Low Cost Locally Prepared Fibrin Glue for Clinical Applications : Reported of 145 Cases

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Abstract

Fibrin glue (FG) is one of the blood products known to be very useful for local hemostatic measure and as a medically valuable tool for adhesion, sealing, anastomosis, repair microvascular and nerve grafts in medical and surgical procedures. Before 1996, FG was used to a limited extent in Thailand due to the high cost. Technology for locally prepared FG was transferred to Bangkok International Hemophilia Training Center of the World Federation of Hemophilia (IHTC-WFH) in July 1996 by Prof. Uri Martinowitz and the late Prof. Henri Horoszowski. Since then FG has been widely used and proved to be very useful in Thailand. This paper reports 145 cases using low cost locally prepared FG at Ramathibodi Hospital during November 1996 to December 1997.

A total of 145 cases with age range from 5 months to 73 years, which included 55 pediatrics and 90 adults, 100 males and 45 females. The amount of FG used was 1-80 ml per case. Clinical procedures included dental surgery (46), open heart surgery (35), ENT (28), orthopedic (13) including 2-3 joint correction in one session in 2 hemophiliacs, neurology (11), plastic repair (7), liver (2) and severe bleeding in dengue hemorrhagic fever (3). Forty-seven cases had hemostatic disorders.

The result of local hemostatic, adhesive and sealant effect of FG was satisfactory with no complications. In open heart surgery, the amount of content in chest drain decreased and none required reopen-surgery to stop bleeding. Dental surgery was performed in 43 patients with bleeding disorders i.e. hemophilia, idiopathic thrombocytopenic purpura, leukemia, severe thrombocytopenia, patients on anticoagulant, etc. Only 3 cases (7%) required blood component compared to all of the 50 no-FG controlled cases (100%) that required blood component therapy.

FG has proved to be very useful in many aspects i.e. minimizing blood product usage, decreasing medical workload, reducing medical cost and increasing patients' convenience and satisfaction in particular.

Key word : Fibrin Glue, Fibrin Adhesive, Fibrin Sealant

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Fibrin glue (FG) is a group of blood products that lead to the formation of a fibrin clot at the site of application. FG consists mainly of fibrinogen and thrombin, providing rapid hemostasis as well as tissue sealing and adhesion. FG is useful for surgical anastomosis, repair of microvascular and nerve grafts, pneumothorax, and tear of dura mater. It is applied for the operation of nonsuturable organs i.e. liver, pancrease, thymus, brain, etc. It has the potential to provide life-saving control of hemorrhage, reduction of blood product consumption, the lowering of viral exposure risk and medical care cost reduction[1,2]. It can be applied to every organ except the eyeball. It cannot stop arterial bleeding.

Commercial, viral-inactivated products are available with enormous expense. In July 1996, the technology in preparing FG and surgical application was transferred to Bangkok IHTC-WFH, Ramathibodi Hospital through the support of the World Federation of Hemophilia and the Israeli Government. Prof. Uri Martinowitz and the late Prof. Henri Horoszowski from Israel came to Bangkok to introduce this valuable technique to Thai physicians at Ramathibodi Hospital[3,4].

Since 1996, FG has been prepared locally in Thailand and applied to patients with various indications. This paper describes the preparation technique of FG and reported its clinical applications.

MATERIAL AND METHOD

The preparation of FG. Two solutions were prepared in two different vials with completely sterile technique in the laminar air flow. Solution 1. One ml contained 40 mmol of calcium chloride 2 mg of gentamicin and bovine (Gentrac, Middleton, Wisconsin, U.S.A.) or human thrombin (Omrix, biopharmaceuticals SA, Belgium) of 250 IU/ml for dental surgery and 500 IU/ml for other procedures. Solution 2. One ml was composed of cryoprecipitate with fibrinogen content of 10-12 mg and tranexamic acid 10 mg (Daiichi Pharmaceutical, Tokyo, Japan) as antifibrinolytic agent. Two sources of cryoprecipitate were used : one from heat-treated freeze dry cryoprecipitate and the other from frozen cryoprecipitate of single random donor. Every unit of fresh frozen plasma for cryoprecipitate preparation was screened for VDRL, HBsAg, anti-HCV, HIV p24 Ag and anti-HIV and kept for 3 months as quarantine plasma. The donor of the cryoprecipitate had two subsequent negative tests for anti-HIV within 3 months in order to avoid HIV infection in the window period. The solutions were prepared in different amounts of 2 and 5 ml (Fig. 1) size with low

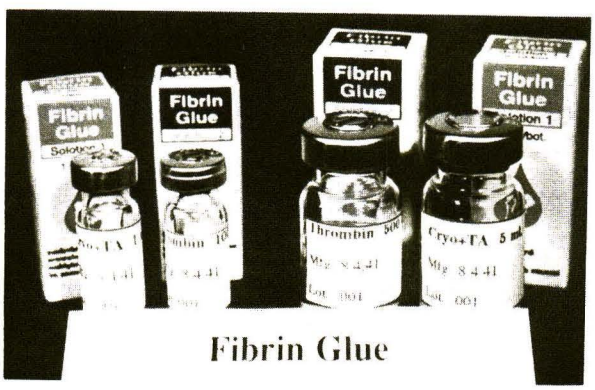

Fig. 1. Solution 1 and 2 for fibrin glue prepared in 2 and 5 ml size by the Thai National Blood Center.

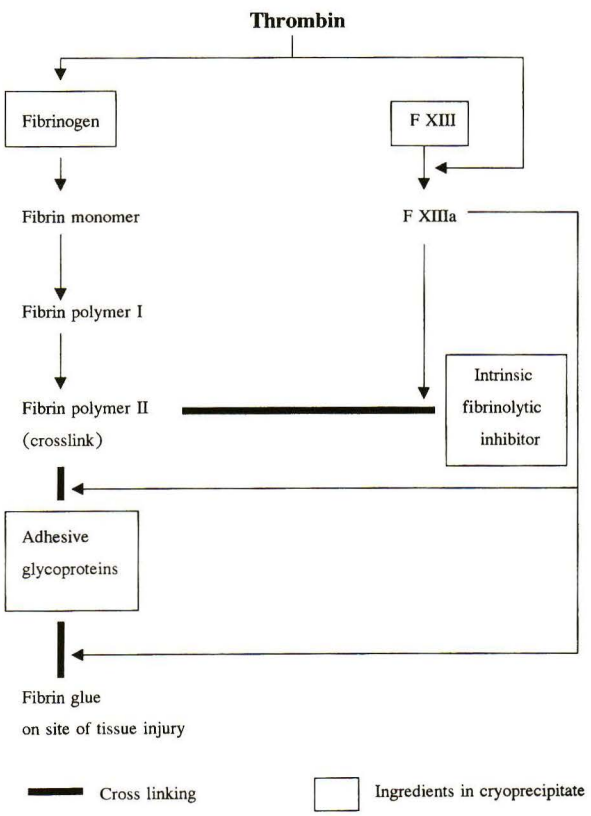

Fig. 2. Mechanism of action of fibrin glue.

Table 1. Type of surgical and medical procedures using FG and the amount of FG used in 145 cases.

Type of procedures	No. of cases	Per cent	FG – ml/case
1. Dental	46	32	1-8
2. Cardiovascular	35	24.2	9-20
3. ENT	28	19	2-5
4. Orthopedic	13	8.9	2-80
5. Neurological	11	7.6	2-6
6. Plastic	7	4.8	2-5
7. Liver	2	1.4	2-5
8. Stop bleeding in dengue hemorrhagic fever	3	2.1	1
Total	145	100	1-80

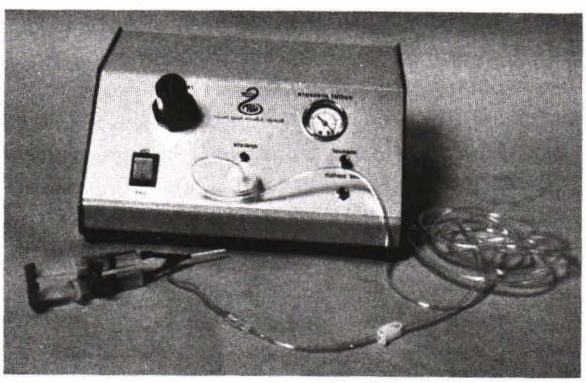

Fig. 3. Two syringes containing cryoprecipitate and thrombin connected to air pump and 3-lumen tube ready for application of fibrin glue to surgical wound or bleeding points.

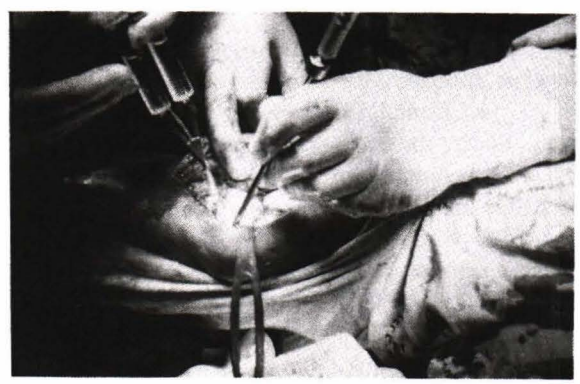

Fig. 4. Using air pump, fibrin glue was sprayed at the surface of surgical wound during knee joint replacement in a patient with hemophilia.

and high concentrations of thrombin for dental surgery and major surgery respectively and kept at the hospital blood bank for 24 hour service. They were kept below -20°C and had to be used within 6 months. When solutions 1 and 2 are mixed together and is applied to the site of injury. Mechanism of action of FG is shown in Fig. 2.

Patients' profile

During November 1996 to December 1997 (14 months), FG was applied to 145 patients with bleeding and non bleeding disorders at Ramathibodi Hospital. The age ranged from 5 months to 73 years with 55 pediatric and 90 adult cases. They were 100 males and 45 females. Type of surgical and medical procedures in which FG was used is shown in Table 1.

Application of FG

Solution 1 and 2 were thawed at room temperature (20-25°C), then solution 1 was drawn up to the first syringe and solution 2 to the second syringe. Both syringes were connected to the sterile spray delivery set and were fixed with syringe bridge and holder.

FG was applied by direct syringe push in a small area such as socket of dental extraction site or spray with air pump machine through 0.2 μm filter for major surgery in a large area such as open heart surgery or liver transplantation (Fig. 3, 4).

Special mouth rinse for dental surgery[5,6]

After dental surgery, all patients received local and systemic antifibrinolytic drug as special mouth rinse. Tranexamic acid (Daiichi Pharmaceutical Tokyo, Japan) solution 250 mg in 50 mL water was used by swishing and swallowing the entire amount every 6 hours for one week.

RESULTS

The concentration of thrombin was finally selected to be 250 units/ml for oral surgery and 500 units/ml for other surgical procedures. The amount of FG used varied from 1 to 80 ml per case.

The type of surgical and medical procedures are shown in Table 1.

The surgical and medical procedures using FG were as follows:

1. Dental surgery was performed in 46 cases. Fourty-three cases had severe bleeding disorders i.e. hemophilia A, B, von Willebrand disease, idiopathic thrombocytopenic purpura, acute leukemia, SLE with thrombocytopenia, histiocytosis, biliary cirrhosis, patients on anticoagulant, dengue hemorrhagic fever, etc. All of them did not receive preoperative blood component therapy. Only 3 cases or 7 per cent required blood component therapy postoperatively compared with all of the 50 no-FG controlled cases (100 per cent) requiring systemic blood component pre and post operative dental surgery. Three cases without bleeding disorders had extensive surgery i.e. periodontal surgery with bone graft, gingival surgery with excessive bleeding in renal transplantation.

2. Cardiovascular surgery was performed in 35 cases using FG for local hemostasis. They were 5 neonates, 10 infants, 10 children and 10 adults. The diseases of the patients are shown in Table 2. It was observed that post-operative bleeding was reduced and none required reopen-surgery to stop bleeding. The amount of fluid from tube drain was less than those without FG application. The amount of blood transfusion was not different among those with or without FG application.

3. Dengue hemorrhagic fever (DHF), FG was first applied to 3 cases of uncontrolled bleeding in dengue shock syndrome. The bleeding problems were :

Case 1 : Hepatic and renal failures with disseminated intravascular coagulation (DIC), blood oozing at the tube drain of peritoneal dialysis.

Table 2. Open heart surgery in which fibrin glue was used.

Type of surgery	No. of cases
Adult	
Coronary artery disease	6
Valvular heart disease	3
Atrial septal defect	1
Total	**10**
Pediatrics	
Ventricular septal defect	12
Transposition of great vessels	2
Pulmonary stenosis and ventricular septal defect	1
Tetralogy of Fallot	1
Atrial septal defect	4
Total anomaly of pulmonary venous return	2
Complex anomalies	1
Others	2
Total	**25**

Table 3. Surgical procedures using FG.

Dental surgery	46
Cardiovascular surgery	35
ENT surgery 28 cases:	
- Chronic otitis media	10
- Allergic rhinitis with nasal obstruction	7
- Tympanoplasty	3
- Laser assisting myringoplasty	1
- Unidentified	7
Orthopedic surgery 13 cases:	
- Brachial plexus injury	9
- Hemophilic arthropathy with 2-3 joint correction in 1 session	2
- Skin muscular defect	1
- Fracture tibia and fibula	1
Neurological surgery 11 cases:	
- Communicating aneurysm	3
- Optic meningioma	2
- Pituitary tumor	2
- Trigeminal neuralgia	1
- CSF rhinorrhea	1
- Optic nerve compression	1
- Repair dura	1
Plastic surgery 7 cases:	
- Myeloplasty (facial lift)	3
- Cavernous hemangioma	3
- Laceration wound	1
Liver surgery 2 cases:	
- Liver transplantation	1
- Hepatic failure with bleeding	1
Bleeding in dengue hemorrhage fever	3

Case 2 : Pulmonary hemorrhage with pleural effusion, blood oozing from the site of inter-costal drainage.

Case 3 : Massive gingivitis and dental caries, blood oozing from oral cavity.

FG were applied to the bleeding sites with gauze packing in cases 1 and 2. The bleeding was stopped in both cases. Dental treatment including dental extraction was performed, followed by FG application at the bleeding site and covered by dental splint. The bleeding was stopped with no systemic replacement therapy despite platelet count less than 10,000/μl with consumptive coagulopathy.

4. Other surgical procedures included ENT, orthopedic, neurological, plastic and liver surgeries are shown in Table 3.

The efficiency of FG in all cases was satisfactory in the aspect of local hemostatic measure, tissue adhesion, sealing, nerve grafts and good wound healing in ENT and plastic surgery. There was no side effect or toxicity or complication from FG observed.

DISCUSSION

Fibrin glue has been used for over two decades, but was seldom used in Thailand because of the unaffordable price. Since low cost locally prepared FG has been available in Thailand in July 1996, it has been widely used in patients with bleeding and non bleeding disorders[3-5]. The surgeons and physicians were satisfied with the use of FG in many aspects i.e. better wound healing, reducing post-operative bleeding, blood product usage, the risk of viral transmission by blood product, operative time, medical cost, days of hospitalization and the workload of physicians, nurses and paramedical personnel and particularly patients' convenience. The physicians and the nurses at the intensive care unit for cardiovascular surgery became less stress because of fewer post-operative bleeding problems. The patients and their families were satisfied and appreciated the result of FG. It has been reported to be very useful in various kinds of surgery[3,4,7-13].

Bovine thrombin was used for the first 18 months in Thailand and then changed to human thrombin. Since February 1998, only human thrombin has been used to prepare fibrin glue by different concentrations in place of bovine thrombin. It has been known that bovine thrombin may cause serious complication from immunological reaction[2]. The high concentration of thrombin results in fast clotting of the FG in the orifice of dental cavity. It prevents sealing at the bleeding site at the surface of the alveolar socket. Low concentration should be prepared for dental surgery. The least concentration of human thrombin which yielded the firm glue is 50 IU/ml for oral surgery and 250 IU/ml for other major surgeries. The thrombin concentration used for dental surgery should not be too high.

Since July 1998 the National Blood Center, Thai Red Cross Society has adopted this technology for low cost locally prepared FG using human thrombin in large scale production to serve the whole country as shown in Fig. 1. The price of FG prepared at National Blood Center is 10 per cent of the price of the imported one. FG becomes more and more popularly used for both physicians and dentists in Thailand.

Gentamicin added to Solution 1 will prevent bacterial infection at the site of FG for 48 hours. FG will be naturally dissolved 5-7 days later by body fibrinolysis by which time the wound should be healed.

Double blind control study for the efficiency of FG could not be conducted because of the ethical aspect as well as the physicians' willingness.

Dental surgery performed in 43 cases of severe bleeding disorders including hemophilia A, B (7 cases), von Willebrand disease, severe thrombocytopenia and coagulation defects. FG definitely minimizes the use of blood product in these patients and reduces the medical cost. It should be noted that before FG was available, all patients with similar bleeding disorders required systemic replacement therapy before and after oral surgery. When FG was used, only 3 out of 43 cases or 7 per cent needed post-operative systemic replacement. The amount of blood product used was much less than those not using FG. The dentist is able to schedule surgery in the morning despite waiting for the availability of blood component, i.e. platelet concentrate, in the afternoon. Patients on anticoagulant do not need to be withdrawn from anticoagulant when oral surgery or dental treatment are required. FG reduces the worriness and offers convenience to patients, physicians and dentists. Antifibrinolytic drug should be applied locally and systemically for oral surgery[5,6].

Two patients suffering from severe hemophilia A with multiple joint defects received 2-3 joint surgical correction in 1 session by using FG 40-80 ml. Continuous infusion of factor VIII concentrate was applied pre- and post-operatively. The patients' problems were two knee joint replacements and tendoachillis lenghtening at one ankle joint in one case and one knee joint replacement and one knee joint synovectomy in the other case. There was no problem of post-operative bleeding or any serious complication. FG has been shown to be enormously useful in many aspects i.e. minimizing the use of factor VIII concentrate about 40-60 per cent[1,7], the time of surgery, the medical cost, the workload of physicians and nurses, the suffering of patients. Without FG, large multiple surgical orthopedic corrections could not be done in one session.

It should be noted that there is high incidence of motorcycle accidents in Thailand causing brachial nerve plexus injury. FG proved to be very useful to repair nerve injury in these cases. A 4-year-old in a car accident which induced tear of dura mater with CSF leakage was successfully healed by using FG. Lymphatic leakage in cardiovascular surgery with tear of thymus gland was satisfactory repaired by FG.

New forms of fibrin sealant[14-17] have been produced despite the frozen liquid form. The most promising one is the dry fibrin sealant bandage or dressing for both medical and surgical applications. A spray powder is currently being developed consisting of finely milled fibrin sealant powder which forms a good fibrin clot upon hydration with blood or other fluids. The other form is a self-expanding sealant foam which is being developed for the treatment of non compressible haemorrhage. It is uniquely designed to treat difficult-to-reach, concealed internal injuries.

Conventional surgical methods for controlling hemorrhage such as tourniquet, pressure and sutures have remained unchanged for centuries. The introduction of fibrin sealant or FG represents the beginning of a paradigm shift for treating hemorrhage not only in patients with bleeding disorders but also in those with non-bleeding disorders. In addition, FG has proven to be a medically valuable tool for adhesion, sealing, anastomosis, repair, microvascular and nerve graft, etc.

Recently, recombinant thrombin, fibrinogen and F XIII have been developed, and the use of recombinant FG seems to be feasible in the future in order to avoid the risk of transfusion transmitted diseases.

In the future, fibrin sealant or FG is expected to become a common place tool utilized by both patient and physician to minimize and control hemorrhage.

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การเตรียมกาวไฟบรินเอง และรายงานการใช้ในผู้ป่วย 145 ราย

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กาวไฟบรินเป็นผลิตภัณฑ์โลหิตชนิดหนึ่ง ซึ่งใช้สำหรับห้ามเลือดเฉพาะที่และใช้อุดปะปิดรูรั่วซึมในอวัยวะต่าง ๆ ใช้ตัดต่อเส้นประสาท เส้นเลือด ใช้ได้กับทุกอวัยวะ ยกเว้น eyeball กาวไฟบรินไม่สามารถห้ามเลือดที่ไหลออกจากหลอดเลือดแดง

เนื่องจากกาวไฟบรินมีราคาสูงมาก จึงมีการใช้น้อยมากในประเทศไทย จนกระทั่งปี พ.ศ.2539 Prof. Uri Martiniwitz และ Prof. Henri Horoszowski ได้มาถ่ายทอดเทคโนโลยีการเตรียมกาวไฟบรินใช้เองด้วยราคาถูกลงอย่างมากที่โรงพยาบาลรามาธิบดี หลังจากนั้นมาได้มีการใช้กาวไฟบรินกันอย่างแพร่หลายในประเทศไทย ทั้งผู้ป่วยที่มีและไม่มีภาวะเลือดออกง่าย

รายงานนี้ได้แสดงการใช้กาวไฟบรินในผู้ป่วย 145 ราย อายุระหว่าง 5 เดือนถึง 73 ปี เป็นเด็ก 55 ราย ผู้ใหญ่ 90 ราย เพศชาย 100 ราย เพศหญิง 45 ราย ปริมาณกาวไฟบรินที่ใช้ในแต่ละรายแตกต่างกัน 1-80 มล./ราย ใช้ในการผ่าตัดและการรักษาโรคต่าง ๆ ดังนี้คือ การผ่าตัดช่องปากและฟัน 46 ราย ผ่าตัดหัวใจ 35 ราย ผ่าตัดหูคอจมูก 28 ราย ศัลยกรรมออร์โธปิดิกส์ 13 ราย ผ่าตัดสมอง 11 ราย ศัลยกรรมตกแต่ง 7 ราย ผ่าตัดตับ 2 ราย และใช้ห้ามเลือดเฉพาะที่ในโรคไข้เลือดออกที่มีอาการเลือดออกรุนแรง 3 ราย

ประสิทธิภาพของกาวไฟบรินในการห้ามเลือดเฉพาะที่และการอุดปะปิดรูรั่วซึมในการผ่าตัดและการรักษาโรคต่าง ๆ ได้ผลเป็นที่น่าพอใจ โดยไม่มีภาวะแทรกซ้อนใด ๆ ในการผ่าตัดช่องหัวใจ ปริมาณเลือดจาก chest drain น้อยกว่ารายที่ไม่ใช้กาวไฟบริน และไม่มีรายใดต้องเปิดผ่าตัดซ้ำเพื่อแก้ปัญหาภาวะเลือดออกหลังผ่าตัด ในการทำฟันผู้ป่วยที่มีปัญหาภาวะเลือดออกผิดปกติ เช่น โรคฮีโมฟีเลีย เกล็ดเลือดต่ำจากมะเร็งและโรคต่าง ๆ ไม่ต้องให้ส่วนประกอบของโลหิตก่อนการผ่าตัดเลย มีเพียง 3 ราย หรือร้อยละ 7 ที่ต้องรับส่วนประกอบโลหิตหลังการผ่าตัดและใช้จำนวนเพียงเล็กน้อย เปรียบเทียบกับ 50 รายที่ไม่ใช้กาวไฟบรินต้องรับส่วนประกอบของโลหิตทั้งก่อนและหลังผ่าตัด

กาวไฟบรินที่เตรียมใช้เองมีราคาถูก มีประโยชน์หลายด้าน ได้แก่ ลดการใช้โลหิต ลดค่าใช้จ่ายในการรักษา ลดภาระของแพทย์และพยาบาล ลดเวลาในการผ่าตัดและการป่วยในโรงพยาบาล สามารถทำผ่าตัดหลายแห่งได้ในคราวเดียวกัน ผู้ป่วยได้รับความสะดวกและพอใจในผลการรักษา

คำสำคัญ : Fibrin Glue, Fibrin Adhesive, Fibrin Sealant

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