Turk Neurosurg 31(5):680-685, 2021

Original Investigation

DOI: 10.5137/1019-5149.JTN.30444-20.2

Received: 24.04.2020
Accepted: 29.06.2020

Published Online: 26.03.2021

Comparison of TachoComb and TissuDura in Terms of Adverse Effects and Complications in Duraplasty in Rats

Ahmet KARKUCAK[1], Dursun TURKOZ[1], Birol BAYRAKTAR[1], Aytac TURKOZ[2], Cengiz COKLUK[3]

[1]University of Health Sciences, Samsun Education and Research Hospital, Department of Neurosurgery. Samsun, Turkey
[2]Medibafra Hospital, Department of Neurosurgery, Samsun, Turkey
[3]Ondokuz Mayis University, Faculty of Medicine, Department of Neurosurgery, Samsun, Turkey

Corresponding author: Dursun TURKOZ ✉ turkozdursun@gmail.com

ABSTRACT

AIM: To compare two synthetic graft materials, TachoComb®, a fibrin sealant composed of collagen, fibrinogen, thrombin and aprotinin and TissuDura®, a collagen-based biomatrix.

MATERIAL and METHODS: Thirty Sprague–Dawley rats were randomly divided into three groups with 10 animals in each group. A dural defect was created on the left parietal bone of each animal, and the dural defect was repaired using either TachoComb® (TachoComb group) or TissuDura® (TissuDura group). Sham animals did not receive any dural graft. After 21 days of follow-up, the brain was dissected, and inflammation, oedema, gliosis and foreign body reaction in the bone and parenchymal tissue were investigated histopathologically.

RESULTS: The TachoComb group showed significantly greater inflammation, gliosis and parenchymal foreign body reaction compared with the sham group. By contrast, the TissuDura group had significantly lower gliosis and insignificantly less inflammation in the bone and parenchymal foreign body reaction compared with the TachoComb group.

CONCLUSION: In conclusion, our results suggest that TissuDura® may be considered more biocompatible than TachoComb® in duraplasty.

KEYWORDS: Dura mater, Gliosis, Inflammation, Rats

INTRODUCTION

The dura mater is the thickest and outermost layer of the meninges of the brain and surrounds and protects the brain and spinal cord. It comprises fibroblasts and large amounts of extracellular collagen (18). Besides the function of the cranial dura to support the brain mechanically, its functional roles include the control of venous blood outflow from the brain (11,61), regulation of neurogenesis and axonal behaviour (56). In the literature, causes of dural defects include trauma (58), and neurosurgical interventions (21), leading to dural tears, tumour infiltration (27), dural arteriovenous fistulas (13,46,57), and empty sella syndrome (40).

Duraplasty is the procedure to repair dural defects by using graft materials from various sources when the primary sutures may be problematic (41). An ideal dural graft should mimic the features of the host dura as much as possible: it should be flexible, relatively inert, elastic in nature and tensile; it should be able to close the subarachnoid space in a watertight manner and be resistant to infections and inexpensive (32,36,59). Autologous tissue (43,63), and various synthetic dural grafts (28,51) may be used while performing duraplasty. Nonautologous dural substitutes are preferred because they are easily acquired; however, disadvantages include haemorrhage (45), cerebrospinal fluid (CSF) leaks (1), eosinophilic aseptic meningitis (4), and extended wound healing period (54). By contrast, despite the benefits of

Ahmet KARKUCAK : 0000-0003-2522-1822
Dursun TURKOZ : 0000-0003-3599-0895
Birol BAYRAKTAR : 0000-0003-4546-2797
Aytac TURKOZ : 0000-0002-6520-2602
Cengiz COKLUK : 0000-0003-2146-3621

autologous grafts, such as they do not arise immune and/or immuno-allergic response, are cheap and very effective in blocking CSF leaks (1,6,20,25), they may lead to increased mortality rates and cause elevated risks of wound breakdown, infection, local pain syndrome and aesthetic problems due to extended wound healing period (1). The goal of achieving a watertight closure to reduce the risks of duraplasty led to a search for new materials for this procedure (60). Synthetic dural grafts are another option for duraplasty, and advantages of synthetic dural grafts include uniformity and availability, and they can be cut to the required shape for duraplasty (51). Various synthetic materials, including polyglycolic acid and polylactic-co-glycolic acid (44), and natural compounds, such as gelatin (22) and collagen (37), have been implicated in duraplasty.

TissuDura (TissuDura®; Baxter, Vienna, Austria) is a natural collagen biomatrix derived from equine Achilles tendon (42). Its biocompatibility with low incidence of inflammation and adhesions, as well as its nontoxic profile make it a valuable candidate for duraplasty (7,16,53). By contrast, TachoComb (TachoComb®; Nycomed, Ismanig, Germany) is a widely used fibrin sealant for tissue adhesion and closure during various surgeries and composed of a collagen patch coated with a combination of human fibrinogen and bovine thrombin and aprotinin (23). The mechanism for successful duraplasty with graft material includes generation of watertight, elastic and durable living tissue barrier with the combination of thrombin, fibrinogen, coagulation factors and fibrinolysis inhibitor aprotinin and with the support of the collagen matrix (2,35,49). TachoComb was known to be advantageous due to its rapid and practical application with coagulation uniformity on the bleeding regions (34).

Our study aimed to compare the efficacy and biocompatibility of the two synthetic collagen-based dural grafts, the TachoComb and TissuDura, in experiment models of dural defect in rats.

MATERIAL and METHODS

Animal Husbandry and Experimental Setup

The present study was approved by local ethics committee (Approval number: 2009/27, date: 27/04/2009) on animal experiments and conducted in experimental animal laboratory in our institution. Thirty Sprague–Dawley rats aged between 16 and 20 weeks weighing 300–400 g in both sexes were equally and randomly divided into three groups: the TachoComb, TissuDura and sham groups. The animals were kept under controlled temperatures (21°C ± 1°C) and lighting conditions (12-h light/dark cycle) in individual cages. Standard rat chow and tap water were provided *ad libitum*. The animals were starved of food for 12 hours with free access to water preoperatively.

For surgery, the animals were anesthetised by intraperitoneal administration of 10 mg/kg xylazine (Rompun®, Bayer) and 80 mg/kg ketamine hydrochloride (Ketalar®, Parke Davis). After anaesthesia was administered, the surgical site was shaved, and the skin was cleaned with 10% povidone iodine solution. Subsequently, 2-cm incisions were carefully performed, and the subcutaneous layers were dissected. A burr hole was carefully created on the parietal bone by using a high-speed dental drill with 3-mm ball-end, and the dura mater was exposed. A 3-mm dural defect was constituted in the dura by using a sterile no. 11 scalpel blade. Either TachoComb® or TissuDura® with a size of 0.5 cm × 0.5 cm was placed on the dural defects in the TachoComb and TissuDura groups, respectively. By contrast, the sham group did not receive any graft placement. The skin and subcutaneous tissue were sutured with 4–0 silk sutures following homeostasis. The incisions were cleaned with 10% povidone iodine solution, and the animals were placed in their prewarmed cages.

The cages were kept under stable temperature to maintain the body temperature of the rats. The animals were administered with 2 mg/kg paracetamol for 3 days *per os*. The rats were postoperatively followed in terms of general behaviour, neurological findings, mobility and infection for 21 days. Development of abnormal posture and motor deficits, rubor at the incision site, signs of infection, such as pus formation and oozing on the incision site and reduced food and water intake, were determined as exclusion criteria.

On postoperative day 21, the rats were decapitated under general anaesthesia, and both cerebral hemispheres and dura mater were removed *en bloc* for histopathological evaluations.

Histopathological Evaluations

The cerebral parenchyma and dura mater were fixed with 10% formalin. Transverse samples containing the lesion area from the cerebral tissue and dura mater were embedded in paraffin blocks. The parietal bone samples were decalcified in acid for 5 days and embedded in paraffin blocks. Slices with 5-µm thickness were taken from the paraffin-embedded samples and stained with haematoxylin and eosin (H&E) and luxol fast blue stains by using standard histological protocols. All histopathologic evaluations were performed under a light microscope by an experienced pathologist who was blinded to the groups. Each slice was evaluated for oedema, gliosis, inflammatory cell accumulation, foreign body reaction and gliosis (Table I).

Statistical Analysis

Scoring data were presented as mean ± standard deviation (SD). Statistical analyses were performed using GraphPad Prism 7 (GraphPad Software, USA). Normal data distribution was compared using Shapiro–Wilk normality test. Data were compared using the Kruskal–Wallis test followed by Dunn multiple comparison test. Statistical significance was accepted for $p<0.05$.

RESULTS

All rats completed the follow-up period of 21 days.

Inflammation

The parenchyma was inflamed in one, seven and three animals in the sham, TachoComb and TissuDura groups, respectively. The parenchymal inflammation scores of the

Table I: Histopathological Scoring Scale for Inflammation, Foreign Body Reaction, Edema and Gliosis

Score	Inflammation	Foreign body reaction	Edema	Gliosis
0	None	None	None	None
1	Mild	Limited	Mild	Mild
2	Moderate	Widespread	Moderate	Moderate
3	Severe	Widespread and necrosis	Severe	Severe

Table II: Histopathological Scoring in Sham, TachoComb and TissuDura Groups of Animals. (Data are represented as mean ± SD; n=10 animals in each groups)

	Inflammation		Edema	Gliosis	Foreign body reaction	
	Parenchyma	Bone			Parenchyma	Bone
Sham	0.1 ± 0.31[b]	0 ± 0[a]	0.2 ± 0.42	0.1 ± 0.31[a]	0 ± 0[b, d]	0 ± 0
TachoComb	1.3 ± 1.16[b]	0.5 ± 0.52[a]	0.6 ± 0.51	0.9 ± 0.73[a, x]	2 ± 0[d]	0.6 ± 0.69
TissuDura	0.3 ± 0.48	0.2 ± 0.42	0.2 ± 0.42	0.2 ± 0.42[x]	1.2 ± 0.42[b]	0.5 ± 0.84

[a and x] p<0.05, [b]p<0.01, [d]p<0.0001.

animals in the TachoComb group was significantly higher than those of the animals in the sham group (p=0.0091; Figure 1A and C), whereas no significant difference was found between the sham and TissuDura groups (p>0.05; Table II). Moreover, parenchymal inflammation in the TissuDura group was lower than that in the TachoComb group animals, but was not significant (p=0.0846; Figure 1B and C).

With regard to the inflammation in the bone, none of the animals in the sham group showed inflammation. By contrast, five and two animals in the TachoComb and TissuDura groups, respectively, showed inflammation in the bone. In the TachoComb group, the mean score of inflammation in the bone was significantly higher than sham group (p=0.0281; Table II). By contrast, no significant differences were found in the inflammation scores in the bone between the TissuDura and sham groups (p>0.05).

Oedema

Oedema was observed in two, six and two animals in the sham, TachoComb and TissuDura groups, respectively. No significant differences were found in the oedema severity between any of the groups (p>0.05; Table II).

Gliosis

The parenchymal gliosis at the vicinity of the primary surgical area or gliosis secondary to the foreign body reaction was evaluated, and moderate and mild gliosis was observed in two and five animals in the TachoComb group. By contrast, mild gliosis was observed in two animals and one animal of the TissuDura and sham groups, respectively. The oedema scores of the TachoComb group of animals were significantly higher than those of both sham and TissuDura groups (p<0.05; Figure 1A-C), whereas no significant differences were found between the sham and TissuDura groups (p>0.05; Table II).

Parenchymal foreign body reaction

Widespread foreign body reaction was observed in all and in two animals in the TachoComb and TissuDura groups, respectively, whereas limited parenchymal foreign body reaction was observed in eight animals in the TissuDura group. The sham group of animals did not exhibit any parenchymal foreign body reaction. The parenchymal foreign body reaction scores were significantly higher in TachoComb and TissuDura groups compared with the sham group (p<0.0001 and p<0.01, respectively), whereas no significant differences were observed between the TachoComb and TissuDura groups (p=0.0912).

Bone Foreign Body Reaction

In the TachoComb group, five animals and one animal had limited and widespread foreign body reaction, respectively. By contrast, seven animals in the TissuDura group had no reaction in the bone tissue, whereas two animals and one animal had widespread and limited foreign body reaction, respectively (Figure 1A and D). The sham group had no foreign body reaction in the bone tissues. No significant differences between the groups were observed in the score of foreign body reaction in the bone (p>0.05; Table II).

DISCUSSION

The dura mater is the outermost and thickest meninx surrounding the brain and spinal cord and forms a protective barrier (53). It also isolates the CSF from the outside medium, protecting the nervous system from infections (14,36). The integrity of the dura mater is disrupted not only due to several reasons, including neoplastic infiltrations (27), and trauma (58), but also during neurosurgical interventions (21). To prevent complications that may occur due to dura mater damage (8,9,19,26,48), watertight repair of the dura should always be performed during the management (7,12,29).

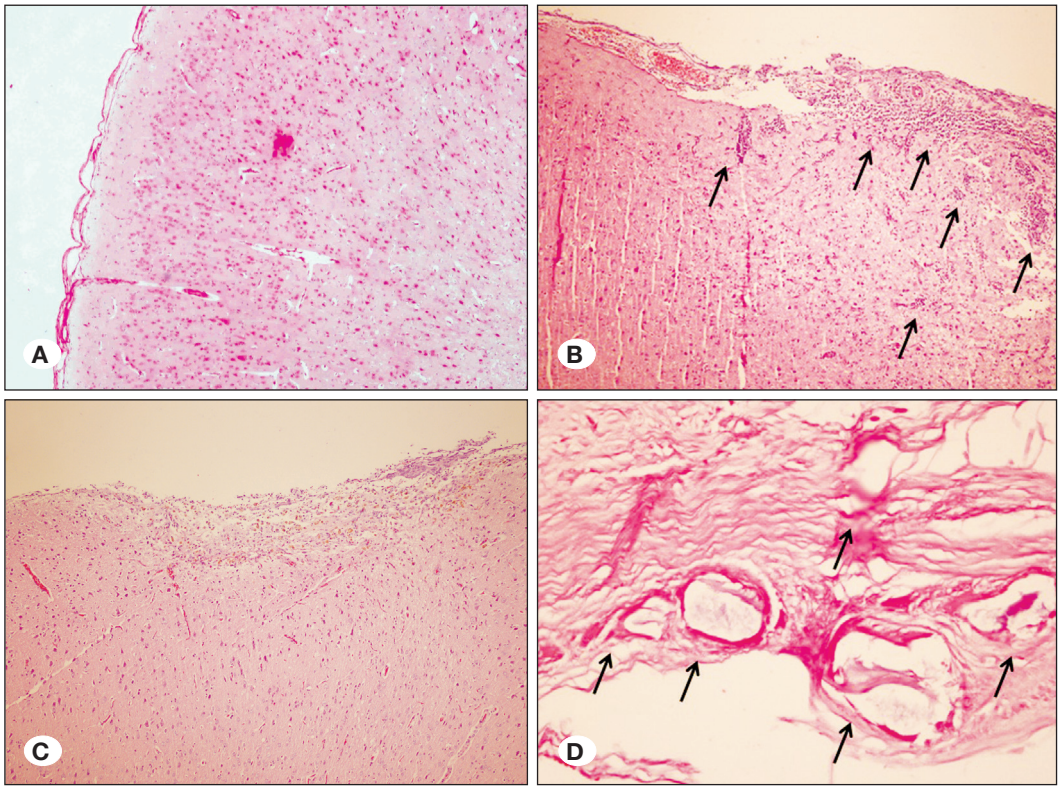

Figure 1: Representative histopathological findings in **A)** the sham (H&E ×200) and **B)** TissuDura groups. The black arrows indicate inflammation in the region of interest (H&E ×200), **C)** TachoComb group. Widespread gliosis is observed in the parenchymal tissue (H&E ×200). **D)** TissuDura group. The black arrows indicate the inflammation in the region of interest (H&E ×400).

Various methods have been performed to repair dural defects. The best method to treat dural tears is primary watertight dural repair (62). In such cases, the nutrition of the autologous tissue is not disturbed, and the tissue is repaired as close as possible to its natural status (31). In cases where the use of this method is feasible, alternative dural graft materials, including autologous, nonautologous and synthetic grafts are used (3,14,36). The advantages of the synthetic dura grafts include their availability (51) with various alternatives (22,37,44,51), their biomechanical properties (24), flexibility (38), and being a self-adhesive (50). Furthermore, other advantages include easiness of application (28), shorter operating room times (5), and reduction in inflammatory or allergic reactions (28).

In recent years, two materials among synthetic grafts, the TachoComb® (Nycomend, Ismany, Germany) (2,23,34) and TissuDura® (Baxter, Deutschland, Germany) (7,16,53) became popular in duraplasty. This paper compared the suitability and adverse effects of TachoComb® and TissuDura® as dural substitutes.

Neuroinflammation is characterised by several factors, including gliotic activity, leucocyte infiltration to the damaged area and increased inflammatory factor levels (52). In our study, we observed significant induced inflammation in the bone and parenchymal tissue in the TachoComb group compared with the sham group. A previous study by Ozel et al. on rats that underwent colon anastomosis, higher perianastomotic inflammation in the surgical area was observed compared with the sutures, suggesting that increased inflammation may increase the duration of the healing process (39). By contrast, no differences were found between the TissuDura and sham groups in terms of inflammation. Although no significant differences between the TachoComb and TissuDura groups were observed with regard to inflammation, the TissuDura tended to cause lower parenchymal inflammation in the surgical area, suggesting that the healing process might be faster in the TissuDura group. Moreover, inflammatory activity upon duraplasty with synthetic materials has been reported by several studies (10,15,17,30). By contrast, gliosis was elevated by TachoComb duraplasty, whereas a significantly lower gliosis was observed in the TissuDura group compared with the TachoComb group.

Foreign body reaction may be observed after duraplasty (33,47,55). In our study, we observed that TachoComb and TissuDura groups showed significantly higher parenchymal foreign body reaction than the sham group. Moreover, the reaction in the TissuDura group was lower than that in the TachoComb group, and the difference was not significant. Additionally, no significant differences were found between three groups in terms of oedema and the foreign body reaction in bone.

CONCLUSION

The material of the dural substitute possesses a great importance in duraplasty. In conclusion, our results suggest that TissuDura® possesses more biocompatibility than TachoComb®.

ACKNOWLEDGEMENTS

This study did not receive any grants, and corporate support and was conducted with the efforts of all authors.

The authors would like to thank Mehmet Kefeli, M.D. for his valuable efforts in evaluating histopathological specimens.

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