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PREVENTING VENTRICULAR CATHETER DISPLACEMENT AND INFECTION WITH THE “CATHETER-LOCKING DEVICE-ASSISTED” TECHNIQUE: A RETROSPECTIVE STUDY OF 231 PATIENTS.

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PII: S1878-8750(23)01652-2

DOI: <https://doi.org/10.1016/j.wneu.2023.11.089>

Reference: WNEU 21467

To appear in: *World Neurosurgery*

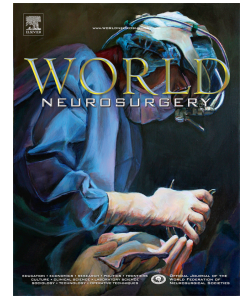
Received Date: 13 November 2023

Accepted Date: 19 November 2023

Please cite this article as: Piccirilli M, Scafa AK, Marchese E, Gallo M, Santoro A, PREVENTING VENTRICULAR CATHETER DISPLACEMENT AND INFECTION WITH THE “CATHETER-LOCKING DEVICE-ASSISTED” TECHNIQUE: A RETROSPECTIVE STUDY OF 231 PATIENTS., *World Neurosurgery* (2023), doi: <https://doi.org/10.1016/j.wneu.2023.11.089>.

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Key words: Complications – External ventricular drain – Hydrocephalus – Infection – Neurosurgical
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Short title: *CLD-assisted Technique: Our Experience*

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Abbreviations List:

CLD: catheter-locking device

CSF: cerebrospinal fluid

CT: computed tomography

C+ T1WI: contrast enhanced T1 weighted image

ETV: endoscopic third ventriculostomy

EVD(s): external ventricular drain(s)

F: female

GCS: Glasgow Coma Scale

ICH: intracerebral hemorrhage

ICU: intensive care unit

IV: intravenous

M: male

MRI: magnetic resonance imaging

NIH: non-infectious hydrocephalus

NPH: normal pressure hydrocephalus

PEEK: polyether ether ketone

POD: postoperative day

SAH: subarachnoid hemorrhage

TBI: traumatic brain injury

VPS(s): ventriculoperitoneal shunt(s)

WHO: World Health Organization

ABSTRACT

Background: Inserting cerebrospinal fluid diversion devices like external ventricular drains (EVDs) and ventriculoperitoneal shunts (VPSs) is a critical procedure. Unfortunately, complications such as catheter misplacement, dislocation, or infection can occur. Various surgical strategies aim to reduce these risks. One recent innovation is the “*catheter-locking device* (CLD)-assisted” technique for EVD surgery. In this study, we examined its application in a larger group of cases encompassing both EVDs and VPSs over a 30-month period, with a focus on these complications.

Methods: All adult patients who underwent a shunt procedure for non-infectious hydrocephalus at our Institution from January 2021 to June 2023 were reviewed. We compared complications between those treated with the “standard” technique (subgroup A) and those managed with the “CLD-assisted” approach (subgroup B).

Results: In the EVD surgical group (initial procedures, $n = 161$), 6 patients (3.7%) required reoperation due to catheter misplacement due to inadvertent migration of the ventricular catheter within the operating room (“early” migration), while 11 patients (6.8%) experienced unintentional postoperative dislodgement (“delayed” migration). Seven patients (4.3%) developed an EVD-related infection after an average duration of 7.4 days. None of these complications were observed in subgroup B patients ($p < .05$). Among VPS patients ($n = 137$), 4 (2.9%), all in subgroup A, required reoperation due to intraoperative migration of the catheter ($p = .121$); no other complications were identified.

Conclusions: The “CLD-assisted” technique may significantly decrease the occurrence of the most common EVD complications and can also prove beneficial in VPS surgery. However, further investigation is necessary.

INTRODUCTION

The insertion of cerebrospinal fluid (CSF) diversion devices, such as external ventricular drains (EVDs) and ventriculoperitoneal shunts (VPSs), is arguably one of the most common and vital life-saving procedures in the field of neurosurgical practice, with over 50,000 shunt placements occurring annually in the USA alone.^{1,2} Unfortunately, *procedural* issues such as inaccurate catheter positioning, as well as *postprocedural* issues like catheter dislocation, obstruction, or infection, may overshadow their benefits.

Various surgical strategies have been described and later employed to reduce the risk of such complications.

We have recently described a novel technique for EVD placement and securing, referred to as the “*catheter-locking device-assisted*” technique, and reported our preliminary data on 15 consecutively treated patients.³

We initially employed this technique for the insertion of EVDs only, but as we grew confident in its potential, we expanded its application to encompass VPS procedures as well.

We provide here data concerning the application of the “*catheter-locking device-assisted*” technique on a larger set of cases, including both EVDs and VPSs, over a period of 30 months. We also present a clinical case from our practice to illustrate its use in a subdural-peritoneal shunt procedure.

MATERIAL AND METHODS

For this single-center retrospective study, we included all patients over 18 years of age who underwent a shunt procedure for the treatment of non-infectious hydrocephalus (NIH) at our Institution (Neurosurgery, Department of Neurology and Psychiatry, “Sapienza” University of Rome) during a 30-month period (January 2021 to June 2023). Excluded from the study were patients who had undergone endoscopic third ventriculostomy (ETV) and those affected by postinfectious hydrocephalus.

All procedures were performed in a neurosurgical operating room under sterile conditions. Frontal horn placement (Kocher’s point) was the choice in all these procedures.

Patients underwent preoperative shaving using an electric clipper and received antibiotic prophylaxis in the perioperative period. Specifically, a 2g IV dose of cefazolin was administered before the incision, followed by 1g IV every 8 hours for 24 hours. IV vancomycin (1g before the incision, followed by 1g IV every 12 hours for 24 hours) was used selectively in patients who were allergic to penicillin or cephalosporin. All patients were provided with antibiotic-impregnated catheters (Bactiseal®, Codman Johnson & Johnson, Raynham, MA, USA).

Each patient in the VPS surgical group received an adjustable pressure valve (Hakim Medos® [Codman Johnson & Johnson, Raynham, MA, USA] or proGAV® 2.0 [Miethke, Aesculap, Potsdam, Tuttlingen, Germany]).

Two distinct methods were employed to ensure “stability” of ventricular catheters.

For the “standard” technique, a linear incision was made. Based on preoperative CT scan, the catheter was inserted to a depth of approximately 5 cm, until CSF was readily collected. Then, depending on the type of surgery, it was either (1) passed under the skin about 5 cm backward from the insertion site and secured to the skin using a non-absorbable suture (EVD surgical group), or (2) connected to the valve (VPS surgical group), relying on the integrity of superficial tissues for stability.

For the “*catheter-locking device-assisted*” technique (Fig. 1-2), a curvilinear incision was made to create a skin flap for effortless catheter removal without wound compression (linear incisions are not recommended). Using a disposable applicator (Fig. 1a-b), the catheter was slid through a biocompatible, non-artifact-inducing catheter-locking device (CLD), consisting of a peripheral “*crown*” with external teeth to secure the craniostomy hole and internal flexible tabs to clamp the catheter, and a central “*insert*” enabling tab widening for catheter release if compressed (Fig. 1c). Proper positioning of the CLD on the ventricular catheter was determined based on preoperative CT scan. At the appropriate depth, the catheter’s stylet was removed, and the crown of the CLD gently pushed in the craniostomy hole. The applicator was then detached, allowing the tabs to secure the catheter. The final steps, depending on the type of surgery, were like those previously described for the “standard” technique. The instrumentation used for the “CLD-assisted” drain placement (NTDRAIN® system, *ntplast*® advanced biomedical solutions, Italy) was designed to secure catheters with an external diameter of 3.0 or 3.3 mm in cranial holes created using a 14 mm perforator. It is not suitable for patients under the age of 16 due to differences in skull bone thickness in children. Additionally, it should not be implanted in patients allergic to polyether ether ketone (PEEK). The device, made of PEEK, is radiolucent and is compatible with MRI.

The choice of either method was based on the surgeon’s individual preferences and/or experience on each specific case.

Each patient underwent at least one cranial CT scan within the first 24 hours after surgery to assess the accurate positioning of the ventricular catheter and rule out any potential complications. Additional CT scans were performed based on the patients’ clinical status.

There was no established practice for regular CSF sampling or fixed interval catheter exchange for EVDs throughout the entire study period. EVD catheters were challenged and removed as soon as possible to minimize prolonged placement. If the progression of the ventricular dilatation was not effectively treated with the external drain, a permanent VP shunt was inserted.

We analyzed and compared complications in cases treated with the “standard” technique and cases managed with the “CLD-assisted” approach. Our primary focus was on instances of ventricular catheter misplacement, dislodgement, and infection, mainly within the scope of EVD surgery; meanwhile, in the context of VPS surgery, our investigation aimed to uncover any potential significance.

We provide the patient counts and proportions for categorical variables, and for continuous variables, we report the average value along with its standard deviation. To assess the differences between the “standard” and “CLD-assisted” surgical groups, we employed χ^2 , Fisher’s and t tests. A p-value < .05 was considered statistically significant.

The definition used for catheter-related CSF infection was derived from the Clinical Practice Guidelines of the “Infectious Diseases Society of America” (IDSA).⁴

RESULTS

Between January 2021 and June 2023, 231 adult patients underwent one or more shunt procedures for the treatment of NIH at our Institution. Median age of patients was 65.4±8.2 years, with a range of 47 to 81 years. 122 patients (52.8%) were females (F/M ratio = 1.1:1). Glasgow Coma Scale (GSC) score at presentation ranged between 6 (EVD surgical group) and 15 (VPS surgical group).

A total of 196 EVDs were placed in 161 patients, Table 1. Spontaneous subarachnoid hemorrhage (SAH) (n = 65, 40.4%) and hypertensive intracerebral hemorrhage (ICH) with ventricular involvement (n = 32, 19.9%) were the leading indications for EVD, followed by traumatic brain injury (TBI) (n = 24, 14.9%), tumor (n = 19, 11.8%), and others (postsurgical hydrocephalus, n = 13, 8.1%; posterior fossa hemorrhage or ischemia, n = 7, 4.3%; 1 aseptic meningitis).

Among initial procedures, 86 (53.4%) were performed using the “standard” technique (subgroup A), while 75 (46.6%) were carried out with the novel “CLD-assisted” technique for ventricular catheter placement and securing (subgroup B). No statistically significant differences were detected when comparing subgroups A and B regarding age, gender, and reasons for catheterization (p > .05), Table 1.

Nine patients (5.6%) required reoperation due to catheter misplacement identified on the first postoperative brain CT scan (≤ 24 hours). Among these cases, 6 (66.7%) were likely attributed to inadvertent migration of the ventricular catheter within the operating room (“early” migration), resulting in depth misplacement. Eleven patients (6.8%) experienced unintentional postoperative dislodgement (“delayed” migration) and pull-out within an average duration of 7.5 days (± 5.0 days, ranging from 1 to 17 days). Of these cases, 6 (54.5%) were attributed to ward hygienic care, while 5 (45.5%) were related to intrahospital transport. Apart from 2 cases of ventricular catheter

misplacement that was unrelated to intraoperative catheter migration, none of the described complications were observed in subgroup B patients ($p < .05$), as shown in Table 2.

A total of 7 patients (4.3%) developed an EVD-related infection after an average duration of 7.4 days (± 5.4 days, range: 3-16 days): 4 out of 7 (57.1%) were diagnosed within 7 days after EVD placement. All of these were verified through CSF microbiological testing, as displayed in Table 2. CSF leakage was noted at the surgical wound site in all cases, except for one, in the days preceding the onset of symptoms. Once again, all observations pertained to subgroup A with a statistically significant difference between subgroups A and B ($p < .05$), Table 2. Five of these patients (71.4%) died, all within 90 days.

The use of the CLD did not result in an increase in catheter obstructions, Table 2.

Among EVD patients, 27 (16.8%) died during the study period, with 16 in subgroup A (18.6%) and 11 in subgroup B (14.7%). The difference was not statistically significant ($p = .505$).

External drainage was continued for an average of 11.5 days (± 4.7 days, range: 5-24 days). Thirty-five EVDs (40.7%) in subgroup A were converted to VPS, while 32 (42.7%) underwent conversion in subgroup B ($p = .800$). The average duration of EVD prior to VPS placement was 12.7 days (± 3.8 days, ranging from 7 to 24 days) in subgroup A, 12.5 days (± 3.6 days, ranging from 9 to 21 days) in subgroup B ($p = .790$).

Excluding the converted EVDs ($n = 67$), a total of 70 “primary” VPSs were performed during the period of observation, 36 (51.4%) using the “standard” technique (subgroup A), 34 (48.6%) with the “CLD-assisted” one (subgroup B). Tumor was the primary reason for permanent catheterization ($n = 39$, 28.5%), followed by normal pressure hydrocephalus (NPH) ($n = 35$, 25.5%), SAH and ICH ($n = 23$, 16.8%). No statistically significant differences were found when analyzing subgroups A ($n = 71$) and B ($n = 66$) in terms of age, gender, and reasons for catheterization ($p > .05$), Table 3. Patients were followed-up for a minimum of 6 months.

Four patients (2.9%), all in subgroup A, required reoperation due to intraoperative migration of the ventricular catheter ($p = .121$). No other complications related to the surgical approach employed were identified.

Again, no statistically significant differences were found regarding mortality during follow-up between subgroups A and B, Table 4.

ILLUSTRATIVE CASE

We report the case of a 75-year-old woman who underwent surgery for a right clinoidal meningioma (WHO grade 1), which was discovered following a decrease in visual acuity (Fig. 3, Fig. 4a). One month after the procedure, the patient was readmitted due to an intractable right frontal

pseudomeningocele, related to the postoperative development of “external” hydrocephalus (Fig. 4b). We chose to perform a subdural-peritoneal shunt, placing a burr hole near the autologous bone flap repositioned in the prior surgery. To prevent displacement, we used the “CLD-assisted” technique to secure the ventricular catheter at the insertion site, as it lacked support from brain parenchyma, unlike traditional VPSs (Fig. 5). An adjustable pressure valve was inserted, with the opening pressure set at 120 mmH₂O. No occurrences of either intraoperative migration or delayed displacement of the catheter were detected. The patient was discharged on POD 5. Upon discharge (Fig. 6a-b), the right frontal CSF collection had nearly disappeared. A 3-month follow-up MRI showed the complete disappearance of the external hydrocephalus (Fig. 6c).

DISCUSSION

The insertion of ventricular catheters is not always as “smooth” and straightforward as it is often assumed to be.

Non-assisted placements frequently require multiple attempts, which can potentially result in improper positioning. Ventricular catheter misplacement is reported in the literature in up to one-third of shunt implantations, depending on the definition used.⁵ It is commonly attributed to issues with the trajectory of the stylet during insertion (mislocation), but can also be due to inadvertent, “early” migration of the ventricular catheter within the operating room (depth misplacement). Currently employed ventricular catheters generally display numerical depth markings which can aid surgeons in proper placement. Moreover, with the contribution of a second operator during catheter insertion, the risk of depth misplacement is further minimized. Nonetheless, “early” migrations can still occur in certain cases, as our series demonstrates.

Unintentional dislocation (“delayed” migration) of the ventricular catheter is another well-recognized issue, although precise data regarding its incidence are still lacking. Unlike misplacement, which can affect both external and internal ventricular shunting procedures, this is a problem that specifically pertains to EVD surgery. The “Roman sandal” technique and its variants, based on the use of sutures, continue to be the most employed method for EVD catheter “fixation”, along with the use of surgical staples. Both sutures and staples, however, can lead to skin erosion over time, which in turn encourages bacterial growth and migration. Furthermore, both tend to gradually loosen, and this could result in the “delayed” dislodgement of the ventricular catheter. In their 10-year cohort, Salem et al.⁶ found a total dislodgement rate of 5.9%, irrespective of the securing method used, with no significant differences found between the sutures and staples groups.

Not long ago, Velásquez et al.⁷ proposed positioning the drain between two hydrocolloid dressings, subsequently secured to the skin using staples. A retrospective analysis spanning 10 years was conducted on a cohort of 435 patients, revealing 2 instances of drain pull-out.

We have recently described a novel approach for the placement and “securing” of ventricular catheters during EVD surgery, which we refer to as the “*catheter-locking device-assisted*” technique.³ Building upon our previously published preliminary data, we were confident that consistent application of this technique would lead to a significant reduction in both “early” and “delayed” migrations. This confidence was indeed supported by the observed decrease in instances of catheter depth misplacement and of unintentional postoperative dislodgement, both of which reached statistical significance in our case series ($p < .05$). Importantly, the advantage of securely “locking” the catheter did not compromise its ease of removal (Fig. 2, Video).

We also believed that using this technique could assist in infection control.

The reported rate of EVD-related infections ranges between 0% and 52%, depending on the definition used.⁸⁻¹³ The introduction of subcutaneous tunneling by Saunders and Lyons in 1979 marked a significant initial step in attempting to reduce the incidence of this complication.¹⁴ Antibiotic- and silver-impregnated catheters, which were introduced in 2003 and 2010 respectively, were devised for the same purpose.^{15,16} The employment of these tools holds significant importance. However, it has not eradicated the likelihood of infection, still related to several factors, including duration of EVD placement, frequency of sampling, length of hospital stays, concurrent systemic infections, and - of course - CSF leakage at the catheter exit site.^{11,13,17} The use of the CLD allows us to anchor the catheter, eliminating the *back-and-forth* movement inherent in the traditional technique (“Roman sandal”). Furthermore, the “sealing” effect on the craniostomy hole prevents any leakage of CSF, serving as a protective barrier against direct microbial transmission. Through our 30-month evaluation, a statistically significant difference regarding infection incidence between the “standard” and the “CLD-assisted” techniques has indeed emerged ($p < .05$). We attribute the reduced incidence of infections with this technique to these factors. These findings prompted us to explore the adaptability of the same technique in the context of VPS surgery.

In our series, four patients required an early VP shunt revision due to intraoperative migration of the ventricular catheter, as observed on the initial postoperative brain CT scan. This complication was exclusively observed in procedures employing the “standard” technique. Although not reaching statistical significance ($p = .121$), we consider this result comparable to that of the EVD surgical group. The use of the “CLD-assisted” technique could be especially important in subdural-peritoneal shunting, as shown in our “illustrative case”. In such situations, due to the absence of brain

parenchymal support for the ventricular catheter, it becomes more susceptible to inadvertent displacement; hence, the use of the CLD may provide significant assistance.

Furthermore, as previously mentioned, the application of this technique allows us to repair the cranial defect, which is often located in a visible, *anterior* position (Kocher's point). This effectively prevents a lasting aesthetic issue in both EVD and VP shunt patients.

Despite the retrospective nature of our data collection for this study, we hold a firm belief in the value of the novel "CLD-assisted" technique. Future investigations, particularly prospective and multicentric studies, are required to validate and expand upon our findings.

CONCLUSIONS

The "*catheter-locking device-assisted*" technique for ventricular catheter placement and securing appears to provide a secure and efficient alternative to the "standard" insertion procedure. Its systematic use could lead to a reduction in the incidence of ventricular catheter migration and infection. It may also prove beneficial in VPS surgery. Further investigation is, of course, necessary.

Declarations of interest: None.

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FIGURE LEGENDS

Fig. 1 – Equipment (1) (a) Insertion procedure. See text for details. (b) Disposable *applier*. The instrument is made up of two halves: an anterior half (*right*) consisting of a “crown-holder” with a lever for the compression of the insert, and a posterior half (*left*) designed for the adjustment of the catheter depth through the burr hole within the operating room. (c) *Catheter-locking device*: peripheral “crown” (*black solid arrow*) with external teeth to secure the craniostomy hole and internal flexible tabs to clamp the catheter (*black dashed arrow*), and a central “insert” enabling tab widening for catheter release if compressed (*black dotted arrow*).

Fig. 2 – Equipment (2) (a) Disposable *activator* for catheter removal. (b) Catheter removal mechanism. By acting with the disposable activator on the insert (orthogonal transcutaneous compression) (*left*), the flexible tabs open and it is thus possible to remove the catheter (*right*).

Fig. 3 – Preoperative brain MRI. (a) Axial section, C+ T1WI, showing a large extra-axial dural-based lesion arising from the right anterior clinoid process. (b) Coronal section, C+ T1WI, demonstrating the encasement of the right internal carotid artery bifurcation by the mass.

Fig. 4 – Postoperative brain CT scans. (a) POD 1 CT scan showing the excision of the lesion without surgical complications. (b) 1-month CT scan showing a voluminous right frontal pseudomeningocele (*white solid arrow*) and signs of external hydrocephalus (*white dotted arrows*).

Fig. 5 – Subdural-peritoneal shunting. Postoperative brain CT scan. (a) Scout view. (b) Coronal section. Notice the perfect fit of the device in the burr-hole used for catheter insertion. (c) Axial section. (d) Sagittal section.

Fig. 6 – Postoperative brain MRIs. (a) MRI before discharge, axial section, C+ T1WI, showing the complete excision of the lesion. (b) MRI before discharge, axial section, C+ T1WI. Notice the reduction of the external hydrocephalus (*white solid arrow*). (c) 3-month follow-up MRI, axial section, C+ T1WI, showing the complete disappearance of the external hydrocephalus.

TABLES

Table 1. Baseline characteristics of patients undergoing EVD during the period of observation.

Characteristics	Subgroup A	Subgroup B	P value
No. of patients	86	75	-
Female patients, n (%)	51 (59.3)	42 (56.0)	.672
Mean age (\pm SD) (yrs)	66.8 \pm 7.8	65.3 \pm 7.7	.208
Indications for catheterization, n (%)			
SAH	36 (41.9)	29 (38.7)	.982
ICH	17 (19.8)	15 (20.0)	
TBI	13 (15.1)	11 (14.7)	
Tumor	10 (11.6)	9 (12.0)	
Others	10 (11.6)	11 (14.7)	

ICH: intracerebral hemorrhage, SAH: subarachnoid hemorrhage, SD: standard deviation, TBI: traumatic brain injury, yrs: years.

The data refer to initial procedures. Reasons for replacement included: misplacement (see text for details) (n = 9), dislodgement (n = 11), CSF infection (n = 7), and obstruction with still need for ventricular drainage (n = 8).

Table 2. Differences in outcome parameters between patients undergoing “standard” EVD surgery (subgroup A) and patients undergoing “CLD-assisted” EVD surgery (subgroup B).

Outcome Parameters	Subgroup A (n = 86)	Subgroup B (n = 75)	P value
“Early” migrations, n (%)	6 (7.0)	0 (0)	.031*
“Delayed” migrations, n (%)	11 (12.8)	0 (0)	.001*
Infections, n (%)	7 (8.1)	0 (0)	.015*
coagulase-negative <i>Staphylococcus</i>	3 (42.9)	-	-
<i>Enterococcus</i> spp.	2 (28.6)		
<i>Klebsiella pneumoniae</i>	1 (14.3)		
<i>Acinetobacter baumannii</i>	1 (14.3)		
Catheter obstruction, n (%)	5 (5.8)	3 (4.0)	.725
Mortality, n (%)	16 (18.6)	11 (14.7)	.505

* Significant at $p < .05$ (Fisher’s exact test).

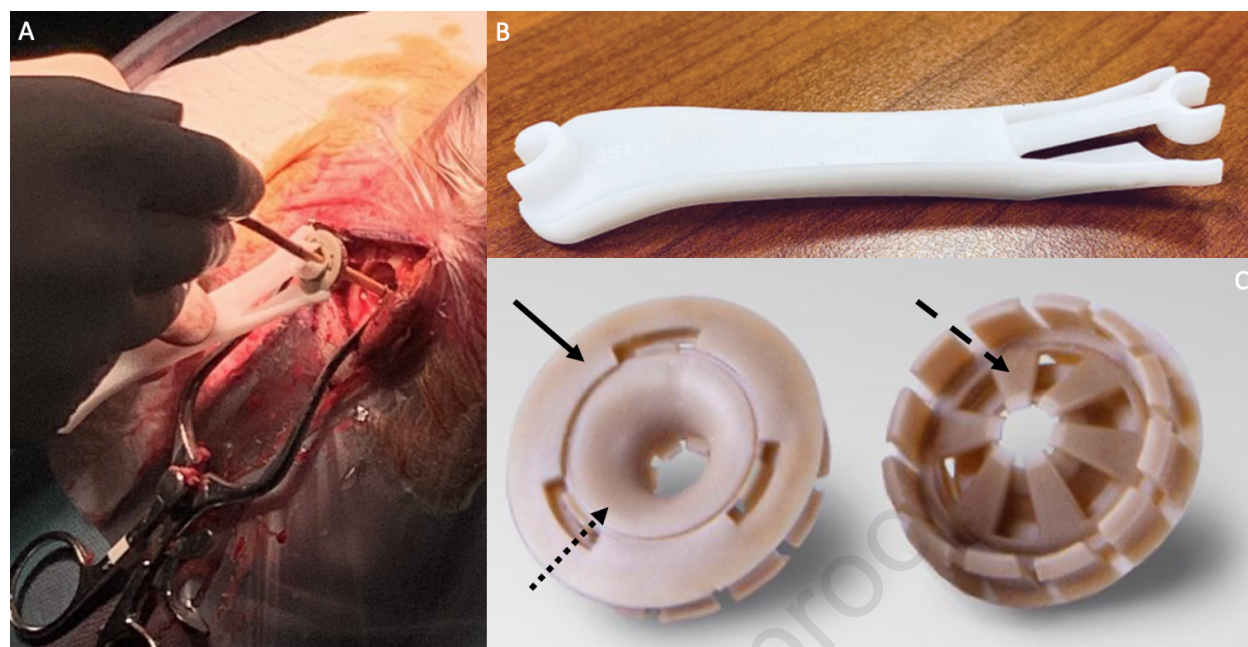
Table 3. Baseline characteristics of patients undergoing VPS during the period of observation.

Characteristics	Subgroup A	Subgroup B	P value
No. of patients	71	66	-
Female patients, n (%)	33 (46.5)	39 (59.1)	.140
Mean age (\pm SD) (yrs)	64.4 \pm 7.7	62.7 \pm 9.5	.261
Indications for catheterization, n (%)			
Tumor	17 (23.9)	22 (33.3)	.522
NPH	21 (29.6)	14 (21.2)	
SAH/ICH	13 (18.3)	10 (15.2)	
Others	20 (28.2)	20 (30.3)	

NPH: normal pressure hydrocephalus, ICH: intracerebral hemorrhage, SAH: subarachnoid hemorrhage, SD: standard deviation, yrs: years.

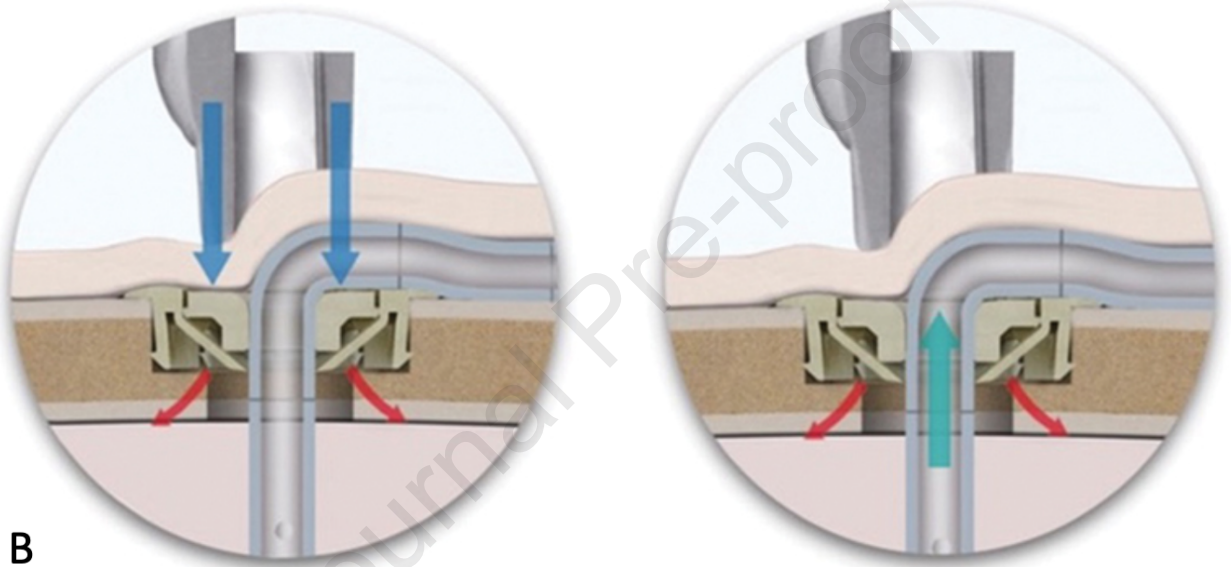
Table 4. Differences in outcome parameters between patients undergoing “standard” VPS surgery (subgroup A) and patients undergoing “CLD-assisted” VPS surgery (subgroup B) during the period of observation. Follow-up duration = 6-32 months.

Outcome Parameters	Subgroup A (n = 71)	Subgroup B (n = 66)	P value
“Early” migrations, n (%)	4 (5.6)	0 (0)	.121
“Delayed” migrations, n (%)	0 (0)	0 (0)	-
Infections, n (%)	0 (0)	0 (0)	-
Mortality, n (%)	12 (16.9)	9 (13.6)	.596

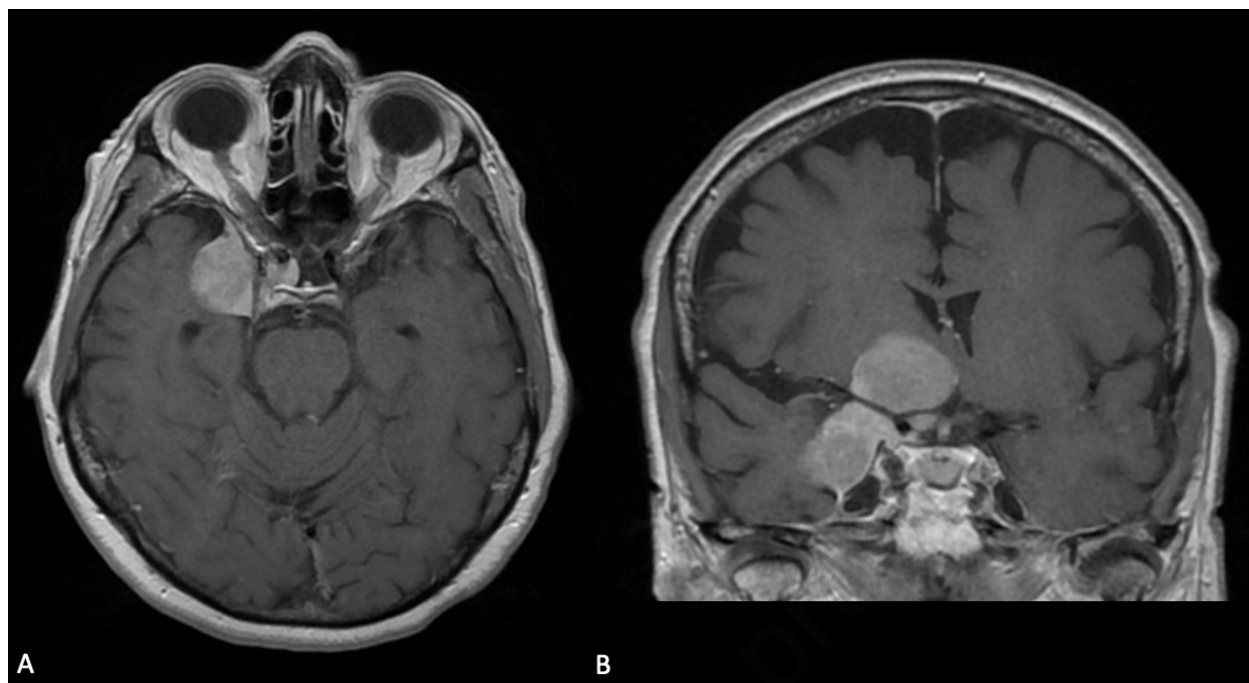


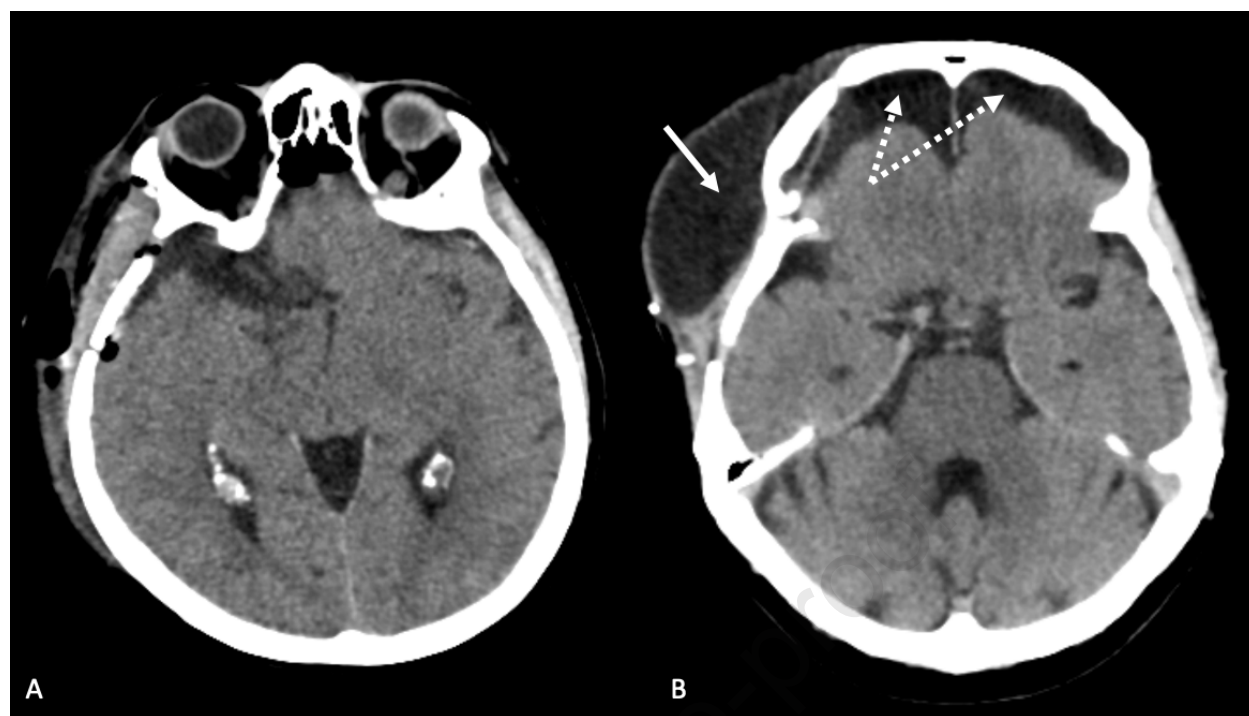


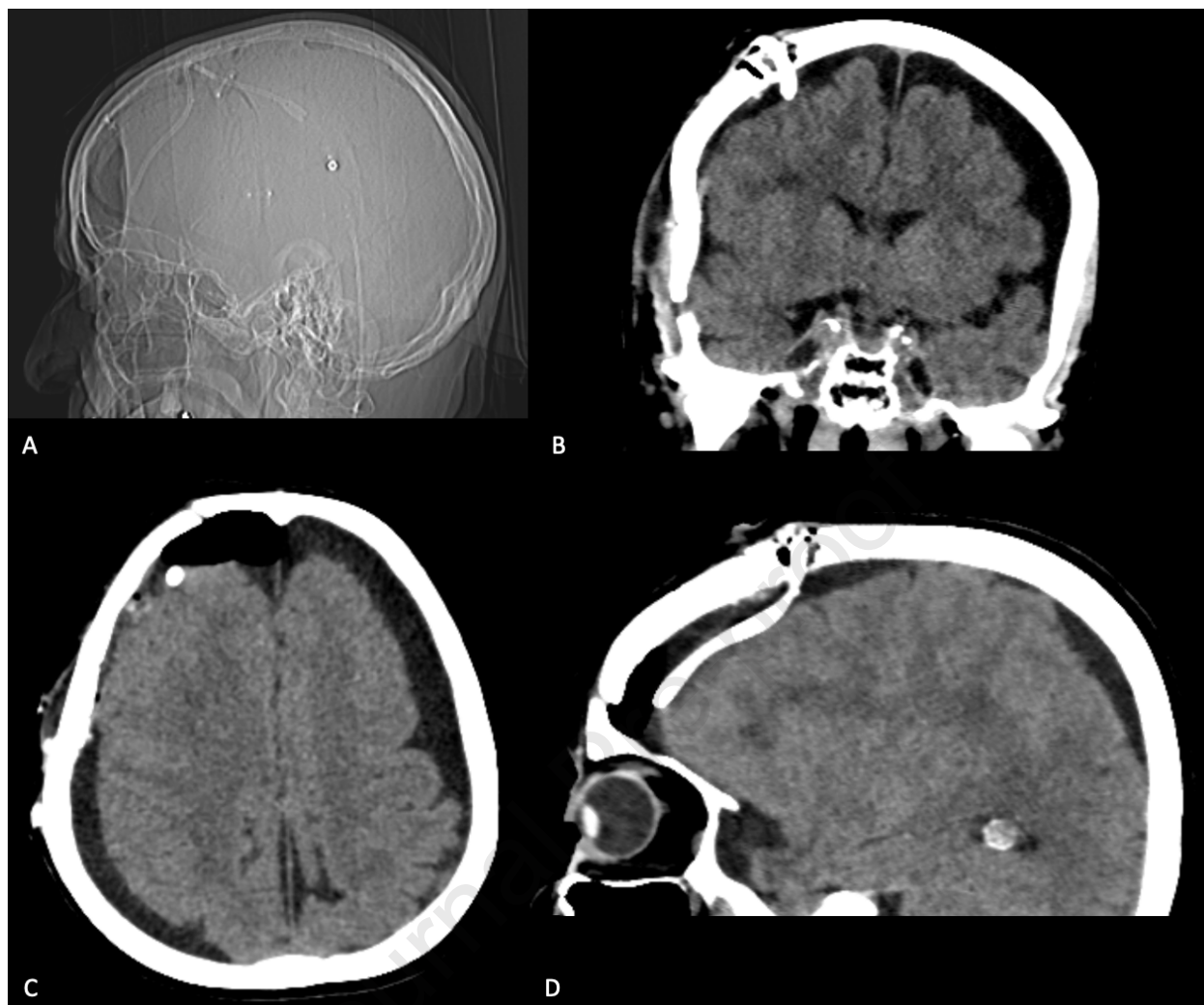
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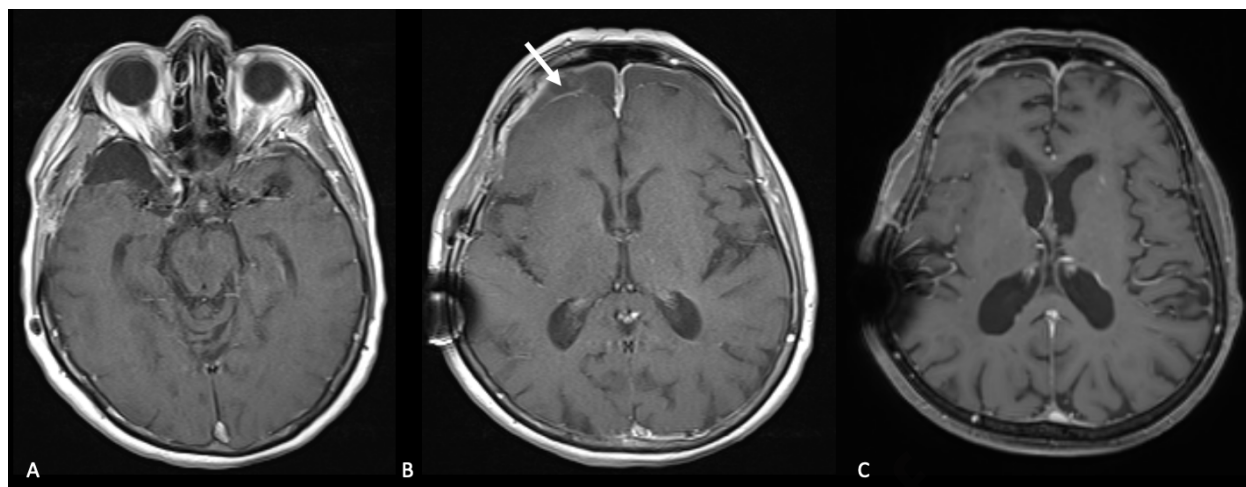


B









Abbreviations List:

CLD: catheter-locking device

CSF: cerebrospinal fluid

CT: computed tomography

C+ T1WI: contrast enhanced T1 weighted image

ETV: endoscopic third ventriculostomy

EVD(s): external ventricular drain(s)

F: female

GCS: Glasgow Coma Scale

ICH: intracerebral hemorrhage

ICU: intensive care unit

IV: intravenous

M: male

MRI: magnetic resonance imaging

NIH: non-infectious hydrocephalus

NPH: normal pressure hydrocephalus

PEEK: polyether ether ketone

POD: postoperative day

SAH: subarachnoid hemorrhage

TBI: traumatic brain injury

VPS(s): ventriculoperitoneal shunt(s)

WHO: World Health Organization

Disclosure-Conflict of Interest (Manuscript Title: PREVENTING VENTRICULAR CATHETER DISPLACEMENT AND INFECTION WITH THE “*CATHETER-LOCKING DEVICE-ASSISTED*” TECHNIQUE: A RETROSPECTIVE STUDY OF 231 PATIENTS.):

We have no conflicts of interest to disclose.

All authors declare that they have no conflicts of interest.

Yours Sincerely,

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