SOP: Minimal invasive image-guided endoscopic surgery

Status	Genehmigt

Organisation	Departement Klinische Forschung
Kürzel	SOP EMINENT-ICH RCT 004

Version	1.0.0
Gültig ab	06.12.2023

Autoren	Tim Hallenberger, Leitung EMINENT-ICH RCT, Freigabe am 29. November 2023
Review	-
Genehmigung	Jehuda Soleman, Leitung EMINENT-ICH RCT, Freigabe am 6. Dezember 2023

Anmerkung

Das vorliegende Dokument ist eine Kopie aus der Applikation «Orca». Das Original, respektive die aktuell gültige Version ist unter orca.dkfbasel.ch verfügbar.

Inhaltsverzeichnis

1. Introduction

This SOP covers all steps of the surgical techique used in the EMINENT-ICH study as well as preparation and postoperative care. This SOP was created to provide an unifor training document for all surgical centres

2. Scope

This SOP is applicable for all patients enrolled in the EMINENT-ICH study that are assigned to the surgical arm.

3. Terms and abbreviations

- Vycor/VBAS ViewSite brain access system
- ICH intracerebral haemorrhage
- CT computed tomography
- INR international normalized ratio
- SBP systolic blood pressure

4. Roles and responsibilities

Investigator: performs surgery

Superuser: performs and teaches surgery

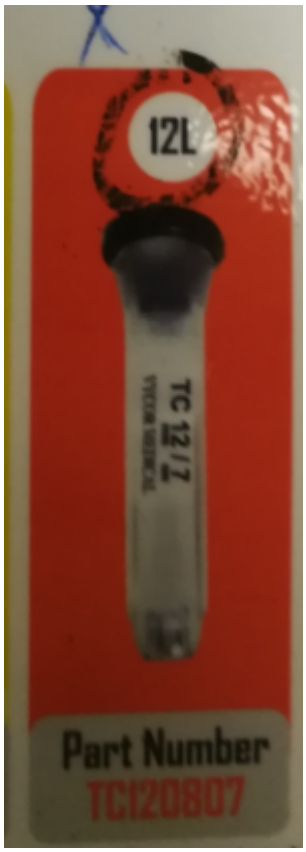
Sponsor: Provides training opportunities

5. Process

5.1. Prerequisits

For the surgery, the following special materials are needed:

- **Vycor 12L**. This refers to the Vycor VBAS Model TC120807 with a width of 12mm and a lenght of 7cm also termed “12L”



Model of the Vycor 12L (12mm width x 7cm lenght)

- A navigated endoscope should be available
- The eligibility criteria of the EMINENT study must be met and the patient be randomised to the surgical arm

5.2. Preoperative Managment

The preopartive managment can be subdivided into different tasks:

5.2.1. Consenting of patients and relatives

Before the surgical intervention can be scheduled, the patients, or an independent physician if the patient is not able to conset him/herself, has to confirm participation (or confirm that the interest of the patient are preserved). Please refer to the SOP Informing and consenting[1].

5.2.2. Imaging studies

For the surgery, a CT scan, ideally with contrast agent series and a slice thickness of 1mm in the native series, is required. This CT serves as basis for the planning of the trajectory. If the surgery takes place 6 hours after the initial admission CT scan, a new scan should be scheduled to account for potential hematoma enlargement.

1. https://orca.dkfbasel.ch/processes/5db373fc-b296-11ed-9631-7fae4f86749b/current

5.2.3. Laboratory studies

For the EMINENT-ICH trial, the INR should be known and be below 1.5, which should be done in routine laboratory studies.

Furthermore, the EMINENT-ICH trial analyses biomarkers in the blood independently of routine laboratory analysis. In larger centres with the capacity to do so, the EMINENT-ICH blood samples should be taken and sent to the respective laboratory. Please consult the SOP "Blood sample handling and storage[1]" for further details. No other lab studies are required.

5.2.4. Emergency categorization

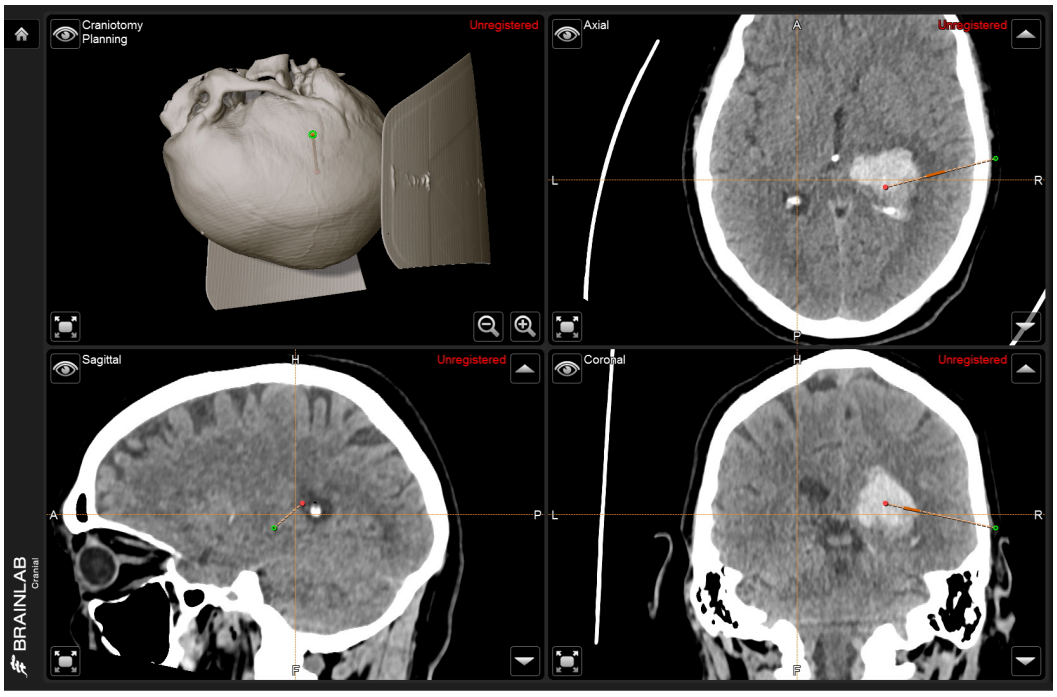
Patients in the surgical arm have to be operated **within 24 hours after bleeding onset**. Therefore, ideally, surgery is scheduled as soon as possible after informed consent was given. Depending on the symptoms and the consciousness of the patient, higher emergency categories (2; 1B) might be required. If the patient is neurologically stable and time allows, emergent surgery during the night shift can be postponed to the next morning.

5.2.5. Planning of the trajectory

The trajectory to the hematoma should ideally be planned

1. with the shortest distance crossing eloquent tissue to the centre of the hematoma in the long axis
2. as being no longer than 7 cm

Emergency/rescue planning in the OR is also possible.



Preplanned trajectory into a deep-seated haemorrhage

5.2.6. Preoperative monitoring

In case the surgery cannot be directly started, preoperative monitoring is required. All patients will receive the standard medical care. Additionally, the should receive surveillance on either an ICU, a stroke unit or a neurosurgical intermediate care. Special attention to blood pressure managment should be payed (<140mmHg SBP), the upper body should be postioned in a 30° angle and constant vital parameter assessment should be provided.

5.3. Positioning and preparation

5.3.1. Preoperative Medication

If patients have an active bleeding but have not received some reversal thereof, tranexamic acid, antidots for anticoagulants or platelet packs should be given.

A single shot of antibiotics (e.g. cefuroxime, depending on hospital specific resistancy schemes) should be applied 30 minutes before the first skin incision.

5.3.2. Positioning of the patient

The patient is positioned in a supine position on his/her back. The head is fixated in a Mayfield/Doro clamp. Headshaving should be made so that an 4 cm straight incision above the hematoma will be possible.

Depending on the location of the bleeding, the head is tilted to either side (e.g. right sided basal ganglia bleeding will be positioned with head tilt to the left to allow sick side up)

1. https://orca.dkfbasel.ch/processes/21b9f3dc-b9dd-11ed-abbf-734654b44418/current

Positioning of the head in a right sided parietal bleeding. Minimal shaving and marking for a straight skin incision

In case of parietal/occipital bleedings, it may be necessary to further tilt the patient by supporting him/her with cushions (modified side positioning).

Modified side positioning with cushions under the shoulder

5.3.3. Positioning of the tools

The camera for the navigation, the screens for navigation and the endoscope and the intrument tables have to be positioned around the patient.

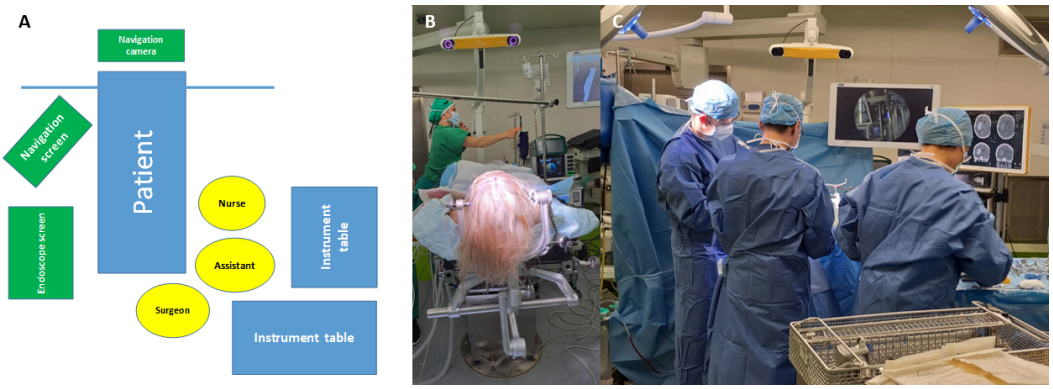
The camera of the navigational device should be at the feet of the patient or directly left or right of the patients feet.

The screen for the endoscope should be placed depending on which side the head of the patient was tilted, i.e. head tilt to the left means the surgeon will stand on the right side of the head. Consequently, the endoscope screen should be on the left side. Depending on personal preference, however, this can also be on the left side.

The navigational tool screen should be placed either directly beside the endoscope screen or alternatively directly beside the assisstant.

The instrument tables should be placed at the head of the patient.

The bipolar station should be placed on the same side of the surgeon.

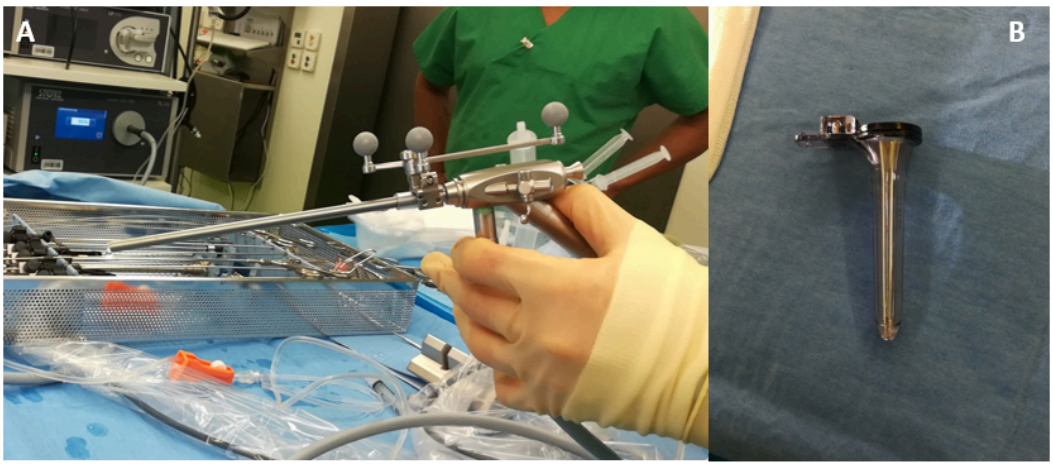


A) Standard position of surgeons and instruments around the patient (head tilt to left); B) Camera position at the feet of the patient; C) Set-up with head tilt to the right and endoscope screen and navigation side by side

5.3.4. Preparation of key surgical steps

Three essential steps should be prepared before the incision is performed.

- the retraction arm and system (Leyla or DoroLuna) should be installed so that the Vycor can be used directly
- The endoscope should be navigated, meaning the navigation reference star has to be fixated and the endoscope registered in the navigation software. It is essential that the long arm of the navigation reference star points to the **rear end** of the endoscope
- the suction device should be fitted with a regulator to regulate the strenght of suction once inside the hematoma cavity



A) Endoscope with mounted navigation reference star, the long arm facing the rear end; B) Vycor trocar

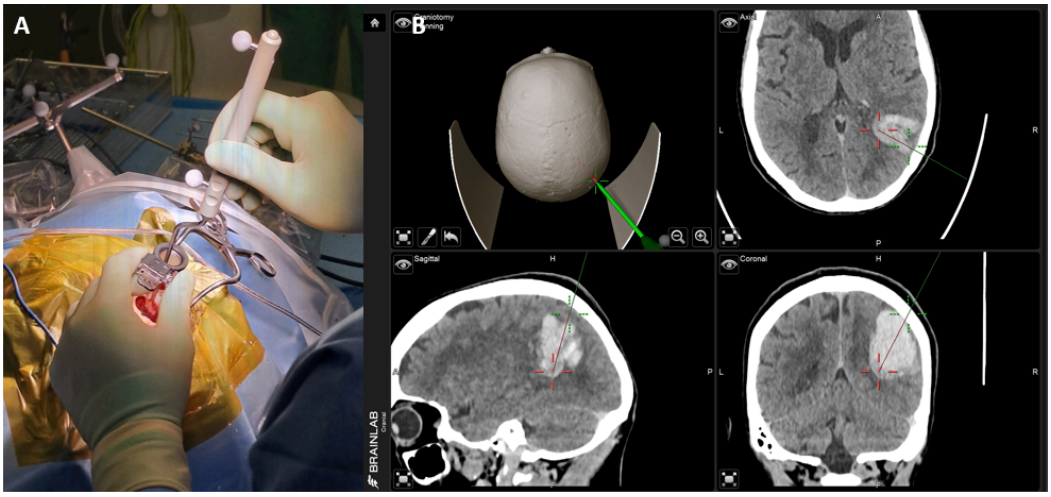
5.4. Surgical steps

1. Team time out
2. 4 cm straight skin incision above the hematoma, coagulation as necessary
3. Use Rasporatorium to expose skull
4. Drill two burr holes side by side. The burr holes should be placed, that the Vycor can be moved to address all angles of the hematoma.

Double burr holes connected with Kerrison punch

5. Connect burr holes with Kerrison punch by removing edges between burr holes
6. Coagulation and hemostasis of osseous bleeding with bone wax
7. Coagulate dura and perform cruciate dural incision
8. Perform small corticotomy for the Vycor
9. Verify the trajectory to the hematoma cavity with the help of the offset function (tip extension) of the navigational software

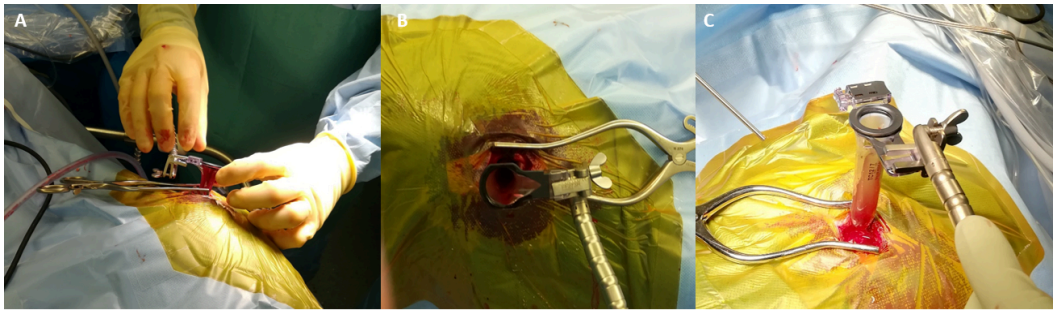
10. Insert the naviagtion stylet into the small dimple in the middle of the Vycor inlay



A) Insertion of the Vycor with the navigation stylet; B) Corresponding trajectory with tip extension predicting the path

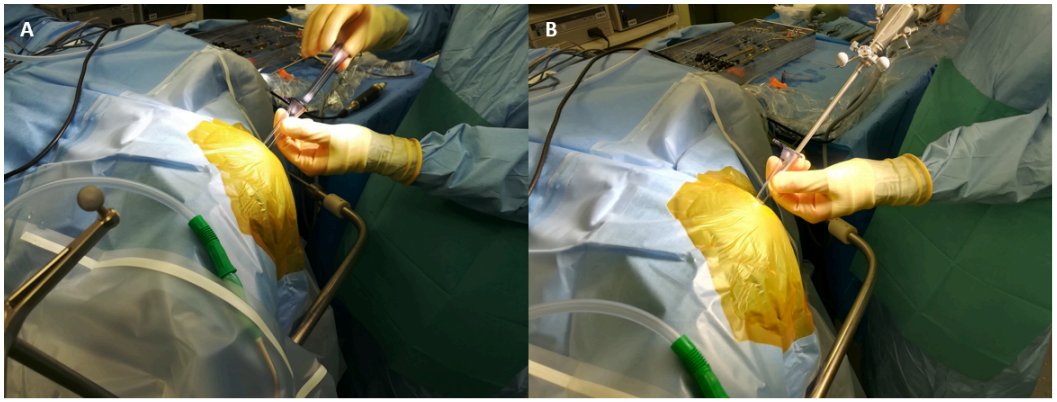
11. Together with the navigation stylet, insert the Vycor into the brain towards the hematoma cavity

12. Insert the Vycor to approx. 2/3 of the hematoma cavity and fix the retraction system



A) Fixation of the Vycor in the retraction system; B) Top view of the fixation; C) Fixation of the retraction system at the pedestal of the Vycor

13. Remove the inlay of the Vycor



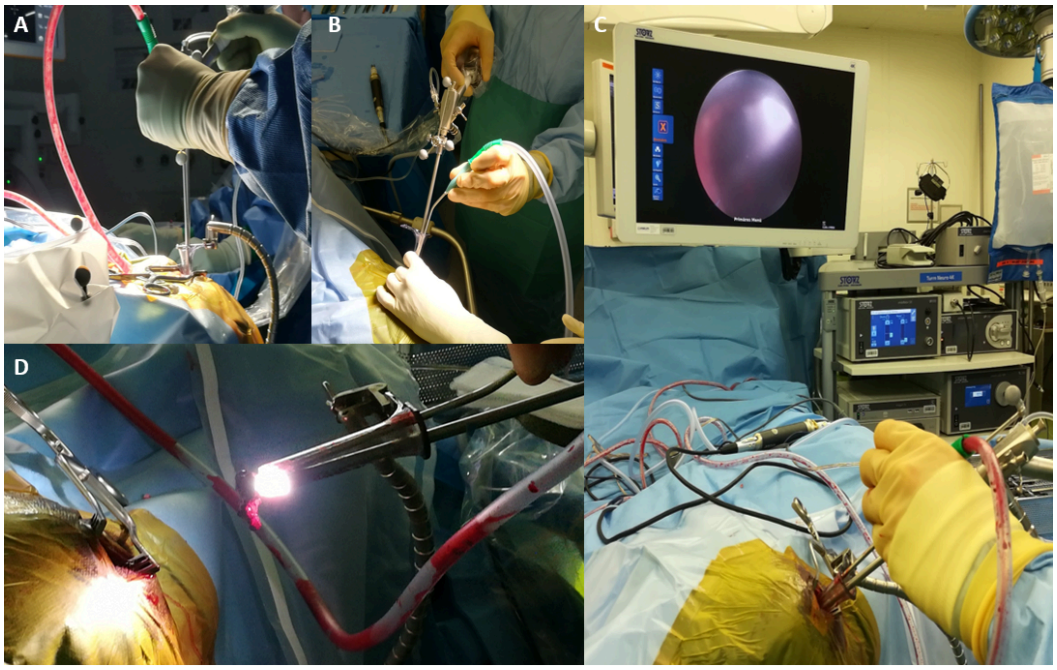
A) Removal of the Vycor inlay; B) Insertion of the endoscope

14. Insert the endoscope into the Vycor and remove the liquified hematoma

15. Slowly work your way towards the distal end of the hematoma cavity under navigational control

16. Use the suction device side-by-side to the endoscope by inserting the suction device in front of the endoscope and the endoscope thereafter so that you always see the tip of the suction device

17. Start removing blood clots by suction at the distal end of the hematoma cavity. Blood clots can be aspirated or removed by fixing the clot with manual regulation of the suction device and in toto removal of endoscope and suction device



A and B) Work with the endoscope in parallel to the suction device; C) View of the surgeon on the endoscope screen while evacuating; D) Complete removal of a clot with the suction device and the endoscope

18. Adjust the Vycor in the retraction system to access all angles of the hematoma cavity

19. Use the navigational softwar as reference when addressing different angles of the hematoma cavity

20. Rinse the hematoma cavity thoroughly to identify ongoing bleeding

21. Coagulate active bleeding sites with low voltage endoscopic bipolars. If bleeding persists, apply Floseal for hemostasis

22. As soon as you see normal brain tissue, you can move to the next area of the hematoma cavity

23. Slowly work towards the Vycor while removing the hematom from distal to proximal by

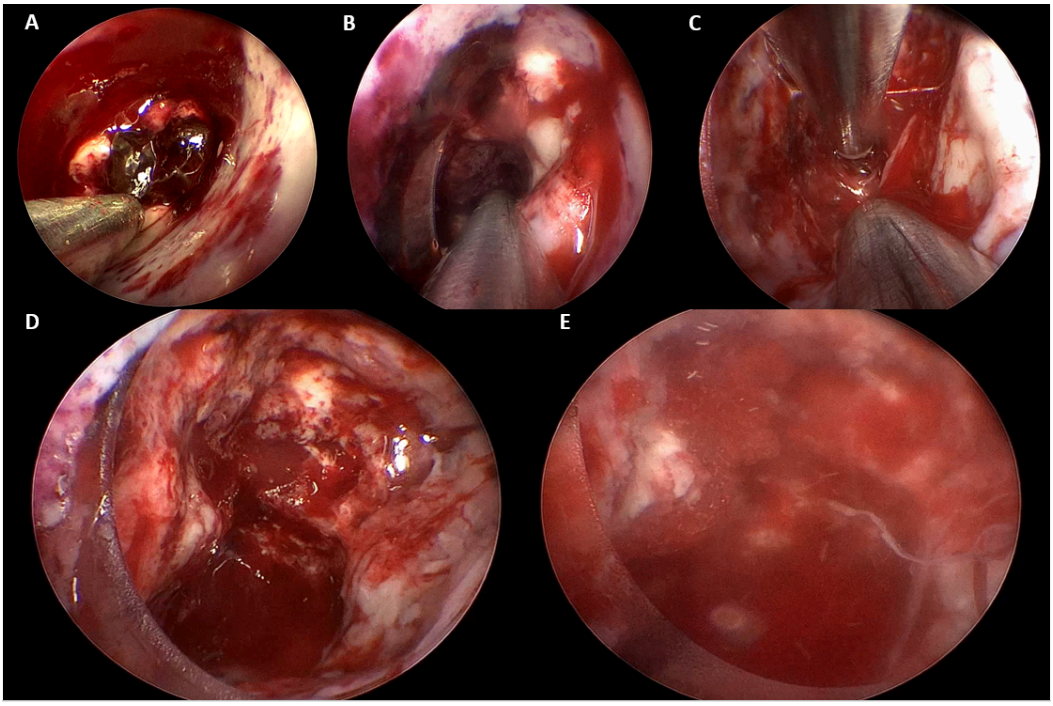
also adjusting the Vycor to a more proximal point in the hematoma cavity

24. Continue clearing the hematoma cavity by removing clots and liquified hematoma

25. Once the hematoma cavity is sufficiently evacuated, open the irrigation tap of the endoscope to gently rinse the whole hematoma cavity again and to re-inflate potential collapsed sections

26. If no ongoing bleeding is seen and the cavity is deemed sufficiently evacuated (approx. 80% evacuated), the hematoma removal is complete

27. If one is unsure whether active bleeding is controlled or not, apply Floseal into the cavity



A) Removal of liquified clot; B) Evacuating the cavity from distal to proximal; C) Coagulating active bleeding sites with the endoscopic bipolar; D) Evacauted distal hematoma cavity; E) Irrigating the whole hematoma cavity for identification of active bleeding sites

28. Remove the Vycor and the retraction system under visual control and address bleedings as necessary

29. Use gel foam (spongostan) or similar to cover the burr holes

30. Close the skin in standard fashion

31. Apply sterile drapings to the wound

32. Directly after surgery, use either intraOP CT or an emergency CT to quantify the amount of hematoma removed

33. In case the hematoma has more than >15mL residual blood on CT imaging, consider re-evacuation (up to the discretion of the surgeon)

5.5. Postoperative management

5.5.1. Care on ward

Patients should be supervised on an ICU or neurosurgical IMC for at least 24 hours after surgery. Treatment should be according to the current best medical standard care i.e. blood pressure managment, prevention of further complications and early rehabilitation including ergo- and logotherapy. Patients should be seen at least every 4 hours initially and every 8 hours on the normal ward afterwards. As soon as the patients are deemed fit, they should be transfered to the normal ward.

Patients should remain with 30° angle of their upper body. Showering is possible after the 3rd postoperative day. In case drainage was inserted, the drainage can be removed after the 2nd postoperative day. Staples/sutures can be removed after the 10th postoperative day. Thrombosis prophylaxis with low molecular weight heparin can be started after the 3rd postopertive day in case no rebleeding was detected on postOP CT scans.

5.5.2. Imaging

A CT scan of the head should be scheduled 24 hours after surgery to exclude rebleeding.

5.6. Follow-up

5.6.1. Discharge managment

Patients should be scheduled for intensive neurorehabilitation and discharged as soon as medically possible and reasonable. If a patient is well enough (mRS <1) direct discharge to the home care can be considered.

5.6.2. Follow-up

Patients should be planned for a clinical out-patient follow-up at 3 and 6 months after surgery with the surgeon conducting the surgery.

6. Metrics

- Amount of residual hematoma volume
- Time of surgery

7. Document filing

This SOP is filed within the QMS of the EMINENT-ICH study, in the respective assistant bureaus and on the EMINENT-ICH website

8. References

- https://link.springer.com/article/10.1007/s00701-022-05326-3[1]

1. https://link.springer.com/article/10.1007/s00701-022-05326-3

Änderungsverzeichnis

Version	Beschreibung
Version: 1.0.0 (aktuell)	Version 1.0