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Research article

Study of absorbable dural sealant to improve complications after craniocerebral surgery and its application strategy and standardized operation procedure

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ABSTRACT

Background: Infection after craniocerebral operation has always been a very focused problem, and dural closure can reduce perioperative infection by reducing drainage volume and subcutaneous effusion, so how to effectively perform dural closure seems to be a small but not negligible problem.

Methods: We proposed a classification and grading system for dural incisions based on the type and degree of suture, and based on the system, a standardized operation process for ADS (absorbable dural sealant) was developed. Then, we conducted a retrospective study. We divided the included patients into 3 groups. Normalized group follows the ADS standard use process proposed by us, while Empirical group does not meet or only partially meets the ADS standard use process, or uses ADS based on its own experience, and Non-sealant group were patients who did not use ADS. And perioperative infection was used as the primary assessment metric to verify the effectiveness of ADS in blocking the dural membrane, and to try to propose a standardized use plan.

Results: A retrospective collection of 383 patients' clinical data was conducted between October 2019 and April 2023 in the Department of Neurosurgery of Qilu Hospital of Shandong University. Of them, 128 belonged to the non-sealant group, 126 to the normalized group, and 129 to the empirical group. In our study, we discovered that, in comparison to the normalized group, postoperative cerebral infection rose by 17.2 % (OR = 2.437, P = 0.004) and 21.9 % (OR = 3.227,

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P < 0.001), respectively, in the empirical group and non-sealant group. In comparison to the normalized group, the empirical group and non-sealant group experienced a 13.2 % (OR = 1.882, P = 0.037) and 24.8 % (OR = 3.346, P < 0.001) increase in subcutaneous effusion development, respectively. Furthermore, when compared to the normalized group, the empirical group's (β = 48.556, P = 0.003) and non-sealant group's (β = 91.960, P < 0.001) subcutaneous or epidural drainage volume was significantly higher.

Conclusions: Correct and standardized use of ADS can improve the watertight suturing of the dura mater and reduce the incidence of postoperative complications such as infection, and is of great significance for perioperative management of neurosurgery.

1. Introduction

Incising the dura is a critical step in neurosurgical craniotomy because the integrity and tightness of the dura directly determines whether postoperative complications such as CSF (Cerebrospinal fluid leakage) [1], pseudomeningocele [2], wound infection, impaired wound healing, and meningitis will occur [3–5]. The traditional dural closure technique mainly involves suturing the two sides of the cut dura together [6], but during the operation, the dura may shrink due to dehydration and be damaged by electric cauterization [7,8]. In instances of damaged and missing dura, artificial dura is required for repair and reconstruction [9], so the integrity and tightness of the dural incision cannot be guaranteed, and even a pinhole in the suture can lead to CSF [8,10]. Therefore, methods to improve the integrity and tightness of the dural incision have become a topic of widespread discussion and research in neurosurgery.

Our team developed the ADS (absorbable dural sealant), which is designed to be used as an adjunct to standard methodsto improve the tightness of the dural incision [11], and reduce the probability of postoperative complications such as CSF, local effusion, and wound infection. However, there is no uniform method for the clinical application of ADS, and each clinician's application method is different, resulting in different sealing effects. Therefore, in our study, we proposed a reasonable application strategy for ADS according to the classification and grading system of dural incisions to improve watertight suturing of dural incision and reduce postoperative complications.

2. Methods

2.1. Strategy and standardized operation procedure for the application of ADS

2.1.1. The type and degree of suture of dural incision

The incision of the dura is a very critical step in neurosurgical craniotomy. It is important to select different dural incisions according to the lesion site, anatomical structure and surgical exposure requirements. We have summarized some common types of surgical dural incisions (Supplemental Fig. 1). We divided the dural incision into five types according to the common types of incision (Fig. 1).

During neurosurgical operation, if the dura mater cannot be sutured tightly because of dehydration, electric cautery defect, lesion erosion and adjacent bone window or venous sinus, the defect needs to be repaired by artificial dura mater. Therefore, based on its degree, the dural incision suture was classified into 5 grades (Fig. 1). We have summarized some surgical photographs of suture (Supplemental Fig. 2).

2.1.2. The classification and grading system of dural incision

We divided the dural incision into 5 types, and the degree of suture into 5 grades. For each type of dural incision, the difficulty of suture, the usage amount of ADS and the choice of artificial dura membrane are different. According to the texture of the artificial dura membrane, it is divided into hard artificial dura membrane and soft artificial dura membrane, and hard artificial dura membrane was selected for sutured ones, soft artificial dura membrane was selected for nonsutured ones. After gaining a comprehensive understanding, we established the following classification and grading system for dural incision (Fig. 2).

2.1.3. The standardized operation procedures of ADS

ADS (Fig. 3) is simple to assemble during clinical use (Supplemental Fig. 3), and its main components have good biocompatibility and adhesion (Supplemental text.1). For conventional types of dural incisions that can closed via grade A, B, or C suturing, the procedures for the standardized use of ADS are as follows:

1. Before dura mater closure, the positive end-expiratory pressure(PEEP) should be increased to 20 cm H_2O for 20 s to check for hemostasis [12,13]. According to the classification of the dural incision, the relative high point of the dural incision is found, and the dura outside the high point is sutured first (label ①②③ indicates the stitching sequence), and the dura at the high point is preserved.(The missing area or excessive tension or no dural edge can be repaired by artificial dural membrane.)
2. Ensure there is no blood or water on the dural surface by drying it with cotton sheets.
3. Spray 2 ml ADS with the dura beyond the high point.

4. Inject water through the unsutured dura at the high point to remove the gas.
5. Suture the dura at the high point.
6. Ensure there is no blood or water on the dural surface by during it with cotton sheets.
7. Apply 1 ml ADS to the dura at the high point. Then, increase the PEEP for the second time to 20 cm H_2O for 20 s to verify that there is no saline or CSF leakage out of the dural closure.

Here, we applied ADS in a standardized manner for a Type 1-Grade A dural incision (Fig. 3) and recorded the video of the operation (Supplemental Video 1).

For nonconventional dural incisions that cannot be sutured directly, artificial dural repair is needed, and the standard application procedures for ADS should also be adjusted accordingly:

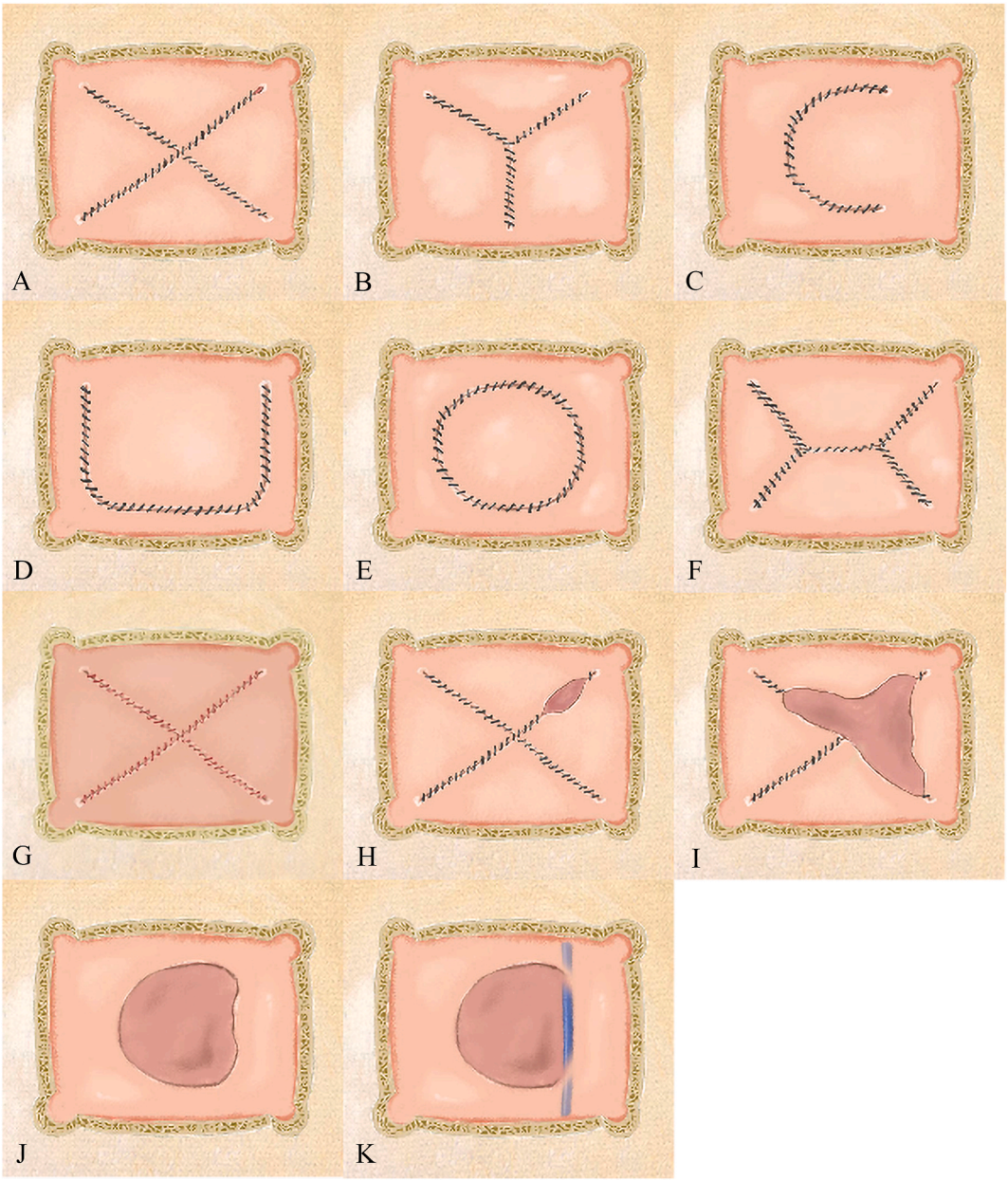

Fig. 1. The type and degree of suture of dural incision. (A) Type 1: "十" shape. (B) Type 2: "Y" shape. (C) Type 3: "C" shape. (D) Type4: "U" shape. (E) (F) Type 5 (other types): "O" shape, "Double Y″ shape. (G) Grade A: dura mater sutured completely. (H) Grade B: dura mater sutured mostly. (I) Grade C: dura mater sutured partially. (J) Grade D: dura mater not sutured: absent but with intact dura border. (K) Grade E: dura mater not sutured: absent and without dura border near bone window or sinus of veins.

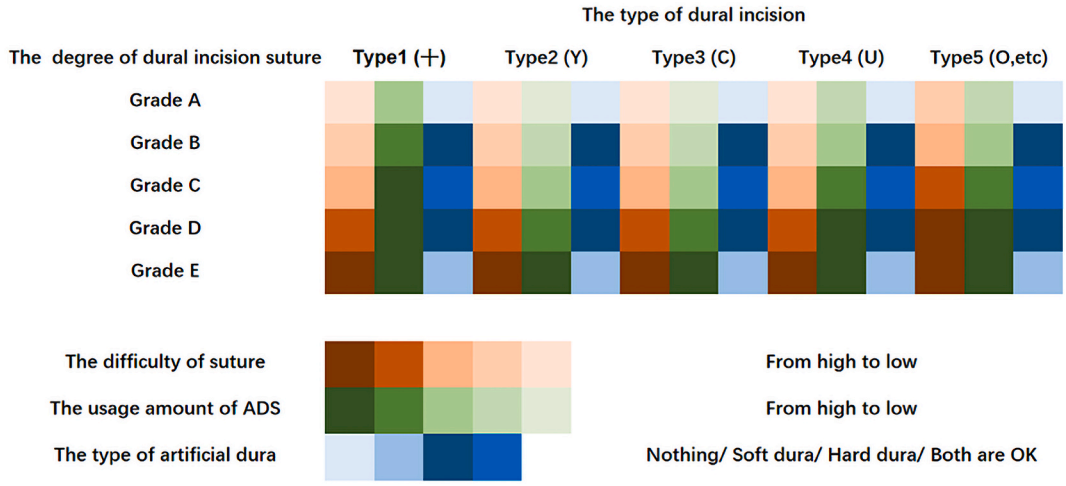

Fig. 2. The classification and grading system of dural incision.

1. Before dura mater closure, increase the positive end-expiratory pressure(PEEP) to 20 cm H2O for 20 s to check for hemostasis [12, 13]. Suitable artificial dura were selected according to the incision type and size, hard artificial dura membrane was selected for sutured ones, soft artificial dura membrane was selected for nonsutured ones, and then the relative high point after repair was

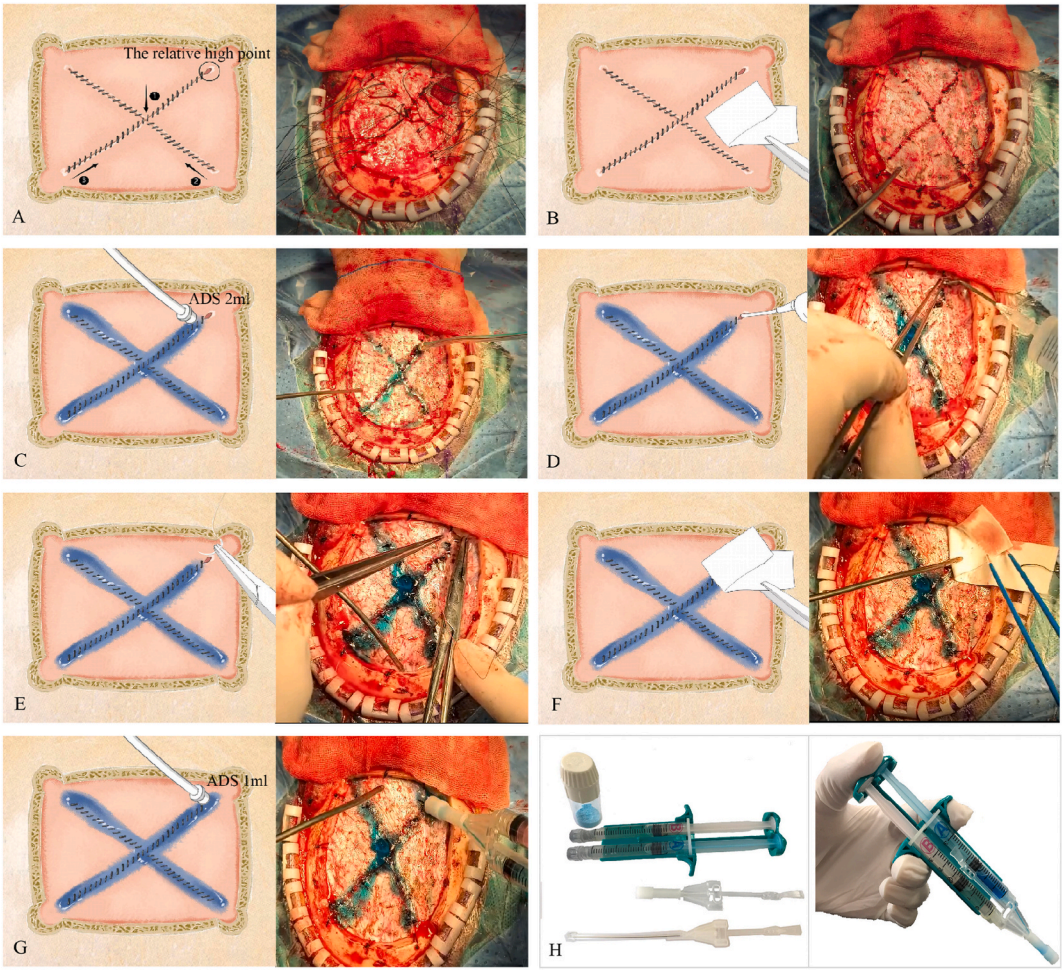

Fig. 3. (A) (B) (C) (D) (E) (F) (G) For conventional types of dural incisions that can closed via grade A, B, or C suturing, the procedures for the standardized use of ADS. (H) Real product photo of ADS.

found, and the dura beyond the high point was sutured first, leaving the dura at the high point.(Skip the stitching step if cannot be sutured)
2. Ensure there is no water or blood on the dural surface by drying it with cotton sheets.
3. Spray 2 ml ADS with the dura beyond the high point.(If the incision is small, the entire area can be covered by spraying (the artificial dural membrane has mild cerebrospinal fluid leakage); if the dural area is large, the amount of ADS may not be sufficient, and only the edge can be closed.)
4. Inject water through the dura at the high point to remove the gas.
5. Suture the dura at the high point.(Skip the suture step if cannot be sutured.)
6. Ensure there is no water or blood on the dural surface by drying it with cotton sheets.
7. Apply 1 ml ADS to the dura at the high point. Then, increase the PEEP for the second time to 20 cm H_2O for 20 s to verify that there is no saline or CSF leakage out of the dural closure.

Here, we applied ADS in a standardized manner for a Type 5-Grade D dural incision (Fig. 4) and recorded the video of the operation (Supplemental Video 2).

Here, ADS was reasonably divided and used, and the total 3 ml of the ADS was divided into 2 ml and 1 ml corresponding to the dura being sutured beyond the high point and the dura being sutured at the high point, respectively, to ensure a standardized and effective tight seal of the dura.

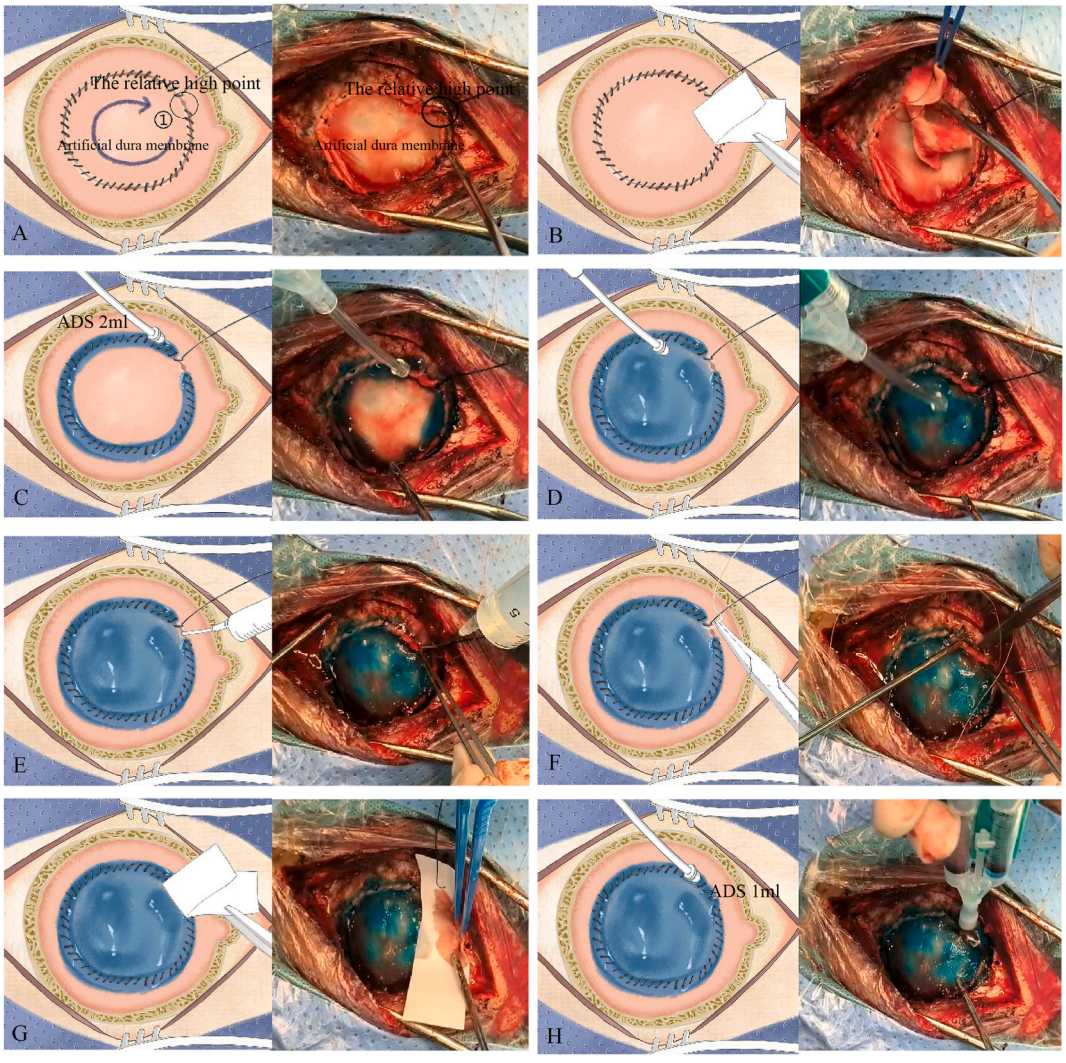

Fig. 4. (A) (B) (C) (D) (E) (F) (G) (H) For nonconventional dural incisions that cannot be sutured directly, and the standard application procedures for ADS.

2.2. To verify the effectiveness of ADS in blocking dura mater and its standardized use

2.2.1. Sample information

The overall design of this study is shown in the Supplemental figure (Supplemental Fig. 4). A retrospective collection of 383 patients' clinical data was conducted between October 2019 and April 2023 in the Department of Neurosurgery of Qilu Hospital of Shandong University. We divided 383 patients into 3 groups. Among them, we named 126 patients who had standardized use of ADS as the normalized group, and 129 patients who did not standardized use of ADS as the empirical group, and 128 patients who did not use ADS as the non-sealant group. The baseline characteristics of treated patients are summarized in Table 1. The mean age of treated patients in our study was approximately 51.4 years (standard deviation: 15.2 years). Approximately 59.5 % (228) of the individuals were women and 40.5 % (155) of the individuals were men. Among the 383 patients, the clinical diagnosis was glioma (102/26.6 %), meningioma (172/44.9 %), and other tumors (109/28.5 %). Among the 383 patients, the site of lesion was base of skull (59/15.4 %), subtentorial (75/19.6 %), and superatentorial (249/65.0 %). The mean surgical time of treated patients in our study was approximately 273.3 min (standard deviation: 82.8 min). After statistical analysis, we found that the three groups were not balanced in terms of age, clinical diagnosis, surgical site and surgical time characteristics ($P < 0.05$). Therefore, we included these variables as covariables (influencing factors) in the multivariable regression analysis model, so as to balance the influence of this factor on the outcome.

2.2.2. Patients

We included patients who underwent craniotomy to open the dura and had subcutaneous or epidural drainage tubes placed during surgery. And patients treated with or without ADS during the surgery. However, we did not include patients with subdural or operative cavity drainage tubes, patients undergoing transnasal sphenoidal approach surgery, and patients undergoing spinal cord surgery. All patients have signed surgical informed consent. Before surgery, all patients and their families voluntarily signed informed consent for implantable consumables, including the use of ADS. However, patients do not decide whether to use ADS before or during surgery, but the doctor chooses to use ADS according to the intraoperative situation. If ADS is applied, the patient's family will be informed. All patient-relevant information was anonymous and deidentified.

2.2.3. Data collection and definitions

The retrospective study had three evaluation indexes. Intracranial infection was the main outcome measure and subcutaneous effusion and subcutaneous or epidural drainage volume were the secondary outcome measure. The surgeon determines whether to place a subcutaneous or epidural drainage tube based on the type, size, location, and surgical status of the lesion, and collects the drainage volume of the postoperative drainage tube from the first day to the day before extubation. Postoperative craniocerebral CT data showed whether there was subcutaneous effusion. All patients included in our study underwent standard postoperative CT review on day 1, day 5, and day 1 before discharge. The use of antibiotics after surgery. In this study, we followed the Chinese expert consensus on the diagnosis and treatment of severe neurosurgical central nervous system infections (2017) and the Chinese expert consensus on the diagnosis and treatment of neurosurgical central nervous system infections (2021) and Infectious Diseases Society of America's Clinical Practice Guidelines for Healthcare-Associated Ventriculitis and Meningitis (2017) for the diagnosis and treatment of intracranial infections and the use of antibiotics. The diagnostic criteria for intracranial infection were as follows: (1) clinical manifestations such as postoperative fever, headache, neck stiffness, or change in consciousness; (2) a CBC (complete blood count) has white blood cell count$>10 \times 10^9$/L, or a neutrophil percentage >80 %; (3) a CSF WBC (white blood cell) count ≥1000 cells/μl and a polykaryocyte percentage ≥75 %; and (4) positive CSF culture. The diagnosis of intracranial infection was made individually for patients meeting the fourth criterion. Patients who are negative for cerebrospinal fluid culture but meet the three diagnostic criteria of 1, 2, and 3 can also be diagnosed with intracranial infection [14,15]. After the diagnosis of intracranial infection, we used antibiotics according to the guidelines. We replaced postoperative infection data with postoperative antibiotic use data. Antibiotics include Vancomycin,

Table 1
Clinical features of 383 patients.

Characteristic	total	Normalized group	Empirical group	Non-sealant group	Statistics	P value
Patients(n)	N = 383	N = 126	N = 129	N = 128		
Age (mean ± SD, yrs)	51.4 ± 15.2	53.5 ± 13.8	48.4 ± 18.7	52.5 ± 12.0	F = 3.975	P < 0.05[a]
Sex						
Female	228(59.5 %)	72(57.1 %)	79(61.2 %)	77(60.2 %)	χ2 = 0.475	P > 0.05[b]
Male	155(40.5 %)	54(42.9 %)	50(38.8 %)	51(39.8 %)		
Clinical diagnosis						
Glioma	102(26.6 %)	33(26.2 %)	47(36.4 %)	22(17.2 %)	χ2 = 17.624	P < 0.05[b]
Meningioma	172(44.9 %)	51(40.5 %)	59(45.8 %)	62(48.4 %)		
others	109(28.5 %)	42(33.3 %)	23(17.8 %)	44(34.4 %)		
Site of lesion						
Base of skull	59(15.4 %)	13(10.3 %)	21(16.3 %)	25(19.5 %)	χ2 = 28.021	P < 0.05[b]
subtentorial	75(19.6 %)	28(22.2 %)	9(7.0 %)	38(29.7 %)		
superatentorial	249(65.0 %)	85(67.5 %)	99(76.7 %)	65(50.8 %)		
surgical time (mean ± SD, mins)	273.3 ± 82.8	263.8 ± 69.8	297.0 ± 99.5	258.6 ± 70.5	F = 8.454	P < 0.05[a]

[a] Values are shown as mean ± SD. SD, Standard Deviation. ANOVA (Analysis of Variance) used.
[b] Values are shown as number, number (%). Chi-Square test used.

Cephalosporins (Ceftriaxone, Cefoperazone) and Carbapenems (Meropenem).

2.2.4. Statistical analysis

The SPSS (Statistical Product Service Solutions) 25.0 software was used to process and analyze all research data. The measurement data were compared by ANOVA (Analysis of Variance), and the mean ± standard deviation ($\bar{x} \pm s$) was used to describe the measurement data. Counting data were described by frequency and percentage (%), and inter-group differences were compared by Chi-Square test. We included the unbalanced variables as covariates (influencing factors) in the multivariable regression model. Multivariable Logistic regression model was used to analyze the relationship between independent variables and binary outcomes. Multivariable Linear regression model was used to analyze the relationship between independent variables and outcome indicators of continuous variables. The P value of less than 0. 05 indicated a statistical significance [16,17]. All figures shown in this article were drawn using GraphPad Prism 10 and Digital plate.

3. Results

3.1. Comparison of the usage of antibiotic of patients treated with and not treated with ADS

The number distribution of antibiotic usage in the three groups is shown in Fig. 5. The number of antibiotic users represents the number of intracranial infection. Among them, the number of antibiotic users in the normalized group, empirical group, non-sealant group was 26 (20.6 %), 48 (37.5 %), 54 (42.2 %), rspectively. Multivariable logistic regression indicated that use of ADS was associated with reduced risk of infection (OR = 3.227, 95 % CI = 1.787–5.962, P < 0.001) after adjusting for other surgical variables (Table 2). In our study, we found that postoperative intracranial infection increased by 17.2 % (OR = 2.437, P = 0.004) and 21.9 % (OR = 3.227, P < 0.001), respectively, in the empirical group and non-sealant group, compared with the normalized group (Table 2). Studies have shown that posterior fossa patients have a higher risk of cerebrospinal fluid leakage and intracranial infection, so we conducted a review of intracranial infection in three groups of subtentorial surgery patients and obtained a supplementary table (Supplemental Table 1). Among them, the number of subtentorial patients in the normalized group, empirical group, non-sealant group was 28 (22.2 %), 9 (7.0 %), 38 (29.7 %), respectively. The number of patients receiving antibiotics in the three groups was 7 (25.0 %), 6 (66.7 %) and 21 (55.3 %), respectively. Then we carried out a multivariable regression analysis model. We found that compared with the normalized group, the OR value of the non-sealant group was 4.031 (P < 0.05), and that of the empirical group was 10.295 (P < 0.05).

3.2. Comparison of the formation of subcutaneous effusion of patients treated with and not treated with ADS

The number distribution of patients with subcutaneous effusion in the three groups is shown in Fig. 5. Among them, the number of

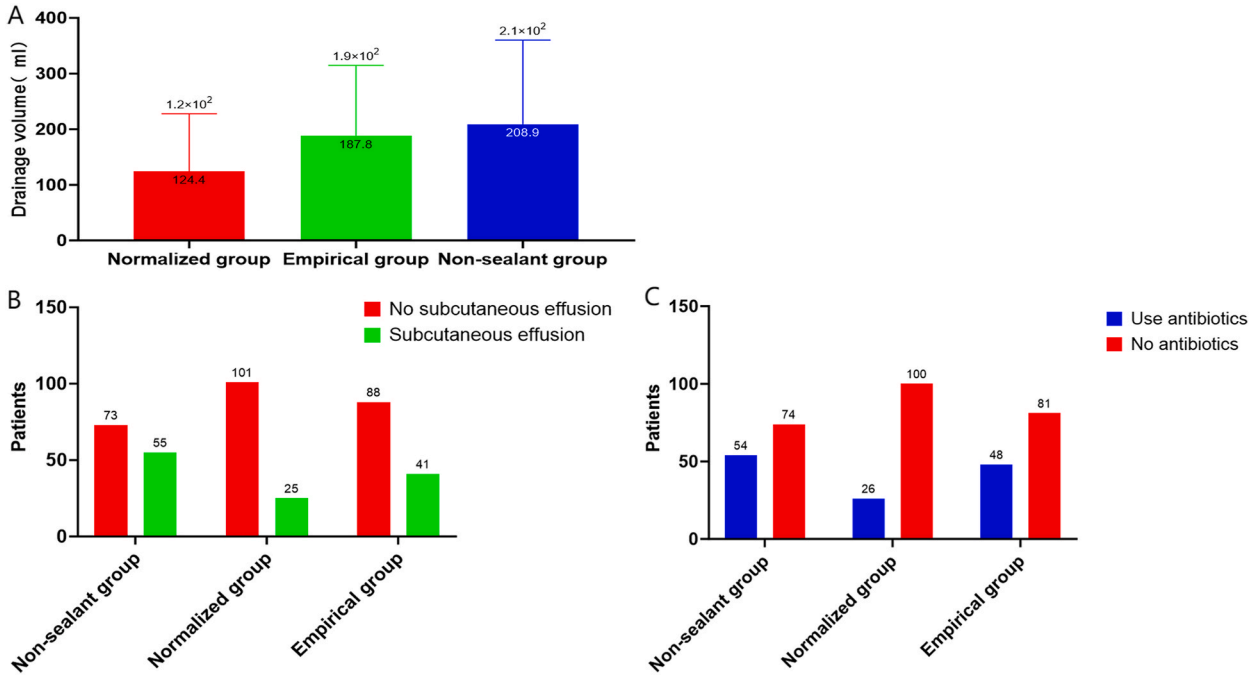

Fig. 5. (A) The average subcutaneous or epidural drainage volume of patients in the three groups. (B) The number distribution of patients with subcutaneous effusion in the three groups. (C) The number distribution of antibiotic usage in the three groups.

Table 2
Comparison of the formation of subcutaneous effusion and the usage of antibiotic of patients treated with and not treated with ADS.

Variable	The formation of subcutaneous effusion			P value[a]	The usage of antibiotic			P value[a]
	No(N = 262)	Yes(N = 121)	OR(95 % OR)		No(N = 255)	Yes(N = 128)	OR(95 % OR)	
Group[c]								
Normalized group	101 (38.5 %)	25 (20.7 %)	Reference	Reference	100 (39.2 %)	26 (20.3 %)	Reference	Reference
Non-sealant group	73 (27.9 %)	55 (45.5 %)	3.346 (1.893–6.054)	<0.001	74 (29 %)	54 (42.2 %)	3.227 (1.787–5.962)	<0.001
Empirical group	88 (33.6 %)	41 (33.9 %)	1.882 (1.045–3.442)	0.037	81 (31.8 %)	48 (37.5 %)	2.437 (1.324–4.573)	0.004
Age (yrs)[b]	50.8 ± 15.6	52.8 ± 14.4	1.008 (0.992–1.024)	0.327	51.1 ± 15.2	52.2 ± 15.3	1.016 (1.000–1.033)	0.047
Surgical time (mins)[b]	277.1 ± 82.7	265.0 ± 82.7	0.999 (0.996–1.002)	0.483	259.0 ± 73.3	301.6 ± 93.0	1.007 (1.003–1.010)	<0.001
Site of lesion[c]								
Base of skull	42 (16 %)	17 (14 %)	Reference	Reference	35 (13.7 %)	24 (18.8 %)	Reference	Reference
subtentorial	57 (21.8 %)	18 (14.9 %)	1.046 (0.427–2.571)	0.922	41 (16.1 %)	34 (26.6 %)	0.896 (0.377–2.122)	0.804
superatentorial	163 (62.2 %)	86 (71.1 %)	1.758 (0.880–3.629)	0.117	179 (70.2 %)	70 (54.7 %)	0.607 (0.296–1.257)	0.175
Clinical diagnosis[c]								
Glioma	71 (27.1 %)	31 (25.6 %)	Reference	Reference	66 (25.9 %)	36 (28.1 %)	Reference	Reference
Meningioma	109 (41.6 %)	63 (52.1 %)	1.349 (0.748–2.450)	0.322	127 (49.8 %)	45 (35.2 %)	0.447 (0.234–0.843)	0.013
others	82 (31.3 %)	27 (22.3 %)	0.868 (0.421–1.770)	0.698	62 (24.3 %)	47 (36.7 %)	1.248 (0.618–2.521)	0.535

SD, Standard Deviation. OR, Odds Ratio.
[a] Logistic regression model was used to bring in independent variables and compare three groups of formation of subcutaneous effusion and the usage of antibiotic. Statistical significance of the difference between Non-sealant group and Normalized group, and between Empirical group and Normalized group.
[b] Values are shown as mean ± SD, OR, 95 % OR.
[c] Values are shown as number, number (%).

subcutaneous effusion in the normalized group, empirical group, non-sealant group was 25 (20.7 %), 41 (33.9 %), 55 (45.5 %), respectively. Multivariable logistic regression indicated that use of ADS was associated with reduced risk of subcutaneous effusion (OR = 3.346, 95 % CI = 1.893–6.054, P < 0.001) after adjusting for other surgical variables (Table 2). we found that formation of subcutaneous effusion increased by 13.2 % (OR = 1.882, P = 0.037) and 24.8 % (OR = 3.346, P < 0.001), respectively, in the empirical group and non-sealant group, compared with the normalized group (Table 2).

3.3. Comparison of subcutaneous or epidural drainage volume of patients treated with and not treated with ADS

The average subcutaneous or epidural drainage volume of patients in the three groups is shown in Fig. 5. Among them, the average

Table 3
Comparison of subcutaneous or epidural drainage volume of patients treated with and not treated with ADS.

Variable	β	SE	T value	P value[a]
Group				
Normalized group	0	0	Reference	Reference
Non-sealant group	91.960	16.02	5.74	<0.001
Empirical group	48.556	16.37	2.97	0.003
Age (mean ± SD, yrs)	0.12	0.44	0.27	0.787
Surgical time (mean ± SD, mins)	0.16	0.08	1.94	0.053
Site of lesion				
Base of skull	0	0	Reference	Reference
subtentorial	−3.28	24.78	−0.13	0.895
superatentorial	39.70	20.19	1.97	0.050
Clinical diagnosis				
Glioma	0	0	Reference	Reference
Meningioma	9.49	17.38	0.55	0.585
others	−35.04	20.06	−1.75	0.082

SE, Standard Error. SD, Standard Deviation.
[a] A linear regression model was used to bring in independent variables and compare three groups of subcutaneous or epidural drainage volume. Statistical significance of the difference between Non-sealant group and Normalized group, and between Empirical group and Normalized group.

drainage volume of the normalized group, empirical group, non-sealant group was 124.4 ml, 187.8 ml, 208.9 ml, respectively. Multivariable linear regression indicated that use of ADS was associated with reduced subcutaneous or epidural drainage volume ($\beta = 91.960$, SE = 16.02, $P < 0.001$) after adjusting for other surgical variables (Table 3). We found that the subcutaneous or epidural drainage volume of empirical group ($\beta = 48.556$, $P = 0.003$) and non-sealant group ($\beta = 91.960$, $P < 0.001$) was greatly increased compared with normalized group (Table 3).

4. Discussion

Complications such as CSF, infection, and subcutaneous effusion after craniocerebral surgery have long troubled neurosurgeons and become a topic of close discussion. So, how to reduce these complications, generation after generation of neurosurgical predecessors continue to explore. Long-term studies have found that the tightness of the dura is closely related to CSF, postoperative infection and other complications. However, the traditional dural sealing technique cannot completely seal the dura. So, we studied the dura mater. Depending on the location of the lesion, anatomical structure, and surgical exposure requirements, we need to choose different dural incisions. We found that a proper dural incision can not only fully expose the surgical area and reduce the bleeding in the surgical area but can also reduce the occurrence of postoperative complications such as cerebrospinal fluid leakage and infection. Therefore, for different lesion sites, there are many classic types of dural incision, such as "十" shape, "Y" shape, "C" shape, "U" shape, "O" shape and so on. For these different types of dural incisions, the goal is to completely and tightly seal the dural incision. Of course, we need to use amending materials to repair dural defects and to supplement the integrity of the dura [18]. Therefore, the hermetic closure of the dura mater can effectively prevent postoperative complications such as subcutaneous effusion, infection, meningitis, pseudomeningocele and seizures, which are critical factors of morbidity and mortality [19–21].

There are a lot of products such as gels, patches and artificial dura that can be used to seal the dura mater; however, the method by which to use such products rationally seem to be the most overlooked problems. For this, our team developed the ADS to further improve the tightness of the dural incision. However, in the process of clinical use of ADS, its specific effect is still unknown, and we found that there is no unified standard for the use of ADS. Neurosurgeons use different methods, thereby resulting in differences in the sealing effect. Therefore, the rational use of ADS is closely related to the incidence of cerebrospinal fluid leakage, postoperative infection and other complications. So, after many years of clinical observation and comparison, with the short-term prognosis of patients as the evaluation index, we decided to use ADS in its routine practice. According to the common shape and degree of suture of dural incision, our team divided dural incisions into five types and five grades. Based on this, we proposed a classification and grading system for dural incisions, and further proposed a standardized application process for ADS.

Although the application of ADS is a very small clinical concern and no one has conducted research, our research team has conducted exploration and observation, and proposed the standardized use of ADS, and there are a lot of clinical data to support the standard. We found that the use of ADS was associated with a reduced risk of intracranial infection and subcutaneous effusion. Through the standardized ADS application strategy proposed by us, the incidence of postoperative intracranial infection and subcutaneous effusion in patients was significantly different from that in the empirical group. It shows that normalized group strictly followed the application strategy of ADS, which further improved the tightness of the dural incision compared with empirical group, and the data from the empirical group showed that the irregular use of ADS resulted in a significant reduction in its sealing effect. Studies have shown that posterior fossa patients have a higher risk of cerebrospinal fluid leakage and intracranial infections. Our data show that standard use of ADS is also associated with a reduced risk of postoperative intracranial infection in posterior fossa patients. As for the difference between the empirical group and the non-sealant group, we speculated that the number of subtentorial patients in the empirical group was too small compared with the non-sealant group, which may need further research and evaluation. These data confirm that the application of ADS is effective for the sealing of dural incision, and the application strategy of ADS proposed by us is reasonable.

The usefulness of dural sealants is a topic of ongoing debate. Kinaci et al. [13] performed a meta-analysis of 2321 intradural cranial cases showing significant difference was found regarding surgical site infection, which was less seen in cases with sealants (RR 0.25, CI 0.13 to 0.48). Hutter et al. [22] performed an RCT comparing standard dural closure using suturing alone with the addition of TachoSil on top. In total, 19 % of the procedures were infratentorial and 81 % supratentorial. The difference in leakage rate was not significant with 9.7 % in the TachoSil and 17.2 % in the control group. Wound infection was 0.9 % versus 4.3 %. Although these studies are not fully comparable with the current study, we also show beneficial results in the current study. In our study, we discovered that, in comparison to the normalized group, postoperative cerebral infection rose by 17.2 % (OR = 2.437) and 21.9 % (OR = 3.227), respectively, in the Non-normalized group and non-sealant group. It can be seen that the application of dural sealant has a preventive effect on postoperative infection.

Of course, there are some limitations in our clinical study. Our study is only a retrospective study, although statistical results have been obtained, but still lack of systematic verification, we need to conduct prospective studies, currently we are in progress. In our evaluation of the effectiveness of ADS in blocking the dura, the diagnosis of postoperative subcutaneous hydrops was made by the surgeon after observing the patient's brain CT to conduct manual drawing and volume measurement. It is subjective. We need further prospective validation to collect complete image data and make accurate measurements through artificial intelligence. Furthermore, small dural spaces can be filled with their own tissue for good biocompatibility in brain surgery [23,24], but when artificial dural repair is needed, the interaction between ADS and artificial dura mater as an artificial substitute requires further study. Finally, our current retrospective clinical trial included an elective patient population that was excluded, including patients undergoing transsphenoidal surgery and patients with a spinal column that opened the dura. While these procedures are associated with a higher risk of postoperative infection and CSF [25–30], the efficacy of ADS may require more detailed evaluation.

5. Conclusions

ADS can be used as an auxiliary sealing means of dural incision to improve the watertight suturing of the dural mater and reduce the occurrence of intracranial infection and other complications. The strategy and standardized procedure for the application of ADS based on the classification and grading system of dural incision is scientific and rigorous and has certain clinical significance and application prospects. We hope that the standardized application of ADS will be further promoted and recognized in clinical practice. We believe that this standard can provide the basis for more clinicians to operate. Correct and standardized use of ADS is of great significance for perioperative management of neurosurgery.

CRediT authorship contribution statement

Caizhi Ma: Writing – original draft, Investigation, Data curation, Conceptualization. **Zhe Han:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Shouji Zhang:** Writing – original draft, Software, Data curation. **Jia Li:** Investigation, Data curation. **Huizhong Chi:** Investigation, Data curation. **Qingtong Wang:** Investigation, Data curation. **Hongyu Zhao:** Formal analysis, Data curation. **Deze Jia:** Data curation. **Kailiang Zhang:** Data curation. **Zichao Feng:** Data curation. **Hongwei Wang:** Data curation. **Jie Gong:** Data curation. **Shilei Ni:** Data curation. **Gang Li:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition. **Xueen Li:** Writing – review & editing, Supervision, Project administration, Methodology, Formal analysis. **Hao Xue:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Ethical approval

This study was reviewed and deemed exempt from ethics approval by Shandong University Qilu Hospital Medical Ethics Committee, dated April 15, 2023. This is an observational retrospective study. The Qilu Hospital of Shandong University Research Ethics Committee has confirmed that no ethical approval is required due to secure data storage and minimal risk to patients.

Data availability statement

All data included in this study are available upon request by contact with corresponding authors.

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Declaration of competing interest

In this study, ADS was jointly developed by our team and Success Bio-Tech Co., Ltd. (China), but our team members had no relationship with the company, and Tong Li and Xing Yuan, the team members involved in the research and development, no longer worked in neurosurgery. This study did not receive any financial support from the company. None of the people with an interest in the study appeared in this article, and none of the people involved in the writing of this article work for the company and have no interest with the company.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2025.e41966.

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