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Reduction of cortical injury using a subdural catheter guidance device: A comparative study on burr hole drainage for chronic subdural hematoma

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Abstract

Chronic subdural hematoma (CSDH) is a chronic hemorrhagic lesion caused by the accumulation of blood between the arachnoid mater and the dura mater. Currently, the most commonly used surgical approach for CSDH is burr hole craniotomy. However, this procedure employs a blind technique, making the cerebral cortex susceptible to injury. The use of a subdural catheter guidance device combined with burr hole drainage in the treatment of CSDH can prevent intraoperative cerebral cortex damage and reduce its potential impact. This study retrospectively analyzed a total of 518 patients with CSDH who underwent surgical treatment at the hospital. Of these, 361 were male (69.69%) and 157 were female (30.31%), with a median age of 59.5 years (range: 12 – 92 years). All patients underwent preoperative head computed tomography and/or magnetic resonance imaging scans, which revealed crescent-shaped mixed-density or iso-dense shadows beneath the inner table of the skull. Informed consent for the burr hole decompression procedure was obtained from all patients. Subsequently, the 518 patients were randomly divided into two groups: The control group (undergoing the procedure without a "guidance device") and the experimental group (undergoing the procedure with a "guidance device"). All patients provided consent for the publication of their clinical details and related images. In the control group, 274 patients with CSDH were treated, among whom 6 cases had post-operative cortical injury complications, with an incidence rate of 2.19%. In the experimental group, 244 patients with CSDH were treated, and no cortical injury complications occurred post-operatively, with an incidence rate of 0. Fisher's exact test (two-tailed) showed p=0.0427, indicating a significant reduction in cortical injury complications with the use of the guidance device. In addition, the conditional maximum-likelihood estimate (CMLE) odds ratio for Fisher's exact test was 0, with a 95% confidence interval ranging from 0.0 to 0.9447, further reflecting the relationship between the relevant factors. This indicates that incorporating a subdural catheter guidance device during burr hole drainage for CSDH can assist surgeons in avoiding damage to the cerebral cortex.

Keywords: Chronic subdural hematoma; One burr-hole craniotomy; Subdural catheterization guidance device; Cortex damage; Drainage tubes

1. Introduction

Chronic subdural hematoma (CSDH) is a significant medical condition that arises from the accumulation of blood between the arachnoid mater and the dura mater. This chronic hemorrhagic lesion has been extensively studied in neurosurgery. The incidence of CSDH in the general population is relatively low, ranging from approximately 1 – 13/100,000 individuals.[1-4] However, the incidence increases significantly with age, reaching 127.1/100,000 individuals in those aged 80 years or older.[5] This age-related trend highlights the vulnerability of the elderly population to this condition.

The vast majority (over 80%) of CSDH patients have a history of traumatic brain injury. The pathophysiological mechanism underlying CSDH involves the tearing of the bridging veins on the brain's surface, which leads to bleeding into the subdural space. This initial hemorrhage triggers a nonspecific inflammatory response within the inner dural layer. The inflammatory process triggers a series of cellular and molecular changes, activating fibroblasts and promoting the release of cytokines. These factors contribute to hematoma formation and the subsequent development of a fibrous membrane around it.[6] As the hematoma grows, it exerts a mass effect on the surrounding brain tissue, resulting in increased intracranial pressure.

The primary symptoms of CSDH are diverse and can significantly impact a patient's quality of life. Increased intracranial pressure often leads to headaches, ranging from mild-to-severe, and may be accompanied by nausea and vomiting. Altered consciousness is another common symptom, with patients experiencing confusion, drowsiness, or, in severe cases, coma. In addition, CSDH can lead to cognitive impairments, such as dementia, apathy, and unresponsiveness, which often develop insidiously and progress over time, highlighting the importance of early diagnosis. In a smaller subset of patients, focal neurological deficits such as hemiplegia, aphasia, and focal epilepsy may arise, depending on the location of the hematoma and the extent of brain tissue compression.[7]

Surgical intervention is the primary treatment for CSDH. However, for patients with contraindications to surgery, such as those with severe comorbidities or poor overall health, symptomatic and supportive treatment may be considered.[8] Currently, the most used surgical technique for CSDH is burr hole craniotomy, which involves making a small opening in the skull to access the subdural space. However, this procedure employs a blind technique, limiting the surgeon's direct visualization of the surgical field. Consequently, the cerebral cortex is highly susceptible to injury. During catheter insertion for drainage, the catheter tip may inadvertently penetrate the brain parenchyma or damage blood vessels on the brain surface, potentially leading to neurological deficits.[9]

Nevertheless, combining a subdural catheter guidance device with burr hole drainage in the treatment of CSDH offers a potential solution to mitigate and prevent intraoperative cerebral cortex damage. By providing a more controlled and directed approach to catheter insertion, the guidance device helps surgeons avoid inadvertent trauma to brain tissue. This study collected cases of CSDH treated with burr hole drainage at the hospital between January 2015 and December 2019. By comparing post-operative outcomes between patients treated with and without the subdural catheter guidance device (Patent Owner: Lepu Medical Shenyang Shenda Endoscope Co., Ltd.), the experimental group demonstrated satisfactory efficacy. This research aims to further evaluate the device's effectiveness in reducing cortical injury and provide evidence for its potential widespread application in CSDH management.

2. Methods

2.1. Eligibility criteria

The inclusion criteria for this study were as follows: Patients aged between 10 and 95 years presenting with clinical symptoms of CSDH, such as headache, dizziness, and limb weakness, with symptoms that are persistent and consistent with the characteristics of CSDH[10]; a definitive diagnosis of CSDH; and patients who had provided complete informed consent. The exclusion criteria included: The presence of an acute subdural hematoma, including recurrent cases, as acute subdural hematoma mostly forms within 72 h after head trauma and presents as a hyperdense shadow on computed tomography (CT)[11]; prior treatment of the target subdural hematoma; a Glasgow Coma Scale score below 9; and a life expectancy of <1 year.[1]

2.2. Surgical procedure

The surgery was performed under local anesthesia, with lidocaine administered at the surgical site. A small arcuate or straight incision, typically 3 – 5 cm in length, was made at the thickest part of the hematoma within the hairline, usually at the highest point of the head. A burr hole was drilled above the superior temporal line, generally at the parietal eminence. Before inserting the subdural catheter guidance device, the burr hole area underwent a thorough examination to ensure the complete absence of bone fragments, soft tissue residues, or other potential debris that could obstruct the insertion procedure. High-magnification surgical loupes were frequently used for meticulous inspection, and sterile saline irrigation was performed to remove any loose particles remaining after

drilling. Simultaneously, the guidance device underwent thorough pre-insertion preparation. A visual inspection was conducted to check for any physical damage, such as cracks or bends. If the device contained mechanical components, they were carefully examined for proper functionality. For guidance devices with adjustable angles, the locking mechanisms were tested to confirm they could securely maintain the required position. Furthermore, the tip of the device was lubricated with a sterile, biocompatible lubricant to facilitate smooth insertion into the subdural space while minimizing tissue irritation and the risk of trauma during the procedure.

During insertion, the first step involved carefully opening and cauterizing the dura mater and the outer membrane of the subdural hematoma using a bipolar cautery device. The device settings were precisely adjusted based on tissue characteristics and membrane thickness. Initially, a low-power setting was used to create a small opening, with gradual increases in power to ensure complete hemostasis and effective cauterization. Subsequently, with gentle, slow, and highly precise movements, the guidance device was inserted into the subdural space through the burr hole (Figure 1A and B). The hematoma cavity in CSDH is typically large enough to accommodate the device. In addition, the structural characteristics and adjustable angle of the guidance device help reduce the risk of direct brain injury during insertion. Nonetheless, careful observation was maintained throughout the procedure to prevent significant damage due to unnoticed septations or adhesions on preoperative imaging. The device's trajectory was carefully monitored to ensure proper alignment with the preplanned path. If necessary, insertion was halted to reevaluate the device's position and direction. Every effort was made to avoid accidental injury to adjacent brain parenchyma, blood vessels, or other critical structures.

With the aid of the guidance device, a soft, graduated catheter was carefully inserted into the hematoma cavity to an appropriate depth. The guidance device ensured that the catheter advanced in the correct direction, minimizing the risk of unintended damage. Through the catheter, slow irrigation with normal saline was performed to remove liquefied or partially liquefied old blood clots. The total volume of irrigation fluid exceeded 2000 mL, and the process continued until clear fluid was observed, indicating successful decompression. Following this, a drainage tube was placed, and its patency was confirmed before suturing the incision. The drainage tube was then connected to a collection bag and secured, with the incision site covered using sterile gauze. A follow-up CT scan was performed on the first post-operative day to evaluate the catheter position and hematoma drainage. Based on the imaging findings, a decision was made regarding the removal of the drainage tube, which was retained for no more than 3 days. All patients received prophylactic antibiotic therapy post-operatively to prevent the risk of infection.

For the control group, the only difference in the surgical procedure was the absence of the guidance device during catheter insertion and irrigation. Instead, the catheter was inserted into the hematoma cavity using a blind approach, advancing slowly while determining the insertion direction and depth based on preoperative imaging assessment. Particular attention was given to any sensation of resistance during the insertion process. Once the catheter was positioned appropriately, normal saline irrigation was performed to achieve decompression.

2.3. Statistical analysis

In this study, Statistical Package for the Social Sciences 26.0 (IBM Corp., Armonk, NY, USA) was employed for comprehensive data analysis. Measurement data were summarized as the mean and standard deviation (SD). Group comparisons were conducted using an independent-sample *t*-test (two-tailed). The decision to apply a two-tailed test was based on extensive evidence from preclinical research, preliminary clinical observations, and prior studies on similar devices. These findings consistently suggest that the combination of the subdural catheter guidance device and burr hole drainage is effective in mitigating and preventing intraoperative cerebral cortex damage. The analysis focused on evaluating this beneficial effect. Count data were presented as the number of cases or as a percentage (%), and comparisons between groups were performed using Fisher's exact test. Statistical significance was defined as a $p<0.05$.

In addition, the demographic information of the experimental and control groups, including age and gender distribution, demonstrates good data quality (Figure A1 and Table A1). Data visualization was performed using the free platform Wei Sheng Xin (https://www.bioinformatics.com.cn/).[12]

3. Results

3.1. Cortical injury complications

A total of 274 patients diagnosed with CSDH were allocated to the control group. Among them, 6 patients experienced post-operative cortical injury complications, resulting in an incidence rate of 2.19% (6/274). In contrast, the experimental group consisted of 244 CSDH patients and none of them developed cortical injury complications post-operatively, leading to an incidence of 0% (0/244) (Figure 2A).

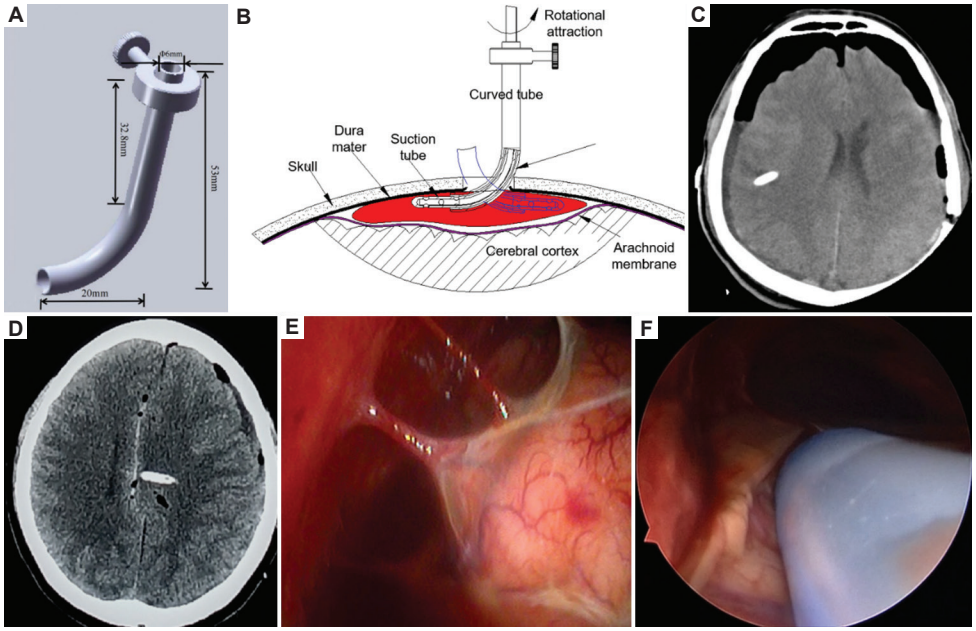


Figure 1. Structural design and surgical application of the subdural catheter guidance device. (A) Three-dimensional schematic of the subdural catheter guidance device and dimensions of key structures; (B) Schematic diagram of surgery using a subdural catheter guidance device; (C and D) Incorrect catheter insertion into the brain parenchyma instead of the hematoma cavity without the use of a guidance device; (E) Post-operative observation showing hematoma elimination using a flexible video-neuro endoscope (capable of angle adjustment); (F) Rigid neuroendoscope (30° field of view) showing the location of the drain.

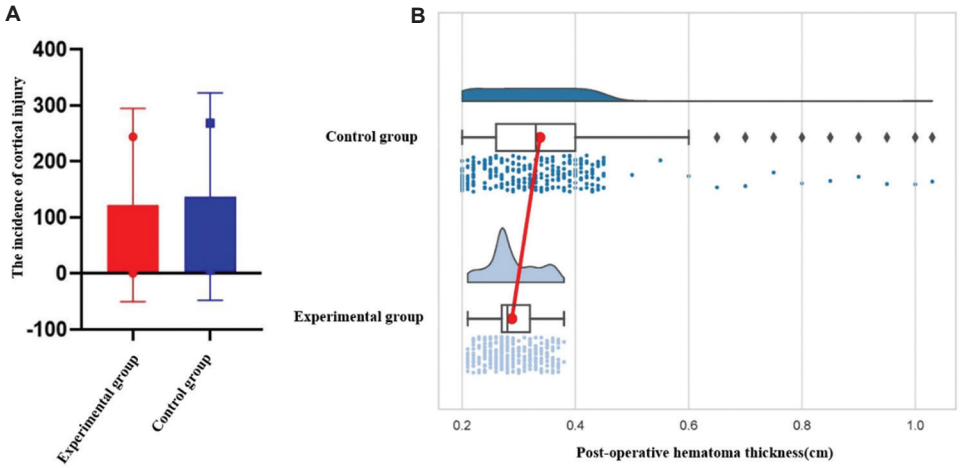


Figure 2. Comparative analysis of surgical outcomes in the two groups. (A) Comparison of cortical injury incidence between the control and experimental groups. (B) Preoperative and post-operative comparison of hematoma thickness.

Fisher's exact test was performed to evaluate the difference in the incidence of cortical injury complications between the experimental and control groups. The statistical analysis resulted in a two-tailed Fisher's exact test p=0.043, suggesting a statistically significant difference between the two groups. In addition, the CMLE odds ratio (OR) was calculated, with a CMLE OR = 0 and an OR 95% confidence interval (CI95) ranging from 0.0 to 0.9447, indicating a potential difference between in cortical injury incidence. Notably, no cases of post-operative seizures or infections were reported in either group.

3.2. Post-operative hematoma thickness

In the control group, post-operative hematoma thickness ranged from 0.20 to 1.03 cm, with a mean (SD) of 0.37 (0.24) cm and an interquartile range (IQR) of 0.17 cm. In the experimental group, hematoma thickness ranged from 0.21 to 1.30 cm, with a mean (SD) of 0.34 (0.46) cm, a

median of 0.32 cm, and an IQR of 0.15 cm. An independent samples *t*-test was conducted to compare the post-operative hematoma thickness between the two groups. The null hypothesis assumed no difference between the control and experimental groups. Before the test, the data were assessed to ensure compliance with the necessary assumptions for an independent samples *t*-test, such as normality of distribution and homogeneity of variances. A two-tailed test was selected, as no prior hypothesis was made regarding the direction of the difference. The t-test results showed a t-statistic of 0.871 and a two-tailed p=0.384. This result implies that the data do not provide strong evidence of a significant difference in post-operative hematoma thickness between the two groups.

To further understand the relationship, additional measures, such as the CI95 of the difference in means, could be considered. However, this information is not available in the current context. It is important to note that the conclusion drawn from the statistical analysis is based on the existing sample and data, and other factors or further research may be necessary for a comprehensive evaluation (Figure 2B). This finding suggests that the two treatment methods may be comparable in terms of their overall average hematoma clearance effect post-operatively. However, further evaluation considering other relevant indicators is warranted.

4. Discussion

CSDH is one of the most common diseases in neurosurgery, and it is more common in the elderly. Surgical intervention is required for patients with significant mass effects of hematoma.[13] CSDH is mainly treated with surgery, with skull drilling and drainage being the preferred method.[14-21] Studies have shown that burr hole drainage offers advantages such as minimal risk of injury, simple operation, fewer complications, and safety.[1,5,13,14,22-27] However, cranial drilling and drainage present several disadvantages, including the small burr hole and the unintended penetration of the catheter tip into the brain parenchyma or damage to blood vessels on the brain surface caused by catheter irrigation under non-direct vision, potentially causing neurological injury.[24,26] Levin *et al*.[28] conducted a comprehensive and in-depth study, which meticulously analyzed a substantial number of patients undergoing surgical procedures involving the placement of drainage tubes. A rather concerning finding emerged: when the placement of these drainage tubes was carried out under indirect vision, it led to various post-operative complications. Specifically, 2.8% of the patients suffered from brain tissue damage. This brain tissue damage could have far-reaching consequences, potentially affecting the patient's neurological functions, cognitive abilities, and overall quality of life. Moreover, 3.9% of the patients developed seizure symptoms. Seizures not only pose an immediate threat to the patients' well-being during the post-operative recovery period but also require additional medical interventions and close monitoring. These results highlight the importance of exploring more accurate and safer methods for drainage tube placement to minimize such risks and improve patient outcomes. During catheterization, the drainage catheter is usually blindly inserted into the subdural space. Thus, the catheter tip may be placed into the brain parenchyma or injure the vessels on the cerebral surface. In some adverse cases reported in the study, it was observed that during the surgical procedure, the drainage catheter was erroneously inserted into the brain parenchyma instead of the hematoma cavity (Figure 1C and D). Due to the presence of pressure within the CSDH cavity, as well as potential blood clots, neurosurgeons might not immediately recognize the mistake during the initial stages of catheter insertion, posing a significant risk. In addition, the catheter direction is not controlled during insertion, which can lead to drainage mispositioning.[28]

This study focused on the impact of a subdural catheter guidance device on post-operative cortical injury complications in patients with CSDH. A total of 274 CSDH patients were assigned to the control group, among whom 6 patients experienced post-operative cortical injury complications, resulting in an incidence rate of 2.19% (6/274). In contrast, the experimental group, consisting of 244 CSDH patients, showed a remarkable outcome, with none developing cortical injury complications post-operatively, resulting in an incidence of 0% (0/244). Fisher's exact test was performed to statistically analyze the difference in the incidence of cortical injury complications between the two groups, resulting in a p-value of 0.0427. The results indicate that the incidence of cortical injury complications in the experimental group was significantly lower than in the control group. In addition, the CMLE OR was 0, with a CI95 of (0.0, 0.9447), confirming the association between the presence of a guidance device during the procedure and reduced cortical injury.

Notably, in this in-depth research, neither the experimental group nor the control group had any reported cases of post-operative seizures or infections. This outstanding result not only indicates the high-quality of surgical procedures but also strongly supports the effectiveness of the subdural catheter guidance device in reducing cortical injury complications during CSDH drainage surgery. Although the guidance device-assisted catheter is not inserted under direct visualization, its unique advantage in minimizing cortical injury is evident.

By precisely guiding the catheter, it enables surgeons to navigate the complex subdural space more accurately, thereby reducing the risk of accidental cortical damage.

However, in clinical practice, surgeons must exercise extreme caution despite the aid of this advanced guidance device. Catheter insertion remains a crucial step that requires close monitoring. Real-time imaging and professional expertise are essential to ensure the catheter follows the correct path while remaining vigilant for any signs of potential venous interference, which could lead to bleeding and complicate the procedure. Moreover, ongoing research continues to optimize the device's design and functionality. By exploring new materials and refining guiding mechanisms, the goal is to further reduce risks and enhance surgical outcomes.

Beyond these aspects, a comprehensive surgical risk assessment should be conducted for each patient before the operation. Factors such as age, overall health condition, and the size and location of the hematoma play significant roles in determining potential risks and the most appropriate surgical approach. In addition, surgeons must undergo specialized training to proficiently operate the guidance device. This training should not only cover its basic operation but also prepare surgeons to manage various unexpected situations during the procedure. With the widespread application of this technology, establishing a standardized clinical operation protocol is essential to ensure its effective and safe implementation across different medical institutions. Overall, with its demonstrated ability to enhance surgical safety and its potential for further improvement, the guidance device holds great promise in CSDH treatment. It may become a standard tool in neurosurgery, ultimately improving patient outcomes.

In recent years, many neurosurgeons have advocated for endoscopic evacuation of CSDH. This approach has shown particularly promising results in cases of multi-compartmental subdural hematomas. The ability to directly visualize the internal structure of the hematoma effectively addresses the issue of cortical injury, which is frequently associated with blind catheter insertion, as previously confirmed by studies.[4,14,23,25] Under endoscopic visualization, the drainage tube can be positioned with a high degree of accuracy. This precision ensures that the drainage process is highly effective, maximizing the removal of the hematoma and promoting the restoration of normal intracranial pressure.[13,19] This is also clearly demonstrated in clinical practice. The endoscope provides real-time guidance during the placement of the drainage tube, allowing for optimal positioning to facilitate the smooth drainage of the hematoma (Figure 1E and F). When comparing rigid and flexible endoscopes, flexible endoscopes offer clear advantages. Their bendable tip provides greater flexibility, allowing access to hard-to-reach areas that rigid endoscopes cannot reach. This flexibility, combined with a wider field of view, significantly enhances their utility in surgical procedures. For example, in burr hole placement and CSDH removal, flexible endoscopes play a crucial role. They facilitate accurate burr hole placement by providing real-time visualization of underlying structures. In CSDH removal, they enable surgeons to clearly identify and precisely remove the hematoma. Overall, their comprehensive view of the surgical site enables surgeons to make better decisions, ultimately improving surgical outcomes and patient safety.

However, it is of utmost importance to note that the majority of neuroendoscopic surgeries typically necessitate general anesthesia.[29] General anesthesia is a multifaceted medical intervention involving a complex set of procedures. It begins with the administration of potent medications that induce unconsciousness, muscle relaxation, and analgesia in the patient. This process is carefully monitored by an anesthesiologist, who continuously assesses the patient's vital signs, including heart rate, blood pressure, and oxygen saturation.[30]

Despite its widespread use, general anesthesia carries inherent risks. One of the most significant concerns is the potential for cardiovascular complications. During general anesthesia, the body's normal physiological responses are altered, which can lead to fluctuations in heart rate and blood pressure. In some cases, this can result in more severe conditions such as heart arrhythmias, myocardial ischemia, or even cardiac arrest.[31] In addition, respiratory risks are also a concern. General anesthesia can suppress the patient's natural breathing reflexes, necessitating mechanical ventilation to ensure adequate oxygenation. This can lead to complications such as pneumonia, atelectasis, or respiratory failure.

In contrast, the subdural catheter guidance device, when utilized in conjunction with burr hole and drainage procedures, often allows the operation to be performed under local anesthesia. This represents a significant advantage in neurosurgery. Local anesthesia involves injecting a numbing agent directly into the surgical site, blocking nerve signals that transmit pain. This allows the patient to remain conscious during the procedure while experiencing minimal discomfort. The use of local anesthesia significantly reduces the risk of anesthesia-related complications. Since the patient's vital functions are not as profoundly affected as they are under general anesthesia, the likelihood of cardiovascular and respiratory complications are greatly diminished. Moreover, local anesthesia eliminates the need for complex intubation and ventilation procedures, minimizing the impact on the patient's overall physiological state. This not only reduces immediate surgical risks but also contributes to

faster recovery and fewer post-operative complications. The subdural catheter guidance device, with its ability to facilitate precise catheter placement under local anesthesia conditions, provides a unique alternative. It combines the crucial benefit of reducing complication risks with effective treatment. This device, equipped with advanced imaging and guidance technologies, enables surgeons to accurately position the catheter within the subdural space, an essential factor for successful CSDH drainage. For surgeons seeking to balance effective hematoma drainage with minimizing anesthesia-related and surgical trauma risks, the subdural catheter guidance device offers a practical and innovative solution. By leveraging its unique features, surgeons can potentially achieve better outcomes in CSDH treatment, including more complete hematoma evacuation, reduced recurrence rates, and improved neurological recovery. In addition, the combination of local anesthesia and the device's precision-guiding capabilities ensures a higher level of patient safety throughout the surgical process.

This study has certain limitations that must be acknowledged. First, the conclusions are derived from single-center data, meaning the patient population in this study is drawn from a single medical institution. As a result, the characteristics of these patients may be specific to that institution, influenced by factors, such as the geographical location of the hospital, doctor referral patterns, and regional patient demographics. For example, if the institution is in a region with a high prevalence of a particular genetic disorder, the patient cohort may be skewed toward individuals with that genetic background, which may not be representative of the broader population. These lack of multi-center data constraints the generalizability of these findings across diverse healthcare settings and patient populations.

In addition, the extended period during which study subjects were selected introduces potential variability due to advancements in surgical equipment and improvements in neurosurgeons' expertise, both of which could have impacted the experimental results. Throughout the study period, the advancements and changes in equipment and expertise could have confounded the results. For instance, the introduction of new surgical instruments such as higher-precision micro-dissectors or advanced imaging-guided systems may bring a different perspective to how diagnostic findings are interpreted. At the same time, neurosurgeons might become more proficient in certain surgical techniques due to the increased training opportunities and the accumulation of practical experiences. Thus, these external factors or changes could present challenges in determining whether any observed differences in patient outcomes are truly attributed to the variables being studied, instead of the application of new equipment or surgeon upskilling.

Furthermore, although efforts to include an appropriate patient cohort, individual differences that could not be assessed remain a limitation. These include but are not limited to, the patient's baseline conditions and their cooperation during local anesthesia procedures, both of which may restrict the generalizability of the findings. Baseline conditions can vary significantly among patients. Pre-existing medical conditions such as diabetes, hypertension, or autoimmune diseases may affect surgical outcomes and the body's response to treatment. In addition, patient cooperation during local anesthesia plays a crucial role. Some individuals may experience heightened anxiety or discomfort, which could lead to movement during the procedure. Such movement could potentially interfere with the accuracy of the surgical steps, such as the precise placement of the guiding device. For instance, a sudden movement during device insertion under local anesthesia may affect its final positioning, potentially impacting the overall outcome of the procedure.

Moreover, this study represents a positive initial attempt at utilizing this type of guiding device. However, due to the lack of access to comparable products for a direct head-to-head study, a comprehensive evaluation of its potential shortcomings or limitations remains challenging. A direct comparison with other guiding devices would have allowed for an objective assessment of key factors such as accuracy, ease of use, and the time required for device setup. Without such a comparison, any conclusions regarding the device's relative performance in the market remain speculative. For example, certain guiding devices may be more user-friendly for neurosurgeons with less experience, while others might offer higher precision in specific neurosurgical procedures. The absence of comparative data limits the ability to determine whether the device is truly the best option in all aspects or if it has areas where it may fall short compared to existing alternatives.

5. Conclusion

This study presents compelling evidence that the use of the subdural catheter guidance device in CSDH treatment represents a significant advancement. A meticulous comparison of patient outcomes with and without the device clearly demonstrates a substantial reduction in the incidence of cortical injury. This decrease in iatrogenic damage is crucial, as it directly enhances patient prognoses and reduces morbidity. The device is ingeniously designed with user-friendly features, allowing surgeons to quickly master its operation. This not only optimizes surgical efficiency but also enhances procedural fluidity. In the evolving landscape of contemporary medical technology and the challenging arena of clinical practice, the subdural catheter guidance device has emerged as an essential tool. It strengthens the safety of CSDH treatment by minimizing

the risks related to blind catheter insertion. Beyond mitigating complications, the device expands neurosurgical treatment options, providing an additional viable approach for CSDH management. This enhanced flexibility enables surgeons to customize treatment strategies with greater precision to individual patient requirements, considering factors such as hematoma size, location, and complexity. Ultimately, this results in more efficient and safer patient management, optimizing recovery outcomes and enhancing the overall standard of care for CSDH patients.

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Conflict of interest

The authors have no relevant financial or non-financial interests to disclose.

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Ethics approval and consent to participate

This study was approved by the Ethics Committee of The First Affiliated Hospital of China Medical University (2023-561-2). Informed consent has been obtained from the participating patients and/or their families before their participation.

Consent for publication

Written informed consent was obtained from all participants included in this study, including consent for the publication of their data and/or images. A Chinese translation of the informed consent form is available from the corresponding author upon reasonable request.

Availability of data

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Appendix

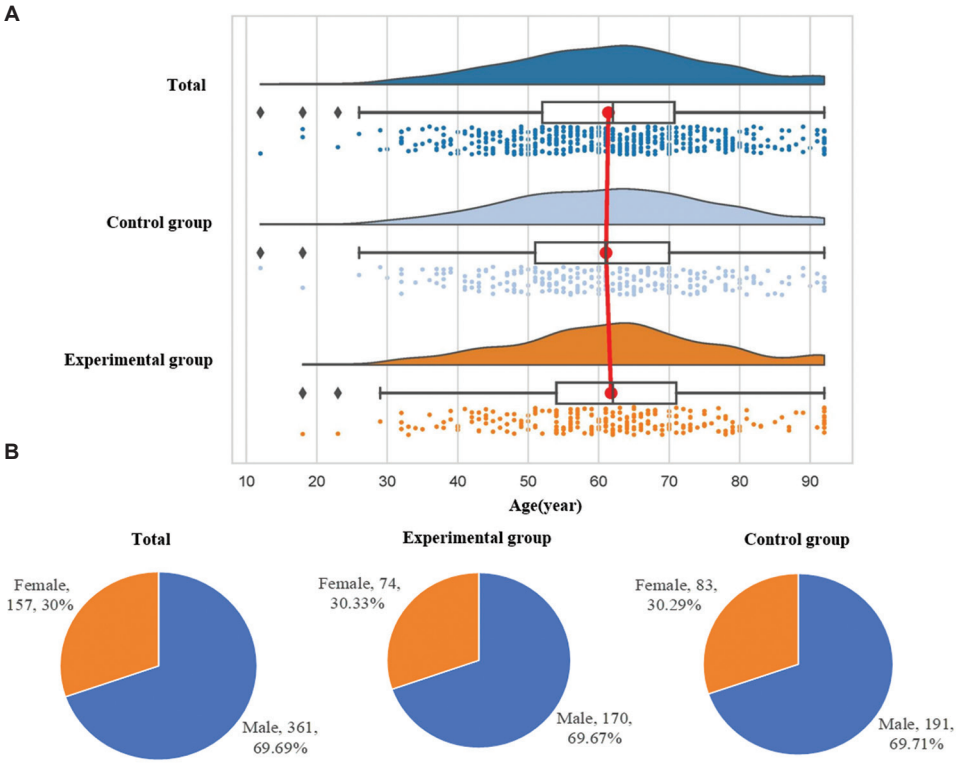


Figure A1. Demographic characteristics of the experimental and control groups. (A) Age composition and distribution of patients in each group. (B) Gender distribution of patients in each group.

Table A1. Demographic characteristics of the experimental and control groups

Characteristics	Control group (*n*=274)	Experimental group (*n*=244)
Age (range, mean±SD)	12 – 92, 61.04±14.70	18–92, 57.6±11.27
Gender (male/female; ***n*** [%])	191 (69.7%)/83 (30.29%)	170 (63.67%)/74 (30.32%)

Abbreviation: SD: Standard deviation.