

The Autologus Production & Use of Fibrin Glue in Urologic Surgery

Background: development of surgical tissue adhesives and sealants is a rapidly expanding area of new surgical research and clinical use. These agents are improving the quality of surgical care, reducing morbidity and mortality, and saving total healthcare expenses.

Fibrin Glue (FG) , created by combining the two principal plasmatic clotting factors fibrinogen and thrombin, mimics the last step of the physiological coagulation cascade to form a fibrin clot independent of the patients' coagulation process.

In this study we evaluate the safety and efficacy of autologous FG by an automated device CryoSeal® FS System and its use in urologic patients.

Materials and methods: FG is produced by an automated device (CryoSeal System) from autologous plasma. The whole process is under control of SOP (selection of patient, identification and labelling, phlebotomy, whole blood centrifugation, plasma extraction, FG production, labelling ,storage and distribution). Amount of FG is 10-15 ml from 250-400 ml of plasma. FG was evaluated for Fibrinogen, Clot Time Assay, F XIII, F VIII, Thrombin Activity.

The study involved a retrospective controlled evaluation of 60 urologic patients operated of radical perineal prostatectomy

Patients were divided into two groups:

Group 1: intraoperative application of FG 25 patients (study group)

Group 2: no application of FG 35 patients (control group)

Inclusion criteria of patients were based on diagnosis of prostatic adenocarcinoma, clinical staging T1-T2 , Surgical technique radical perineal prostatectomy performed by the same surgical team, normal hemocoagulative status.

Exclusion criteria were: patients not eligible for autologous blood predonation and/or patients with coagulation impairments or antiaggregant or anticoagulant therapy.

All patients were studied for Estimated Blood Lost (EBL), hospital stay and postoperative complications.

EBL was calculated in accordance with Goodnough formula.

Results: Quality control of FG production gave these results: Fibrinogen 36+/- 12 mg/ml, FVIII 4+/- 1 IU/ml, F XIII ,Thrombin activity 40 +/-2 IU/ml, Clot Time Assay 6+/-2 sec.

Clinical evaluation of two groups are reported in following table:

	Group 1	Group 2	p
Patients	25	35	
EBL ^o	556 ml	634 ml	n.s.
Patients transfused	0	8	p<0.01
Homologous blood	0	14	p<0.01
Complications	3	9	n.s.
anemia	1	5	p<0.03
Hospital stay (days) ^o	4	6	n.s.

^o mean

Conclusion

- ? This procedure allows the blood transfusion center to produce a standardized product having similar characteristics of the pharmaceutical products and to produce a consistent amount of FG components from a single unit of autologous blood (10-15 ml)
- ? The processing time is relatively short, about one hour as compare to 2-3 days for standard methodology.
- ? No patient of study group was transfused with homologous blood while 8 patients of control group received 14 transfusions; this acquisition is suggestive for blood saving.
- ? Immediate postoperative complications were lower in the study group compared to the control group.
- ? The hospital stay of the study group is shorter then the control group. This data needs further investigations for social and economic evaluation.