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Clinical Research

A STUDY TO EVALUATE THE EFFICACY OF VARIOUS DURAL SUBSTITUTES IN DURAL RECONSTRUCTION

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ABSTRACT

Introduction: The duramater is a very important structure in the craniospinal cavity which maintains the internal milieu of the brain and protects the brain from external invasion. A good water tight closure of dura ensures an effective safe guard against cerebrospinal fluid (CSF)leak and subsequent infection. An ineffective dural closure leads to avoidable morbidity and mortality.

Materials & methods: A retrospective study was conducted in a single institute from September 2015 to Sept 2017 to evaluate the efficacy of Available dural substitute. This included Fibrin sealant, collagen based dural substitute, synthetic dural substitutes and synthetic sealants .They were used as a standalone or in combination with autologous duroplasty. The efficacy was compared for two weeks following surgery.Parameters checked postoperatively were CSF leak, local infection/inflammation, seizures or systemic signs of hypersensitivity. Preoperatively the user friendliness and time taken to control CSF leak were evaluated and conclusions were drawn.

Observation: In all a total of 553 cases were included in the study and 200 cases underwent auto graft duroplasty, Collagen based dural substitute was used in 135 cases, fibrin sealant in 177 cases , Tissue Patch (synthetic adhesive sealant) in 33 cases, Goretex synthetic patch in 05 cases and PolyTetra FlorEthylene (PTFE)patch in 03 cases.43% of duroplasties was carried out using auto graft as a standalone, while 57% required an additional supplementation with one or two of the available substitutes.

Result: Collagen based dural substitutes had a success rate of 92.6% while autologous dural repair group showed a success of 91%. Although fibrin sealant group had a success rate of 95% it was mostly used as an adjunct and only in 15 cases as a standalone .The success rates with synthetic C SF sealant, Synthetic patch(G patch) and PTFE graft were 87.2%,80% and 66.7% respectively.

Conclusion: The present study suggests that Collagen based dural substitutes offer a definite advantage to the surgeon in effectively control in postoperative CSF leak. Its use in appropriate setting offers a definite advantage in improving the postoperative outcomes.

KEYWORDS : Dural Substitute, Dural Reconstruction, Collagen based dural matrix

Introduction

Dura mater also called the tough mother is a protective meningeal covering of the neuraxis, serving as a barrier in separating the intra dural from extra dural contents of cranium. The embryology of the meninges is complex as it has both mesenchymal and neural crest origin. The knowledge of this covering is very important to the operating surgeon as this is the barrier which is invaded before one has to enter the brain or spinal cord. Closure of this layer is equally important as CSF leak and subsequent infection can lead to unacceptable morbidity and mortality. In addition to a good closure technique the surgeon relies on dural substitutes which aid him in providing a cerebro spinal fluid (CSF) barrier. Various dural substitutes are available in the market each claiming supremacy over the other. This is the first retrospective study which compares the efficacy of the current available substitutes.

Materials and Methods

This was a retrospective study conducted in a single institute from September 2015 to Sept 2017. A total of 553 dural reconstruction procedures were performed in a single institute. Standalone auto grafts using the pericranium, temporalis fascia or tensor fascia lata (TFL) was the first choice offered for water tight dural closure. Where ever it was not possible or feasible, other biomaterials or synthetic substitutes were used. In majority they were used as adjuncts rather than as standalones. Efficacy was judged in prevention of CSF Leak for a period of 7 days post operatively. Other factors evaluated were the ease of use and the operating time.

Observation

Table 1. Showing our experience of using the various dural substitutes

Our Institutional Experience(Sept 2016 till date)

Technique of Duroplasty employed(Total 553 Cases)	Total cases	Complication	Success rate
Auto graft(Percranium,Temp Fascia,TFL)	200	18	91 %
Collagen Based Graft(Duragen ,Durafoam)	135	10	92.6%
Tissue Patch	33	4	87.2%
Fibrin Sealant	177	9	95 %
PTFE	03	1	66.7%
G Patch	05	1	80 %

Table 2. Showing the success rate with standalone versus supplemented techniques

Stand alone Vs Multiple methods

Duroplasty Technique	Cases	Success Rate
Single stand alone	43%	94%
Two or more Methods employed	57%	96%

Results

1. Autologous Graft: This is the safest substitute as there is minimal risk of infection as its body's own. It was found ideal to cover large dural skull base defects. In most cases watertight duroplasty could be achieved with sutures. The undesirable effects included donor site morbidity which included pain and infection in 9% of the cases. Suturing and hemostasis increased the Operating time by 10 to 15%. A 91% success rate was achieved in terms of prevention of CSF Leak within the first seven days following surgery.

2. Collagen based graft: Amongst the collagen based grafts we used the standard collagen based dural substitute(Durafoam) and Ultra pure type I collagen based dural substitute (Duragen) We found them to be Immunologically well tolerated causing no foreign body reaction. We could achieve a 93% watertight closure rate. In most of the cases it was used as a standalone substitute. Unlike other synthetic grafts there was no encapsulation or graft rejection found .In the re do cases there was minimal adhesion formation where there was significant disruption of pia arachnoid. All cases were used as overlay grafts thereby achieving lesser operation time. Infection was encountered in one case of traumatic brain injury. Although ultra-pure collagen has most of the properties required for an ideal dural substitute its use is contraindicated in infection, neural tube defects and anterior dural defects of the spine. Its use should be avoided in patients with history of bovine allergy.

3. Fibrin Sealant: Fibrin serves as an adjunct when water tight dural closure is desired. In our series it was used in majority of cases as an additional reinforcement for watertight closure. When used, it helped in achieving 95 % success rate. Fibrin offers the advantage of addressing intra as well as extradural bleed. Being a liquid sealant, it can reach to in accessible regions. It is of immense use in emergency situations where patient has coexisting coagulopathy. When used as a standalone ,CSF leak was higher. Fibrin Lacks regeneration property, hence it does not affect dural reconstruction.

4. PTFE: PTFE use in our series gave us a success rate of 66%.We found it good for skull base dural reconstruction where mechanical support is desirable. It was not suited for infected cases. It's found to reduce scalp vascularity, hence needs to be used with caution in redo cases and irradiated scalps where compromised vascularity may delay wound closure. We also found PTFE unsuitable for irregular dural surfaces as PTFE is non-conforming. It is unsuitable for infected cases.

5. Tissue Patch: Tissue patch can only be used to reinforce the CSF leak as an adjunct. Its known to cause an Inflammatory reaction. Its one side acts as a sealant while the other serves as a barrier. Use must be restricted when using near vital structures with closed space as it has a tendency to swell. In our series we achieved 88% success rate with use of Tissue patch. It was used as an adjunct. We did not use it in cases where CNS infection was present or suspected.

6. G Patch: G patch was used in5 cases in our series and we achieved a success rate of 80%. Its use is restricted due to its relatively rigid nature with propensity to cause mild to moderate inflammatory reaction. It is non-resorb able and causes encapsulation and dural thickening. The rigidness may help in reconstruction of dural defects where mechanical support is required to cover and protect the underlying structures. Like other synthetic substitutes, it puts the under lying Scalp vascularity in jeopardy.

Discussion

An ideal dural substitute must resemble the natural dura mater in all its properties. It should be Immunologically inert, provoke no inflammation in the host body, must not adhere to the underlying brain, be bio-degradable/ bio-resorb able, be durable yet flexible, must aid in achieving watertight closure thereby forming a good protective barrier. From the operating surgeon's perspective, its use should be less technically demanding and must not compromise on the operating time. From the patients point of view it should not cause additional pain or morbidity and the cost factor needs to be considered especially developing countries.

Watertight dural closure following any neurosurgical procedure seems to be an accepted norm worldwide. [1].Animal studies have shown that Polyglactin (Vicryl) use for suturing dural margins offers advantage over other suture materials like polyglycolic acid, polyester and silk .Bertil and colleagues through animal experiments showed that absorbable suture caused lesser foreign body reaction. Use of Polyglactin caused no subdural adhesions in reoperations.[2]. Continuous interlocking sutures seem more effective in controlling CSF leak than interrupted sutures. However use of fibrin sealant as an adjunct helps in achieving better results irrespective of the suturing technique adopted.[3]

Valsalva maneuver may serve as a useful confirmatory test of satisfactory water tight dural closure. However there is no scientific evidence validating this procedure.

Brian P. Walcott and colleagues studied the effects of synthetic graft for dural reconstruction in elective cranial surgeries and concluded that use of synthetic dural reconstruction material was not associated with surgical site infection or increased incidence of CSF leak.[4]

Fibrin sealant seems to be a useful adjunct in preventing dural leaks. Pinar Akdemir Ozisik et al through rat experiments, have shown than, fibrin glue offers a better safety profile and better watertight closure as compared to n-Butyl methacrylate and CO2 laser techniques.[5]. Parizek and colleagues carried out detailed evaluation of 2959 allogeneic and xenogeneic dense connective tissue grafts (fascia lata, pericardium, and dura mater) used in the course of 20 years for duraplasty in neurosurgery and concluded that irrespective of the dural graft material used, they could achieve a success rate of 96.9%.[6]. Technology has transcended all aspects of neurosurgery. The search and research for an ideal dural substitute continues. Autografts, allografts, xenografts as well as synthetic materials have been used for dural repair so far. [7,8,9] .

Despite the encouraging progress achieved in the recent years in areas such as polymer science, cell biology, immunology and biotechnology, biocompatibility of biomaterials remains a pressing challenge.

[10] . In USA alone, there are at least 13 million biomaterial-based implants which are used in clinical setting annually.[11]. Currently, there have been several FDA (Food and Drug Administration) approved collagen-containing products that have entered into the market for treating exuding diabetic ulcers, spinal dural repair, and regeneration of bone graft substitute.[12,13] Current research and practices prove collagen to be ideally suited for dural reconstructive procedures. Collagen as a dural replacement material was utilized as early as 1965. It has a large surface area for CSF absorption, which helps the graft adhere to dura via surface tension.

Collagen is known to be chemotactic with regard to fibroblasts and promotes rapid re-colonization of the collagen implant by the host. Collagen is relatively stiffer than other elastic proteins such as elastin, but it is an elastic material with a high resilience of nearly 90 %, and is capable of reversible deformation. Biologically, collagen serves as a natural substrate for cellular activities, which makes collagen an excellent material for tissue engineering applications.[14]

DuraGen (Integra Life sciences, Plainsboro, NJ, USA) is a suture less dural substitute graft composed of purified type I collagen extracted from bovine Achilles tendon. The collagen matrix provides a scaffold for invasion of host fibroblasts, promotes fibrin clot, and is fully reabsorbed within 6to8 weeks as the wound heals.

This not only repairs the defect but in due course of time restores a normal dura thereby preventing peri-dural fibrosis.[15] Pradeep and Colleagues studied the radiological findings in Cranial and spinal cases undergoing dural collagen matrix reconstruction and concluded that it provided 100% CSF containment while complication were less than 3.2 % which included radiologically evident pseudomenngocele,sub dural and sub galeal collections. The same group also found similar results in posterior fossa surgeries.[16].

Jorn A Horaczek and colleagues evaluated collagen based dural graft in covering large dural defects in patients undergoing decompressive Hemicraniectomies. They found that the operating time was considerably reduced and so were the complication rates and overall treatment time. However there was no change in the rehabilitative outcomes.[17]. This aspect needs further elucidation as one needs to see if the cost of using a large collagen based graft translates to reducing the cost of treatment .

Conflicts of Interest

None

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