Use of Novel Automated Active Irrigation With Drainage Versus Passive Drainage Alone for Chronic Subdural Hematoma

A Propensity Score-Matched Comparative Study With Volumetric Analysis

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Background [1-9]

Standard Treatment

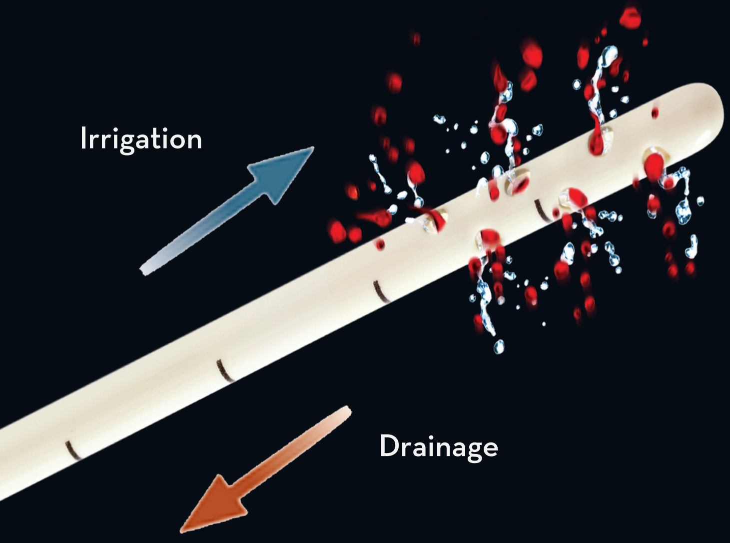
- Chronic subdural hematomas (cSDH) are common, with an incidence 1.7-14/100000 people.
- Standard treatment often involves a craniotomy with passive drainage to remove blood products.
- Though considered the gold standard, passive drainage be complicated by catheter occlusion requiring repeat placements and infections. Additionally, recurrence and suboptimal evacuation remain concerns.

New Active Drainage System

- The IRRA*flow*® system (IRRAS) is a new, active drainage system, that utilizes a dual-lumen catheter to irrigate and drain automatically.
- Recently, there has been some success in utilizing the IRRA*flow*® system to treat chronic subdural hematomas, however large scale data is still lacking.

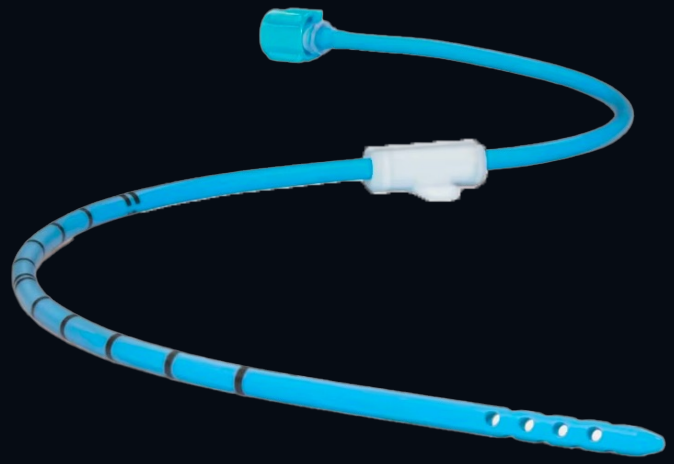
Objectives

- To compare the use of a novel double-lumen active automated irrigation and drainage system, IRRA*flow*®, for patients with cSDH with passive drainage using clinical outcomes, propensity score matching (PSM), and volumetric analysis.



Cross-sectional image of IRRA*flow* dual-lumen catheter

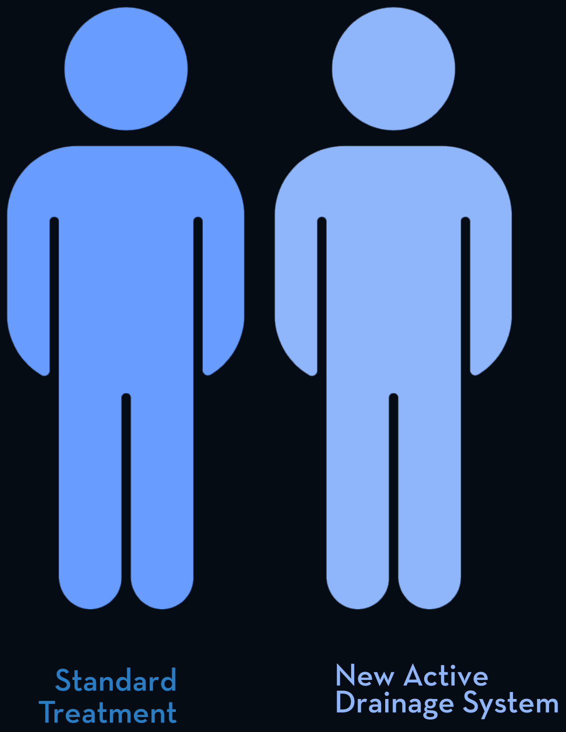
vs.



Passive drainage

Methods-Patient Population

- A prospectively maintained database was retrospectively searched for consecutive patients who presented with cSDH between September 2020 and April 2022.
- Patients were dichotomized into groups treated with active irrigation and drainage using IRRA*flow*® and those treated with standard-of-care passive drains (TLS® Surgical Drainage System catheter [Stryker] or Jackson-Pratt® surgical drain [Cardinal Health) in the subdural space.
- Basic demographic data, medical history, use of antiplatelet or anticoagulation medication, and baseline neurologic status (Glasgow Coma Scale and modified Rankin Scale) were recorded.



Methods-Outcomes

- Procedural characteristics recorded:
  - Modality of treatment (craniotomy or burr-hole surgical evacuation)
  - Catheter placement details
  - Irrigation fluid used
  - Initial drainage height of the catheter
  - Total drainage volume
  - Initial active irrigation rate (for the IRRA*flow*® catheter)

- Procedural outcomes recorded:
  - Seizure activity
  - Hemorrhage during catheter placement
  - Repeat subdural evacuation requiring intervention
  - Catheter occlusions or related infections requiring replacement
  - Any subsequent revision
  - Rate of conversion of the IRRA*flow*® catheter to a standard drain

- Outcome metrics assessed:
  - Length of intensive care unit (ICU) stay
  - Total hospital length of stay (LOS)
    - For patients readmitted for recurrent hematoma, LOS was calculated to reflect the sum of the length (days) of all admissions. Immediate follow-up data included discharge mRS and GCS scores and all-cause in-hospital mortality.

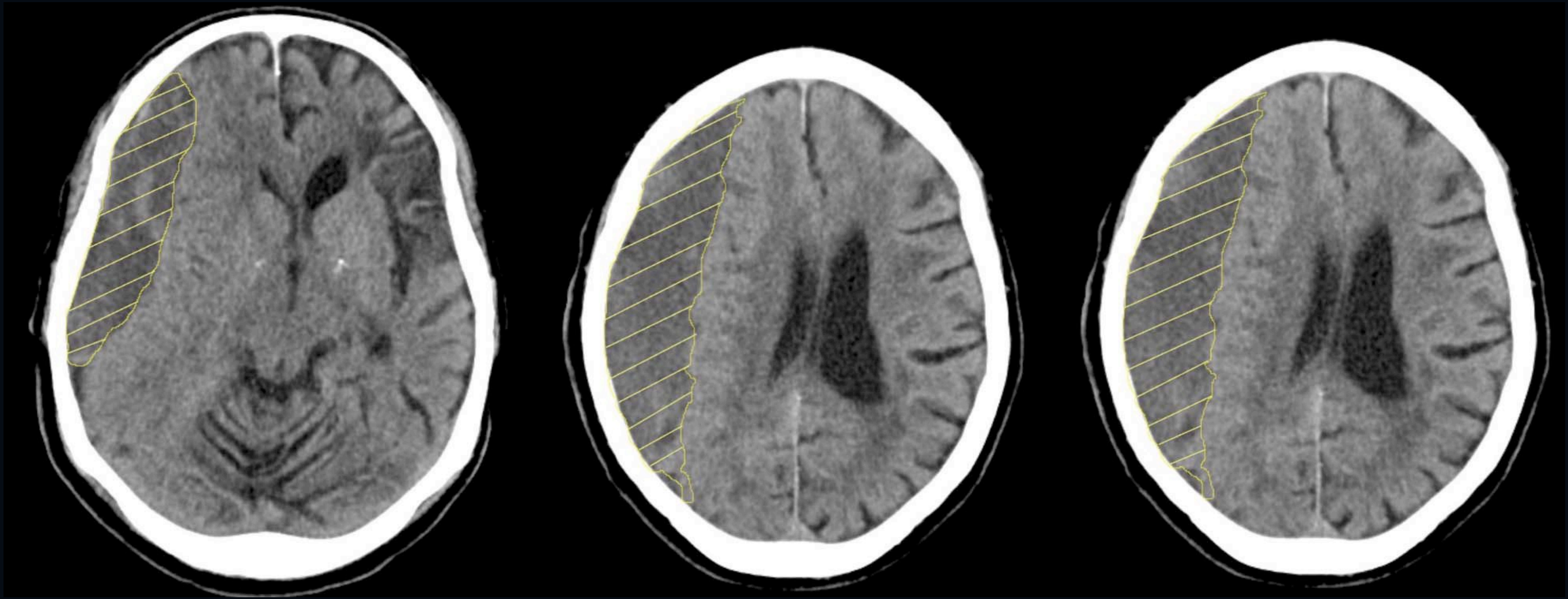
Methods-Propensity Score Matching

- One-to-one propensity score matching (PSM) was conducted to control for treatment selection bias using nearest-neighbor technique without replacement for comorbidities and presentation severity.
- Covariates included in the PSM model included age, sex, race, comorbidities, smoking status, prehospital Modified Rankin Score (mRS) and admission Glasgow Coma Scale (GCS) scores, and hematoma volume at presentation.
- Balance in these baseline variables was estimated using standardized mean differences, with a 10% difference regarded as imbalanced.

Methods-Volumetric Analysis

- For volumetric analysis, the Non-contrast computed tomography (NCCT) images for each patient obtained preoperatively, postoperatively, and at discharge were retrieved from our database.
- A digital imaging and communications in medicine file was loaded into ImageJ processing software where it was used along with a region-of-interest selection tool to outline the hematoma mass at each frame of the NCCT images.
- The hematoma was highlighted manually by 2 authors blinded to the type of drainage using the selection tool to precisely outline the hematoma area present in each layer of the brain.
- The area measurements were summed together and multiplied by layer height and pixel spacing in x and y directions to derive a total volume measurement for the hematoma. This process was repeated to determine the hematoma volume for each patient at each of the 3 time points studied.

Methods-Volumetric Analysis



Noncontrast computed tomography axial images showing chronic subdural hematoma segmentation at 3 different levels using ImageJ software (https://imagejnih.gov/ij/). The area of the hematoma is precisely outlined using the software selection tool and later calculated as volumes.

IRRA*flow*® Placement

- After hematoma evacuation (burr hole or craniotomy), the IRRA*flow*® system was primed and its drainage catheter placed in the subdural space.
- The dura was then reflected and the craniotomy or burr-hole site was closed.
- The drain was secured with 3-0 nylon sutures. Standard passive drains were placed in similar fashion. Drains were placed anterior to posterior in both groups.

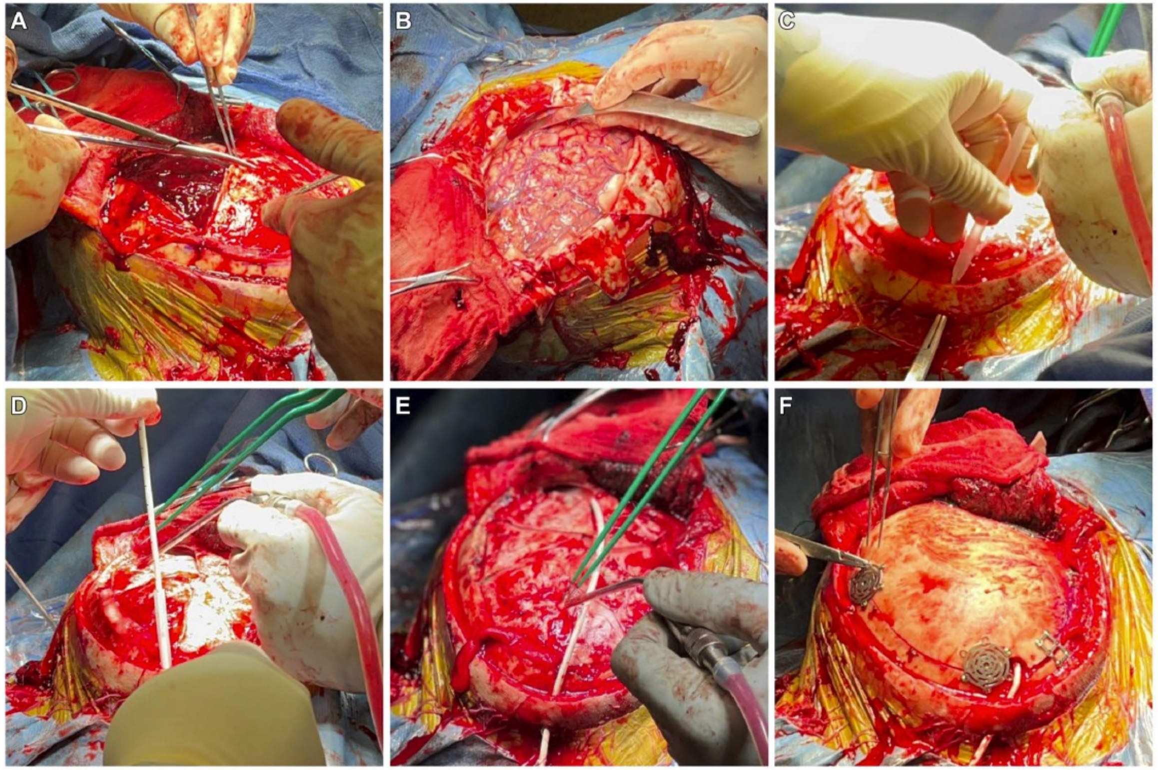


FIGURE 1. *Intraoperative photographs.* **A**, *Right-sided chronic subdural hematoma collection demonstrated on opening the dura after subtotal craniotomy.* **B**, *Complete hematoma evacuation.* **C**, *A plastic passer is tunneled anterior to posterior using forceps followed by* **D**, *placement of the IRRAflow catheter (IRRAS) through the passer.* **E**, *The IRRAflow catheter is pulled through, with the plastic passer removed afterward (performed to maintain sterility and to avoid issues with multiple stopcocks being used for irrigation).* **F**, *Anterior-posterior placement before bone placement.*

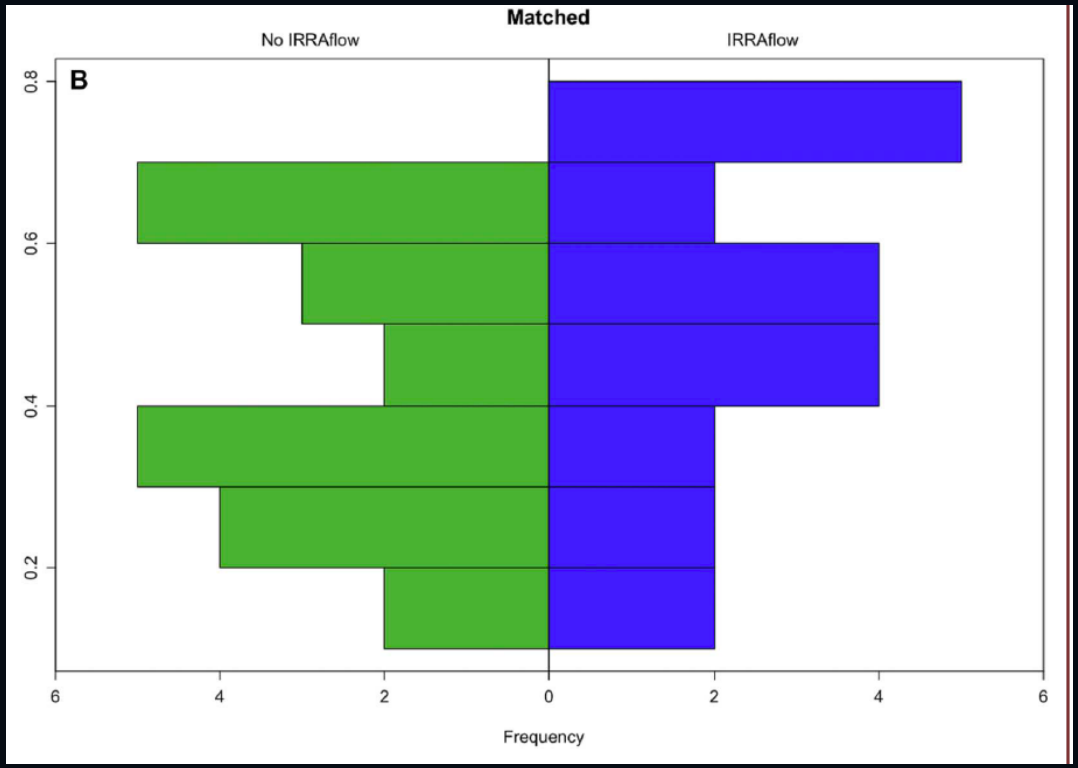
IRRA*flow*® Management

- An initial flow rate of 20 mL/hour that was gradually titrated to a maximum rate of 120mL/hour for active irrigation and drainage was established for all patients.
- The drainage bag resembles the drainage receptacle of a Foley catheter and can be leveled like a standard ventricular drain. The bag height is generally set to -15 or -20 cm at the level of the tragus.
- Gravity acts as the driving force to promote fluid egress from the subdural space.

FIGURE 2. *Postoperative setup.* **A**, *Fluid exchange system shown with an irrigating pump and drainage mechanism that interact with the dual-lumen catheter* **B**, *to irrigate the surgical site with sterile saline solution (black arrowhead) and drain (white arrowhead) residual blood from the subdural space.* **C**, *The digital pump used by the IRRAflow system to actively exchange fluid automatically sends a bolus of fluid into the irrigation channel of the catheter. This irrigation bolus serves to dilute further any solid particles that may have built up in the ventricles and keeps the catheter tip clear of solid debris, which can frequently obstruct drainage with an external ventricular drain. The second lumen of the catheter is then used to drain this diluted material while also checking the patient's intracranial pressure. This illustration was reproduced with permission from IRRAS, all rights reserved.*

Results

- 55 patients included prior to propensity score matching (34 standard drainage and 21 IRRA*flow*®). After matching, 21 patients remained in each group.



Histogram for propensity score distribution after matching for age, sex, race-ethnicity, comorbidities (diabetes mellitus, hyperlipidemia, hypertension, and atrial fibrillation), smoking status, prehospital modified Rankin Scale score admission Glasgow Coma Scale score, and hematoma volume at presentation. X-axis demonstrates frequency or the number of patients with an individual propensity score (Y-axis).

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Patient Characteristics and Basic Demographics

TABLE 1. Patient Characteristics and Basic Demographics

Variable	Before propensity score matching: Passive drainage alone (n = 34)	Before propensity score matching: Active and continuous irrigation with drainage (n = 21)	*P*-value	After propensity score matching: Passive drainage alone (n = 21)	After propensity score matching: Active and continuous irrigation with drainage (n = 21)	*P*-value
Age, y (mean ± SD)	71.9 ± 10.0	73.7 ± 13.0	.538	72.0 ± 9.8	73.7 ± 13.0	.562
Sex (n [% of all cases])						
Women	11 (32.4)	4 (19)	.444	6 (28.6)	4 (19)	.717
Men	23 (67.6)	17 (81)	.444	15 (71.4)	17 (81)	.717
Race–ethnicity (n [%])						
White	26 (76.5)	18 (85.7)	.369	16 (76.2)	18 (85.7)	.190
African American	5 (14.7)	3 (14.3)	.369	2 (9.5)	3 (14.3)	.190
Comorbidities (n [%])						
Diabetes mellitus	9 (26.5)	3 (14.3)	.467	4 (19)	3 (14.3)	1.000
Hypertension	25 (73.5)	20 (95.2)	.095	19 (90.5)	20 (95.2)	1.000
Hyperlipidemia	11 (32.4)	13 (61.9)	.062	10 (47.6)	13 (61.9)	.535
Atrial fibrillation	8 (23.5)	6 (28.6)	.922	5 (23.8)	6 (28.6)	1.000
Smoking status (n [%])						
Active smoker	12 (35.3)	10 (47.6)	.533	9 (42.9)	10 (47.6)	1.000
Nonsmoker	22 (64.7)	11 (52.4)	.533	12 (57.1)	11 (52.4)	1.000
Previous smoker	0 (0)	0 (0)	.533	0 (0)	0 (0)	1.000
Prehospital mRS (mean ± SD)	1.4 ± 1.4	1.4 ± 0.9	.473	1.4 ± 1.4	1.4 ± 0.9	.521
Admission GCS (median [IQR])	14 (14-15)	14 (14-15)	.704	14 (14-15)	14 (14-15)	.798
Anticoagulation (n [%])	2 (5.9)	3 (14.3)	.568	2 (9.5)	3 (14.3)	1.000
Antiplatelet therapy (n [%])						
Aspirin	0 (0)	8 (38.1)	***<.001***	0 (0)	8 (38.1)	.469
Clopidogrel	1 (2.9)	2 (9.5)	.665	1 (4.8)	2 (9.5)	1.000
Presenting symptoms (n [%])						
Hemiparesis	13 (38.2)	9 (42.9)	.335	9 (42.9)	9 (42.9)	.688
Altered mental status	9 (26.5)	2 (9.5)	.335	3 (14.3)	2 (9.5)	.688
Headache	11 (32.4)	9 (42.9)	.335	8 (38.1)	9 (42.9)	.688
Dysarthria	0 (0)	0 (0)	.335	0 (0)	0 (0)	.688
Hematoma volume at presentation, mL (mean ± SD)	9.9 ± 5.0	9.8 ± 5.8	.634	8.6 ± 5.2	9.8 ± 5.8	.801
Brain volume at presentation, mL (mean ± SD)	1357.5 ± 141.3	1354.9 ± 170.0	.869	1345.3 ± 131.6	1354.9 ± 170.0	.651

GCS, Glasgow Coma Scale (score); mRS, modified Rankin Scale (score).
Statistical significance is indicated with bold italics.

Figure adapted from Operative Neurosurgery

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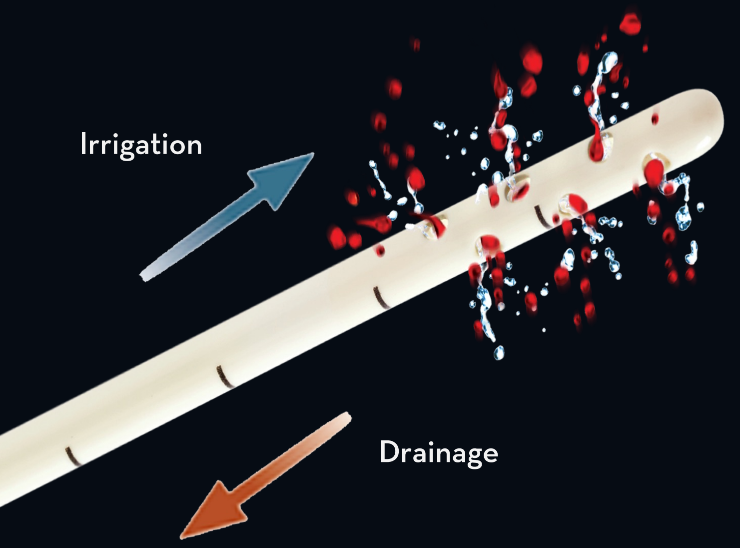
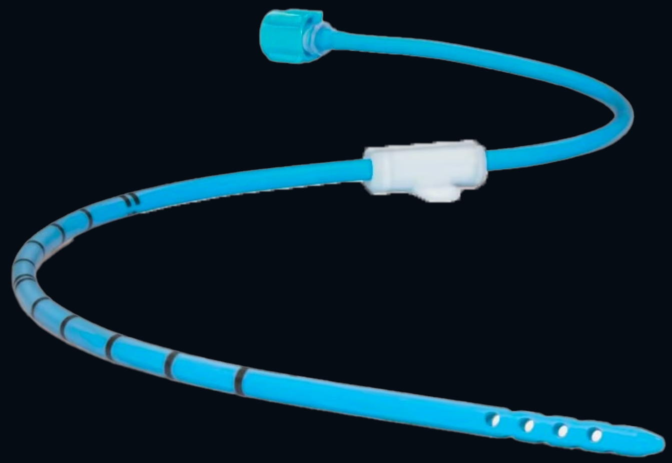
Results-Procedural Outcomes

- A significantly higher rate of hematoma clearance was found in the active irrigation and drainage group (IRRA*flow*® group) than in the passive irrigation group (0.5 ± 0.4 vs 0.4 ± 0.5 mL/day; odds ratio [OR] = 1.291; P = .002).
- This was despite similar mean total duration of catheter placement (IRRA*flow*®, 3.7 ± 2.2 days; passive irrigation, 4.4 ± 4.1 days; OR = 0.982; P = .737).



Cross-sectional image of
IRRA*flow* dual-lumen catheter

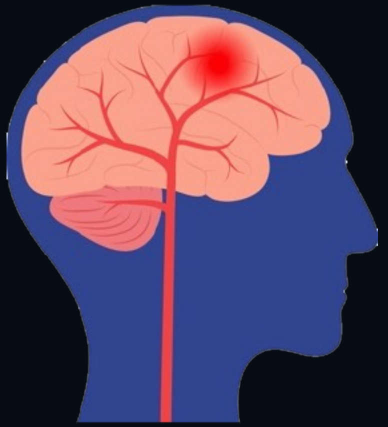
vs.



Passive drainage

Results-Procedural Outcomes

IRRA*flow*® resulted in statistically significant outcomes with:



Improved hematoma clearance rate

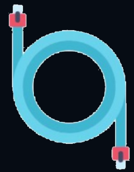
- *Confidence that outcomes would be* ***repeated 97.8% of the time***

IRRA*flow*®	**0.5 ± 0.4 mL/day**
Passive Drainage	0.4 ± 0.5 mL/day

Lower catheter-related infections

- *Confidence that outcomes would be* ***repeated 96.1% of the time***

The use of IRRA*flow*® resulted in:



	Catheter Placement Duration	Length of Stay	Seizure Activity
IRRA*flow*®	**3.7 ± 2.2**	**6.8 ± 3.0**	**0 patients**
Passive Drainage	4.4 ± 4.1	10.6 ± 16.2	3 patients

Larger data set is required for statistical significance

- *The p-value obtained demonstrates a trend but not statistically significant.*

Multivariate Logistic Regression Analysis After Propensity Score Matching

TABLE 3. Multivariate Logistic Regression Analysis After Propensity Score Matching

Radiographic and clinical outcomes	Passive drainage vs active and continuous irrigation with drainage OR (95% CI)	*P*-value
Treatment group (craniotomy)	0.755 (0.534-1.068)	.130
Duration of catheter placement	1.005 (0.949-1.063)	.877
Number of catheter revisions	0.403 (0.091-1.790)	.249
Catheter-related infections	0.051 (0.004-0.697)	***.039***
Shunt placement	5.479 (0.518-36.921)	.104
Hematoma expansion at discharge	0.551 (0.272-1.114)	.110
Repeat subdural evacuation	0.685 (0.367-1.280)	.252
Hematoma volume postevacuation	0.878 (0.788-0.979)	.131
Brain volume postevacuation	1.000 (0.997-1.003)	.086
Hematoma volume at discharge	1.192 (0.982-2.867)	.139
Brain volume at discharge	0.997 (0.994-1.000)	.109
Hematoma clearance rate	1.830 (1.143-2.932)	***.022***
Length of hospital stay	0.999 (0.977-1.022)	.919
Length of ICU stay	1.086 (0.978-1.206)	.141
Seizure activity	0.597 (0.351-1.018)	.075
Other adverse events	0.822 (0.307-2.200)	.702
Good outcome (discharge mRS of 0-2)	1.201 (0.970-1.486)	.112
Discharge GCS	0.997 (0.994-1.000)	.109

GCS, Glasgow Coma Scale (score); ICU, intensive care unit; mRS, modified Rankin Scale (score); OR, odds ratio.
Statistical significance is indicated with bold italics.

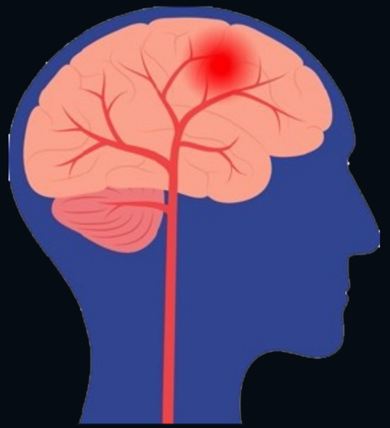
Figure adapted from Operative Neurosurgery

Discussion [10-14]

- Addition of irrigation with passive drainage in the treatment of cSDH is not novel and has shown some benefit in previous studies.
- Hennig and Kloster demonstrated a reduced rate of hematoma recurrence in patients who underwent continuous irrigation (2.6% vs 23.8%).
- Sjavik et al also demonstrated similar findings. They found continuous irrigation reduced the recurrence of cSDH requiring another surgery compared to standard passive drainage (10.8% vs 20%, p=<.001)

Discussion

- Theories on the benefit of active drainage:
  - Better hematoma clearance
  - Improved brain re-expansion
- Our study demonstrated use of the IRRA*flow*® resulted in faster hematoma clearance and a trend toward reduced LOS (6.8 days vs 10.6 days, p=.829). Further studies with standardized treatment protocols and a larger patient population are needed to further explore this.



Improved hematoma clearance rate

- *Confidence that outcomes would be* ***repeated 97.8% of the time***

IRRAflow®	**0.5 ± 0.4 mL/day**
Passive Drainage	0.4 ± 0.5 mL/day

Discussion [13]

- Though the Sjavik et al demonstrated reduced rate of hematoma occurrence with irrigation, there was a higher rate of complications compared with passive drainage only (14.5% vs 7.2%).
- Our study demonstrated a lower rate of catheter-related infections using the IRRA*flow*® system, potentially due to the automated nature of the irrigation. Other studies used manual irrigation.

Lower catheter-related infections

- *Confidence that outcomes would be* ***repeated 96.1% of the time***

Conclusion

- Active and automated continuous irrigation plus drainage after cSDH surgical evacuation using the IRRA*flow*® system resulted in faster hematoma clearance and led to favorable clinical outcomes and low complication and revision rates compared with passive irrigation.

The use of IRRA*flow*® resulted in:

	Catheter Placement Duration	Length of Stay	Seizure Activity
IRRA*flow*®	**3.7 ± 2.2**	**6.8 ± 3.0**	**0 patients**
Passive Drainage	4.4 ± 4.1	10.6 ± 16.2	3 patients

Larger data set is required for statistical significance

- *The p-value obtained demonstrates a trend but not statistically significant.*

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Thank you