DOI: 10.5114/kitp.2016.62607

Application of the CardioCel bovine pericardial patch – a preliminary report

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Kardiochirurgia i Torakochirurgia Polska 2016; 13 (3): 210-212

Abstract

Introduction: Animal pericardial patches are widely used in adult and pediatric cardiac surgery. A search is ongoing for a new material with optimal surgical properties that will reduce intraoperative bleeding and the occurrence of restenosis, calcification, and pseudoaneurysms in long-term observation. One product of interest is the CardioCel bovine pericardial patch.

Aim: Evaluation of the short-term results of CardioCel bovine pericardial patch implantation during pediatric cardiac surgery.

Material and methods: The study included 8 patients who underwent surgical correction of congenital cardiac defects between January 2015 and February 2016. Pericardial patches were used to repair supravalvular aortic stenosis and reconstruct the aortic arch and pulmonary arteries. The age of the patients ranged from 10 days to 14 years.

Results: There were no hospital deaths. The new material exhibited satisfactory durability and elasticity during surgery, facilitating optimal adaptation of the patch to the patient's tissues. No significant bleeding was reported from the suture site. The median duration of follow-up was 58 days. During the follow-up, there were no symptoms of pseudoaneurysm formation, patch thickening, or calcification in the areas where the pericardial patches were implanted. No clinical or laboratory symptoms of infection were observed in locations where the new material was applied.

Conclusions: Satisfactory surgical properties of the patch were observed intraoperatively. Positive results using the new pericardial patch were obtained in short-term follow-up.

Key words: pericardial patch, aortic arch, stenosis.

Streszczenie

Wstęp: Zwierzęce łaty osierdziowe znajdują obecnie szerokie zastosowanie w kardiochirurgii dorosłych oraz dzieci. Trwa poszukiwanie materiału, który będzie cechował się optymalnymi właściwościami chirurgicznymi, ograniczy krwawienia śródoperacyjne oraz powstawanie ponownych zwężeń, zwapnień i pseudotętniaków w okresie odległym. Jednym z interesujących produktów jest wołowa łata osierdziowa CardioCel.

Cel: Wstępna ocena wykorzystania łaty osierdziowej CardioCel u pacjentów pediatrycznych poddanych korekcji wrodzonej wady serca wymagającej zastosowania implantu do poszerzenia operowanych struktur.

Materiał i metody: Badaniem objęto 8 pacjentów, którzy zostali poddani korekcji wrodzonej wady serca od stycznia 2015 do lutego 2016 r. Łatę wykorzystano do plastyki zwężenia nadzastawkowego aorty, plastyki łuku aorty oraz tętnic płucnych. Wiek pacjentów wynosił od 10 dni do 14 lat.

Wyniki: Nie odnotowano zgonów wewnątrzszpitalnych. Śródoperacyjnie stwierdzono zadowalającą wytrzymałość oraz elastyczność nowego materiału, co umożliwiało jego optymalne dopasowanie do tkanek natywnych. Podczas operacji nie obserwowano istotnego krwawienia z miejsc wszywania łaty. Mediana czasu obserwacji wynosiła 58 dni. Podczas wstępnych obserwacji nie stwierdzono tętniaków, pogrubienia łaty oraz procesu kalcyfikacji w miejscach wszycia implantu u wszystkich pacjentów. Nie odnotowano klinicznych oraz laboratoryjnych objawów infekcji mogącej mieć związek z implantacją łaty.

Wnioski: Śródoperacyjnie zaobserwowano zadowalające właściwości chirurgiczne łaty. Wykazano pozytywne wyniki z wykorzystaniem nowego implantu podczas wczesnych obserwacji.

Słowa kluczowe: łata osierdziowa, łuk aorty, zwężenie.

Introduction

Pericardial patches made from animal tissue have a wide range of applications in various fields of surgery including vascular and general surgery, urology, and cardiac surgery. Some noteworthy applications of pericardial patches in cardiac surgery include the reconstruction of the

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Received: 31.05.2016, **accepted:** 22.07.2016.

aorta and pulmonary vessels, closure of interatrial defects, closure of interventricular defects, and reconstruction of atrioventricular valves [1–3]. Their advantages include the ease with which they can be obtained and used as well as the fact that they are associated with less intraoperative bleeding from the suture line in comparison with artificial materials [1, 4, 5]. The disadvantages include the development of secondary stenosis at the suture site (resulting from fibrosis and calcification), the possibility of aneurysm development, and, often, high prices of the products [5]. Many implants are available on the market: biointegral pericardial patches, the bovine collagen membrane Tutopatch, and the equine pericardial patch from Edwards Lifesciences. One of the newest products on the market is the bovine pericardial patch CardioCel, distinguished from the other available products by the fact that glutaraldehyde is not used during its processing.

Aim

The aim of this report is to provide preliminary analysis of the effects of the CardioCel pericardial patch in pediatric patients undergoing congenital heart defect correction requiring the use of the implant.

Material and methods

The study included 8 patients who underwent repair of congenital heart defects under extracorporeal circulation and were implanted with CardioCel pericardial patches during the period between January 2015 and February 2016. The age of the patients ranged from 10 days to 14 years. The patients underwent three types of procedures: aortic arch reconstruction, repair of supravalvular aortic stenosis, and pulmonary artery reconstruction. The demographic details of the patients and the types of procedures are presented in Table I.

The study employed data originating from the patients' medical records, operative protocols, and the local hospital database, as well as results of echocardiography, angiography, and computed tomography (angio-CT).

The patch

Intraoperatively, the patch required no further preparation. After being taken out of the container, it was ready to be used.

Its mechanical endurance was found to be satisfactory: the sutures held without rupturing the graft, and the implant's elasticity facilitated optimal adaptation of the patch to the native tissue. No significant bleeding from the suture site was observed during the procedures. Perioperatively, there were no clinical or laboratory signs of infection that could be associated with the patch implantation.

Results

There was no in-hospital mortality; all the patients included in the study were alive at the conclusion of the follow-up. The length of hospital stay ranged from 8 to 58 days (median: 15 days). The observed complications included: pneumonia in 2 patients, vocal cord paralysis in 2 patients, and paralysis of the left diaphragmatic dome in 1 patient (which necessitated a plication procedure during the same hospitalization).

The postoperative follow-up lasted from 14 to 219 days (median: 58 days). During this time, no aneurysms, patch thickening, or calcification at the suture site occurred in any of the patients. There were no clinical or laboratory signs of infection that could be associated with the patch implantation.

In 2 patients, stenosis was observed at the suture site. In the patient with aortic arch hypoplasia, atrioventricular septal defect, and Down's syndrome, the stenosis at the suture site was observed from the first days after the procedure performed to widen the aortic arch. Follow-up transthoracic echocardiography revealed no signs of coarctation at the suture site; the mean flow velocity in the aortic arch was 3.0 m/s, and the flow in the abdominal aorta corresponded with the arterial flow. In the patient who underwent repair of supravalvular stenosis of the ascending aorta and reconstruction of the pulmonary trunk and right pulmonary artery, increasing stenosis is observed at both

Tab. I. Characteristics of patients, types of procedures, and application of pericardial patches

No.	Gender (M/F)	Age [days]	Body mass [kg]	Diagnosis	Type of procedure with pericardial patch implantation
1	F	50	3	HAA, VSD, MV stenosis	HAA correction (patch) + VSD correction + TV plasty
2	M	55	2.9	HAA, VSD	HAA correction (patch) + VSD correction
3	M	50	3.5	HAA, aberrant LSCA	HAA correction (patch) + aberrant LSCA correction
4	F	5088	47	VSD, post PAB, LPA stenosis	LPA and PA plasty (patch), VSD correction, TV plasty
5	M	10	2.9	ToF, LPA stenosis	Central anastomosis, LPA plasty (patch)
6	M	4620	62	Supravalvular AS	Plasty of supravalvular AS (patch)
7	M	201	7.9	Supravalvular AS, supravalvular PS, RPA stenosis, Williams syndrome	Plasty (patch) of supravalvular AS, supravalvular PS, and RPA
8	F	38	3	HAA, AVSD, Down syndrome	HAA correction (patch) + PAB

HAA – hypoplastic aortic arch, VSD – ventricular septal defect, PAB – pulmonary artery banding, LPA – left pulmonary artery, RPA – right pulmonary artery, TV – tricuspid valve, AS – aortic stenosis, ToF – tetralogy of Fallot, AVSD – atrioventricular septal defect, PS – pulmonary stenosis, LSCA – left subclavian artery

suture sites (MVF 4.5 m/s in the ascending aorta and MVF 3.3 m/s in the pulmonary vessels). No significant clinical consequences of the stenosis were observed in either of the patients; both remain under out-patient observation.

Discussion

The use of bovine pericardium has many applications in both adult and pediatric cardiac surgery [1–4]. Many cardiac surgeons use it, appreciating the wide selection of implants and their potential advantages. Currently, a search is ongoing for a material that will have optimal surgical properties and will limit the occurrence of complications such as secondary stenosis, intraoperative bleeding, infections at the suture site, and aneurysm development [5–7].

This report presents preliminary experiences with the use of a next-generation acellular bovine pericardial patch – CardioCel. According to the manufacturer, the patch can be used for intracardiac defect corrections, atrioventricular valve reconstruction, or vascular repair. Neethling *et al.* demonstrated satisfactory results of using the patch for correcting intracardiac defects and performing vascular reconstruction in a group of 30 children [8]. Favorable properties of the patch as a potential material for valve reconstructions have been demonstrated in an animal model [9]. Mazzitelli *et al.* were the first to report the use of CardioCel for reconstructing the aortic valve in 3 pediatric patients, with good results [10]. The abovementioned reports present successful preliminary results, but are limited by small sample sizes and short follow-up periods.

Conclusions

In our material, the patch was employed to reconstruct the aorta and pulmonary arteries. Satisfactory properties of the patch were observed intraoperatively. The use of the patch was associated with positive results according to the preliminary observations made at our center; however, precise analysis requires studies on larger patient samples and with longer periods of follow-up.

Disclosure

Authors report no conflict of interest.

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