Needed Innovation for Neurocritical Care
Neurocritical care

**IRRAflow**: The world’s first irrigating ventricular drainage system brings intelligence to intracranial fluid management

Every two seconds, someone on earth will have a stroke. Every 10 seconds, stroke claims a life. With little respect for age, as a third of strokes occur in people below the age of 65, that aftermath can leave behind a path of devastation—for both the patient and their families (Global status report on noncommunicable diseases, 2011).

WHILE THE PAST COUPLE OF YEARS have seen significant amounts of innovation within ischemic stroke, modernisation within the haemorrhagic stroke field has been limited in comparison. Where ischemic strokes are caused by blood clots blocking the flow of blood and oxygen to the brain, haemorrhagic strokes occur when a weakened vessel ruptures and bleeds into the brain. With the latter accounting for only 15% of all strokes, they remain responsible for 40% of all stroke deaths (Murakos & Velkamp, 2014). Non-surgical treatment, combined usually with invasive intracranial pressure (ICP) monitoring and passive cerebrospinal fluid (CSF) drainage, remains the standard of care for haemorrhagic events. Yet, these passive techniques are associated with a list of well-documented complications, including occlusions, infections, excessive drainage, and secondary haemorrhage (Le Fevre, 2017).

Yet, the IRRAflow CNS system overcomes these practical hurdles. They have demonstrated shorter treatment times and less-than-expected post-treatment residual blood volumes in over 100 patients in Greece, Germany and Finland (Venkataramana, et al, 2012). Panotopoulos also told NeuroNews, “To date, in the early European clinical experience—probably because of the underlying design elements—there have been no documented blockages or probe-associated infections detected in any IRRAflow treatment. This was also the case in the previous embolisms during the development of our fluid exchange principal.”

Additionally, the safety of IRRAflow is not to be underestimated. “IRRAflow irrigates automatically, reliably, and continuously monitors ICP and alerts hospital personnel with visual and auditory alarms immediately when the patient’s ICP is out of the pressure range set by the treating neurosurgeon, which eliminates any delays in detecting the under- or over-drainage and any treatment’s compromise,” summarised Panotopoulos.

Given IRRAflow has been recently launched in the USA, NeuroNews sat down with three physicians to discuss their initial experience with the product, and further spoke to Dr. Andrew Carlson who explains the value of the product, and further spoke to Dr. Sumeet Vadera in the USA,以及芬兰（Venkataramana，等，2012）。由于目前的治疗手段，如开颅手术，虽然可以完全清除颅内血肿，但往往需要在颅骨边缘进行开颅，开放颅脑，导致出血。除了年龄和血管收缩，血管破裂和出血。一些年长的患者，他们的脑组织会因为老化而萎缩，导致更多的出血。随着社会老龄化，这种并发症越来越常见。由于出血位置的复杂性，使得外科医生无法完全清除颅内血肿，可能导致出血。

**A shortened surgical time and length of stay for subdural haematomas**

Dr. Sumeet Vadera is an associate professor of neurological surgery at the University of California, Irvine, (USA). As the first physician in the USA to use IRRAflow for patient care, he spoke to NeuroNews about his experiences using the technology so far, in the context of treating chronic subdural haematomas.

Can you tell us about the incidence of chronic subdural haematomas and the typical patient? It is a very prevalent problem, making it getting more common over time as society ages. As an individual gets older, their brain shrinks, and the veins that cross from the brain to the covering of the brain get stretched, meaning that even minor bumps to the head can cause them to tear and bleed. Some of the older population are also on aspirins or other blood thinning medications, which can disrupt the normal ability of blood to clot, so they are also at risk for these haematomas.

What is the current standard of care for treating chronic subdural haematomas? There are several different methods to treat chronic subdural haematomas. One method is to do a burr hole evacuation, which means you make a small incision in the skin and a single burr hole. Then you open the covering of the brain, and drain out as much fluid as you can. The other option is to carry out a mini-craniotomy by making a small window in the bone, open the covering of the brain and, again, try to get out as much of that blood clot as you can. Sometimes, physicians will leave drains in the cavity to continue to remove any additional fluid that remains.

Use these techniques, what are some of the issues you have experienced? There are two downsides to the burr hole method: there is a risk of turning a chronic subdural haematoma into an acute subdural haematoma—after draining the chronic blood, you unknowingly create a new source of bleeding which can cause an acute blood clot and new symptoms. One reassuring issue, particularly with the burr hole, is that you do not drain out enough fluid. So, at times, you might have to go back to drain out more fluid.

With an open craniotomy, you can create an acute subdural haematoma, and we have all seen these type of complications in the past. Also, there is often some residual blood following in the subdural space after surgery. But, with IRRAflow, you can irrigate and get even more blood out after the surgery. Even if you do get some acute bleeding, what happens is that the irrigation (IRRAflow) continues to wash and drain without allowing it to clot.

What caused you to want to try IRRAflow? I was the first one in the country, in the USA, to try out IRRAflow. Part of the reason I was keen to try it was because I like trying new technology and techniques, but part of it is that it really made sense at the time. We had problems following surgeries where we had created acute subdural haematomas or had not managed to drain as much fluid as we would have wanted, meaning the patient’s length of stay in the intensive care unit (ICU) gets extended. So, I wanted to try it to assess if we would have any improvement. In our experience thus far, with several patients that we have used this device on, we have seen an improvement in these factors with minimal complications and a reduction in the needed treatment time.

Have you experienced any other changes? The procedural time does tend to be a little shorter. Normally, we spend a lot of time trying to get every last drop of blood that we can see. Now, we can allow ourselves to be a little less aggressive, which then shortens the period of surgery, meaning the patient is under anaesthesia for a shorter length of time. And, by putting a catheter in, we then drain and treat the last bit of fluid or any new fluid that occurs after the surgery. So, overall, it has been a win for us by reducing both surgical time and length of stay.

How has IRRAflow solved issues with the current standard of care for the treatment of chronic subdural haematomas? In our experience, there are several benefits. First, it shortens the length of time because you can place it into any pocket where you think blood or fluid might accumulate. Second, the length of stay is shorter, on average with the five patients we have treated. And, number three, if any acute blood forms, there is a reduced risk that acute subdural haematoma may form. I think that, partly, IRRAflow breaks it down and drains it before that haematoma forms. We have seen in a couple of patients that this is the case. From my perspective, I have seen several improvements over our current standard of care, a traditional external ventricular drain, and the patients seem to be happy with it.

**Introducing IRRAflow**

**IRRAflow demonstrating active fluid exchange**

**Chronic subdural haematomas**

**Neurocritical care**

**CASE REVIEW: Chronic Subdural Haematoma**

**Male, 82 years old**

**Pathology treatment**

- 2.5cm left convexity mixed density extra-axial haematoma causing a 3mm rightward midline shift and subfalcine herniation.

**Treatment description**

- Mini craniotomy for evacuation of the subdural haematoma
- Active fluid exchange performed with the IRRAflow system, with an irrigation rate of 40ml/hour

**Pre-IRRAflow Treatment**

**Post-IRRAflow Treatment**

**Treatment results**

- Active irrigation and associated drainage assisted in providing controlled re-expansion of brain tissue back into the subdural space
- Complete resolution of the midline shift
- No catheter occlusion seen
- No drainage-related infection

*The opinions and views in this article are those of the respondents and not of IRRAflow.*
The irrigation of antibiotics: Hope for rare infections

An infection to the ventricles in the brain, also known as ventriculitis, more often than not presents as a life-threatening condition. Dr. Behnam Rezai Jahromi, Helsinki University Hospital (Helsinki, Finland) speaks to NeuroNews about how IRRAflow has provided needed change, and how the technology will continue to shape treatment approaches in the future.

What is the current standard of care for treating ventriculitis?

Ventriculitis is a rare reservoir of infection where the brain’s ventricular system is infected by bacteria, which means patients are actually given antibiotics and hoping that this is going to elicit a positive result, when unfortunately, most of the time this rationale does not result in good outcomes.

It is a very serious disease with a mortality rate of 80–100%. In terms of its incidence, it varies within the literature. It is fairly rare and predominantly occurs with patients that have another significant disease. So, these patients have needed critical attention many times in the past with a very long treatment period. Unfortunately, even when they undergo treatment for months in an intensive care unit, most of the time, the patients die anyway.

What are some of the issues that you have experienced with the current standard?

The care of ventriculitis is through the delivery of either IV or intrathecal antibiotics, which means they are delivered straight to the brain via an external ventricular drainage system. The current standard is not enough to actually save the patients’ lives and their neural tissue. It is very heartbreaking to see patients dying in the 21st century because of an infection. Even though we have antibiotics that should work on that particular bacteria, unfortunately, it is very hard to get those antibiotics into the system of the brain and to treat the infection. The problem is that the antibiotic is not penetrating to the place that we want.

However, with this IRRAflow system, we had the ability to actually deliver the antibiotic to the infected area in a way that was not previously possible. We have had two cases that we have treated here in Helsinki, and we have been successful. We were able to wash the bacterial mass away and were able to deliver antibiotics to the ventricular system, which eliminated the infection.

If you were to design a product to assist in treating ventriculitis, what would that look like?

If I had to innovate something, I hope that I, myself, would have the same idea that IRRAflow encompasses. The idea is that it would use the cerebrospinal fluid, to deliver the drug needed at the same time, and check the intracranial pressure. IRRAflow is all of the factors that are needed when treating these ill patients. So, we were happy to have the device available to take care of this rare disease. [Without treatment with IRRAflow, those two] patients’ mortality would have been extremely high, probably 100% in both cases.

How did you come to find out about IRRAflow and what caused you to want to try it?

I heard about it when IRRAflow was demonstrated to us in Helsinki previously. When we had the first ventriculitis patient in our intensive care unit with this very severe disease, we were certain that the patient would die if we did not take any action, so it came to mind that we should try this IRRAflow device. So, I contacted IRRA, and they were kind enough to quickly provide the system and provide us with the system and needed training. We then implanted the device and started our journey with the device.

What has been your experience with IRRAflow to date, and how has it provided needed change?

If the patient is in a good condition before developing ventriculitis, they would typically struggle with the infection in the intensive care unit for months. But, in our cases using IRRAflow, we were able to treat ventriculitis in a matter of weeks, and they actually survived, with one of the patients able to go back to his normal life.

When it comes to ventriculitis, it has changed the idea that we are able to proactively take care of the infection areas in the brain. We are working now to publish this early experience, and I hope that, after our publication becomes public, other experiences are also published on the device so that we can continue to collect more data.

It seems to me that, with our experience, IRRAflow will become standard of treatment in these types of case. If you think about it, it is actually a very classic way of thinking to treat ventriculitis. You want to irrigate to prevent colonisation, deliver a drug, and take steps to remove the mass. Previously, this was not possible, but, with IRRAflow, it is.

We were certain these patients would die if we did not take action.

Can you see any other indications for it?

The device has many potential applications. For example, drug delivery straight to the brain might be one of the future uses of the device. There will need to be many scientific studies done, which will enable us to see how effective it will be, but it is very promising. It has a good future, not only in these rare ventriculitis cases, but also in more common intracranial haemorrhage and also intraventricular haemorrhage cases.

The message is quite clear. We have to get the publications out so everybody can see them and start to use the device themselves, to get their own data published, to stimulate discussions about it.

Intraventricular haemorrhage

An innovative approach to treating intraventricular haemorrhage

Speaking to NeuroNews, Dr. Gregory Fautheree from The NeuroMedical Center, Baton Rouge, USA, explains how IRRAflow, and the context of treating intraventricular haemorrhage, outlines his latest experience with the device.

Why and how do haemorrhagic events occur in the ventricles?

The most common reason to bleed into the ventricles is high blood pressure. Other reasons for ventricular blood are ruptured aneurysms, trauma, and blood vessel malformations that rupture. When blood gets into the ventricles, it starts off very solid—much like a scab. But overtime, it slowly liquefies and washes away with that spinal fluid circulation. Unfortunately, because the spinal fluid circulation is like plumbing a pipe, that solid blood can enter the pipes, the ventricles, and can cause pressure build up, or hydrocephalus.

To treat intraventricular haemorrhage, we traditionally use a ventriculostomy, which is a drain placed into a ventricle that works by gravity drainage. That is where this product comes in, as [IRRAflow] not only works from gravity drawing, but also has an irritating effect and can measure intracranial pressure (ICP) at the same time. By irrigating the ventricle as well as draining it, it helps the blood dissolve, and the movement helps to keep the solid blood in solution instead of settling and clogging the circulation.

What are some of the issues that you have experienced with the current standard of care?

The drain sits in the ventricle, connected to a sterile system at the bedside that can assist in treating ventriculitis, what would you want?

A sterile system at the bedside that can irrigate is a necessity. In the ventricles, stagnation leads in this case to clots and bacteria growth. So anything that has forward pressure in a pipe is going to result in less infection.

How did you come to hear about IRRAflow?

I was contacted by the company as they knew that I had treated a lot of strokes as well as cranial work and ran it by me to see if it was a product that I would have some use for. I was extremely intrigued by it as there is nothing on the market like it. There was recent European data on its efficacy, and all of it made good sense. As a result, I thought that it made sense to give it a try.

Could you tell me more about your personal experience using this technology?

The patients that I have used it in had extensive intraventricular haemorrhage with a large volume of blood. These patients would have likely required multiple ventriculostomies or drains, due to clot. With IRRAflow, they did not require change.

This product is very difficult to clog as it is self-irrigating, and it continuously tells you what the ICP is. If I were to clog up, the pressure would rise, and it will tell you. And, on top of that, one of the ways that we treat these haemorrhages is to administ a clot-busting drug, I.PA. When we do that, we inspect and clamp the drain, let it sit for an hour, and then open [the drain] to gravity.

But the beauty of IRRAflow is that, if you want to give that clot-busting drug, you are already irrigating fluid through the system. So you add the IPA to the fluid, and it slowly irrigates it, which I found works much better than the bolus technique. I.PA is a continuous fluid introduction, I have found that the drug can be introduced over a longer period at a smaller, safer amount with better results.*

Do you see the patient’s clinical outcomes improving with IRRAflow compared to the current standard of care?

I hope. Our experience is too early so there is not enough data out there to know. I do know that, without a doubt, it is going to improve ICP length of stay, and I expect it to improve infection rates. So, from that standpoint, yes, there will be an improvement in outcome.

*Currently, the use of the IRRAflow OD System is indicated when Intracranial Pressure monitoring is required, and for external draining intracranial fluid as a means of reducing intracranial pressure. IRRAflow makes no claims as to the ability, safety and efficacy of using a thrombolytic or other pharmacological agent through the system.
What is multimodal monitoring?

The idea of multimodal monitoring is to try to measure various functions of the brain, in order to better direct our therapy to what that individual patient needs, as each patient is not the same. A certain intervention might be helpful in one patient, for example, raising the blood pressure. But this might actually be harmful in another patient as it may cause the pressure in the brain to go up too high. So, by using multimodal monitoring, the idea is that we can get a snapshot into various different brain systems. We can understand the pressure in the brain; we can understand more about the blood flow, oxygen to the brain, [as well as] more about the physiology of the brain, like whether there are seizures. And, even the metabolism of the brain, like how well the brain tissue itself is functioning.

To what extent does it help to individualize care?

The most obvious is the management of intracranial pressure as that is the parameter that is most commonly measured. We know that treatment directed at lowering the pressure is better. Since we are actually able to monitor that, how can we confirm that, on pressure is better. Since we are actually able to monitor the intracranial pressure as that is the parameter we can with brain tissue itself is functioning.

What are some of the disadvantages of current technology?

I would say that there are basically two different kinds of standard of care. One is a more minimalist approach where very few of these parameters are monitored. In that situation, we just cannot get the same information about what is happening in the brain with regards to brain tissue oxygenation, metabolism, or pressure that we can with invasive monitoring. Even in centres where multimodal monitoring is used to direct patient care, the challenge is to try to figure out how we can place multiple probes that allow us to get these different pieces of information in a way that is safe for the patient, does not require drilling [burr] holes all over the head, and can also give us reliable and consistent results. With other systems that are available, you often have to at least drill several holes in the head to be able to put the monitors in. They may not all be in the exact same place, or have the same relationship. They might be in a different part of the brain, from one patient to the next. This creates additional variability that can make the data harder to interpret and can also affect the reliability of the data.

Why is Hummingbird different, and what advantages does it offer you?

There are two big advantages of the Hummingbird system. One is that it allows for placement of whichever probes you would like to place; an oxygen probe, a blood flow probe, a microdialysis probe, or a seizure detection electrode. Any of these probes can be placed through the side ports. Also, these additional access lumens are structured with a slight angulation at the bottom of the port, so the position of the tip of your desired lumen will always be the same within the frontal lobe of the brain.

This ensures that you do not have to worry about the possibility that the probe is going to be positioned at various depths or within different parts of the brain.

The other big advantage is that the Hummingbird multimodal bolt allows all of these monitors, as well as an integrated external ventricular drain to drain extra spinal fluid if the pressure increases, to be placed through one burr hole. You no longer have to drill multiple access sites, and your probes are all in the same relationship to each other. The especially nice thing about the pressure measurement is that, even if the ventricular catheter with Hummingbird does not go into the ventricle (if there is a clot or the ventricle has collapsed), you can measure the intracranial pressure (ICP) using the parenchymal monitor built into the catheter. With a normal external ventricular drain system, you would not be able to measure pressure if these events occur.

So I think those are the big advantages: having the ventricular drain built into the same delivery system as all the other, providing the ability to measure independent of the ventricles, and having the multiple side ports integrated into one bolt. Also, Hummingbird is completely a bolt-based system, which allows for a much simpler placement and set-up because you do not have to do any tunnelling. All of the aiming and positioning is done upfront when you first drill the hole. Our experience is that, overall, the risk of infection is lower using this bolt-based system, a lot of the potential headaches, such as draining pulled out, have really improved with the use of a bolt-based multimodal monitoring system like Hummingbird.

Do you see Hummingbird changing procedural time?

I think certainly, when compared to placing multiple different systems, it improves time, efficiency and reliability in terms of where you are placing the probes. In a shorter period of time, you can place multiple probes with the exact same orientation to each other, rather than trying to fit in several bolts or external ventricular drains with other systems.

Dr. Andrew Carlson

What does Hummingbird advance our understanding of neurocritical care in ways we have not explored before?

Yes, it definitely does. I think it does on two levels. It gives us insight into what we are going on with that patient and how we, as a neurocritical care team, can do a better job.

For example, do we need more oxygen or more blood flow, or do we need to lower the intracranial pressure? All of these decisions are things that we would just be doing blindly if we did not have this kind of monitoring.

Secondly, from a larger perspective, it really is giving us a better insight into generating more generalisable knowledge. Here at the University of New Mexico (Albuquerque, USA), we now have a database of over 300 patients whose treatment has been guided by this same Hummingbird monitoring system set-up. We are now able to examine the data to look for correlations with outcomes and treatments that we carry out in order to try to confirm overall what are the things we are doing that are helpful versus what might not be helpful. The data can also help guide us toward the topics that should be focused upon for the next big studies.*

*The opinions and views in this article are those of the respondents and not of IRRA.

References

Bringing Needed Innovation to Neurocritical Care
Offering a full product portfolio from the IRRAflo and Hummingbird product lines

Bolt-based Parenchymal ICP Monitoring
Parenchymal ICP Control Module
Single Access Multimodal Monitoring System with Drainage

The world’s first irrigating ventricular drainage system!

For more information, visit IRRAS.com.