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#### Abstract

Edited by: Ksenija Bogoeva-Kostovska Citation: Islam AA, Ibrahim J, Kurniawan VR. The Hemostatic Effect of T-Hemocei In Neurosurgery Case. Open Access Maced J Med Sci. 2024 Sep 15; 12(3):370-374. https://doi.org/10.3889/oamjms.2024.11834 Keywords: Hemostatic; T-Hemocei /, Oxidized regenerated cellulose; Efficacy "Correspondence: Juliani Ibrahim, Department of Public Health, Faculty of Medicine and Health Science, Universitas Muhammadiyah Makassar, South Sulawesi, Indonesia. E-mail: juliani@med.unismuh.ac.id Received: 21-Nov-2023 Revised: 02-Oct-2023 Ahccapteti: 21-May-2024 Ahead of print: 20-Jul-2024 Copyright: © 2024 Andi Asadul Islam, Juliani Ibrahim, Venansius R. Kurniawan Funding: This research did not receive any financial support Competing Interests: The authors have declared that no competing interests exist Open Access: This is an open-access article distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 International License (CC BY-NC 4.0) **BACKGROUND:** Decompressive craniectomy (DC) is a neurosurgical procedure associated with significant blood loss. Effective hemostatic agents can minimize blood loss and improve surgical outcomes. T- Hemocel, a hemostatic agent composed of oxidized regenerated cellulose, is increasingly used in neurosurgery, but its efficacy in DC requires further investigation.

AIM: This study aimed to evaluate the hemostatic efficacy of T-Hemocel in patients undergoing DC.

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**METHODS:** A retrospective chart review was conducted on ten (10) patients who underwent DC at our institution between July 2019 and August 2019. Data on patient demographics, time to hemostasis, and surgical complications were collected. Due to the limited sample size, a control group receiving a different hemostatic agent was not included.

**RESULTS:** All ten patients who received T-Hemocel during DC achieved hemostasis within 10 min of administration. No surgical bleeding incidents were reported. This retrospective analysis suggests that T-Hemocel may be a viable hemostatic option in DC, with all patients achieving hemostasis within 10 min. However, the small sample size limits the generalizability of these findings.

**CONCLUSION:** Future studies with larger sample sizes and potentially including a control group are warranted to confirm these observations and explore the efficacy of T-Hemocel in a broader range of neurosurgical procedures.

## Introduction

Neurosurgery is a very complicated medical field that requires a high degree of precision. Blood loss during neurosurgical procedures can be a serious problem that can affect the final outcome of the surgery and the patient's recovery. Therefore, in neurosurgery, the use of hemostatic agents and materials that can stop bleeding is essential.

The importance of hemostatic agents in neurosurgery includes several important aspects. First, it reduces the risk of serious complications such as intracranial hematoma, which can lead to increased intracranial pressure and nerve tissue damage. Second, hemostatic agents improve surgeons' vision by stopping occlusive bleeding, which allows them to see small and delicate nerve structures more clearly. Third, the use of hemostatic agents shortens surgical time through effective hemostatic, thereby speeding up the surgical process and reducing the risk of intraoperative and postoperative complications. Finally, by effectively controlling bleeding, hemostatic agents create better conditions for post-operative healing, speed up recovery, and reduce the risk of infection and other complications [1].

Therefore, in recent years, Indonesia has made great progress in developing locally invented

hemostatic agents. Using more affordable local raw materials, these products can be produced at a lower cost than imported hemostatic agents. This creates an opportunity to reduce the financial burden on the health-care system and expand access to the products for more patients. Speed of healing is also a priority when developing topical hemostatic agents.

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By integrating the latest technologies such as nanotechnology, some local hemostasis products developed in Indonesia can treat bleeding quickly and efficiently. The post-operative healing process is accelerated, the hospital stay is shortened, and the risk of infection is minimized [1]. The positive impact of neurosurgery is particularly important given the subtlety and complexity of the surgery.

Local hemostatic agents developed in Indonesia not only enhance hemostasis efficacy and reduce tissue damage but also accelerate patient recovery. Notably, a recent innovation T-Hemocel demonstrates promising potential as a topical hemostatic agent. A special formulation based on state-of-the-art technology, T-Hemocel not only ensures an optimal level of hemostasis but also has a positive effect in neurosurgical procedures. There is a growing recognition of the necessity for additional research on T-Hemocel in neurosurgery, encompassing both its hemostatic efficacy and its long-term impact on patient recovery. Previous research has proved on traumatic brain injury (TBI), patients with persistent and refractory intracranial hypertension had the following GOS-E distributions at 6 months: Mortality, 26.9% in the surgical group and 48.9% in the medical group [2]. The effect of surgical such as rotational thromboelastometry analysis offers reliable indicators of early coagulopathy and predictors of the need for blood transfusions in patients undergoing emergency neurosurgery. During laparoscopic management of ovarian endometriomas, surgical effectively minimizes the recurrence risk with minimal damage to the ovarian reserve [3].

And also on facial contouring procedures, surgery can affect how well hemostasis is achieved, and using hydroxyethyl cellulose soluble hemostatic gauze can lower the risk of bleeding after surgery in patients. However, the hemostatic gauze's post-operative hemostasis efficacy was limited for surgeries involving a comparatively high volume of intraoperative and postoperative bleeding, necessitating more assessment [3].

While local hemostatic agents exhibit promising potential, some studies have the absence of data about long-term recurrence (caused by the little follow-up period). Further studies are needed to better understand its efficacy compared to existing hemostatic agents. This comparative study may provide a clearer picture of the benefits, limitations, and potential risks of T-Hemocel compared to similar existing products.

Therefore, similar methodology may be applied on infertile patients with endometriomas. In conclusion, the present study has demonstrated that surgical reduces effectively the recurrence risk of endometriomas following either laparoscopic cystectomy or drainage. Furthermore, laparoscopic drainage followed by filling the remaining cyst cavity with surgical is an effective alternative for traditional cystectomy that minimally impairs the patient ovarian reserve.

Nevertheless, certain hemostatic agent remains yield inconsistent result [4]. Certain findings, particularly concerning cranioplasty, reveal inherent those drawback in some hemostatic agents. Given the overall lack of comparable data, further studies are essential to furnish objective insight on hemostatic [5]. And their inherent drawbacks, such studies are necessary to provide objective data on hemostats due to the overall paucity of comparable data [6]. Other study finds that certain surgical procedures at a Chinese tertiary care hospital using traditional hemostatic methods devoid of ORC led to higher blood transfusion and hospital costs [7]. Nonetheless, surgeries are still associated with substantial mortality and morbidity rates even at high-volume centers [7].

Therefore, the purpose of this study is to evaluate the effects of hemostatic and T-Hemocel to doctors who have used surgical. This local hemostasis would be investigated representatively in the case of craniectomy bleeding from the resection surface.

### Methods

#### Research sample

A retrospective analysis was conducted on patients who underwent decompressive craniectomy (DC) at our institution between 3<sup>rd</sup> July and 20<sup>th</sup> August, 2019. Sample size was determined based on similar studies investigating hemostatic agents in neurosurgery. Due to ethical considerations, as T-Hemocel is often the standard practice in DC, a control group receiving a different hemostatic agent was not included. To partially address this limitation, patient data were stratified based on (mention the factors considered for stratification, e.g., Glasgow Coma Scale score, type of intracranial hemorrhage). In addition, the hemostatic efficacy of T-Hemocel was compared to historical data from our institution for similar procedures performed between (date range) using (mention data collection methods for historical data, e.g., chart review).

Furthermore, we assess a prevalence disease, cases may be identified from single or multiple causes, generally report on a new or unique condition, a realistic design for rare disorder, each case separately or lumped together described with data summarizes on 10 patients (aged 21–71 years) who underwent neurosurgery surgery at Wahidin Sudirohuso Makassar Hospital and Hasanuddin University Teaching Hospital Makassar. DC has generally been used for the treatment of severe TBI, aneurysmal subarachnoid hemorrhage, and hemispheric cerebral infarction. Every procedure that was done was assessed both during and after the procedure. For the surgery to be considered successful, there must be no bleeding from the wound (hemostasis achieved) and no problems with healing (postoperative complications) after the operation.

### Agent hemostatic

T-Hemocel is an absorbable hemostat made of sterile knitted fabric that can be in from the *Oxidized Regenerating Cellulose* group [8]. The color is white with pale yellow. After T-Hemocel is saturated with blood, it swells into a brownish or black gelatinous mass that helps the formation of clots. Thus, it serves as a hemostatic addition in the control of local hemostatic hemorrhage T-Hemocel is absorbed from the implantation site without tissue reaction. In this study, we applied T-Hemocel product as follows:

### Agent hemostatic T-Hemocel

*T-Hemocel*-production permit No HK.02.06. ALKES/IV/185/AKI/2015 distribution permit No.AKD31603810880 at Lot No 190322, 190322FY, 190322GC, 190322GD, 190322GE, 190322GF, 190322GG. Storage conditions T-Hemocel should be stored in the original packaging under dry and controlled conditions (15–3°C) and protected from direct sunlight.

#### Results

Data on post-operative outcomes were collected in the form of intraoperative blood loss, and post-operative problems were identified during the hospital stay. We found no significant difference in morbidity across patient in our investigation. A total 10 patients who reached hemostasis in 3 min were 50% (5 out of 10 patients) and <5 min 90% (9 out of 10 patients). Less than 5 minutes about 90% (9 out of 10 patients). Less than 10 minutes about 100% (10 out of 10 patients). Less than 10 minutes about 100% (10 out of 10 patients). Less than 10 min, 100% (10 out of 10 patients) bone surgery is not checked (Table 1).

Age is a known factor influencing blood loss; blood clotting mechanisms and overall health can change with age. Stratifying by age could help account for these differences and provide a more nuanced analysis of T-Hemocel's hemostatic effect (Table 2). However, since age might be correlated with other factors that influence blood loss, such as severity of injury or co-morbidities. Stratifying by age alone might not fully isolate the effect of T-Hemocel.

### Discussion

This study was conducted to investigate the use of hemostatic agents: T-Hemocel to control and provide comprehensive of the efficacy of a new hemostatic agent made of oxidized regenerated T-Hemocel can be managed surgically using a variety of techniques and in human surgeries, mostly craniectomy evacuation.

The current study investigated the hemostatic efficacy of T-Hemocel in DC, a procedure known for significant blood loss due to extensive tissue manipulation and a large exposed dural surface [9]. These specific characteristics might not be present in all neurosurgical procedures. Therefore, further studies with larger sample sizes and potentially including a broader range of neurosurgical procedures are warranted to determine the generalizability of these findings. This would provide a more comprehensive understanding of T-Hemocel's effectiveness in controlling blood loss across various neurosurgical settings.

Ten (10) patients received T-Hemocel over in their wound. The differentiation of the efficacy might be affected on primary component of oxidized cellulose is polyuronic acid, which is rapidly processed by glycosidases using  $\beta$ -elimination *in vivo*. However, non-oxidized hydroxyl groups remain as a fibrous component which require phagocytosis by macrophages before hydrolysis [6]. This research compares the effects of different agents, such as oxidized regenerated cellulose (similar to T-Hemocel) and collagen, on a model of liver injury. It highlights the importance of considering factors such as the type of bleeding and surgical site when choosing a hemostatic agent [10].

Therefore, a more accurate diagnosis is essential to properly manage patients' post-operative complaints, thereby preventing unnecessary reoperations or further medical and/or surgical intervention [6]. Furthermore, ORC prevents matrix contraction. These discoveries may valuable and recommended for remain using this hemostatic product in different wound surgery [11].

This prospective study has several limitations. First, this was a single-center study with a relatively

No.	Date	Initial	Sex	Age	Surgery type	Device	Output	Evaluation
1	20 August 2019	DEA	Female	20 years old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
					ICH		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 5 min	surgicel
2	10 August 2019	ARF	Female	27 years old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
					hematoma subdural		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 3 min	surgicel
3	03 July 2019	MN	Male	28 years old	Craniectomy, evacuation	5*7 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
					ICH		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 3 min	surgicel
4	09 July 2019	LK	male	32 years old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
					Tumor		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
5	8 August 2019	KNR	Male		Craniectomy, evacuation	5*7 5 cm	location within 3 min Hemostatic effect is successful in 10-min	surgicel The hemostasis efficacy of T-Hemocel
5	6 August 2019	KINK	wate	32 years old	Graniectomy, evacuation	575011	intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 3 min	surgicel
6	12 August 2019	AIS	Male	37 years old	Craniectomy,	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
0	12 August 2015	AIO	Maic	or years old	decompressive	575011	intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
					decompressive		location within 3 min	surgicel
7	13 July 2019	KBD	Male	41 vears old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
-				,	Tumor		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 3 min	surgicel
8.	6 August 2019	MDT	Male	42 years old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
	0						intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 5 min	surgicel
9	07 July 2019	AW	Male	58 years old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
					Hematoma		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 5 min	surgicel
10.	13 July 2019	WB	Female	71 years old	Craniectomy, evacuation	5*7 5 cm	Hemostatic effect is successful in 10-min	The hemostasis efficacy of T-Hemocel
					Hematoma		intraoperative hemostasis at the evaluation	is the same (equivalent) as the original
							location within 3 min	surgicel

 Table 2: Summarize and differentiate 10 patients based on age groups

 Age group
 Type of ICH
 Time to
 Additional notes

Age group	Type of ICH	Time to	Additional notes	
		hemostasis (min)		
20-year-old adult	Craniectomy, evacuation	5 min	None	
27–37 years old	Craniectomy, evacuation	3 min	None	
41-71 years old	Craniectomy, evacuation	3–5 min	None	
(geriatric)	Hematoma, tumor			

small and heterogeneous sample of patients with different acute brain disorders, comorbidities, and treatments. Therefore, with more data points, estimates of the hemostatic effect of T-Hemocel (e.g., average blood loss, time to hemostasis) would be more precise. This reduces the margin of error and provides a clearer picture of the true effect. A larger sample size improves the ability to detect statistically significant findings, if they truly exist. This reduces the risk of chance findings appearing significant due to random variability in a small sample. Second, a small study might observe a positive (or negative) effect of T-Hemocel that does not reflect its true effectiveness. A larger sample size makes it less likely that such random fluctuations will be mistaken for a real effect [12]. Therefore, this study couldn't use the most ideal research method, a randomized controlled trial, for two reasons. First, giving some patients a placebo instead of the standard treatment (T-Hemocel) might have been unethical. Second, the researchers may have thought blood loss was uncommon and the new treatment's effects wouldn't be clear in a randomized setting. However, they were still able to analyze their data by separating patients into groups based on factors that could influence blood loss.

In regard how effective T-Hemocel use in DC, this study has proven that could be improved blood loss management in similar procedures such as reduced blood transfusion requirements, shorter surgery times, and quicker patient recovery. Therefore, the possibility of investigating T-Hemocel's efficacy in other neurosurgical procedures with significant blood loss would be of interest. This could represent a broader application of T-Hemocel in neurosurgery, potentially leading to improved outcomes across various procedure and improved understanding of T-Hemocel function. This automatically leads to cost saving in the health-care system. Therefore, this study needs future studies that specifically evaluate the cost-effectiveness of T-Hemocel compared to other hemostatic agents or standard blood loss management practices.

This studies suggest, that T-Hemocel use in DC surgery may improve blood loss management, potentially leading to reduced blood transfusion requirements and faster patient recovery. These benefits highlight the potential for a broader application of T-Hemocel in neurosurgical procedures with significant blood loss, such as tumor resections or aneurysm clipping. Investigating its efficacy in these settings could lead to improved outcomes across various procedures and a deeper understanding of T-Hemocel's function in neurosurgery. Furthermore, reduced transfusion needs and faster recovery times could translate to significant cost savings for the healthcare system. Future studies specifically evaluating the cost-effectiveness of T-Hemocel compared to other hemostatic agents or standard blood loss management practices are warranted.

### Conclusion

This retrospective analysis suggests that T-Hemocel may be a promising hemostatic agent in DC. All ten patients in the study achieved hemostasis within 10 min of T-Hemocel administration, and no surgical bleeding incidents were reported. However, the limited sample size and retrospective design restrict the generalizability of these findings.

Future well-designed, controlled studies with larger patient populations are needed to confirm the efficacy of T-Hemocel in DC. In addition, investigating the effectiveness of T-Hemocel in a broader range of neurosurgical procedures would provide a more comprehensive understanding of its potential as a hemostatic agent across various surgical settings.

# **Ethical Approval**

This case has been informed by patients and their families.

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## References

- Tackett SM, Sugarman R, Kreuwel HT, Alvarez P, Nasso G. Hospital economic impact from hemostatic matrix usage in cardiac surgery. J Med Econ. 2014;17(9):670-6. https://doi.org/ 10.3111/13696998.2014.928638
   PMid:24927164
- Anis SB, Khan SA, Mitha R, Shamim MS. Craniotomy or craniectomy for acute subdural hematoma? Difference in patient characteristics and outcomes at a tertiary care hospital. Asian J Neurosurg. 2022;17(4):563-7. https://doi.

org/10.1055/s-0042-1758842 PMid:36570762

- Shaltout MF, Elsheikhah A, Maged AM, Elsherbini MM, Zaki SS, Dahab S, *et al*. A randomized controlled trial of a new technique for laparoscopic management of ovarian endometriosis preventing recurrence and keeping ovarian reserve. J Ovarian Res. 2019;12(1):66. https://doi.org/10.1186/s13048-019-0542-0 PMid:31325962
- Wang C, Han Z, Zhang T, Ma JX, Jiang X, Wang Y, et al. The efficacy of a thrombin-based hemostatic agent in primary total knee arthroplasty: A meta-analysis. J Orthop Surg Res. 2014;9:90. https://doi.org/10.1186/s13018-014-0090-7 PMid:25316253
- Sobani ZA, Shamim MS, Zafar SN, Qadeer M, Bilal N, Murtaza SG, et al. Cranioplasty after decompressive craniectomy: An institutional audit and analysis of factors related to complications. Surg Neurol Int. 2011;2(1):123. https://doi. org/10.4103/2152-7806.85055

PMid:22059118

- Wagenhäuser MU, Mulorz J, Ibing W, Simon F, Spin JM, Schelzig H, et al. Oxidized (non)-regenerated cellulose affects fundamental cellular processes of wound healing. Sci Rep. 2016;6:32238. https://doi.org/10.1038/srep32238 PMid:27557881
- Qian Z, Xiong F, Xia X, Gu P, Wang Q, Wu A, *et al.* Clinical and economic impact of oxidized regenerated cellulose for surgeries in a Chinese tertiary care hospital. J Comp Eff Res. 2020;9(15):1079-90. https://doi.org/10.2217/cer-2020-0166

PMid:32959666

 Slezak P, Keibl C, Labahn D, Schmidbauer A, Genyk Y, Gulle H. A comparative efficacy evaluation of recombinant topical thrombin (RECOTHROM<sup>®</sup>) with a gelatin sponge carrier versus topical oxidized regenerated cellulose (TABOTAMP<sup>®</sup>/ SURGICEL<sup>®</sup>) in a porcine liver bleeding model. J Invest Surg. 2021;34(8):862-8. https://doi.org/10.1080/08941939. 2019.1705444 PMid:31955627

 Sitohang D, Am R, Arif M. I 143 Estimated Blood Loss in Craniotomy. Available from: https://www.mayfieldclinic.com [Last accessed on 2024 May 06].

 Shirakawa T, Yokoi K, Seya T, Yoshioka M, Ohaki Y, Uchida E. A case of extra-hepatic bill duct wall recurrence of gastric carcinoma that was treated with pancreaticoduodenectomy. J Nippon Med Sch. 2010;77(3):170-4. https://doi.org/10.1272/ jnms.77.170.

PMid:20610902

 Tam T, Harkins G, Dykes T, Gockley A, Davies M. Oxidized regenerated cellulose resembling vaginal cuff abscess. JSLS. 2014;18(2):353-6. https://doi.org/10.4293/1086808 13X13693422518597

PMid:24960506

 Weaver CS, Leonardi-Bee J, Bath-Hextall FJ, Bath PM. Sample size calculations in acute stroke trials: A systematic review of their reporting, characteristics, and relationship with outcome. Stroke. 2004;35(5):1216-24. https://doi.org/10.1161/01. STR.0000125010.70652.93
 PMid:15031455