



INTRODUCING AN

# ACTIVE FLUID EXCHANGE SYSTEM

Automated Irrigation

Controlled Drainage

Continuous ICP Monitoring



“ It is astonishing to observe that the only treatments currently available (with limited efficacy) were developed in the 80s ”

**Matteo Riva**

Neurosurgery Consultant at Erasmus Hospital of Brussels,  
Research Fellow at the Catholic University of Leuven

## Historic shortcomings of legacy drainage technology



Market-leading EVDs become blocked up to

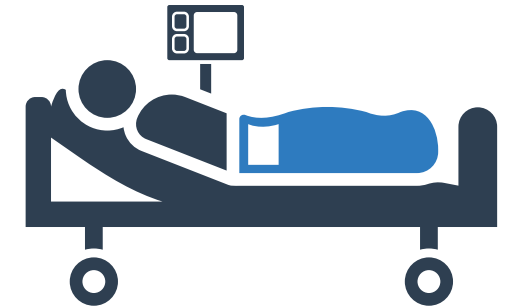
**47%** of the time<sup>1</sup>,

which can cause an increased risk of infection, and prolonging the length of stay in the ICU.



EVD-related Infections

Up to **22%**<sup>2</sup>  
**11%** in key study



Cost, increased length of stay after infection

**\$84,773** for  
**10 days**

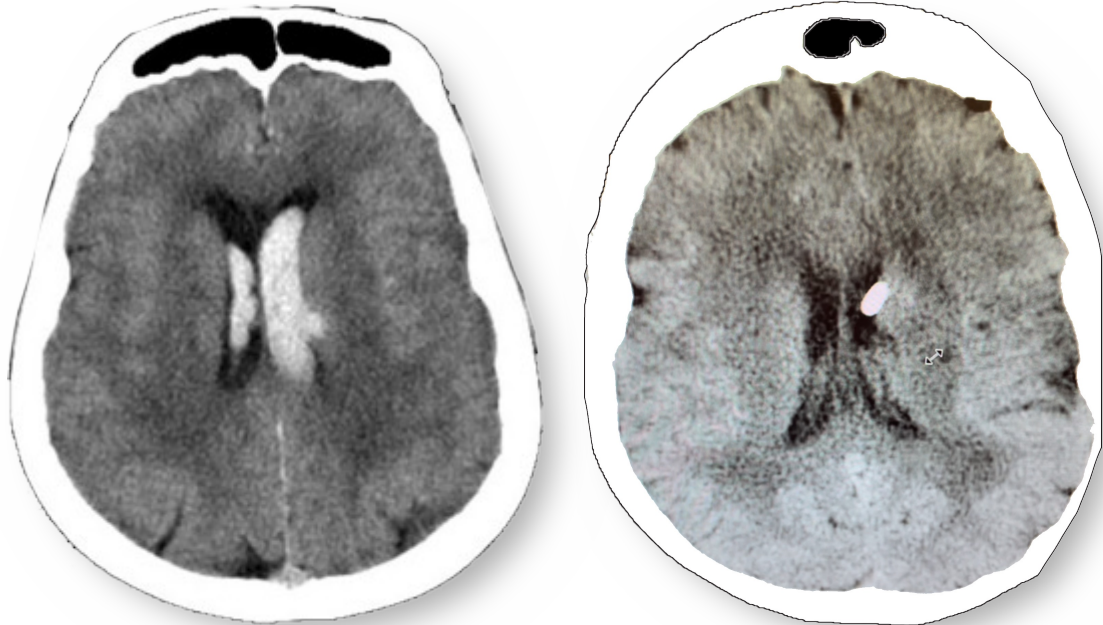
1. Fargen KM, Hoh BL, Neal D, O'Connor T, Rivera-Zengotita M, Murad GJ. The burden and risk factors of ventriculostomy occlusion in a high-volume cerebrovascular practice: results of an ongoing prospective database. *Journal of Neurosurgery*. 2015;1-8.  
2. Lele AV, et al. Perioperative Management of Adult Patients With External Ventricular and Lumbar Drains: Guidelines From the Society for Neuroscience in Anesthesiology and Critical Care. *J Neurosurg Anesthesiol*. 2017 Jul;29(3):191-210. doi: 10.1097/ANA.000000000000040.

# What treatment time would you guess?

Chronic Subdural Hematoma



IPH with Ventricular Extension



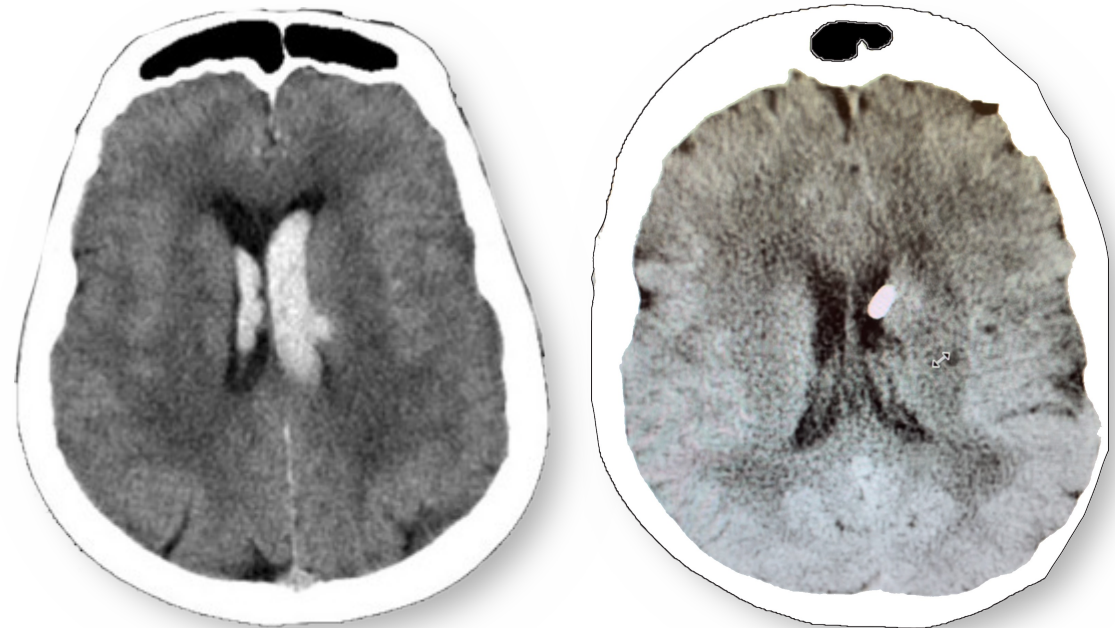
# What treatment time would you guess?

## Chronic Subdural Hematoma



**<24 hrs.**  
Treatment  
Time

## IPH with Ventricular Extension



**36 hrs.**  
Treatment  
Time



The IRRAflow system is a **dynamic solution for advanced fluid management** in the intracerebral space that enables therapeutic treatment for **intracranial bleeding**.



**Automated Irrigation**



**Controlled Drainage**



**ICP Monitoring**





# Active Fluid Exchange System



IRRAflow Tube Set & Intelligent Digital Cassette



IRRAflow Dual-lumen Catheter

IRRAflow Control Unit & Drainage Collection Bag

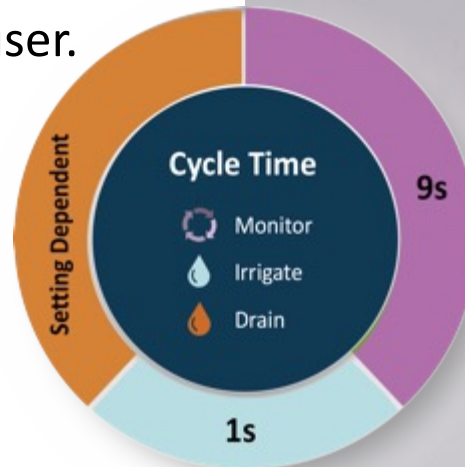




# How it works

## IRRAflow offers a customizable patient treatment:

- Goal is to treat a patient based on their clinical condition and ICP.
- Machine operates in a cyclical fashion between:  
💧 Irrigation, 🔄 Monitoring, and 🔴 Drainage
- Irrigation volume and rate are controlled by the user.
- ICP Alarms are selected to assist in ensuring there is not too much irrigation nor over-drainage.



IF-505\_A





Marketing-leading EVD



Automated Irrigation



Controlled Drainage

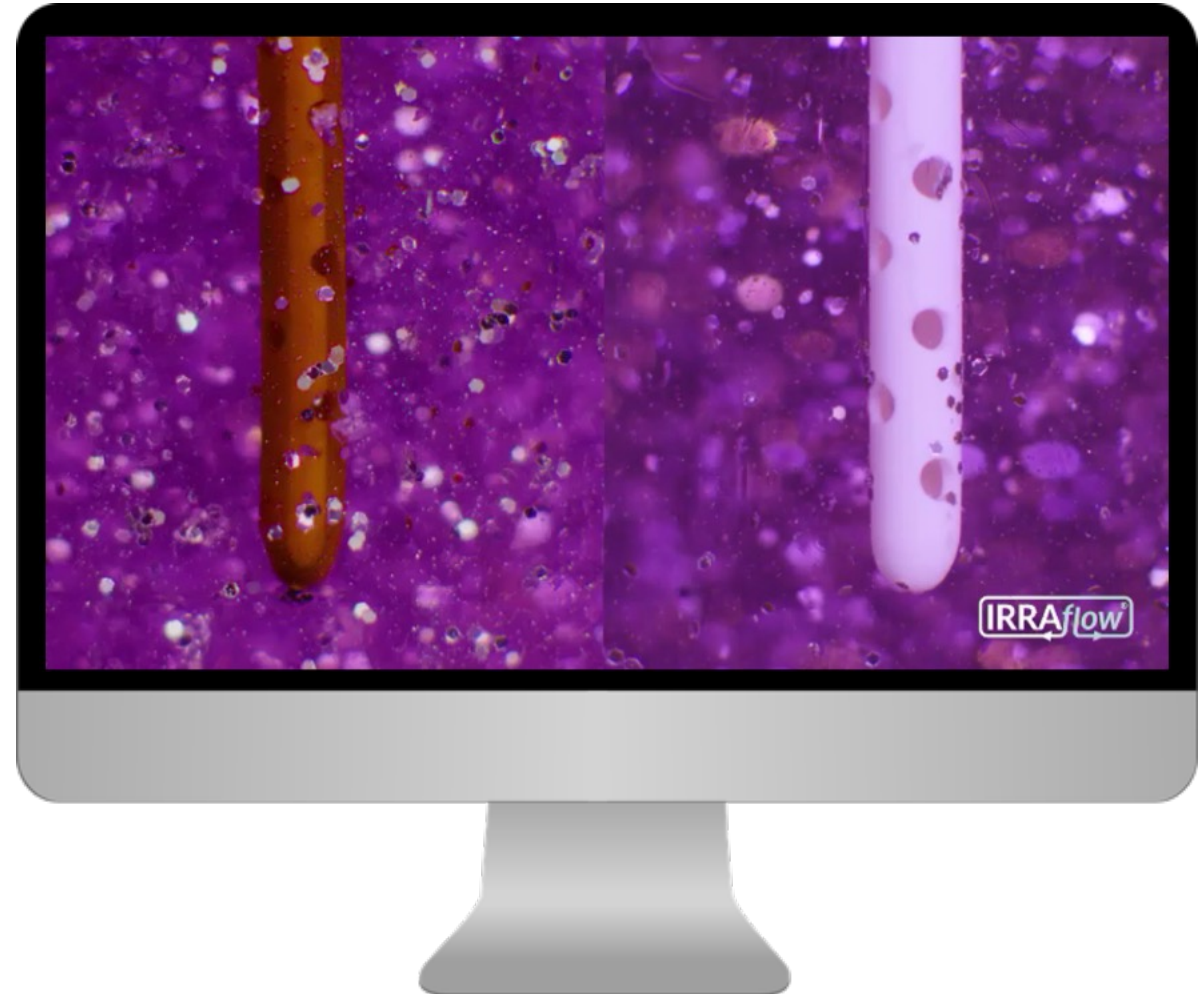


ICP Monitoring

0% catheter occlusion rate observed when system's irrigation is actively employed

# 0 Catheter Occlusions

Compared to documented literature showing up to 47% EVD occlusion rate<sup>1</sup>

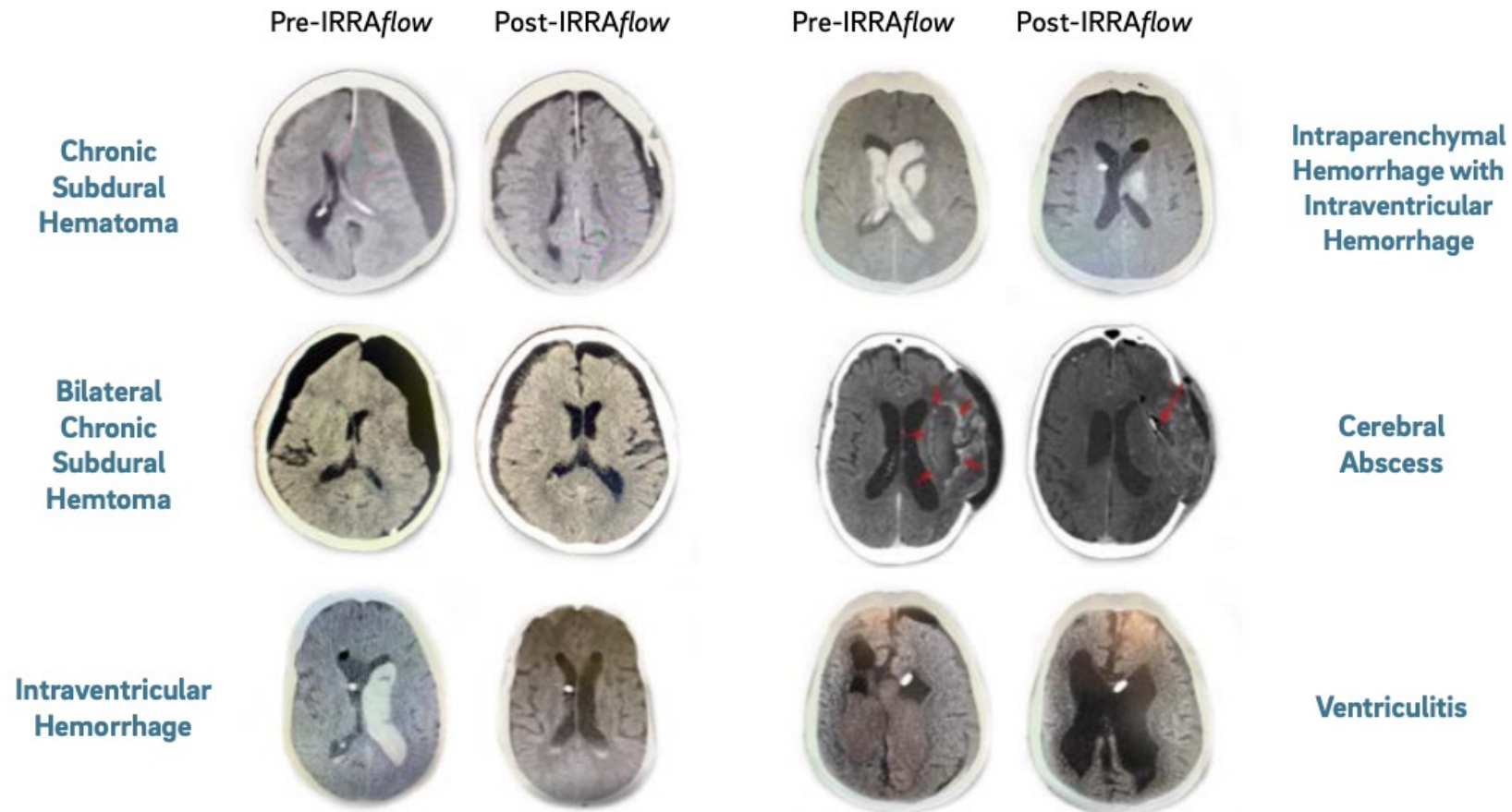


1. Fargen KM, et al. The burden and risk factors of ventriculostomy occlusion in a high-volume cerebrovascular practice: results of an ongoing prospective database. J Neurosurg 124:1805–1812, 2016



# IRRAflow CAN TREAT MULTIPLE DISEASE STATES

The IRRAflow system has been used to treat a variety of pathologies; acute and chronic SDH, IVH, IPH with Ventricular involvement, SAH, Ventriculitis, and Cerebral Abscesses.

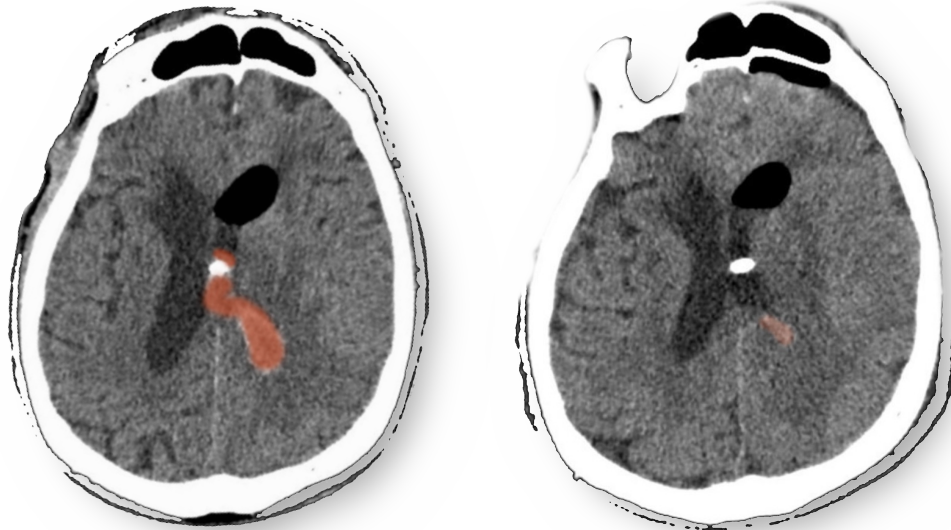


# Intraventricular Hemorrhage

## Targeted drug delivery in intracranial space

Endoscopic images confirm impact of *IRRAflow's* automated irrigation

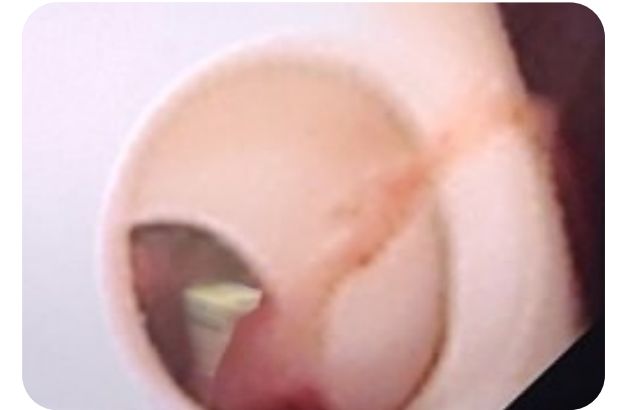
No occlusion formation even in heavy clot burden



Pre-IRRAflow

Post-IRRAflow

- *IRRAflow* inserted directly in clot
- Irrigation performed with tPA
- Endoscopic evaluation performed on day 4 to remove persistent clot



Irrigation cleansing the catheter holes, keeping the **catheter free of occlusions**

# Early Experience with Patient Treatment & Drug Delivery with **IRRAflow**<sup>®</sup>:

An Automatically Irrigating and Draining Ventricular Catheter

Presented by surgeons from **WVU Rockefeller Neuroscience Institute** at The Neurosurgical Society of the Virginias Annual Meeting

45

IRRAflow patient treatments



Post-IRRAflow

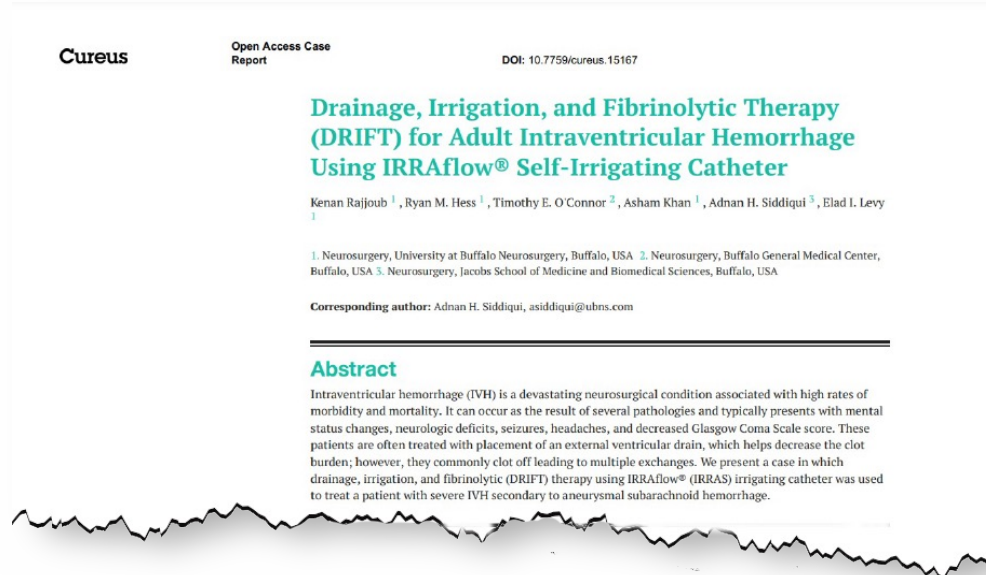
Complications	Ventriculitis	1 (2.2%)
	Mortality	9 (20%)
Intrathecal Medications administered	tPA	9 (20%)
	Vancomycin	2 (4.4%)
<b>Catheter Occlusion</b>		<b>0%*</b>
<b>Shunt dependence (IVH)</b>		<b>3/23 (13%)**</b>
<b>Vasospasm</b>	<b>Clinical</b>	<b>2/12 (17%)***</b>
	<b>Radiographic</b>	<b>3/12 (25%)***</b>
<b>SDH</b>	<b>MLS before: 4.9±2.6</b> <b>MLS after 2d: 0.8± 1.2</b>	<b>Percentage improved 13/13 (100%)</b>

**\* Compared to 19% permanent, 41% temporary occlusion.**  
*Fargen et al. JNS 2016*

**\*\*Compared to 18% in literature. Clear III trial.**  
*Murthy et al. Neurology 2017.*

**\*\*\*Compared to 40-70% in literature.**  
*Bracard et al. Interventional Neuroradiology 2008*

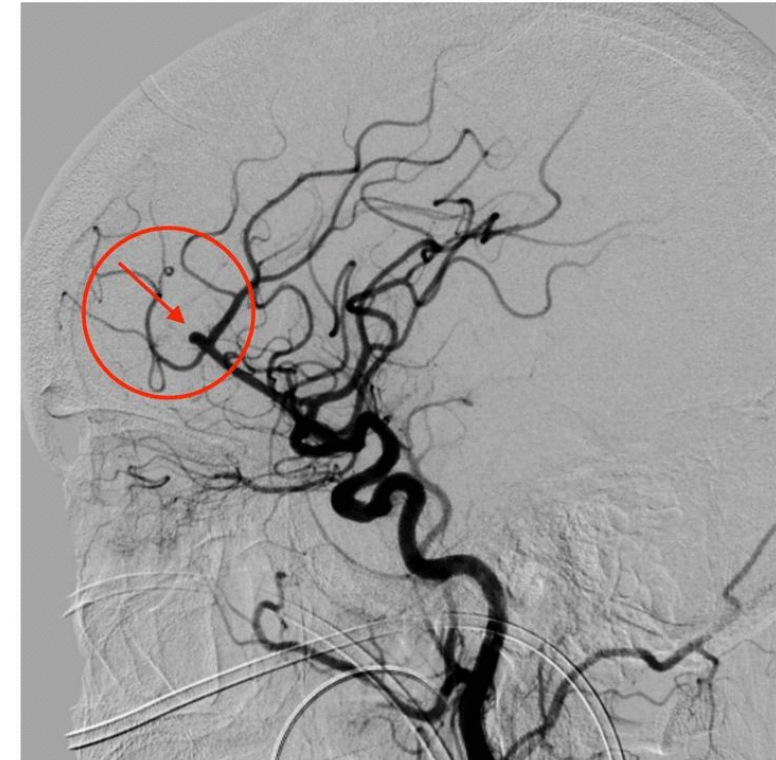
# Published literature highlighting clinical superiority of IRRAf<sup>low</sup> versus traditional drainage



***“Our case demonstrates clear radiographic and clinical superiority of the IRRAf<sup>low</sup> system compared to standard EVD.”***

**“The placement of a self-irrigating catheter such as the IRRAf<sup>low</sup> system is a **safe and effective way to avoid complications** related to standard EVD placement, such as clotting and replacement. It leads to **superior radiographic clearance of hemorrhage** from the ventricles and can **easily be used as a delivery method for intraventricular tPA** to good effect.”**

 Buffalo General Medical Center  
 Gates Vascular Institute  
*A Kaleida Health Facility*



**Cerebral angiogram demonstrating aneurysm**



## Presented at CNS Annual Meeting 2021

- Active Fluid Exchange with infused tPA significantly increases the removal of blood and reduces treatment time
- All cases demonstrated removal of 90% of blood in 72 hours
- All cases were completed in ~5 days

# Active CSF exchange system is effective for IVH treatment

## Active Removal of Cerebral Haemorrhage

Behnam Reza Jahromi, Päivi Tanskanen, Felix Göhre, Johanna Pekkola, Jari Siironen

### INTRODUCTION

- Intracerebral haemorrhage (ICH) associated with intraventricular hematoma (IVH) has higher rates of morbidity and mortality.
- Removal of IVH depends on passive external ventricular drainage, which is time consuming and gives opportunity to IVH re-organize and have negative effect on neural tissue.

### OBJECTIVES

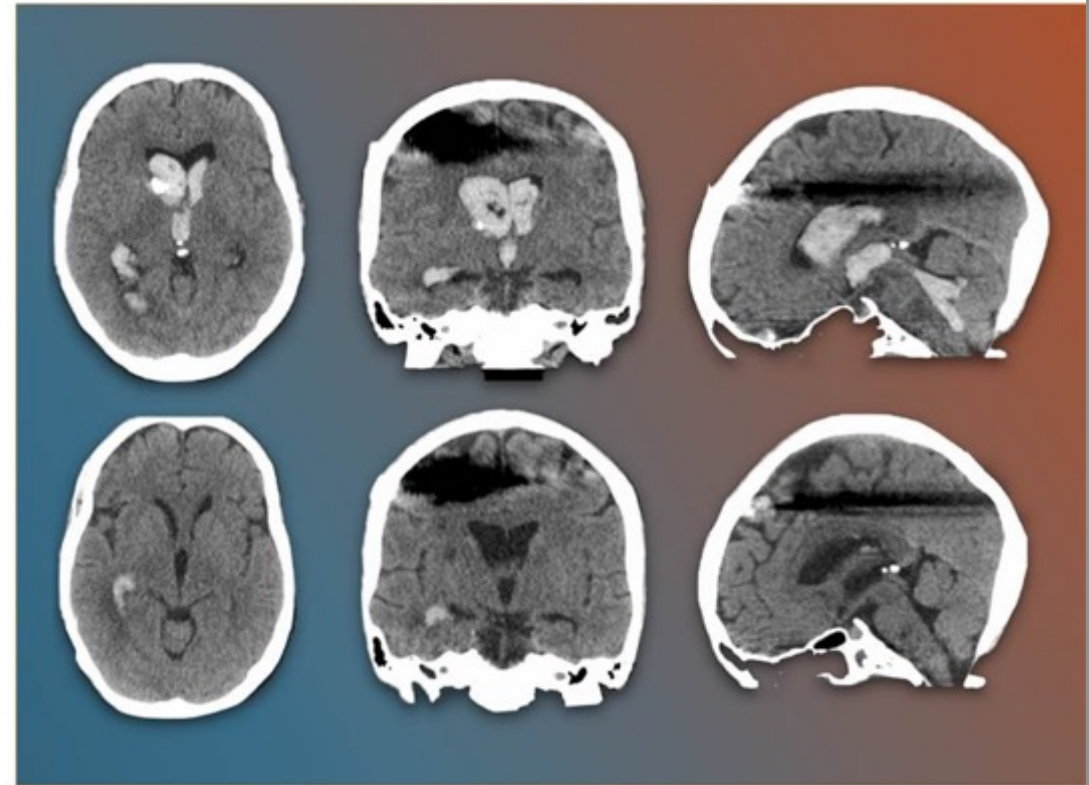
- Expedient removal of ICH and IVH should result in less organization of blood in the cerebrospinal fluid thus minimizing neural toxicity and facilitating better neurologic outcomes for patient and reduction in ICU time.
- We tested a novel fluid exchange system (active EVD) with controlled tPA infusion on 5 ICH and IVH cases to determine if rapid removal of blood could occur.

### METHODS

- In 2 cases, 2mg of tPA was administered manually over 2 consecutive days. In the other 3 cases, 2mg of tPA in 1,000 cc's of fluid was continuously infused over a period of 2 consecutive days.

### RESULTS

- In all 5 cases, CT demonstrated 90% removal of blood occurring in 72 hours or less.
- Further, in all cases, complete treatment with the device, from catheter insertion to removal, was completed in an average of 5 days.
- Figure 1 and 2 demonstrates removal of IVH in 47h with 2.4mg tpa.



### CONCLUSIONS

- Active removal of IVH with infusion of tPA and fluid exchange significantly increases the removal of blood and reduces treatment times compared to standard EVD treatment.
- Further, our case series substantiated a significant reduction in ICH.
- For this reason, we need future studies to assess the impact of tPA administration in ICH with active fluid exchange on neurological outcomes, ICU treatment time and need of standard EVD treatment

# Expanding Collection of Clinical Evidence Published

Two peer-reviewed publications now showing ability to directly deliver antibiotics

## Treatment of Pyogenic Ventriculitis



### Active Cerebrospinal Fluid Exchange System for Treatment of Pyogenic Ventriculitis

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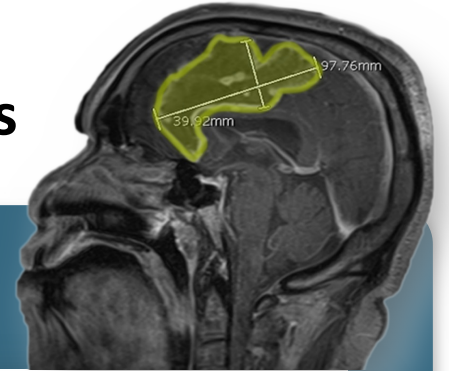
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- “This new technique allowed us to change the composition of CSF to an antibiotic-consisted fluid.”
- “Allowed for targeted antibiotics in the CSF while simultaneously removing bacterial mass without harming brain tissue and controlling ICP and pH.”

Behnam Rezaei Jahromi, MD, Päivi Tanskanen, MD, Anniina Koski-Pälken, MD, PhD, Christoph Schwartz, MD, MHBA, Päivi Koroknay-Pal, MD, PhD, Inka Romo, MD, PhD, Mika Niemelä, MD, PhD, Jari Siironen, MD, PhD, Active Cerebrospinal Fluid Exchange System for Treatment of Pyogenic Ventriculitis, *Neurosurgery Open*, Volume 2, Issue 4, December 2021, okab030, <https://doi.org/10.1093/neuopn/okab030>

## Continuous antibiotic administration for abscess



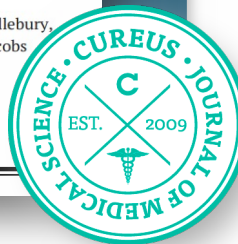
Buffalo General Medical Center  
Gates Vascular Institute  
A Kaleida Health Facility

### Continuous Antibiotic Administration Using IRRFlow® Catheter for Treatment of Intracranial Abscess

Ryan M. Hess<sup>1</sup>, Audrey Lazar<sup>2</sup>, David Smolar<sup>3</sup>, Timothy E. O'Connor<sup>4</sup>, Asham Khan<sup>1</sup>, Adnan H. Siddiqui<sup>1</sup>, Elad I. Levy<sup>1</sup>

1. Neurosurgery, University at Buffalo Neurosurgery, Buffalo, USA 2. Neurosurgery, Middlebury College, Middlebury, USA 3. Neurosurgery, Buffalo General Medical Center, Buffalo, USA 4. Neurosurgery, University at Buffalo, Jacobs School of Medicine and Biomedical Sciences, Buffalo, USA

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“This novel approach appears to be safe and resulted in continued decrease in the abscess burden following surgical drainage.”

Hess R M, Lazar A, Smolar D, et al. (October 26, 2021) Continuous Antibiotic Administration Using IRRFlow® Catheter for Treatment of Intracranial Abscess. *Cureus* 13(10): e19061. doi:10.7759/cureus.19061



# Per Case Cost Comparison



drives per-patient savings across total cost of care

Medical Center Variable	Approximate Per-Patient Expense	IRRAflow Variable	Per-Patient Cost
External Drainage Set	\$150	Intelligent Digital Pump	\$3,500
EVD	\$400	Dual Lumen Catheter	\$500
Drainage Bags	\$75	Drainage Bag	-
Cranial Access Kit	\$265	Cranial Access Kit	-
Continuous ICP Monitoring Probe	\$650	Continuous ICP Monitoring Probe	-
Amortized Cost of ICP Capital	Unknown	Amortized Cost of ICP Capital	-
Published Cost of Complication	Approximate Cost	IRRAflow Variable	Per-Patient Cost
Cost of EVD occlusion (EVD replacement, tPA for flushing)	\$476 <sup>1</sup> per occurrence	Cost of EVD occlusion	-
Cost of added physician time	Unknown	Cost of added physician time	-
<b>Infection</b> 5% infection rate across 100 patients 5 x \$84,773 = \$400,000/100 = \$4,239	\$4,239	<b>Infection</b>	-
Length of Stay Cost	Published Cost	Length of Stay Cost	Published Cost
<b>1 day longer treatment time</b> Cleveland Clinic published cost of ICU day	\$5,136 <sup>3</sup> per day	<b>Reduced treatment time</b>	-
<b>TOTAL PER CASE COST</b>	<b>~\$11,391*</b>	<b>TOTAL PER CASE COST</b>	<b>\$4,000</b>

1. Lele AV, et al. Perioperative Management of Adult Patients With External Ventricular and Lumbar Drains: Guidelines From the Society for Neuroscience in Anesthesiology and Critical Care. J Neurosurg Anesthesiol. 2017 Jul;29(3):191-210. doi: 10.1097/ANA.000000000000040.

2. Hersh EH, Yaeger KA, Neifert SN, Kim J, Dangayach NS, Weiss N, Patterns of Healthcare Costs Due to External Ventricular Drain Infections, World Neurosurgery (2019), doi: https://doi.org/10.1016/j.wneu.2019.03.197.

3. <https://my.clevelandclinic.org/-/scassets/files/org/locations/price-lists/main-campus-hospital-patient-price-list.ashx>

\*Depending on EVD occlusion and infection rate



Ready to try something new?

**IRRAflow offers a customizable patient treatment:**

1. Addresses historic shortcomings of traditional care.
2. Versatile to treat a variety of disease state.
3. Published literature demonstrates system effectiveness and superiority vs. traditional passive drainage.
4. Clinical data and commercial use establishes significant economic savings.



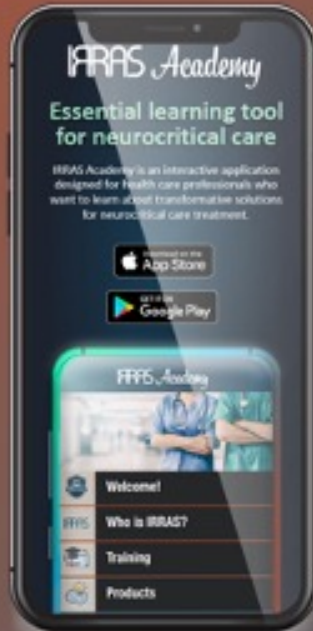


# IRRAS

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