

Introduction : One-third of patients with aneurysmal subarachnoid hemorrhage develop clinically significant vasospasm leading to high morbidity and mortality. It remains the most common cause of immediate postoperative mortality in aneurysmal subarachnoid hemorrhage. Several theories have been proposed as the cause of vasospasm. Most agree that the remnants of blood products remaining in subarachnoid spaces are the main cause of this dreaded complication. Hence, removal of cisternal blood by infusion of subarachnoid spaces during surgery has become an established practice. However, it alone cannot effectively remove blood products completely from different areas of subarachnoid space.

Infusion into the subarachnoid space and intracranial space occupying lesion cavities has always been a challenging task amongst neurosurgeons. The intention was to treat the pathology directly with instillation of drug in this "privileged" space or to remove the debris /toxins which would have taken a long time for getting absorbed. Many basic infusion pumps have been tried in the past for this purpose. Since these devices were based on passive infusion system, the main risk was an increase in the intracranial pressure. Many studies have utilized these primitive pumps through a blind catheter, with no proven benefit due to uncertainty of removal of blood products resulting in failure of therapeutic goal. Also, there were unacceptable complications for obvious reasons. It is widely accepted that: a) Degradation products of blood are the causative factor of vasospasm b) The amount of subarachnoid blood seen on admission CT is correlated to the risk of vasospasm c) Reducing the subarachnoid clot burden at the time of surgery reduces the risk of vasospasm.

Measures : Fluid Exchange Catheter System

The bilateral brain catheter was connected to the FLUX (Fig. 5) after confirming the proper position of the catheter in the cisternal space intended. The system has two separate circuits for infusion and aspiration processes (Figs. 3 and 4). The rate of infusion and aspiration is adjusted according to the amount of subarachnoid blood to be cleared. The rate of infusion may also be adjusted depending on the drug concentration needed in the treatment. This is monitored by a pressure sensor (Fig. 2) which raises an alarm if the pressure in the system is exceeded that of the set pressure. In case of this occurrence, the necessary steps can be taken to rectify the same. The infusion / aspiration cycles were prefixed to run for 72 hours in this study. The velocity of fluid exchange was adjusted depending on the amount of subarachnoid blood and presence of vasospasm. We had used an average of 5L of Ringer Lactate solution mixed with papaverine (at a concentration of 8x10-5M) starting immediately after the surgery. CT scans were performed at 72 hours to show the extent of removal of subarachnoid blood products. The catheter was removed once the repeat CT scan showed satisfactory clearance.

Objective : We have developed an advanced 'Fluid Exchange Catheter System' (FLUX) which can control the instillation volume and the aspiration quantity. This has infusion as well as aspiration capabilities with measurements of volume and pressure. This infuses and aspirates micro liters of infusion fluid in a cyclical fashion ensuring isobaric exchanges of the fluids. Because of the ability to regulate the rate of infusion and aspiration, we can confidently utilize this system without causing increased intracranial pressure. We have designed this pilot study so as to ascertain the safety and efficacy of this FLUX to infuse the subarachnoid cisternal spaces in patients with aneurysmal subarachnoid hemorrhage after clipping the aneurysm.

Method : We have used the 'Fluid Exchange Catheter System' to irrigate subarachnoid cisternal spaces following aneurysmal subarachnoid hemorrhage. The Institutional Ethical Committee (IEC) approval was taken following the standard operating procedure. We studied three patients in this pilot feasibility study. All three patients had subarachnoid hemorrhage due to aneurysmal rupture. After suitable angiographic studies, these patients underwent craniotomy to clip their aneurysms.



Fig.1 Biluminal Brain cath. Fig.2 Pressure sensor Fig.3 Infusion tubing set Fig.4 Aspiration tubing set Fig.5 Assembled FLUX pumps

Technique of catheter insertion

At the end of the procedure, the biluminal brain catheter (Fig. 1) was placed in the subarachnoid cistern having maximum density of blood in the preoperative CT scan. This catheter was kept away from the clip. The catheter was brought out of dura, skull and scalp via a separate stab incision about 3 cm from the main incision. No additional papaverine was instilled during the procedure. The placement of the brain catheter was confirmed with a CT scan done before transferring the patient to Intensive Care Unit.

Patient 1: This 48 years old lady had presented with sudden onset of headache, was diagnosed to have subarachnoid hemorrhage (Fig 6) due to ruptured anterior communicating artery aneurysm. After clipping the aneurysm, the pump was connected and infusion-aspiration was started as per protocol. A repeat CT scan (Fig. 7) done after 72 hours showed near total resolution of blood products. She did not develop any vasospasm and was neurologically intact at the end of 3 month follow up.

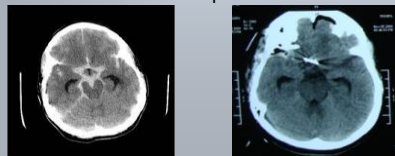


Fig.6 - Preop CT Fig. 7- Postop CT (72 h.)

Patient 2: This 41 year old lady doctor had presented with severe headache and loss of consciousness. A CT scan (Fig 8) revealed the presence of subarachnoid hemorrhage. The Digital subtraction angiography showed a right middle cerebral artery aneurysm. She underwent craniotomy and clipping the aneurysm followed by biluminal catheter insertion. She was started on the FLUX and the cisterns were infused-aspirated. A CT scan done after 72 hours (Fig 9) showed complete clearance of subarachnoid blood. She subsequently developed clinical vasospasm which was managed with 'triple H' therapy successfully. At the end of 3 month follow up, she was intact neurologically.

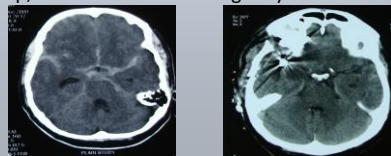


Fig. 8 - Preop CT Fig. 9 - Postop CT (72 h.)

Patient 3: This 55 years lady had sudden onset headache followed by loss of consciousness. She was diagnosed to have right internal carotid artery aneurysm (Fig 10). She underwent successful aneurysm clipping surgery. We continued infusion-aspiration technique for 72 hours and repeated a CT scan (Fig 11) which showed satisfactory removal of blood from all cisterns. She made uneventful recovery and was neurologically intact at follow up.

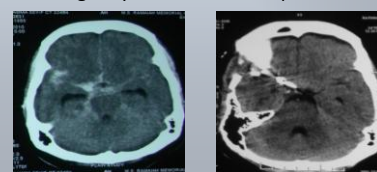


Fig. 10 - Preop CT Fig. 11 - Postop CT (72 h.)

Results : All three patients were studied for the amount of blood remaining after 72 hours of infusion aspiration technique. All of them showed good clearance of blood from their subarachnoid cisterns. There were no procedure related complications or morbidity. The patient no - 2 had clinically significant vasospasm after surgery viewed without morbidity. This was believed due to significant clearance of subarachnoid blood. The other patients also made good uneventful recovery. There were no hardware related issues during this study. This shows that our FLUX is effective, safe and controlled method for clearing subarachnoid blood in cisterns after aneurysm rupture. This will significantly reduce the incidence of vasospasm. In case of established vasospasm, the infused papaverine is shown to reduce the severity of spasm.

Conclusion : At this point of time, there is no commercially available automated pressure alarmed infusion aspiration system for neurosurgical practice and no other method to clear the subarachnoid spaces from blood satisfactorily. Our Fluid Exchange Catheter System is an effective, safe and controlled method to irrigate and aspirate the blood in subarachnoid spaces. This drastically reduces the amount of blood products, thereby minimizing the risk of developing vasospasm and its associated problems. This system needs further evaluation in large scale clinical studies to prove its role in many other brain disorders. Since it is volume controlled and pressure regulated, it is safe to use intracranially without the risk of elevating the ICP.

Further Directions: We have used FLUX system in a total of 40 patients (including 3 patients mentioned in this study). The details are as follows: intracerebral hematomas (22), intraventricular hematomas (5), subdural hematomas (4), brain abscesses(2), gliomas with bleed (2), ventriculitis (1), craniopharyngioma intracavitary chemotherapy (1). The system was effective in all these indications and we did not have procedure or hardware related complications in any of our patients studied. We conclude that the FLUX system is effective, safe and highly adaptable in routine neurosurgical practice.

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