Intraparenchymal Hematoma –

Who warrants surgical decompression/MIS evacuation?

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Photo courtesy of Dr. Warren Selman

What we will cover

- Intracerebral hemorrhage
  - {with surgical management}

- A vision for the future

Ischemic

Hemorrhagic

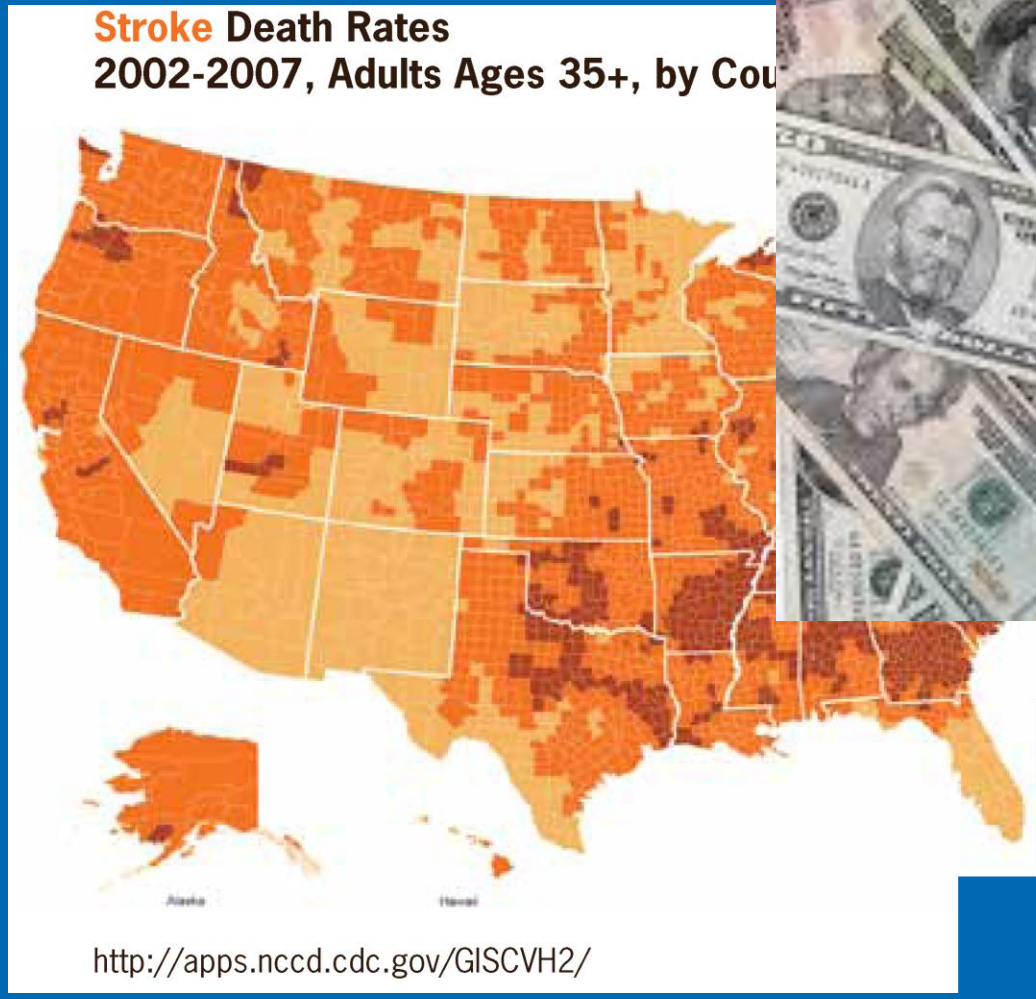
Hemorrhagic Stroke

15% of all strokes are hemorrhagic

Many causes, most common:

- **HTN**
- **Vascular (AVM/aneurysm)**
- **CAA**

Stroke is an Epidemic



- 5th leading cause of death in the US
- 2nd leading cause of death globally

Classification of Hemorrhagic Stroke

ICH score:

- **Size**
- **Location**
- **GCS**
- **IVH**

- Predicts all cause 30 day mortality

Traditional indications for surgical intervention

- Size >30cc
- Midline shift/ Elevated ICP
- Poor neurological exam (GCS)
- Herniation

Criticisms and concerns:

Significant Morbidity

Questionable impact on outcomes

Move to MIS

Is there a better way?
Does it lead to improved outcomes?

Less invasive evacuation of hematoma

- Less disruption of normal tissue

Less surgical morbidity

Evolution of MIS evacuation

Select trial review

- STITCH II
- CLEAR III
- MISTIE III

- **ENRICH**

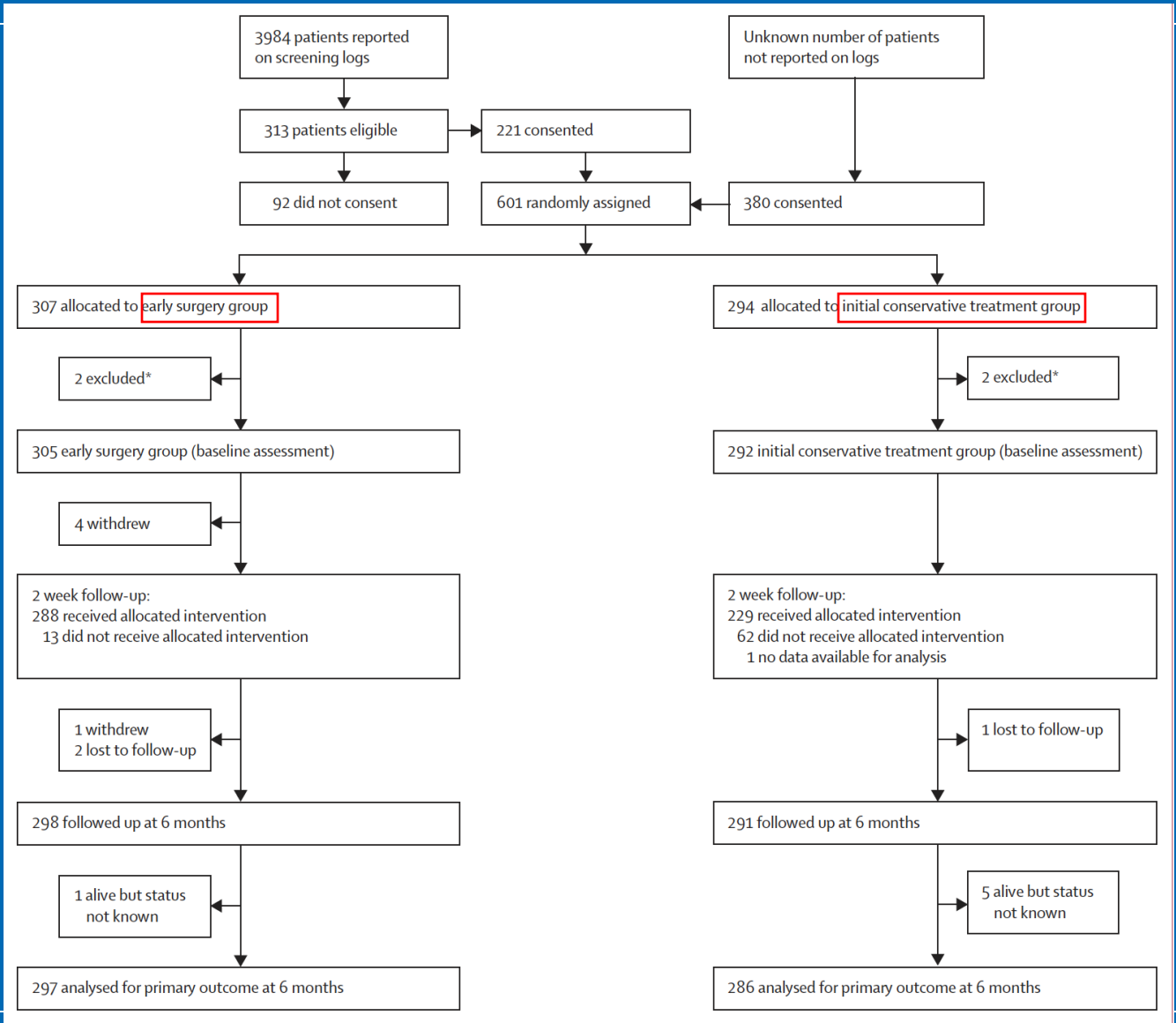
STITCH II

Early surgery at 12 hours vs. medical management alone

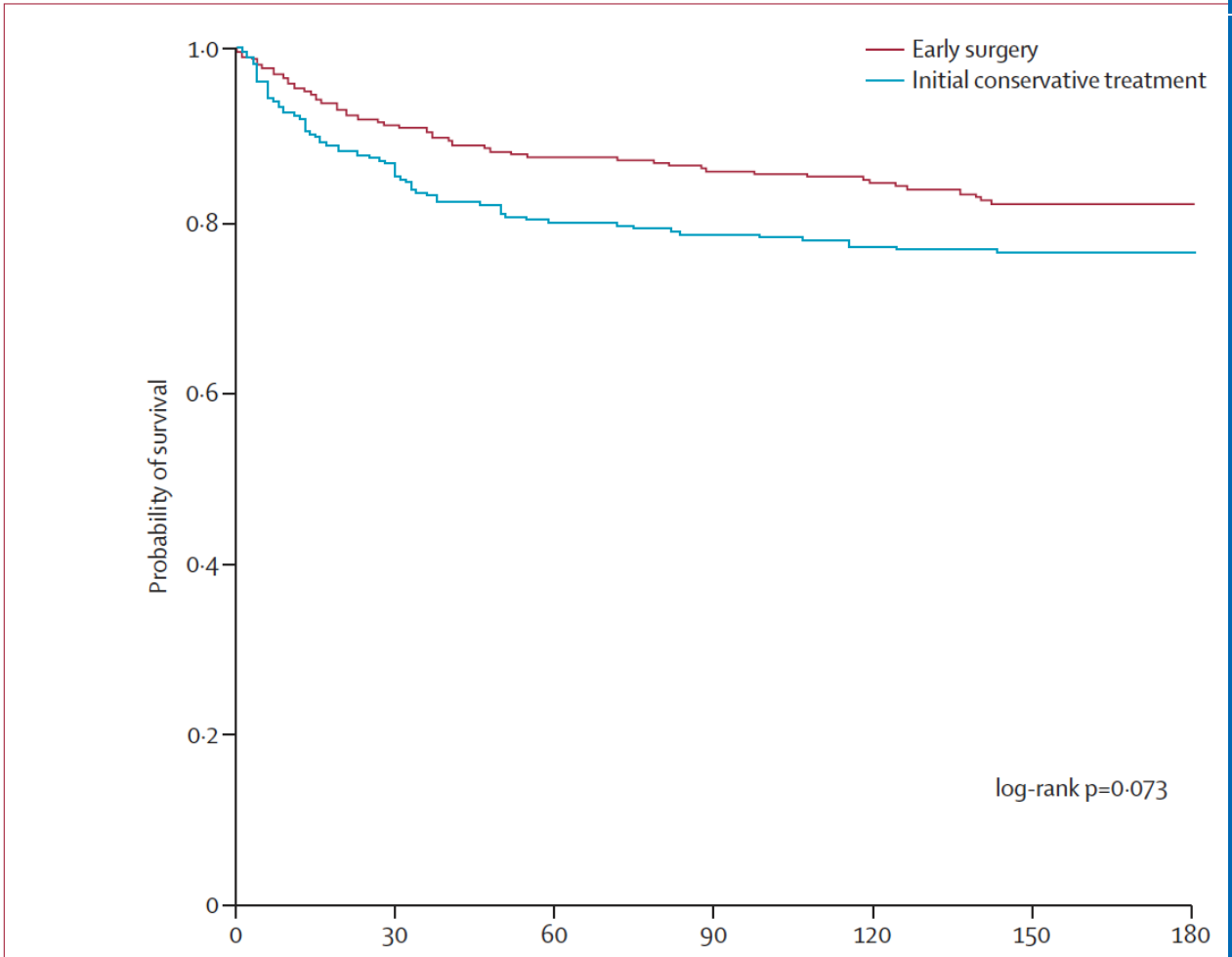
- Any surgical intervention allowed
- Significant crossover from medical arm to surgical arm (62 of 292)

Interpretation The STICH II results confirm that early surgery does not increase the rate of death or disability at 6 months and might have a small but clinically relevant survival advantage for patients with spontaneous superficial intracerebral haemorrhage without intraventricular haemorrhage.

STITCH II


3984 patients reported on screening logs
Unknown number of patients not reported on logs
313 patients eligible
221 consented
92 did not consent
601 randomly assigned
380 consented
307 allocated to early surgery group
294 allocated to initial conservative treatment group
2 excluded*
2 excluded*
305 early surgery group (baseline assessment)
292 initial conservative treatment group (baseline assessment)
4 withdrew
2 week follow-up:
288 received allocated intervention
13 did not receive allocated intervention
2 week follow-up:
229 received allocated intervention
62 did not receive allocated intervention
1 no data available for analysis
1 withdrew
2 lost to follow-up
1 lost to follow-up
298 followed up at 6 months
291 followed up at 6 months
1 alive but status not known
5 alive but status not known
297 analysed for primary outcome at 6 months
286 analysed for primary outcome at 6 months

STITCH II


Early surgery
Initial conservative treatment
1·0
0·8
0·6
0·4
0·2
0
Probability of survival
log-rank p=0·073
0
30
60
90
120
150
180
Days since randomisation
Number at risk
Early surgery 300 271 260 255 251 231 169
Initial conservative treatment 292 252 232 237 222 202 148

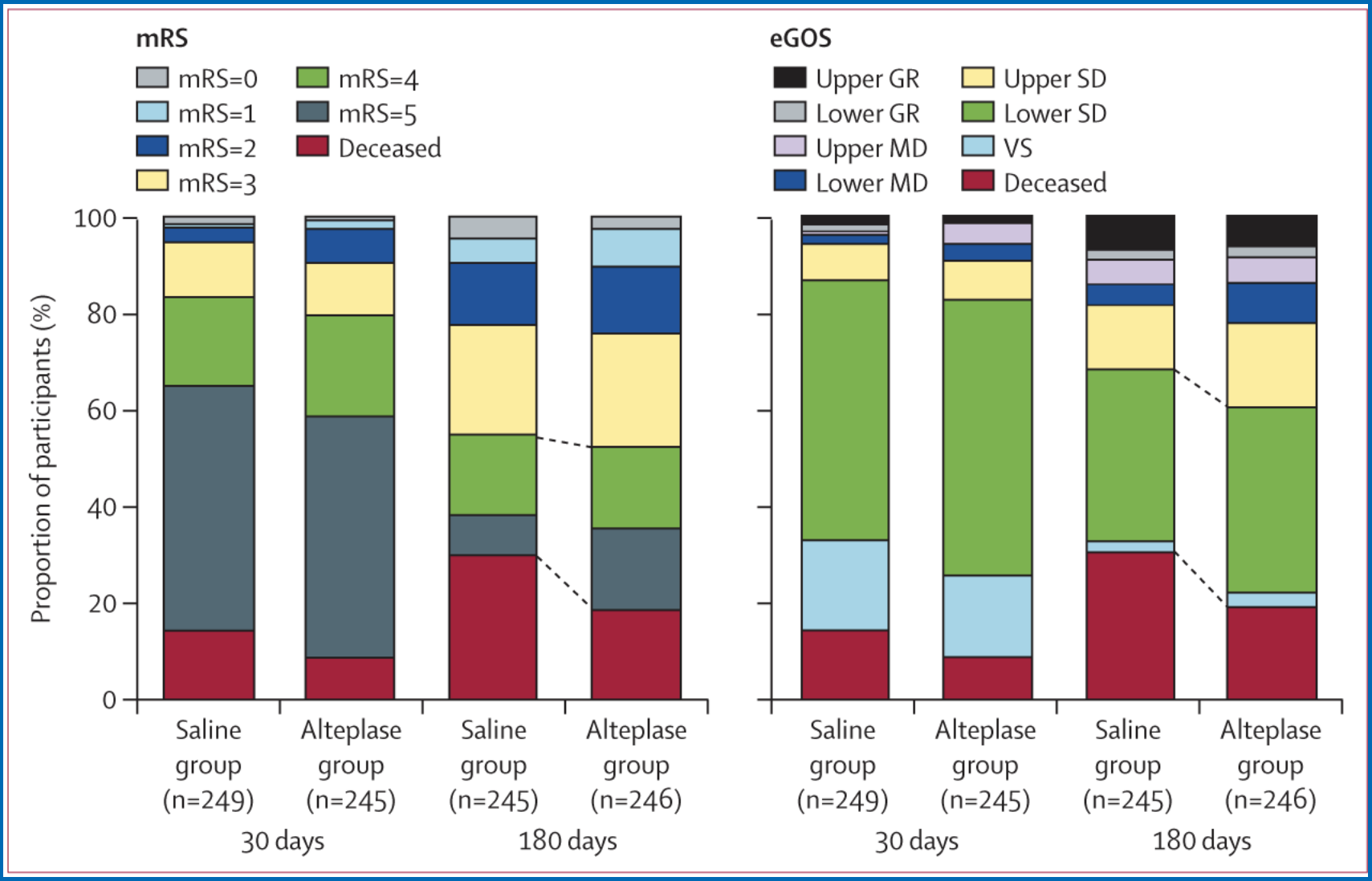
CLEAR III

Use of IT alteplase vs. saline

- Does demonstrate safety
- No significant change in outcomes amongst groups

Interpretation—In patients with intraventricular haemorrhage and a routine extraventricular drain, irrigation with alteplase did not substantially improve functional outcomes at the mRS 3 cutoff compared with irrigation with saline. Protocol-based use of alteplase with extraventricular drain seems safe. Future investigation is needed to determine whether a greater frequency of complete intraventricular haemorrhage removal via alteplase produces gains in functional status.

CLEAR III


mRS
mRS=0
mRS=1
mRS=2
mRS=3
mRS=4
mRS=5
Deceased
eGOS
Upper GR
Lower GR
Upper MD
Lower MD
Upper SD
Lower SD
VS
Deceased
Proportion of participants (%)
100
80
60
40
20
0
Saline group (n=249)
Alteplase group (n=245)
Saline group (n=245)
Alteplase group (n=246)
30 days
180 days
Saline group (n=249)
Alteplase group (n=245)
Saline group (n=245)
Alteplase group (n=246)
30 days
180 days

MISTIE III

Open craniotomy has not been shown to improve outcomes.

Does a minimally invasive surgery have the opportunity to improve outcomes?

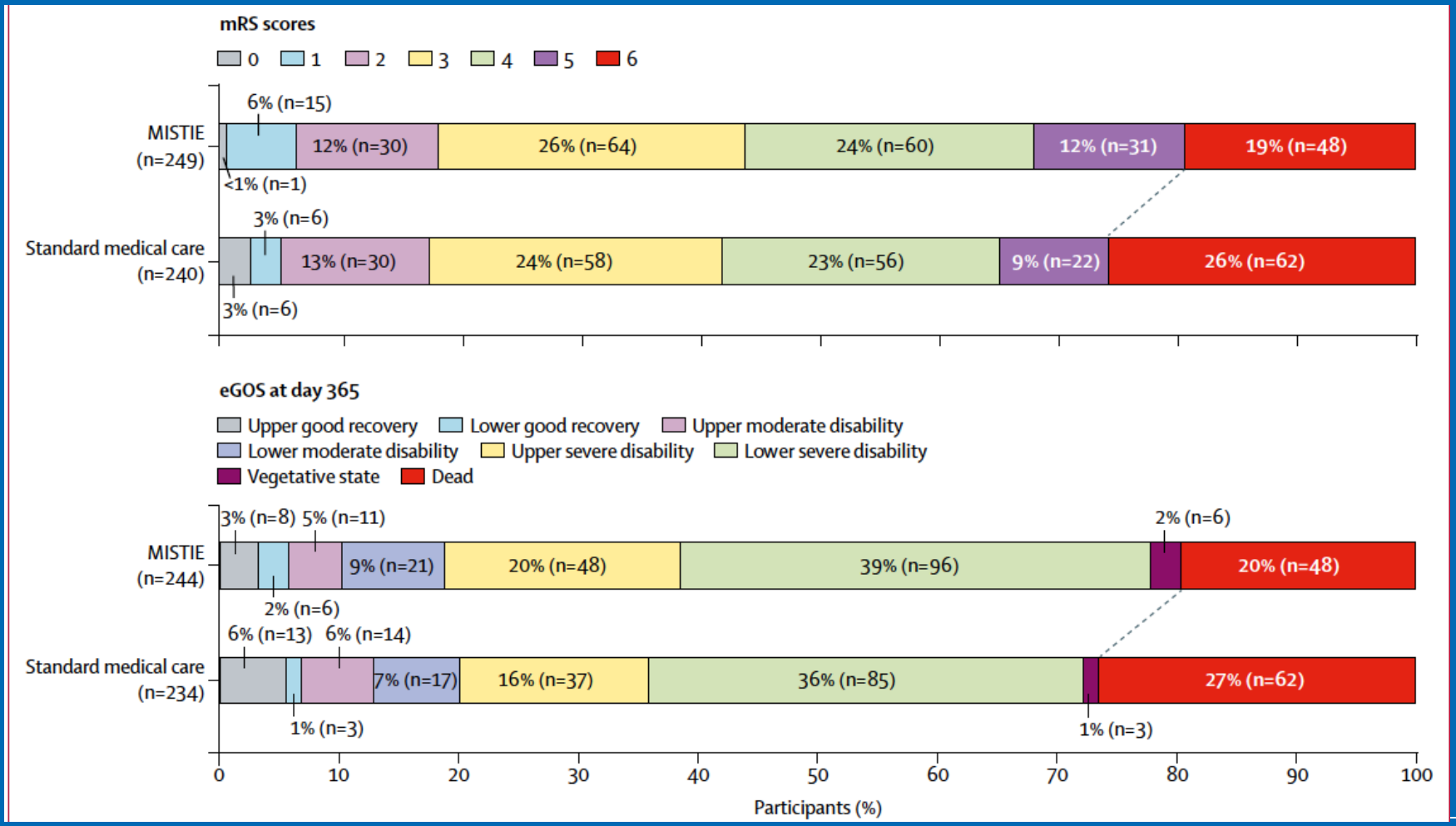
Interpretation For moderate to large intracerebral haemorrhage, MISTIE did not improve the proportion of patients who achieved a good response 365 days after intracerebral haemorrhage. The procedure was safely adopted by our sample of surgeons.

MISTIE III

- MIS placement of rigid catheter 2/3 of the way into the hematoma
- Evacuate hematoma
- Placement of soft catheter into hematoma bed
- Administration of alteplase
- Aim for less than 15ml residual hematoma

- **Mean reduction in hematoma size 69%

MISTIE III


mRS scores
0
1
2
3
4
5
6
MISTIE (n=249)
6% (n=15)
12% (n=30)
26% (n=64)
24% (n=60)
12% (n=31)
19% (n=48)
<1% (n=1)
Standard medical care (n=240)
3% (n=6)
13% (n=30)
24% (n=58)
23% (n=56)
9% (n=22)
26% (n=62)
3% (n=6)
eGOS at day 365
Upper good recovery
Lower good recovery
Upper moderate disability
Lower moderate disability
Upper severe disability
Lower severe disability
Vegetative state
Dead
MISTIE (n=244)
3% (n=8)
5% (n=11)
9% (n=21)
20% (n=48)
39% (n=96)
2% (n=6)
20% (n=48)
2% (n=6)
Standard medical care (n=234)
6% (n=13)
6% (n=14)
7% (n=17)
16% (n=37)
36% (n=85)
27% (n=62)
1% (n=3)
1% (n=3)
0
10
20
30
40
50
60
70
80
90
100
Participants (%)

Select hypotheses regarding why surgical trials have failed to show benefit

- Heterogenous patient population
- Primary brain injury resulting from hemorrhage may be difficult to recover from
- Ideal candidates and timing has been difficult to determine
- At times, significant crossover of patients from medical management to surgical groups
- Slow recruitment and difficulty determining ideal study design

ENRICH

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

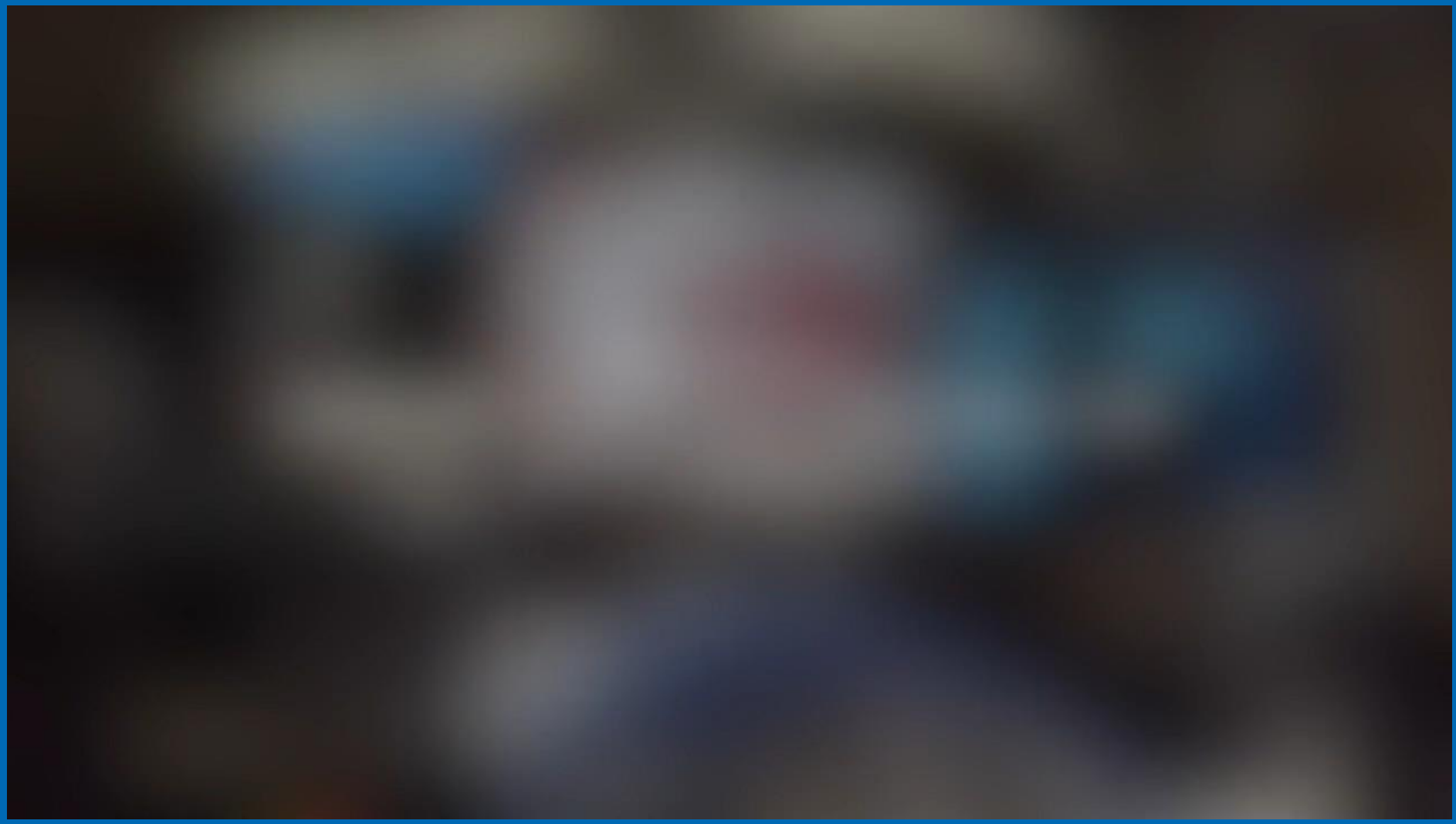
Trial of Early Minimally Invasive Removal of Intracerebral Hemorrhage

G. Pradilla, J.J. Ratcliff, A.J. Hall, B.R. Saville, J.W. Allen, G. Paulon, A. McGlothlin, R.J. Lewis, M. Fitzgerald, A.F. Caveney, X.T. Li, M. Bain, J. Gomes, B. Jankowitz, G. Zenonos, B.J. Molyneaux, J. Davies, A. Siddiqui, M.R. Chicoine, S.G. Keyrouz, J.A. Grossberg, M.V. Shah, R. Singh, B.N. Bohnstedt, M. Frankel, D.W. Wright, and D.L. Barrow, for the ENRICH trial investigators*

ENRICH

- MIS vs BMT
- Hematoma volume 30-80ml
- Lobar or anterior basal ganglia
- Primary efficacy endpoint was utility weighted mRS (0-1)
- Primary safety endpoint was death at 30 days

What is MIS (Perifascicular)?



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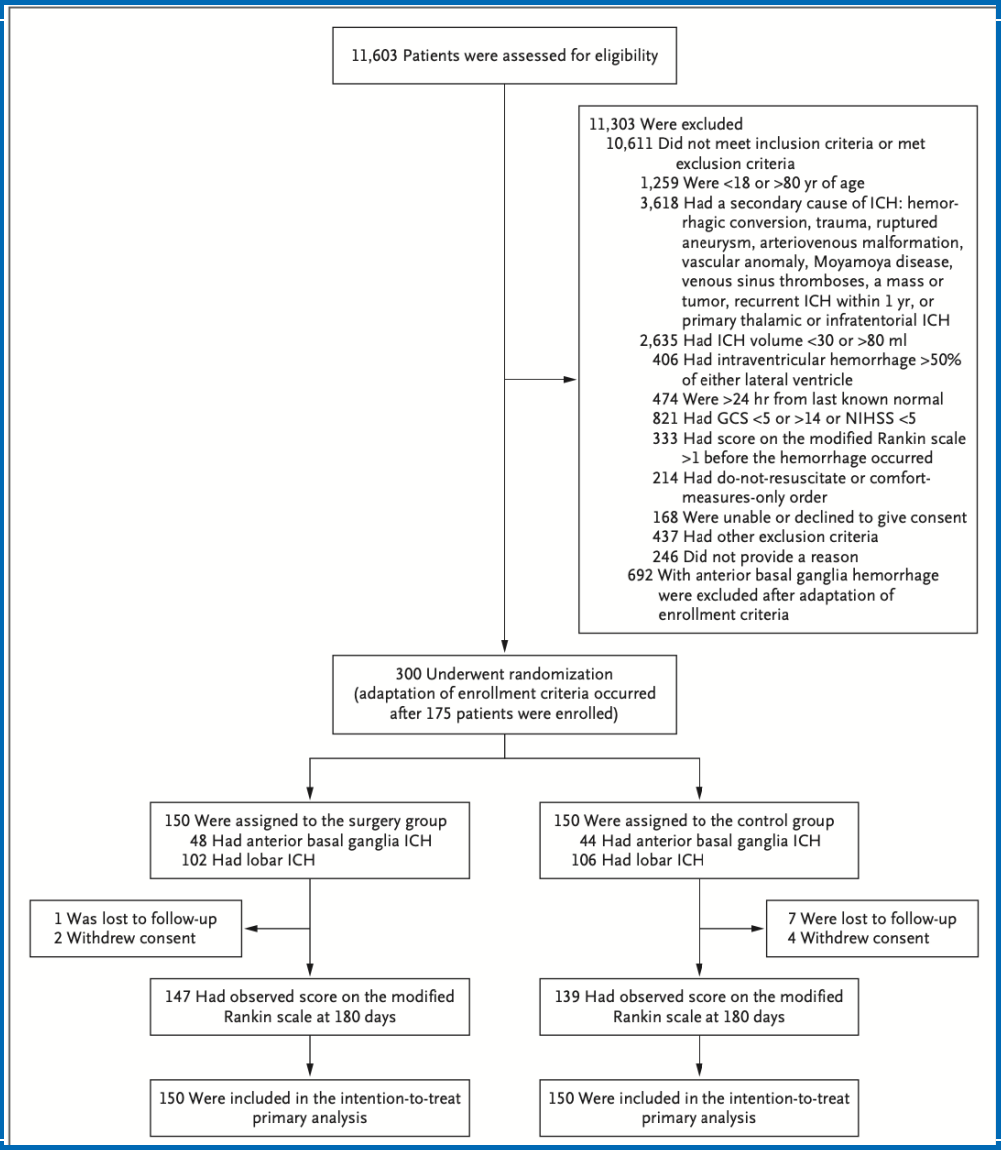
11,603 Patients were assessed for eligibility
11,303 Were excluded
10,611 Did not meet inclusion criteria or met exclusion criteria
1,259 Were <18 or >80 yr of age
3,618 Had a secondary cause of ICH: hemorrhagic conversion, trauma, ruptured aneurysm, arteriovenous malformation, vascular anomaly, Moyamoya disease, venous sinus thromboses, a mass or tumor, recurrent ICH within 1 yr, or primary thalamic or infratentorial ICH
2,635 Had ICH volume <30 or >80 ml
406 Had intraventricular hemorrhage >50% of either lateral ventricle
474 Were >24 hr from last known normal
821 Had GCS <5 or >14 or NIHSS <5
333 Had score on the modified Rankin scale >1 before the hemorrhage occurred
214 Had do-not-resuscitate or comfort-measures-only order
168 Were unable or declined to give consent
437 Had other exclusion criteria
246 Did not provide a reason
692 With anterior basal ganglia hemorrhage were excluded after adaptation of enrollment criteria
300 Underwent randomization (adaptation of enrollment criteria occurred after 175 patients were enrolled)
150 Were assigned to the surgery group
48 Had anterior basal ganglia ICH
102 Had lobar ICH
150 Were assigned to the control group
44 Had anterior basal ganglia ICH
106 Had lobar ICH
1 Was lost to follow-up
2 Withdrew consent
7 Were lost to follow-up
4 Withdrew consent
147 Had observed score on the modified Rankin scale at 180 days
139 Had observed score on the modified Rankin scale at 180 days
150 Were included in the intention-to-treat primary analysis
150 Were included in the intention-to-treat primary analysis

ENRICH

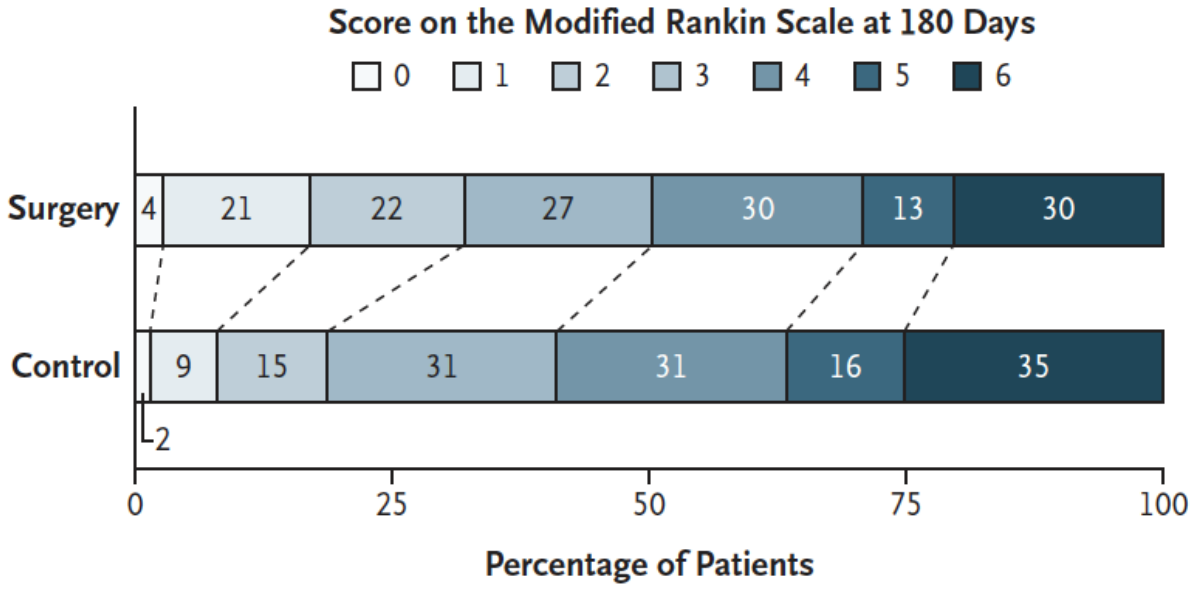

Figure 2. Distribution of Surgery Effect and Observed Scores on the Modified Rankin Scale.

The raw distribution of scores for disability on the observed modified Rankin scale at 180 days is shown according to treatment group. Scores on the modified Rankin scale range from 0 to 6, with a score of 1 or lower indicating no or minimal deficit and 6 indicating death.

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Table 3. Safety End Points.*

End Point	Surgery Group (N=150)	Control Group (N=150)	Estimated Difference (95% Credible Interval)	Posterior Probability of Superiority
Death by 30 days — no. (%)	14 (9.3)	27 (18.0)	−8.7 (−16.4 to −1.0)	0.987
Postoperative rebleeding associated with neurologic deterioration — no. (%)†	5 (3.3)	NA		NA
Change in hematoma volume — ml‡	−43.9±30.09	4.0±17.82	−47.91 (−53.59 to −42.36)	>0.999
One or more serious adverse events — no. (%)	95 (63.3)	118 (78.7)	−15.3 (−25.4 to −5.2)	0.998
Death in the hospital after randomization — no. (%)	7 (4.7)	19 (12.7)	−8.0 (−14.5 to −1.8)	0.994

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Table 2. Efficacy End Points.*

End Point	No. of Patients			Value for Surgery Group	Value for Control Group	Estimated Difference (95% Credible Interval)†	Posterior Probability of Superiority‡
	Surgery	Control	Total				
Primary end point							
Mean score on the utility-weighted modified Rankin scale at 180 days§	147	139	286	0.458	0.374	0.084 (0.005 to 0.163)	0.981
Anterior basal ganglia hemorrhage location	40	47	87	0.340	0.381	−0.013 (−0.147 to 0.116)	
Lobar hemorrhage location	99	100	199	0.513	0.371	0.127 (0.035 to 0.219)	
Secondary end points¶							**Odds Ratio (95% Credible Interval)‖**
ICU length of stay — days**	141	132	273	6.9±6.8	9.7±7.6	−2.832 (−4.527 to −1.134)	
Hospital length of stay — days**	141	132	273	14.9±11.2	18.1±11.9	−3.125 (−5.903 to −0.393)	

Conclusions

- MIS surgery, based on ENRICH, shows promise
- Improved patient outcomes
- Patient safety

Thank you

Questions?