

Application of Fibrin Sealant in Cleft Palate Surgery

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Abstract

Background: In conventional cleft palate surgeries, bleeding is controlled by bipolar cauterization and external pressure. However in case of extensive cauterization, tissue necrosis can result in palatal fistulas post-operatively. We report the application of fibrin sealant as an adjunct hemostatic agent in cleft palate surgeries. *Aim:* To study the application of fibrin sealant in cleft palate surgery. *Settings & Design:* Tertiary Care Centre, Case Report. *Methods & Material:* Five cleft palate patients were selected in non-randomized manner in whom intra-operative bleeding could not be controlled by conventional hemostatic methods. Fibrin sealant was applied to achieve Hemostasis. *Statistical Analysis:* None *Results:* Fibrin sealant was used successfully in five patients operated for cleft palate surgery to control bleeding. No complications or adverse reactions were noted. *Conclusions:* Fibrin sealant can be effectively used as an adjunct to control hemostasis for cleft palate surgery.

Keywords: Fibrin Sealant; Cleft Palate Surgery; Hemostatic Agents.

Introduction

Bleeding is a frequent problem encountered cleft palate surgery especially in wide cleft palates requiring tissue mobilization. Hemostasis is usually achieved by the conventional methods of bipolar cautery or external pressure. However extensive cauterization can lead to tissue necrosis, presenting

postoperatively as a palatal fistula. Though fibrin sealants were first introduced in 1970, it was only approved by FDA in 1998 [3]. In India, biological fibrin sealant was introduced in 2007 and has been utilized in various surgical specialties [6]. The purpose of this study was to highlight the application of fibrin sealant as adjunct hemostatic agent in cleft palate surgery. On internet search (Google), we did not find any article reported from India utilizing Fibrin sealant as an adjunct for hemostasis in cleft palate surgery, hence this study is reported.

Methods

This study was conducted in the Department of Plastic Surgery, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Pondicherry during the period November 2014 to March 2015. Prospectively in a non-randomized manner five patients of cleft palate who underwent surgery & in whom biological fibrin sealant was used as an adjunct for hemostasis were included in the study. Informed consent was taken. Demographic details of patients were recorded in the study proforma. After conventional hemostatic methods (pressure & bipolar cauterization) could not control bleeding, biological human derived aprotinin free fibrin sealant available in the department was used to control bleeding to avoid excessive cauterization of tissues. Results were evaluated by recording whether biological sealant was effective as an adjunct for hemostasis.

Results

Demographic details including age, gender, diagnosis etc are mentioned in Table 1 and Image 1.

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Fibrin sealant was successful control of bleeding in all the five patients under study. No complications or adverse reactions were noted.

Table 1: Demographic & clinical details

S.No.	Age (years)	Gender	Diagnosis	Type of Repair	Amount of Bleeding prior to application of Fibrin Sealant (ml)	Hemostasis with Fibrin sealant successful or not
1	1	Male	Incomplete cleft of hard and soft palate	Von Langenbeck's Repair	15	Yes
2	1	Male	Complete cleft of hard and soft palate	Von Langenbeck's Repair	20	Yes
3	5	Female	Incomplete cleft of hard and soft palate	Bardach's two flap palatoplasty	25	Yes
4	8	Male	Incomplete cleft of hard and soft palate	Von Langenbeck's Repair	15	Yes
5	3	Male	Complete cleft of hard and soft palate	Bardach's two flap palatoplasty	15	Yes

Image 1: Cleft palate surgery with fibrin sealant being applied



Discussion

The use of fibrin sealants or fibrin glues as a topical hemostatic agent and tissue adhesive has increased over the past 3 decades. Fibrin was first used as a hemostat in 1909 by Bergel [1]. Fibrinogen was first used as an adhesive to repair severed nerves in animal models by Young and Medawar in the 1940's [10]. In 1944, Cronkite et al [2] and Tidrick et al [8] were the first to combine fibrinogen and thrombin for anchoring skin grafts. A concentrated form of fibrinogen was used for nerve attachment by Matras in 1972 [5]. The Food and Drug Administration (FDA) approved the liquid fibrin sealant in 1998 [3] and the fibrin sealant patch in 2010 [9].

All fibrin sealants are made up of two components, mainly purified fibrinogen and thrombin obtained from human and/or bovine blood. It acts on the last stage of the clotting cycle in which in the presence of calcium and Factor XIII a fibrin clot is formed, which

gets naturally reabsorbed into the body over a period of time as the clot breaks down by fibrinolysis [7]. The components of the fibrin sealant come in 2 separate vials containing freeze dried fibrinogen and thrombin, which after thawing are inserted in an applicator device mixing both solutions simultaneously and in equal quantity. This activated solution is applied over the required area to form a thin layer. The solution requires 2 minutes for polymerization post application to adhere and form a biolayer. Fibrin sealants are used for hemostasis, as tissue adhesives and to support wound healing. It is being utilized more frequently as well as in a wide variety of cases in almost all surgical specialities [6]. It has been used in thoracic surgery for pneumonectomies, lobectomies to reinforce the staple/suture lines and to seal air leaks and close bronchopleural fistulas. In cardiovascular surgery, it has been used to seal needle holes of suture lines, cannulation sites, vascular anastomotic sites with or without graft and to arrest diffuse

mediastinal bleeding. In ophthalmology, it has been used to assist intraocular lens fixation and sealing tissues for various surgeries like trabeculectomy, pterygium, and glaucoma. In General Surgery, it has been used for surgeries for ventral and inguinal hernias, in hepatic surgeries for hemostasis of raw areas, in traumatic splenic surgeries and as an adjuvant to strengthen the anastomotic staple/suture line in gastrointestinal surgeries. In Neurosurgery it has been used for augmentation of dural repairs and for dural closure. It has been used in Plastic surgery for hemostasis following debridement for burns, as a tissue adhesive for skin grafting, as an adjunct in maxillofacial surgeries and in cosmetic surgeries like rhytidectomies. It has been also used in various other surgical specialities like otorhinolaryngology, orthopedic surgery, head and neck surgery, obstetrical and gynaecological surgeries and urology.

The fibrin sealant has the following advantages:

1. It is a biological solution acting by natural clotting mechanism.
2. It gets reabsorbed without any irritation to tissues.
3. Advantageous hemostatic time < 2 mins
4. Easy to apply
5. An adjunct tissue adhesive to strengthen the repair

The disadvantages of the fibrin sealant are:

1. Expensive
2. Little adhesive strength
3. Risk of transmission of blood borne pathogen (very low)
4. Risk of hypersensitivity reaction to the solution

It is contraindicated in brisk arterial or venous bleeding, intravascular injection and hypersensitivity reaction to blood products [4].

Bleeding in cleft palate surgeries are managed conventionally by using a bipolar cautery and application of pressure. Extensive cauterization or excessive pressure can lead to tissue necrosis which may later present as a palatal fistula. Fibrin sealants are biological solutions that can be used as adjuncts to conventional methods to apply over raw areas for immediate hemostasis avoiding further manipulation. In all five patients of our study the

hemostasis was achieved immediately allowing surgery to proceed without any further need for cauterization or manipulation of tissues for hemostasis. No complications or adverse reactions were noted in the patients. We conclude that fibrin sealants can be effectively used as an adjunct to achieve hemostasis in cleft palate surgeries in case of troublesome bleeding. It provides immediate hemostasis and acts as a tissue adhesive to augment the cleft palate repair. However a large volume randomized controlled trial is required to assess the efficacy of fibrin sealant in cleft palate surgery.

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