



POLYMERIC SEALANT (COSEAL) IS IT WORTH IN CONGENITAL HEART SURGERY

Amit Mishra*, Hardik Patel, Komal Shah, Manish Hinduja, Vivek Wadhawa, Pratik Shah, Himani Pandya, Jigar Patel, Jigar Surti

U.N.Mehta Institute of Cardiology and Research Center, (Affiliated to B.J.Medical College), Civil hospital Campus, Asarwa, Ahmedabad-380016; Gujarat, India.

Corresponding Author:- Amit Mishra
E-mail: drmishraamit@yahoo.com

Article Info

Received 21/07/2015

Revised 27/07/2015

Accepted 02/08/2015

Key words: Sealant, Congenital heart surgeries, Post-operative outcome.

ABSTRACT

Our institute being a tertiary referral center in western part of India, we perform nearly 400 neonatal cardiac surgeries every year. The prospective study was designed to look for the effectiveness of the polymeric sealant (CoSeal) in controlling bleeding, and adhesion prevention, in the neonatal congenital heart diseases. From January 2013 to April 2015, 98 patients who underwent various congenital heart disease surgeries were included in the study. The sprayable polymeric matrix - Coseal surgical sealant was electively used in 57 patients (group 1) undergoing arterial switch, norwood and complex neonatal arch repairs. In group 2 no surgical sealant was used and 41 patients from surgeries apart from group 1 were enrolled. The groups were compared for demographic, pre-operative, operative and post-operative characteristics. The results showed better intra- and post-operative outcome in group 1 patients as compare to group 2 patients, which was statistically significant ($p < 0.05$). Amongst operative parameters, mean CPB time (162.67 ± 49.05 vs 182.29 ± 40.84 min) and aortic cross clamp time (125.72 ± 34.8 vs 147.12 ± 58.67 min) were significantly lower in patients where sealant was used. Post-operative complications namely - incidence of leaving the chest open (19.64%), greater days of ventilation (4.43 ± 2.86 days), higher ICU stay duration (10.07 ± 5.8) and hospital stay (14.02 ± 6.12 days) were more prevalent in group 2 patients. The use of polymeric sealant has helped us in improving our overall results of congenital surgeries as well as in reducing post-operative morbidity, complications and the overall cost of surgery.

INTRODUCTION

Our institute being the tertiary referral center of the western part of the country, the incidence of neonatal complex heart surgeries at our institute is high. The majority of our neonatal surgeries are for pulmonary atresia, obstructed total anomalous pulmonary venous connection, transposition of great arteries and hypoplastic left heart syndrome. The present study was designed to improve our overall results of neonatal complex surgeries, prevent bleeding, reduce time of ventilation, ICU stay, and hospital stay and to make the procedures cost effective. The arterial switch, norwood and complex neonatal arch repairs are the early infantile operations being performed at our

institute, where extensive suture lines and prolong bypass time are involved. Hence the Sealant was selectively used in these patients and the results are compared with the patients where the CoSeal sealant was not used [1].

MATERIAL AND METHOD

From January 2013 to April 2015, 57 patients of age ranging from 4 days to 3 years underwent arterial switch of these 31 patients had transposition of great arteries with intact ventricular septum, 15 patients had transposition of great arteries with VSD and nine patients had taussing-bing anomaly. Two patients underwent



Norwood operation. All patients were operated by a single surgeon. The CoSeal sealant (Angiotech Biomaterials Corp, Palo Alto, CA, USA; manufactured and distributed by Baxter Healthcare, Deerfield, IL USA) [6] was electively used in all the above patients who were enrolled in group 1.

The 41 patients of age ranging from 6 days to 4 years who underwent arterial switch operation from the January 2007 to December 2011 were randomly selected (group 2) of these 20 patients had transposition of great arteries with intact ventricular septum and 21 patients had transposition of great arteries with VSD. Three of these patients had additional aortopulmonary window and 5 patients had Taussingbing anomaly. The demographic, pre-, intra- and post-operative details of the patients were collected [2-4].

The standard technique of cardiopulmonary bypass with aortic and single venous cannula for TGA with intact ventricular septum and bi-cavalvenous cannulation for Taussing-bing and patients with transposition of great arteries with VSD were used.

The sprayable polymeric matrix, CoSeal surgical (CoSeal) Sealant was granted marketing clearance by the U.S. Food and Drug Administration (FDA) in 2001 and is indicated for use in vascular reconstructions to achieve adjunctive homeostasis by mechanically sealing areas of leakage. The Technique of preparation and use of high pressure Sealant was given in detail by John A Eleftheriades et al [5]. The CoSeal was electively used in patients who underwent arterial switch operation at the time before completion of procedure (before removing the cross clamp) when operative field was relatively dry which is one of the requirement for the sealant to be effective. We prefer to

close Patent Foramen Ovale (PFO) on a brief period of circulatory arrest especially in the patients of TGA with intact septum and this was the time when the sealant was used. We make sure that the operative field remain dry for the period of 2 minutes [6].

RESULTS

It was observed minimal incidence of bleeding in post-operative period and lower the incidence of primary chest closure (80.70% vs 39.02%) was observed. Similarly the duration of mechanical ventilation in group 1 was 4.43 ± 2.86 days as compared group 2 where the incidence of mechanical ventilation was 7.02 ± 3.86 days. The average number of days stay in ICU in group 1 was 10.07 ± 5.8 where as in group 2 it was 12.56 ± 5.23 days. The total number of days spent in Hospital was 14.02 ± 6.12 in group 1 compared to group 2 where hospital stay was 17.18 ± 8.94 days. A higher incidence of wound infection was observed in group 2 (7.32%) as compared to the group 1 (1.75%). One of our patient required re exploration on day five because of supravalvular pulmonary stenosis due to chunk of glue between the aorta and pulmonary artery which was comprising main pulmonary artery. This patient had smooth recovery following re-exploration.

The overall cost of surgery cannot be statistically analyzed due to constantly varying cost of disposable, consumable, inotropic and due to changing antibiotics protocols at institute. Hence it was not possible to analyse the exact cost of the procedure but we believe with the use of CoSeal sealant there was significant decrease in post-operative morbidities and hence is thought to reduce the overall cost.

Table 1. Demographic and preoperative characteristics of the study population BMI-Body Mass Index, CPB- Cardiac Pulmonary Bypass, ICU-Intensive Care Unit

| Variables | | CoSeal Sealant [N-57] | Control [N-41] | P Value |
|--|--------|-----------------------|--------------------|---------|
| Gender | Male | 49(85.96) | 23(56.10) | 0.0021 |
| | Female | 8(14.04) | 18(43.90) | |
| Age (days) | | 55.58 ± 57.67 | 56 ± 37.74 | 0.9676 |
| Weight(kg) | | 3.2 ± 0.8 | 3.63 ± 1.64 | 0.0912 |
| BMI | | 11.85 ± 2.18 | 12.01 ± 2.20 | 0.7218 |
| Pre-operative characteristics | | | | |
| Emergency | | 15(26.79) | 7(17.07) | 0.0842 |
| Intra operative characteristics | | | | |
| CPB time (minutes) | | 162.67 ± 49.05 | 182.29 ± 40.84 | 0.0391 |
| Aortic cross clamp time (minutes) | | 125.72 ± 34.8 | 147.12 ± 58.67 | 0.0446 |
| Post-operative characteristics | | | | |
| Leaving chest open | | 11(19.64) | 25(60.98) | <0.0001 |
| Re-exploration | | 3(5.36) | 6(14.63) | 0.2187 |
| Wound Infection | | 1(1.75) | 3(7.32) | 0.3923 |
| Days of ventilation | | 4.43 ± 2.86 | 7.02 ± 3.86 | 0.0002 |
| Duration of ICU Stay | | 10.07 ± 5.8 | 12.56 ± 5.23 | 0.0315 |
| Hospital Stay (Days) | | 14.02 ± 6.12 | 17.18 ± 8.94 | 0.0404 |



DISCUSSION

Every year nearly 600 patients undergo complex congenital heart surgery at our institute. Nearly 150 patients undergo arterial switch operation, norwood and complex aortic arch repair. These operations are not only complex but they also have lot of suture lines and prolong bypass time as a result of that there is high incidence of post-operative bleeding needing blood and blood products (FFP and platelet concentrate) and leaving of chest open for the first 24 to 48 hours. This also lead to bleeding from needle holes causing increased requirement of blood and blood products and post-operative hemodynamic instability leading to increase doses of inotrops forming a vicious cycle. The CoSeal is a synthetic hydrogel consisting of two solutions - high molecular weight poly ethylene glycol in a liquid sodium phosphate buffer [1] This sprayable polymeric was originally developed and was used as a vascular sealant in cardiac surgery. CoSeal is also reported to have role in prevention of prolong air leaks after lung resection (JCS) [2] and prevention of adhesion formation however we have no experience as none of our patient in whom the CoSeal was used underwent reoperation [1-3]. Only one of our patient who underwent right pulmonary artery plasty, CoSeal was not used. However 3 of our patients where CoSeal was used and the chest was left electively open because of myocardial oedema or hemodynamic instability it was observed that at the time of chest closure on next day the blood clots can be easily removed from the surface of heart in the form of a sheet and the thin gelatinous membrane can be seen on the heart probably this gelatinous membrane prevents the adhesion

formation with the adjacent structure and helps in re-sternotomy.

CoSeal offers the advantage of minimizing bleeding in general and from the needle holes. The immediate sealing success obtained with CoSeal is very likely due to the fact that this matrix when applied to suture line forms a direct mechanical barrier to blood flow [4]. This sealant produces an adherent nearly clear and a gel-like pseudo-clot at the site of application, which requires no participation of the coagulation cascade Hence CoSeal is effective even in the face of marked deficiencies in the patients intrinsic cascade mechanism which is commonly seen in newborn with low platelet count, after heparinization for CPB and DHCA [5].

CONCLUSION

We believe that a good surgical outcome depends on a meticulous surgical job. However there are instances where in spite of a good surgical repair patients life is at risk because of prolong operative time due to complexity of procedure causing post-operative bleeding. In arterial switch the neo ascending aorta becomes the posterior structure after the operation and the posterior suture line is almost impossible to inspect after the bypass is weaned off. It not only causes hemodynamic instability but also endangers the life of a new born patient and, this was the reason for us to start using CoSeal electively in such complex operations. Ever since we have started using Selant our results of complex neonatal cardiac operations have improved a lot.

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