

Original Article**Cryocalcium Glue: a new formulation for dural repair augmentation**

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ABSTRACT

Background: Cerebrospinal fluid leakage is a major problem in neurosurgical operations. For preventing it, the dural closure should be augmented. Current glues which use for augmentation are prepared with mixing cryoprecipitate, bovine thrombin and calcium gluconate in suitable concentrations which are expensive and unavailable anywhere. A new formulation is introduced here.

Methods: This is a prospective randomized clinical trial in patients who need dural patch graft by using Cryocalcium glue, mixing the cryoprecipitate, calcium gluconate and patient's own blood as the origin of thrombin, in our operating room.

Results: Comparing two groups of cases(106) and controls(100), we found overall C.S.F leak 3.8% and 15% respectively, with 3.6%, Zero%, Zero% and 16.7% in supratentorial, infratentorial, skull base and spinal cord operations in cases versus 12%, 20%, 33% and 28.6% in controls respectively.

conclusion: Using Cryocalcium glue for dural closure augmentation was with better results in comparison with control group. In addition in reviewing literature, comparing this new formulation and old fashion of fibrin glue, revealed that the new one, if not better, is similar to the old one in quality point of view.

Key words: C.S.F. Leakage, Dural augmentation, Fibrin glue (sealant)

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Cerebrospinal fluid (CSF) Leakage has been a troublesome problem in neurosurgical practice for many years. To avoid this, surgeons try to close the dura with watertight suturing. It is always neither easy to prevent CSF Leakage after watertight closure of the dura nor possible in skull base procedures, especially in a narrow space.

A wide variety of agents have used for augmentation of dural closure. The fibrin glue is the most popular one among them. Out of Iran, it is prepared by blood banks or by surgeons in operating suites, through mixing bovine thrombin and suitable Volume of cryoprecipitate. Cryoprecipitate contains fibrinogen and factor 13, as the major part. This fibrin glue is commercially inaccessible and very expensive and should be imported from the other countries. Its high cost is mostly due to the high price of the bovine thrombin.

Because the bovine thrombin is not available in Iran's hospitals, we tried to introduce a new for-

mulation of glue. It was made up from cryoprecipitate (fibrinogen and human factor 13), calcium gluconate and patient's own blood as the origin of human thrombin. This formulation was not used before.

The fibrin clot, which is the final product of the coagulation cascade, forms the ultimate new glue. It is less expensive and so easily available in all modern surgical centers in Iran.

Subjects and Methods

This clinical trial study performed in Al-zahra & Kashani Hospitals in Isfahan since 2001-2003. The patients need dural graft during neurosurgical procedures as supratentorial, infratentorial, skull base, or spinal cord surgery.

The patients divided to case and control groups randomly in the end of dural closure.

In both groups, wound closure performed similarly, using silk 3-0 sutures. In case group, the patients received complete dural coverage by

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cryocalcium glue instead of no intervention in control group.

The cryocalcium glue prepared as following; In a sterile condition conventional full thickness Gel foam (in size of dural exposure) soaked in cryoprecipitate (same patient's blood type and 10 ml per 20 cm² Gel foam were used) and calcium gluconate 10% (1 ml per 5ml of cryoprecipitate), mixed five minutes before appliance with 1-2 ml of own patient's blood.

For two weeks post operation, all patients followed for any evidence of CSF leakage as subcutaneous collection or open leakage. Information regarding age, neurosurgical procedure, and the size of dural graft patch (in cm²) recorded. Collected data analyzed by SPSS software in chi-square, T-student and ANOVA tests.

Results

Two hundred and six patients were studied as case group (106 patients) and control group (100 patients). The mean ages of case and control groups were 42.8 ± 20 versus 40.6 ± 20.4 years respectively (P=0.437; T-test). No local or systemic reaction to the glue was noted.

Four patients (3.8%) in case group and 15 patients (15%) in control group had CSF leakage as subcutaneous collection (P=0.005 in Chi-Square Test). The frequency of CSF leakage in different neurosurgical procedures was listed in Table 1.

The mean sizes of dural patch grafts were 17.2 ± 8.37 cm² versus 17.96 ± 8.98 in case and control groups respectively (P=0.571; T-test). It was 10,25 cm² versus 17.54 cm² in case group with or without CSF leak respectively (P=0.02; T-test).

The mean sizes of dural patch grafts were 21.66 cm² versus 17.30 cm² in control group with or without CSF leak respectively (P=0.18; T-test).

Discussion

After operations, overall CSF leakage was significantly lower in patients received Cryocalcium glue (3.9 fold). Both groups had the same size of dural patch. Fukumoto has showed the sealant effect of commercial fibrin glue in 22 patients with different neurosurgical procedures⁴.

In supratentorial operations, CSF leak was significantly lower in cases than controls (3.3 fold). Drake and Faulkner have previously demonstrated this significant effect of fibrin sealants in rat models². None of the patients who received Cryocalcium glue in a posterior fossa operation and dural patch graft had CSF leak regarding to 3 patients in control group (P=0.058). The prevention of CSF leakage was evident in spinal cord operation with dural patch graft too (16.7% vs. 28.6% in case and control group respectively, P=0.05). With regular fibrin glue in spine surgery, the similar results have reported by Ebstein et al⁵. Here is limited result in skull base surgery due to small number of patients (4 in case & 3 in Control group) and just one patient in control group had postoperative CSF leakage (33%). In addition, Toma has been used fibrin sealants in skull base surgery successfully⁶.

In dural repair augmentation, the cryocalcium glue prevents CSF leakage effectively. It is a safe, easily available and non-expensive alternative for current fibrin glues. The cryocalcium glue is a good alternative in our institutions.

Table 1: Types of neurosurgical procedures and CSF leakage in patients received cryocalcium glue and control group.

Procedure	Case group		Control group	
	Total	Leak	Total	Leak
Supratentorial	83	3(3.6%)	75	9 (12%)
Infratentorial	13	0	15	3(20%)
Skull Base	4	0	3	1(33%)
Spinal Cord	6	1 (16.7%)	7	2(28.6%)

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