patch is not currently available in other regions. CardioCel® is expected to be launched by the Allied Healthcare Group Ltd. in the global market pending regulatory approval.

In summary, we have shown that in paediatric patients with a range of congenital heart deformations, followed for 12–36 months, the ABPP demonstrated durability, efficacy and favourable haemodynamic properties. No clinically significant calcification was observed, and there was no graft-related morbidity or mortality. The ABPP may provide a solution to the current need for durable, safe and effective implants within the context of the changing demographics of CHD.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the contributions of Stephen Brown and Coert de Vries. The authors also thank Brad Dalton for editorial assistance and Carla Prins for coordinating the administrative tasks.

FUNDING

This work was supported by Allied HealthCare Group Ltd.

Conflict of interest: W.M.L. Neethling is an advisory consultant of Celxcel Ltd., a fully owned subsidiary of Allied HealthCare Group Ltd. Geoff Strange is an advisory consultant for the Allied HealthCare Group Ltd.

REFERENCES


eComment. Autologous pericardium is superior to conventional bovine patch in congenital heart disease reconstructive surgery: an appraisal for tissue-engineered xenograft

Author: Giacomo Bianchi
Ospedale del Cuore “G. Pasquinucci”, Fondazione Toscana “G. Monasterio”, Massa, Italy.
doi: 10.1093/icvts/ivt368 © The Author 2013. Published by Oxford University Press on behalf of the European Association for Cardio-Thoracic Surgery. All rights reserved.

We have read with interest the paper from Neethling et al. about the use of an engineered bovine pericardial patch for reconstructive congenital heart surgery [1].

Congenital heart surgery requires patch material for the reconstruction of vascular structures or restoration of cardiac septation in the vast majority of interventions. From the outset, autologous and xenograft pericardium have been widely used and preferred over prosthetic materials because of their ease in both handling and shaping. Although autologous pericardium is readily available during primary correction of congenital heart defects, it is preferred over prosthetic materials because of their ease in both handling and shaping.
a considerable amount of available pericardium is required. Thus, bovine pericardium could provide an “off-the-shelf” solution with unlimited availability. Accordingly, the bovine pericardial patch has been extensively used over the last years, especially in congenital aortic arch surgery, due to its lower cost and virtual absence of the development of anti-HLA antibodies associated with the use of cryopreserved allograft material, although it was not superior to the other materials in terms of freedom from aortic arch restenosis [2].

The use of bovine pericardium also showed a tendency to be associated with re-intervention (HR 1.81; 95% CI 0.90-3.64) as demonstrated by Ashcraft et al. [3]. A recent comparison of the mechanical properties of materials used in the setting of aortic arch reconstruction, revealed that bovine pericardium is 16.4 times stiffer than the pathological aorta, while fixed human pericardium was only 7.1 times stiffer [4]. It is intuitive that in small calibre vessels, the compliance mismatch between the prosthetic material and the vessel itself could trigger abnormal intimal hyperplasia, eventually leading to restenosis or distortion.

In our experience, the use of autologous glutaraldehyde-fixed pericardium showed good results in terms of ease of use and tailoring, its availability even in redo cases, high haemostatic nature and low immunogenicity [5]. In our opinion, an autologous patch must be used when available, while only tissue-engineered bovine pericardium, as reported by Neethling et al. should be used, in order to minimize its aforementioned intrinsic problems.

Conflict of interest: none declared

References