ORIGINAL RESEARCH

A Comparative Study in Use of Duragen (Collagen Matrix) and Pericranial Graft in Cases of Cranial Dural Defect Repair

[1]Dr. Maheswar Murmu, [2]Dr. Shahid Iftekhar Sadique, [3]Dr. Gitanjali Datta

[1] PDT, Mch, [2]Mch, Associate Professor, [3]Mch, Associate Professor, Department Of Neurosurgery, Bangur Institute of Neurosciences, IPGMER & SSKM Hospital, Kolkata 700020, West Bengal, India

Corresponding Author
Dr. Shahid Iftekhar Sadique
Associate Professor, [3]Mch, Associate Professor, Department Of Neurosurgery, Bangur Institute of Neurosciences, IPGMER & SSKM Hospital, Kolkata 700020, West Bengal, India

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Abstract
Aim: To compare the outcome of dural closure between autologous pericranial graft and collagen matrix graft.
Materials And Methods: The present prospective study was conducted at Indoor ward male and female**,** Department of neurosurgery, Bangur Institute of Neurosciences, IPGMER and SSKM Hospital, Kolkata from July 2021-December 2022 among 50 patients admitted with cranial Dural defect repaired. Out of 50 patients admitted with cranial dural defect repaired; 25 patients undergoing duragen assisted repaired and the remaining 25 patient's pericranial graft repaired.
Results: Most common etiology among the study subjects was tumour followed by trauma and vascular condition.Mean hospital stay (in days) was found to be 5.24±2.48 and 5.41±2.62 in duragen and pericranial graft group respectively.Only one subject suffered from postoperative complication in duragen group while the same was reported among 11 patients in pericranial graft group with statistically significant difference as $p<0.05$.
Conclusion: There is a significant reduction in the time for doing cranial dural defect repair while using collagen matrix (DuraGen) for dural closure as compared with pericranial graft. Significant reduction in time for doing cranial dural defect repair might mean in itself a reduction in surgical trauma as well as duration of hospital stay.
Keywords: Dural Closure, Pericranial Graft, Collagen Matrix Graft

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 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. Dura mater may be damaged as a result of trauma, surgery, or tumor involvement.[1-4]The incidence of cerebrospinal fluid (CSF) leak after cranial surgery ranges between 1-14% in the literature. CSF leak has also been associated with significant medical costs due to prolonged hospital stay andneedforadditionalinterventions[5].Pseudomeningocele swithout CSF leak can present with cosmetic deformity and debilitating symptoms such as positional headache. The incidence of clinically relevant pseudomeningocele in the literature ranges from 4-23%.[6-7]It is a common practice to reapproximate the dura to mitigate the leakage of CSF. Dural closure also limits muscle and epidural scar tissue from coming into contact with the brain following the operation. Duraplasty occurs by interposing a graft material between the dural defects (secondary closure). Duraplasty materials vary from autologous substances, such as pericranium and fat, to synthetic, such as acellular human dermis or collagen matrix. Closure of dural defects is a necessity afterneurosurgical procedures to prevent cerebrospinal fluid (CSF) leakage and to reduce the risk of perioperative infections. In several surgical settings primary closure is technically impossible, e.g. due to coagulation-induced shrinkage or retraction of dura,

surgical excision of dura (resection of meningiomas), or dural injury and laceration after trauma and therefore reconstruction of the dural defect using a substitute is required. Reconstruction with endogenous material is most common.[8]German has recently summarized the various techniques used for dura repair in the anterior fossa. They presented an original method of performing this operation with pericranium from the squamous portion of the frontal bone. This method allows the dura graft to retain its own blood supply, which makes survival more prompt, especially in the presence of bacteria, and utilizes tissues available within the operative field.[11] Indeed, over several decades, poor biological performance has excluded from clinical use a. dozens of dural grafts substitutes ranging from metal b. foils to various synthetic polymer sheets. In contrast, xenogeneic collagen-based dural graft substitutes have become increasingly popular. These devices are c. typically composed of animal collagens processed to d. remove cellular and other immunogenic components. For example, Dura-Guard is a strong, drapabledura implant readily sutured to surrounding tissues and is produced from processed sheets of bovine pericardium.[12,13]DuraGen(IntegraLifesciences) is a suturelessdural 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 as the wound heals[8]. Previous studies using DuraGen™ showed that duraonlay grafts may be superior to other synthetic devices for duraplasty since they do not require labour-intensive suturing, allow dura reconstruction with sufficient tightness to avoid perioperative CSF fistulas effectively, and cause no major reaction of the surrounding tissue.[4,5]The present study was conducted to compare the outcome of dural closure between autologous pericranial graft and collagen matrix graft. The study aims to examine whether the use of duragen significantly reduce the operating time in cranial Dural defects repair. It also aims to examine whether there is any difference in cerebrospinal fluid (CSF) collection postoperatively, morbidity, mortality, regarding cost effectiveness and hospital stay.

Materials And Methods

The present prospective study was conducted at Indoor ward male and female**,** Department of neurosurgery, Bangur Institute of Neurosciences, IPGMER and SSKM Hospital, Kolkata from July 2021-December 2022 among 50 patients admitted with cranial Dural defect repaired. Out of 50 patients admitted with cranial dural defect repaired; 25 patients undergoing duragen assisted repaired and the remaining 25 patient's pericranial graft repaired.

Inclusion Criteria:

All patients of cranial duraldefects requiring intervention.

Exclusion Criteria:

1. Patients with dural defect on medical management not suitable for surgical intervention.
2. Patients with bleeding diathesis.
3. Patients unfit for anaesthesia.

Statistical analysis

Data collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS Inc, Chicago, USA). Difference between two groups was determined using t test as well as chi square test and the level of significance was set at $p < 0.05$.

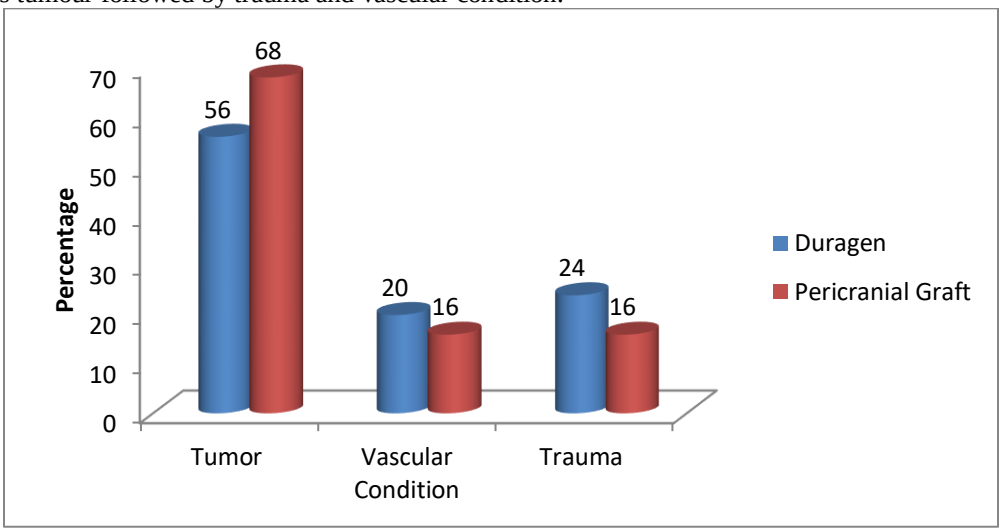
Results

In both the groups; males were comparatively more as compared to females. There was approximate equal distribution of male and female in both the groups.Mean age (in years) was found to be 36.19±6.23 and 34.92±5.71 in duragen and pericranial graft group respectively. When age was compared between the two groups, statistically insignificant difference was found as $p>0.05$ (table 1).

Table 1:Gender distribution among the study groups

Gender	Duragen		Pericranial Graft		Chi Square	p value
	N	%	N	%		
Male	21	84	19	76	0.36	0.78
Female	4	16	6	24		
Total	25	100	25	100		
					t test	p value
Age in years, Mean±SD	36.19±6.23		34.92±5.71		0.67	0.46

Graph 1 shows the etiology of cranial dural defect among the study groups. Most common etiology among the study subjects was tumour followed by trauma and vascular condition.



Graph: 1Etiology of cranial dural defect among the study groups

In this study, mean operating time was found to be higher in pericranial graft group (163.52±17.24) as compared to duragen group (126.83±18.12). When mean operating time was comparedbetween pericranial graft and duragen group using t test, statistically significant difference was found as $p<0.05$ (table 2).

Table:2 Mean operating time among the study groups

Group	Operating Time (in min)		t test	p value
	Mean	SD		
Duragen	126.83	18.12	4.07	0.009*
Pericranial Graft	163.52	17.24		

*: statistically significant

Mean hospital stay (in days) was found to be 5.24±2.48 and 5.41±2.62 in duragen and pericranial graft group respectively. When hospital stay (in days) was compared between the two groups, statistically insignificant difference was found as $p>0.05$ (table 3).

Table 3: Mean hospital stay (in days) among the study groups

Group	Hospital Stay (in days)		t test	p value
	Mean	SD		
Duragen	5.24	2.48	0.26	0.71
Pericranial Graft	5.41	2.62		

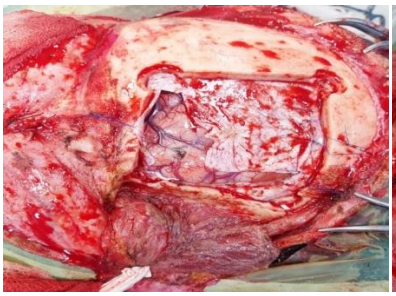
Only one subject suffered from postoperative complication in duragen group while the same was reported among 11 patients in pericranial graft group. Complications revealed in pericranial graft group was CSF leak (n=4, 16%), wound infection (n=3, 12%), wound dehiscence (n=2, 8%) and subcutaneous CSF accumulation (n=2, 8%). When postoperative complications were compared between the two groups using chi square test, statistically significant difference was found as $p<0.05$ (table 4).

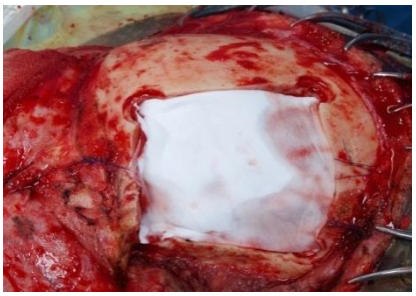
Table4: Postoperative complications among the study groups

Complications	Duragen		Pericranial Graft		Chi Square	p value
	N	%	N	%		
CSF Leak	0	0	4	16	6.72	0.006*
Wound Infection	0	0	3	12		
Wound Dehiscence	0	0	2	8		

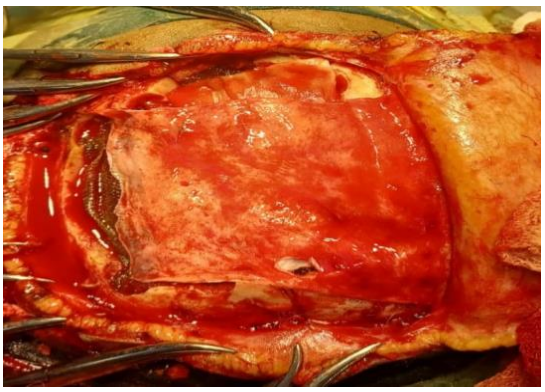
Subcutaneous CSF Accumulation	1	4	2	8		

*: statistically significant





Picture1: Intra-operative images of cranial dural defectPictute 2: Duragen assisted cranial dural defect repair



Picture 3: Pericranial graft assisted cranial dural defect repair

Discussion

Duraplasty material and/or technique is driven primarily by surgeon preference, as the literature is fraught with contradictory reports regarding their safety and efficacy. A commonly used safety endpoint is the occurrence of a postoperative infection. While some studies report an association between synthetic dural grafts and infection others report no such difference. The efficacy of a dural closure technique relates to its ability to prevent a CSF leak. However, several studies have reported that a watertight closure is not necessary for supratentorial surgery. These 2 outcomes, infection and CSF leak, can also be dependent variables, such that infection is sometimes believed to result in CSF leak and vice versa. Thus, in deciding whether to use a synthetic dural substitute, the surgeon must weigh the potential benefit of improved dural closure compared with primary closure against the potential increase in infection.[14]In both the groups; males were comparatively more as compared to females.Rajesh Kumar Barooahet al[15] in their study too reported male dominance. Asman Ali et al[16] in their study similarly showed that majority of the patients (55%) were male.Mean age (in years) was found to be 36.19±6.23 and 34.92±5.71 in duragen and pericranial graft group respectively. When age was compared between the two groups, statistically insignificant difference was found as p>0.05.Asman Ali et al[16] in their study revealed that ages ranged from 19-68 years (mean 42.3 years). These findings are similar to this study. Similar age distribution was found by Rajesh Kumar Barooahet al[15] in their study. Most common etiology among the study subjects was tumour followed by trauma and vascular condition. According to Asman Ali et al[16], the most common indication for duraplasty was tumor resection which is similar to the present study. Mean hospital stay (in days) was found to be 5.24±2.48 and 5.41±2.62 in duragen and pericranial graft group respectively. When hospital stay (in days) was compared between the two groups, statistically insignificant difference was found as p>0.05. In this study, mean operating time was found to be higher in pericranial graft group (163.52±17.24) as compared to duragen group (126.83±18.12). When mean operating time was compared between pericranial graft and duragen group usingt test, statistically significant difference was found as p<0.05. Similarly Rajesh Kumar Barooah et al[15] in their study found that the use of collagen matrix in decompressivecraniectomy resulted in decrease in mean operative time during the first surgery by average 45 minutes ($p < 0.5$) as compared to the use of autologous graft. There is reduction in the operating time during second surgery

(cranioplasty) by 35 minutes ($p < 0.5$). They also revealed lesser hospital stay (in days) in duragen as compared to pericranial graft group.The unique advantages of biological and synthetic grafts support their current usage. First, xenografts were used more often in decompressivecraniectomy for evacuation of traumatic subdural hematoma; these products incorporate into native dura and often do not require suturing, which can be useful in trauma cases requiring fast closure. Animal-derived collagen matrices that do not require suturing, like Tissue Dura (Baxter) and DuraGen, have additional implications for reduction of operative time and placement in difficult locations. Danish et al[6] reported shorter operating room times when using nonsuturedxenografts rather than allografts, which minimizes anesthesia-related complications and medical costs. Horaczeket al[1] in their study had similar findings of significant reduction in time in hemicraniectomy using DuraGen as dural substitute. Hence, a significant amount of time was saved by using DuraGen as dural substitute as compared with allogenic graft.

Only one subject suffered from postoperative complication in duragen group while the same was reported among 11 patients in pericranial graft group. Complications revealed in pericranial graft group was CSF leak (n=4, 16%), wound infection (n=3, 12%), wound dehiscence (n=2, 8%) and subcutaneous CSF accumulation (n=2, 8%). When postoperative complications were compared between the two groups using chi square test, statistically significant difference was found as $p<0.05$.Various studies[3,8,9,17] concluded that the dura substitute DuraGen (semisynthetic collagen matrices of bovine origin) is a promising alternative to duraplasty with endogenous periosteum, which is consistent with other studies. Similarly, in our studies, we found that semisynthetic collagen is an attractive option for duraplasty and various complications such as CSF leak, pseudomeningocele, aseptic meningitis, and wound infection were found to be within the acceptable range, which are not much different from other study results.Similarly distribution of complications was revealed by Rajesh Kumar Barooahet al[15] in their study.It was also found that with duragen, 2nd surgery during cranioplasty become easier as it is easy to raise flap and less time required. DuraGen was found to be completely uptaken by the dural layer as the whole dural layer during cranioplasty was found to be uniform. Hence, the time taken during the dural separation on using DuraGen was found to be significantly less than while using temporalis fascia (where more adhesion and more time taken was encountered). Hence, it was found that the time taken during cranioplasty was significantly less in the DuraGen group. Rajesh Kumar Barooahet al[15] in their study too reported similar results.

Limitation

Due to the fact that the sample size in our series is not being too large, the actual result of our series may not be the similar to the result when it is conducted in a much larger study population. Furthermore, there are various unknown confounding factors that could not be assessed which may have an impact on the result of these analyses.

Conclusion

There is a significant reduction in the time for doing cranial dural defect repair while using collagen matrix (DuraGen) for dural closure as compared with pericranial graft. Significant reduction in time for doing cranial dural defect repair might mean in itself a reduction in surgical trauma, exposure to anaesthesia as well as duration of hospital stay. While doing cranial dural defect repair, the time taken for the dural separation as well as the total time of cranioplasty in those using DuraGen was significantly less. CSF leakage was not found in the group using DuraGen.

We believe that this study forms a basis for further research work and assessment in an order to make a precise guideline for the non-watertight dural reconstruction with a nonsuturable, absorbable collagen matrix onlay graft in elective cranial surgery. In addition to clinical effectiveness, future study should focus on the cost-effectiveness of DuraGen.

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