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Work in progress report - Congenital Resternotomy in pediatric cardiac surgery: CoSeal[®] initial experience

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Abstract

Sternal re-entry adds supplementary risk to cardiac re-operations and it may represent the most important factor in the entire hazard estimation. A new anti-adhesive substance, based on a polyethylene glycol material, has been proposed to solve this problem. Results and surgical observations at chest re-entry in five patients treated with this synthetic polymer are herein discussed.

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Keywords: Pediatric cardiac surgery; Reoperation; Pericardial adhesions

1. Introduction

Staged procedures to treat complex variants of congenital heart disease are more frequently used due to survival improvements in neonatal cardiac surgery. Therefore, an increasing number of patients will require repeat sternotomy during childhood [1]. Pericardial adhesions can severely complicate re-operations by making re-entry hazardous, impeding orientation and visibility, increasing the amount of blood loss, and prolonging the operation time [2]. For these reasons, many technical variations and anti-adhesive materials have been proposed in recent years. Expanded polytetrafluoroethylene (PTFE) (Gore-Tex, W.L. Gore & Associates, AZ, USA) pericardial membrane or sodium hyaluronate and carboxy-methylcellulose membrane (CV Septrafilm, Genzyme, Cambridge, MA, USA) are some anti-adhesive materials now regularly used in pediatric cardiac surgery [3–5]. A different approach to the problem is being offered with an in situ-forming polyethylene glycol material (CoSeal[®], Baxter Biosurgery Europe, Germany). We report our preliminary experience in five patients re-operated after treatment with this product.

2. Patients and methods

Since March 2005 we have used an in situ-forming polyethylene glycol (PEG) material (CoSeal[®], Baxter Biosurgery Europe, Germany) on some patients scheduled for staged surgical procedures. Thirteen patients were selected for CoSeal[®] administration at operation. Six patients had tetralogy of Fallot, two with pulmonary arteries discontinuity, six had single ventricle variants and one had pulmonary atresia-intact ventricular septum (PA-IVS). Mean age at operation was 30 months (range: 5 days–370 months, median 17 days). Surgical procedures were: modified Bla-

lock-Taussig shunt (MBT) with PTFE conduit in seven cases, re-establishment of pulmonary arteries continuity in two (associated with a transannular patch in one case), bidirectional cavo-pulmonary anastomosis in two, pulmonary artery banding in one and Norwood operation in one. Two patients had undergone previous surgery. Before sternal closure a thin layer of CoSeal[®] was homogeneously sprayed in the mediastinum covering the visible surface of the heart and great vessels.

A subtle gel membrane was recognizable shortly after. One neonate who underwent MBT shunt for PA-IVS received 4 ml of CoSeal before sternal closure and experienced cardiac tamponade eight hours after the operation, due to CoSeal[®] increase in volume.

Since then we have carefully followed a body-weight related dosage protocol to avoid mechanical compression of the heart due to a four times swelling of material volume after being sprayed (Table 1).

No other substance administration related problems have been observed.

The remaining patients' postoperative course was uneventful and they were all discharged after a mean hospitalization of nine days (8–11). After a mean period of nine months (8–14) five of these patients (two males) were readmitted to complete the surgical program. Diagnoses were: tetralogy of Fallot in four cases, two with pulmonary artery discontinuity, and single ventricle variant in one. Previous procedures were: modified Blalock-Taussig 3.5 mm PTFE shunt (=4), transannular patch (=1). In two patients pulmonary arteries continuity establishment was associated. All procedures but one were carried out without cardiopulmonary bypass.

No additional measures were undertaken to prevent cardiac or great vessels damage and no patient underwent femoro-femoral cardiopulmonary bypass before sternal re-opening. The xiphoid appendage was dissected free and the posterior aspect of the sternum was exposed as far as

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Table 1
CoSeal body weight related dosage protocol

Patient weight	CoSeal dose
<3 kg	1 ml
3–10 kg	1–2 ml
> 10 kg	2–4 ml



Fig. 1. Thin retrosternal membrane of connective tissue.

possible before sternal splitting by an oscillating saw. A thin and fragile layer of connective tissue was recognizable under the posterior aspect of the sternum (Fig. 1); underneath this membrane, the heart was almost completely free from adhesions to the pericardium. Sporadic light adhesions were present at the level of the atria and the great arteries (Fig. 2) and the dissection was easily carried out with electrocautery or with gentle traction on the cardiac structures. Dissected tissues were poorly vascularized, therefore bleeding was nearly absent. All the cardiac and mediastinal structures were clearly recognizable, hence contributing to a significant reduction in the length of the operation.

In order to obtain an objective quantification of the adhesions, a score of tenacity was graded on a three-point scale: filmy and avascular (0), dense and/or vascular (1), cohesive (2). Seven regions were evaluated in each patient.



Fig. 2. Sporadic light adhesion at atrial level.

The total score was 0 in two patients, 1 in two and 2 in the remaining patient.

Sternal re-opening was absolutely comparable to primary sternotomy in each patient of this short series irrespective of the use of cardiopulmonary bypass at the previous surgery

Postoperative courses were completely uneventful in each case.

3. Discussion

It is not clear whether sternal re-opening adds risk to the operation or not. According to Follis and colleagues [6], the risk of catastrophic hemorrhage during sternal re-entry is not easy to be estimated and it is often underreported. It may be approximated to 0.5%–1% with an associated mortality of 21%. The presence of a conduit is the only risk factor for catastrophic hemorrhage that has conclusively been demonstrated.

On the other hand, Russell and colleagues [1] reported on 165 patients who had undergone 192 repeat sternotomies. Hospital mortality was 2.6% compared to 3.8% of a control group. Cardiac laceration occurred in 10 of 192 re-operations (5.2%). Nevertheless, the rate of complications and the overall 120-month survival was not significantly different between the two groups [1].

We believe that chest re-entry might constitute an additional risk to the operation and indisputably it leads to a sensibly longer operation time.

Consequently, a number of pericardial substitutes and/or barrier materials have been developed and proposed to facilitate chest re-entry minimizing either patients' risk and wasting time. The ideal barrier should prevent necrosis, dryness and inflammation and should not increase risk of infection. Moreover, it should be easy to position, possibly with no sutures, and it must not structurally restrict the heart.

PTFE membrane is currently one of the most commonly utilized pericardial substitutes and it is very effective in preventing heart injury during re-sternotomy by creating a retrosternal barrier [5]. However, this material provokes a foreign body reaction leading to more tenacious adhesions all around the heart [7]

The CoSeal® is a synthetic hydrogel consisting of two solutions of high molecular weight of poly ethylene glycol in a liquid sodium phosphate buffer. This sprayable polymeric matrix was originally developed and used as a vascular sealant in cardiac surgery. It offers two advantages: a sealant attribute that can be useful in preventing and minimizing serous leakage from prostheses or bleeding in general, and it is very effective in reducing pericardial adhesions so that re-sternotomy can be performed without the risk of heart trauma. In our experience, it was very effective in both actions: as a sealant at first operation and preventing adhesions at reoperation.

The positive impression coming from our initial experience seems to confirm the data reported by Konertz et al. [8] who reported the use of CoSeal® on 16 patients scheduled for sternal reopening.

In conclusion, the problem of reoperation in pediatric cardiac surgery is very important and the initial results of

this new antiadhesive material are rather promising. Greater experience is mandatory to include CoSeal® among the substances that are now regularly in use.

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