

# Evakuering af intracerebrale hæmatomer med minimal invasiv teknik

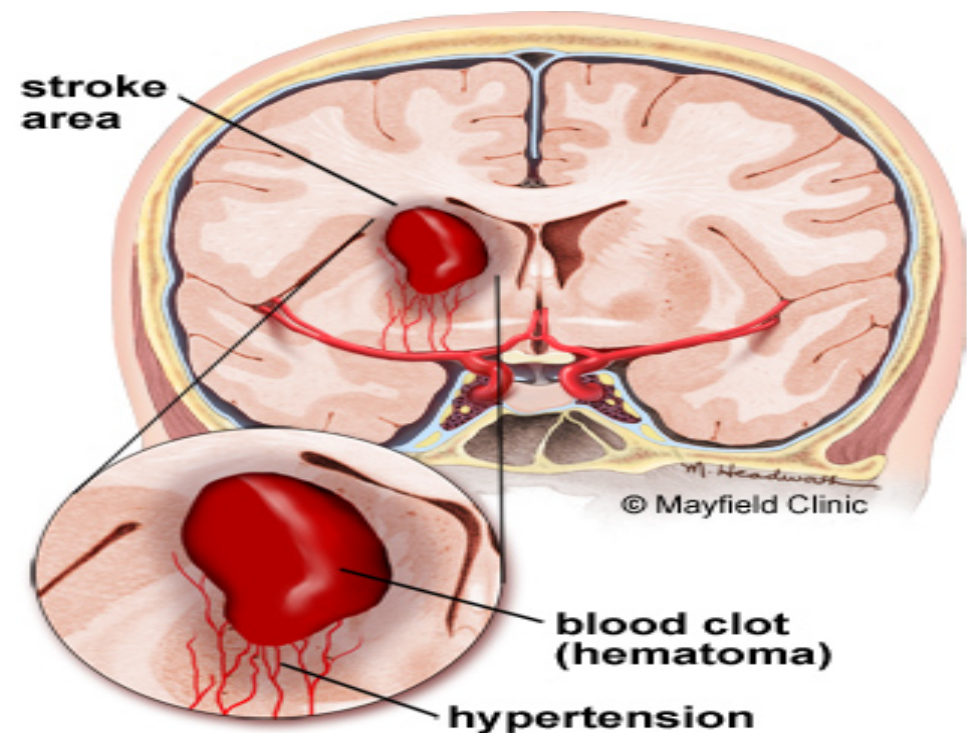
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AUH

Intracerebralt hæmatom, alvorlig prognose og stor usikkerhed vedrørende effekten af kirurgisk behandling.

- Udgør ca 10% af apoplexifælde
- Masse effekt
- Toksisk effekt - penumbra



# Kirurgisk behandling

Supratentorial: kontroversiel

Cerebellum: veletableret

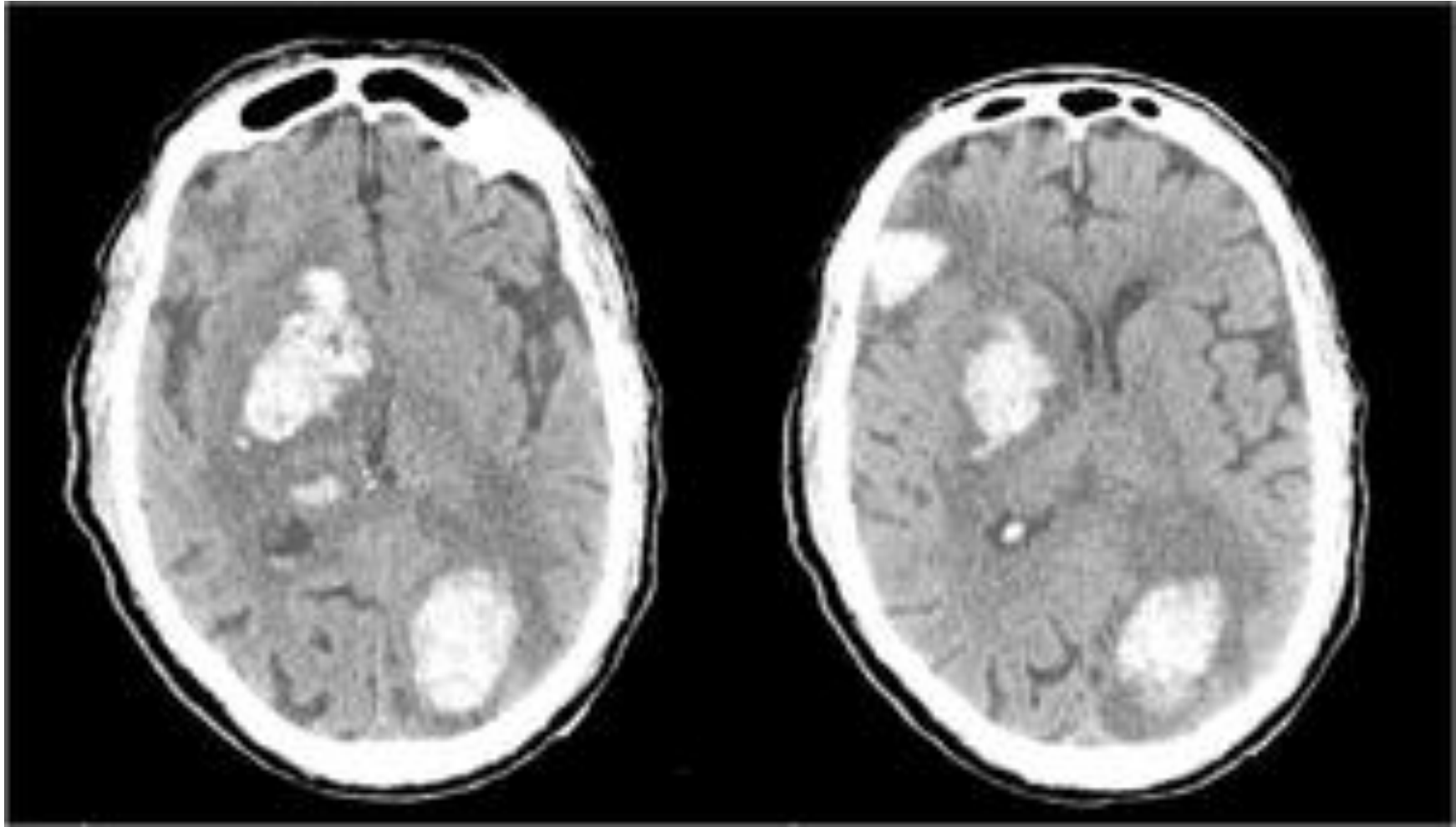
## Formål:

- Dekompression, ophæve massevirkning, nedsætte ICP
- Lukke en evt. blødningskilde
- Redde funktionsdygtigt væv i den omgivende penumbra zone

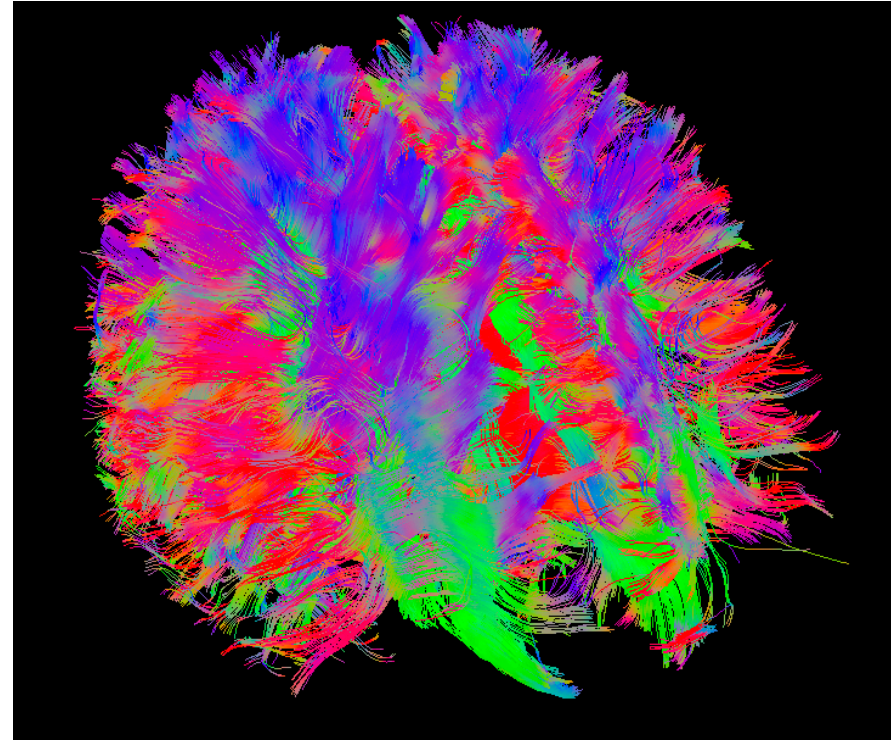
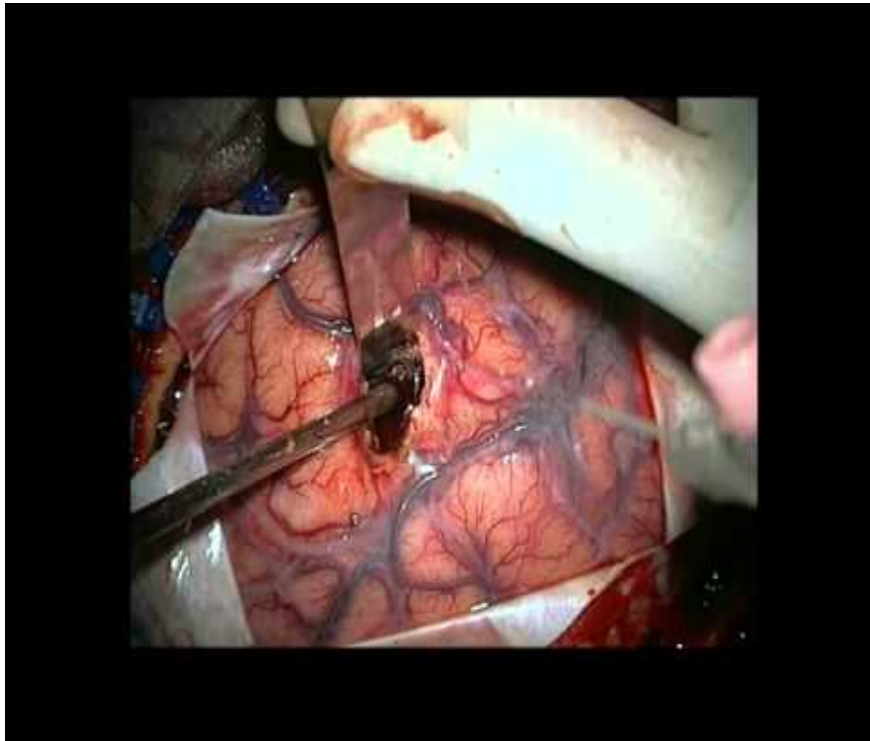
# Kirurgi contra konservativ behandling

- STICH (tidlig kirurgi(kraniotomi) mod medicinsk beh.)
- STICH II (som ovenfor men nu kun superficielle lobære hæmatomer)
- MISTIE (minimal invasiv kirurgi med actilyse mod medicinsk beh.)
- CLEAR II (minimal invasiv kirurgi med intraventrikulær actilyse)

## ICH localisation



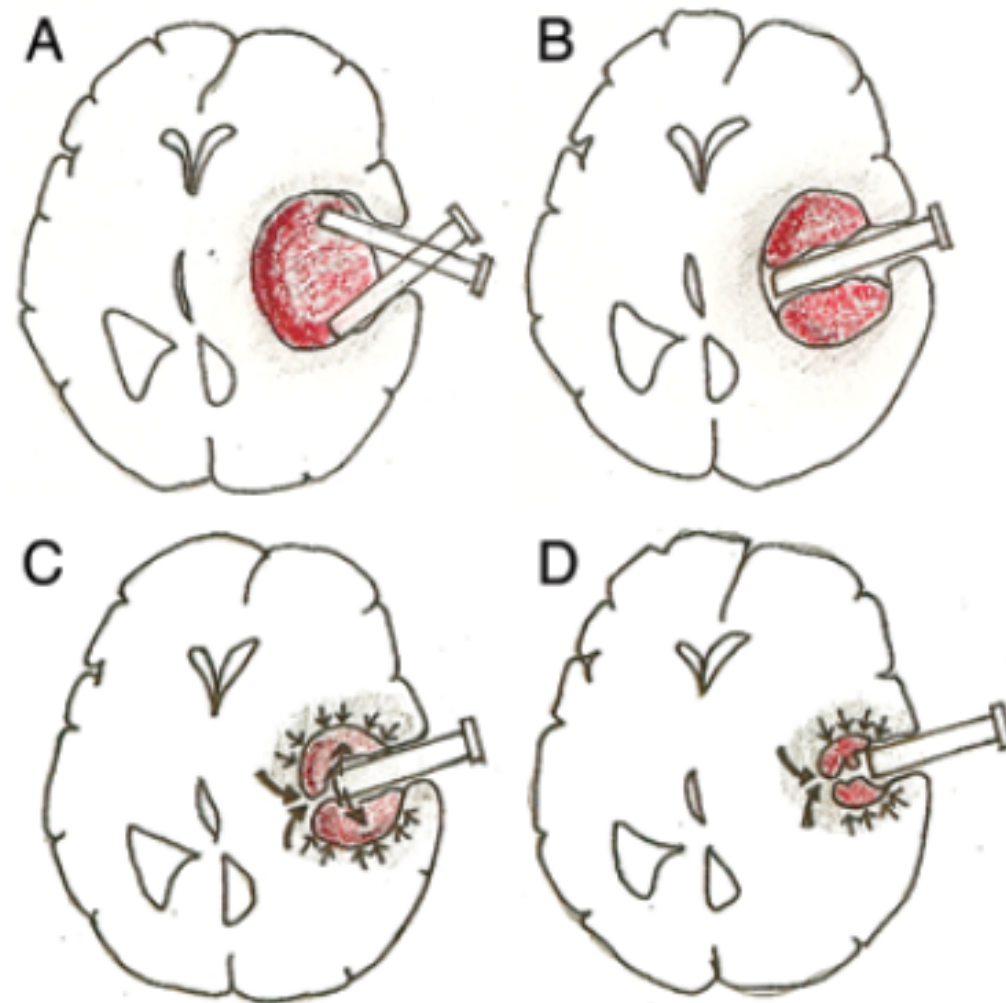
# Hæmatomevacuering via kraniotomi



Manglende videnskabelig dokumentation har ført til stor usikkerhed vedrørende indikationen for kirurgisk behandling

Kan vi gøre det bedre?

# Evacuering af intracerebrale hæmatomer med minimal invasiv teknik





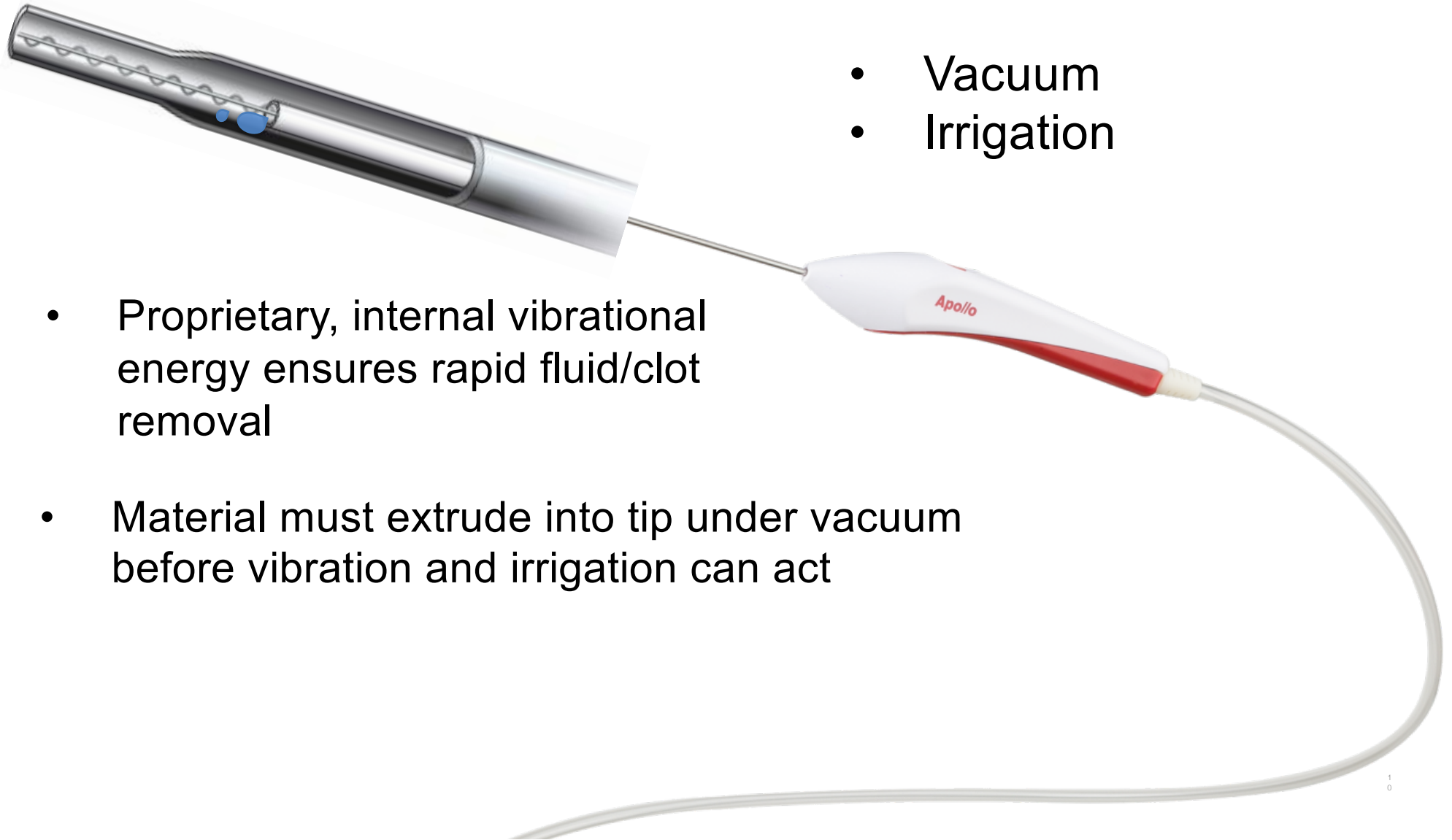
# Endoskopisk udstyr



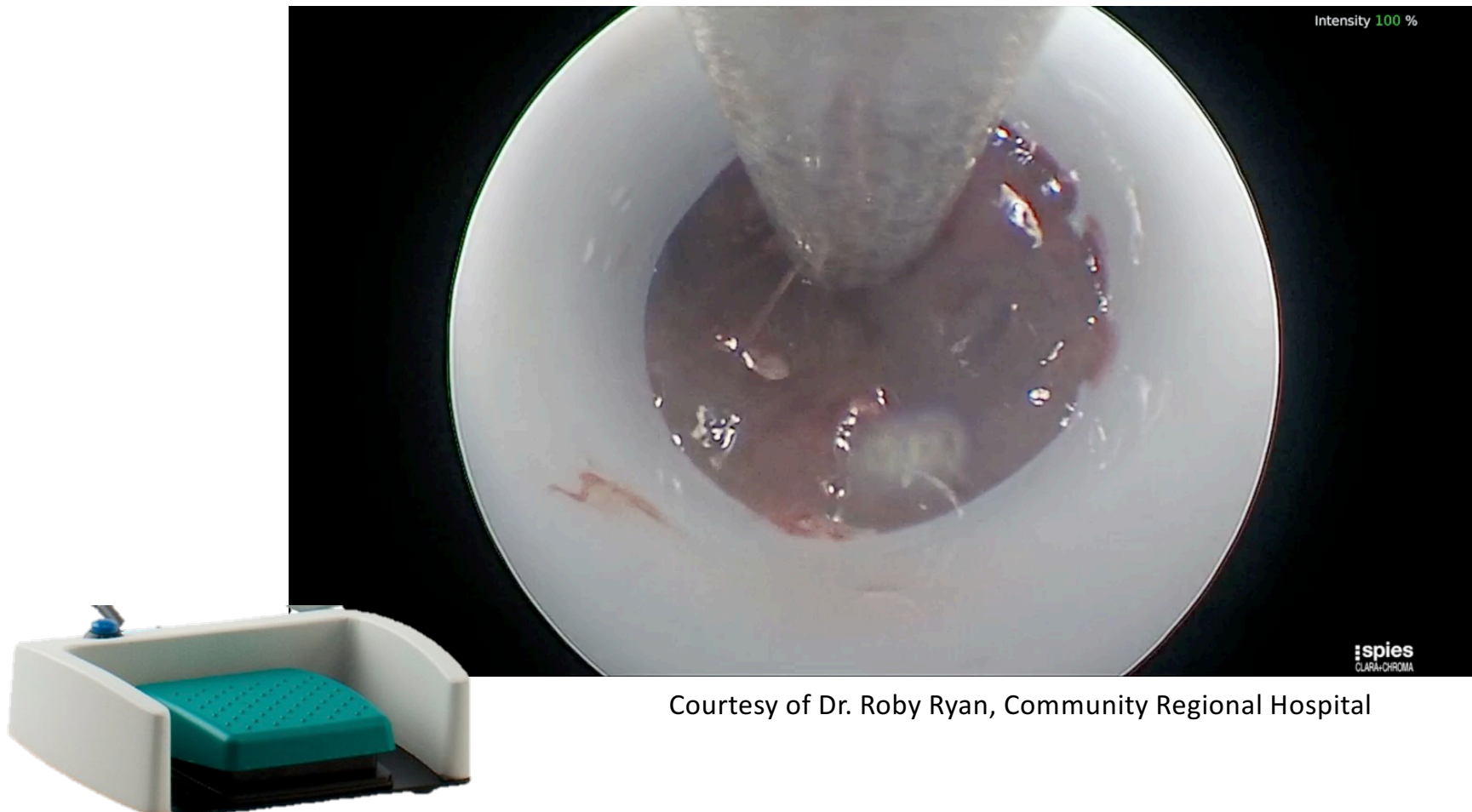
# The Apollo™ System Wand

- Vacuum
- Irrigation

- Proprietary, internal vibrational energy ensures rapid fluid/clot removal
- Material must extrude into tip under vacuum before vibration and irrigation can act



# Consistent Use Of Vibration Will Ensure Extraction



Courtesy of Dr. Roby Ryan, Community Regional Hospital



A prospective multicenter randomized controlled post-market clinical follow-up (PMCF) study comparing the effectiveness and safety of the Apollo System<sup>®</sup> versus medical management (MM) for patients with intra-cerebral hemorrhage (ICH).



# Primary Endpoint

- Effectiveness: modified Rankin score (mRS) of  $\leq 3$  at 180 days
- Safety: Rate of mortality at 30 days

0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

# Inclusion criteria (abbreviated)

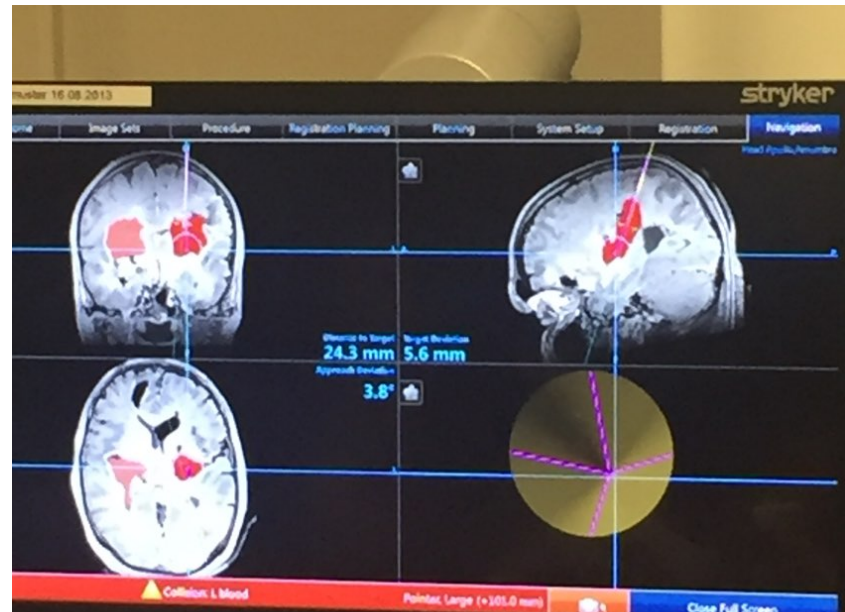
1. Patient age  $\geq 18$  and  $\leq 80$ , or age  $< 85$  with baseline mRS=0
2. Supratentorial ICH of volume  $\geq 20$  mL  $< 80$  ml
3. Hemostasis (hemorrhage increase of less than 5 ml as confirmed by 2 CT/MR taken a minimum of 6 hours apart)
4. NIHSS  $\geq 6$
5. Presenting GCS 5-15
6. Historical mRS 0 or 1
7. Symptom onset  $< 24$  h prior initial CT
8. Apollo MIES can be initiated within 72h of ictus/bleed
9. SBP can be controlled  $< 180$  mmHg and sustained at this level for at least 6 hours
10. Written Informed Consent

# Exclusion criteria

## 1. Imaging

- a) Expanding hemorrhage
- b) “Arterial spot sign” identified on CTA
- c) Hemorrhagic lesion such as a vascular malformation (cavernous malformation, AVM etc), aneurysm, neoplasm
- d) Hemorrhagic conversion of an underlying ischemic stroke
- e) Infratentorial hemorrhage
- f) Large associated intra-ventricular hemorrhage requiring treatment for IVH-related mass effect or shift due to trapped ventricle (EVD for ICP management is allowed)
- g) Midbrain extension/involvement

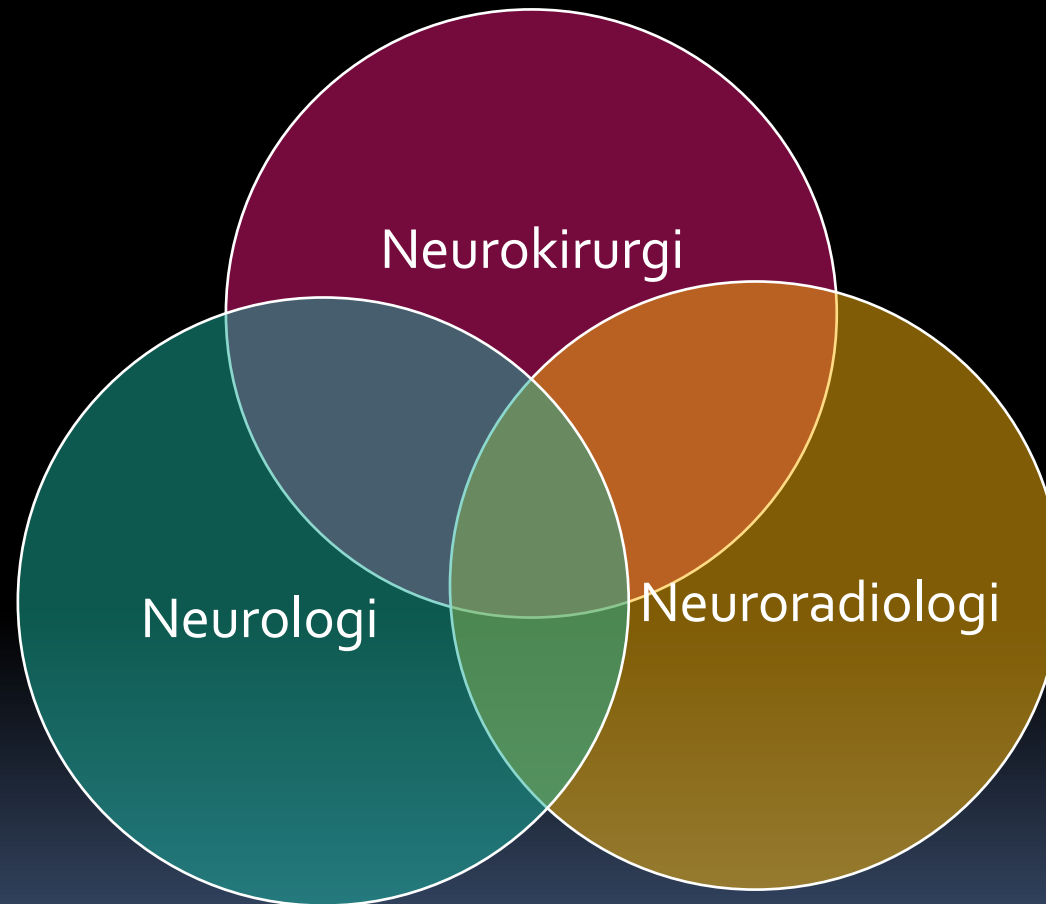




# Initial Multicenter Technical Experience With the Apollo Device for Minimally Invasive Intracerebral Hematoma Evacuation

- Retrospektiv analyse
- Gennemsnitsalder 62 år
- Volumen af ICH = 45 ml +/- 31 ml
- Efter evakuering 22 ml +/- 24 ml
- Komplikationer til proceduren hos 6,9 %
- Mortalitet 13,8 %

# DANSK STROKE CENTER VISIONEN



Tak!

