Decompressive Craniectomy(DC) in Severe Traumatic Brain Injury(TBI)

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The K-Hotel Apr 26, 2019

Introduction

Traumatic brain injury(TBI)

- **Major public health problem**

  ICP elevation d/t mass effect from hematoma/contusion/swelling…

  Ischemia d/t reduction of cerebral perfusion pressure(CPP)

Decompressive craniectomy(DC)

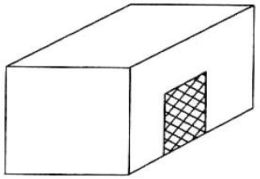
- **Removal of large part of the un-expandable skull**
- Opening of the dura or not

Physiological viewpoints

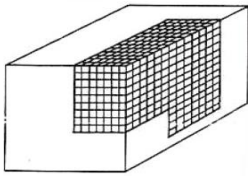
- Helps to **overcome rigid** and **non-compliant nature** of skull/dura mater
- **Reduction of ICP**

History

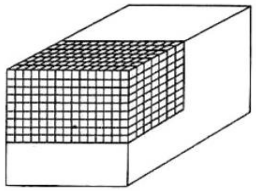
- B.C 4000 Ancient Incas trephined the skull
- Kocher(1901) first proposed DC as surgical decompression in post-traumatic brain swelling
- Cushing(1905) Ranshoff(1971) Kjellberg(1971)



subtemporal CE

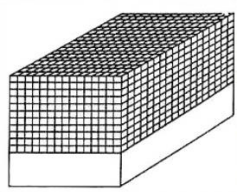


hemicraniectomy

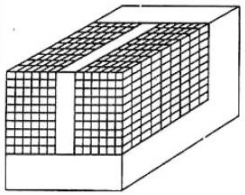


bifrontal CE

Miyazaki(1973) Guerra(1999)



total calvariectomy

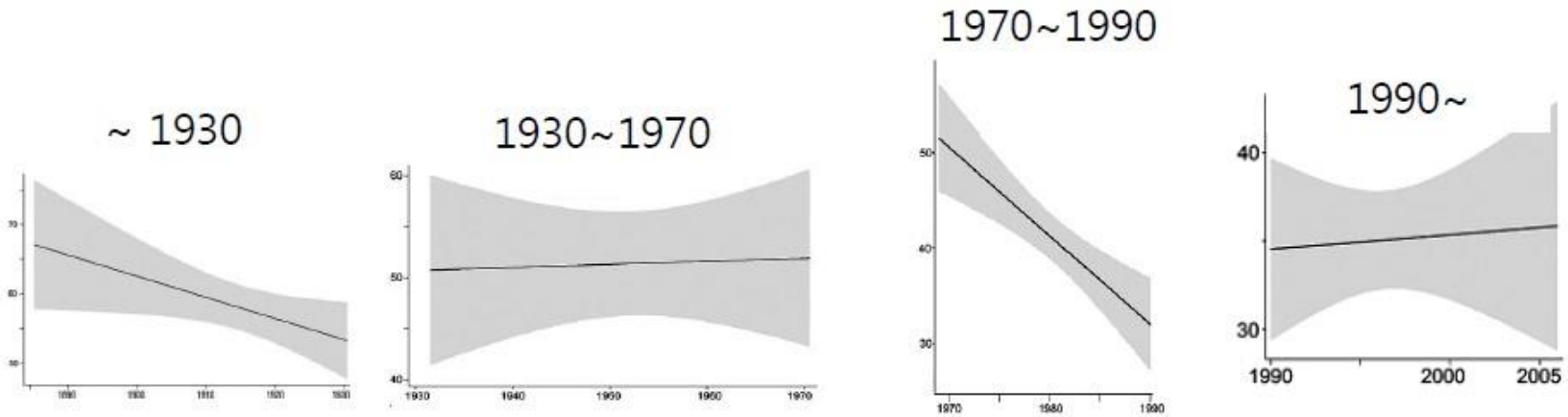


bilateral F-T-P craniectomy

Mortality in TBI

150 Years of Treating Severe Traumatic Brain Injury: A Systematic Review of Progress in Mortality

Sherman C. Stein,[1] Patrick Georgoff,[1] Sudha Meghan,[1] Kasim Mizra,[1] and Seema S. Sonnad[2]



No observed improvement in mortality since 1990

J Neurotrauma 2010

DC in MCA stroke

Clinical Trials of DC for malignant MCA stroke

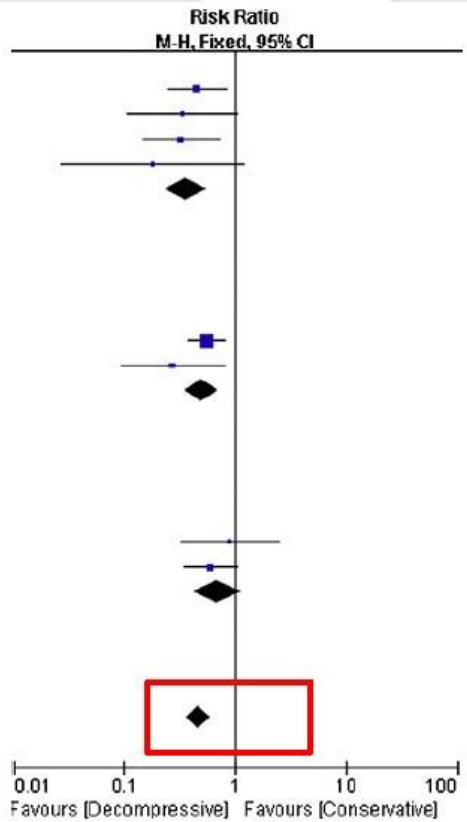
Study	Inclusion criteria	Surgical intervention	*n*	Primary end point	Reason for early termination
DECIMAL[73]	Patients aged 18–55 years, within 24 h of stroke onset, and involvement of more than 50% of the MCA territory on CT or a DWI infarct volume more than 145 cm³	DC performed <6 h after randomization and ≤30 h after the onset of symptoms Mean time from onset of stroke to DC: 20.5 h (95% CI 4.2–36.8)	38	Favourable outcome defined as mRS score ≤3 at 6 months	Survival benefit with DC and consideration that data would be pooled with that of other trials
DESTINY[74]	Patients aged 18–60 years, within 48 h of stroke onset, and involvement of at least two-thirds of MC[illegible]	Onset of symptoms >12 h and <36 h [illegible]	[illegible]	[illegible] months	[illegible] th DC and [illegible] data would [illegible] with that of other trials
HAMLET[72]	Pa[illegible] years, wit[illegible] of stroke onset, and involvement of at least two-thirds of MCA territory	Treatment started within 3 h of randomization Median time from symptom onset to randomization (DC arm): 41 h (IQR 29–50)	64	Favourable outcome defined as mRS score ≤3 at 12 months	Data monitoring committee advised that no statistically significant difference would be found for the primary end point with the planned sample size
Zhao *et al.*[76]	Patients aged 18–80 years, within 48 h of stroke onset, and involvement of at least two-thirds of MCA territory	Mean time from symptom onset to randomization (DC arm): 23.6 h (95% CI 11–36.2)	47	Favourable outcome defined as mRS score ≤4 at 6 months	Safety monitoring committee found a significant difference between the two arms in terms of the primary end point during the third interim analysis

Abbreviations: DC, decompressive craniectomy; DWI, diffusion-weighted imaging; IQR, interquartile range; MCA, middle cerebral artery; mRS, modified Rankin Scale.

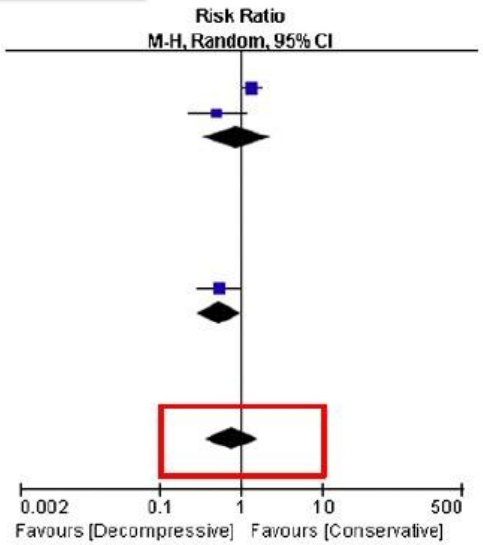
Early DC decrease mortality with mod to severe disability

DC for MCA infarct vs. TBI

DC for MCA infarction



DC for severe TBI



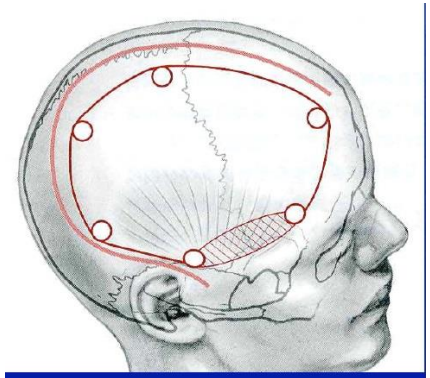
J Clinic Neuroscience 2016

Controversial Issues on DC

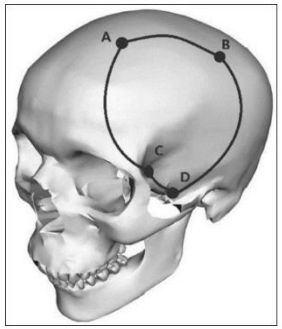
- Decompressive craniectomy in trauma unlike in stroke remains controversial
  - Animal study; cerebral edema /hemorrhagic infarct /cortical necrosis
  - Decreased ICP→ improved CPP/ increased O_2 tension
- There are no class I evidences on DC and outcomes
- Surgical methods are variable but rare comparative studies.
- DC have chances of complications.

No Standardized Methods of DC

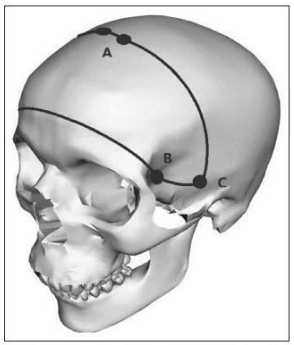
- Sub-temporal decompression; skull beneath the temporal m.
- Circular decompression; limited space but helpful
- Fronto-temporal or temporo-parietal DC
- Large fronto-temporo-parietal DC
  - Improved outcome than routine craniectomy
- Hemisphere craniectomy
- Bifrontal CE in diffuse TBI(Polin technique)
  - ant.roof of orbit / 3-5cm behind coronal S. / temporal base
  - anterior falx division or not / sagittal sinus ligation or division



skin incision & craniectomy

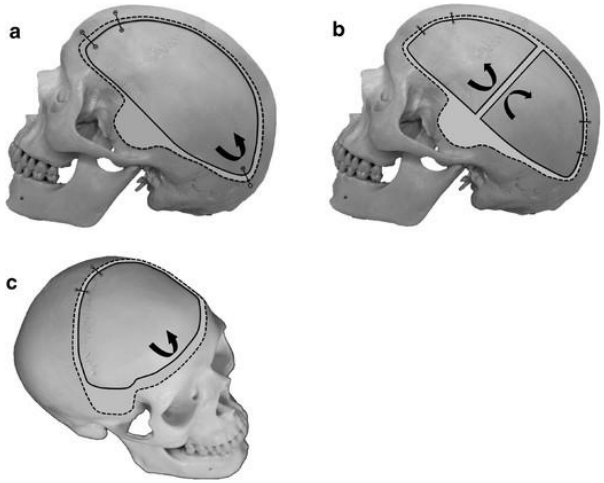


vs.



Additional Methods of DC

- Tucci flap by Keith Tucci (2006)
  - Cranial defect with risk of injury to decrease cortical perfusion
  - Leave the bone flap in position
  - One side secured and plate serving as "hinge"
  - Float skull during intracranial hypertension



- CE c removal of temporalis muscle by Zhang et al
  - Resect the temporalis m. above inf. edge of bone window
  - Average additional space→26.5cm^3

Dura open or Not

- Dura open; increase the risk of secondary surgical complication
  - Herniation through the craniectomy defect
  - Epilepsy
  - Intracranial infection
  - CSF leakage
- Loose closure of dura
  - Expansion of edematous dura into durotomy "bag"
  - Closed scalp without restriction

  ** Ventricular ICP gain by monitoring [Yoo et al (1999)]

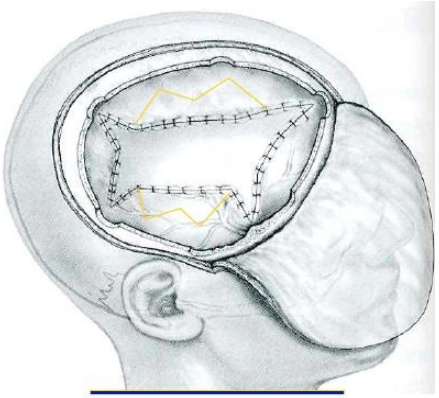
  bilateral craniectomy→ 50.2 ± 16.6%

  duraplasty→ 15.7 ± 16.5%
- DC alone without durotomy; reduce ICP 15%

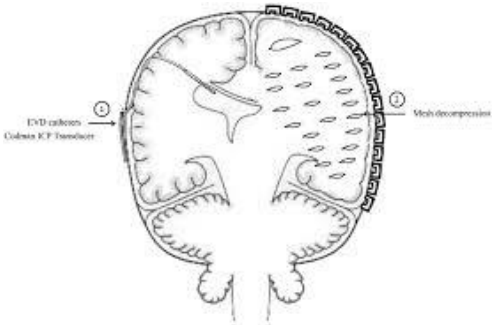
  Duraplasty; reduce additional ICP 55% (Schmidek H 2006)

Technical Considerations

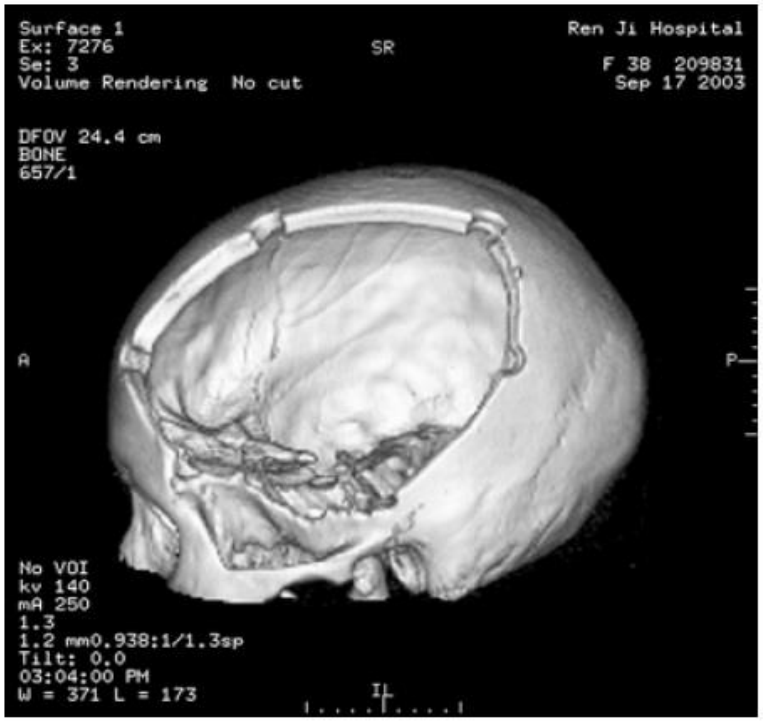
- 2 main methods of dural augumentation c duroplasty
  - Dura is enlarged by pt's own tissue; temporalis fascia
    temporalis muscle
    galea aponeurotica
  - Artificial dura substitute or bovine pericardium

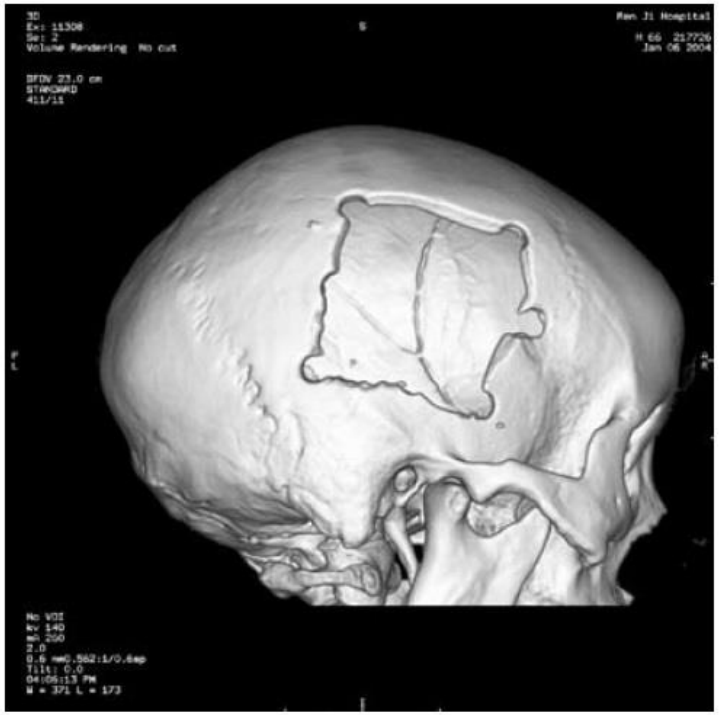


- Dural incisions
  - Stellate fashion; preservation of vessels in dura
    "vascular tunnel" →avoid ischemia
  - Lattice fashion by Mitchell et al
    made a series of dural incisions(2cm long 1cm intervals)
    allow it to stretch and expand



Size of Craniectomy





- Correlated with degree of expansion
  - Small CE; infarction & hemorrhage around craniectomy margin
    * Doubling diameter; 6→ 12cm, increasing volume 9→ 86ml
  - Large CE; decompression of basal cistern & minimize brainstem comp.
    * Out-fracture of middle cranial fossa is important
    ** CE range of 10x15cm + lower margin ~ 1cm from floor of MCF

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Volume 22, Number 6, 2005

Pp. 623–628

Efficacy of Standard Trauma Craniectomy for Refractory Intracranial Hypertension with Severe Traumatic Brain Injury: A Multicenter, Prospective, Randomized Controlled Study

JI-YAO JIANG,[1] WEI XU,[2] WEI-PING LI,[3] WEN-HUI XU,[4] JUN ZHANG,[5] YING-HUI BAO,[1] YU-HUA YING,[1] and QI-ZHONG LUO[1]

- Compare the effect of standard trauma craniectomy(STC) group vs. limited craniectomy (LC) group
- 5 Chinese centers of 486 patients
- 241 pts→ unilateral frontotemporoparietal bone flap (12 x 15cm)
  245 pts→ routine temporoparietal bone flap (6 x 8cm)

TABLE 2. OUTCOMES IN STC AND LC GROUPS

Group	n	*GR/MD*	*SD/PVS*	*Death*
STC	241	96 (39.8%)(96/241)	82 (34.0%)(82/241)	63 (26.2%)(63/241)
LC	245	70 (28.6%)(70/245)	89 (36.3%)(89/245)	86 (35.1%)(86/245)

STC, standard trauma craniectomy; LC, limited craniectomy; GR, good recovery; MD, moderate deficit; SD, severe deficit; PVS, persistent vegetative status.

Complications

More than 50% chances of complications related to this

Margined contusion

Extracranial herniation

Epilepsy

CSF leakage

Subdural effusion

Hydrocephlaus

Syndrome of trephined

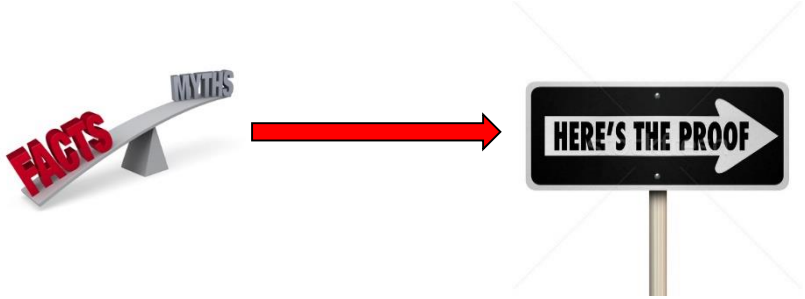
Infection…

TABLE 2 | Types, causes, consequences, and measures to avoid or treat complications.

Types of complications	Causes	Consequences	Measures to avoid or mitigate the complication
Expansion of conservatively managed contusions and appearance of new bleed	Loss of tamponade effect compounding the natural tendency of contusions to progress	Deterioration in sensorium, the need for evacuation	Early and more frequent scans after decompressive craniectomies at 24 and 48 h, especially in patients with contusions and contralateral calvarial fractures
Extracranial cerebral herniation	Brain edema, inadequate size of the craniectomy	Venous compromise at the edge of the craniectomy leading to further bulge and damage	Adequate size of decompressive craniectomy, re-exploration to increase the size of the decompression (rescue decompression), inserting vascular cushion at draining veins
Postoperative epilepsy	Reduced threshold for seizures but not known if the incidence is higher than if the patient has not undergone decompression. Possible effect of stretching of the scar due to sinking scalp flap	Increased metabolic demand, desaturation	Adequate dose of antiepileptic agents, early cranioplasty, as soon as possible (ASAP)
CSF leakage	Brain bulge and inability to perform watertight dural closure	Meningitis	Early detection and resuturing, water tight duraplasty
Subdural effusion	CSF flow abnormality	Usually resolves on its own	The superior and medial margin of the craniotomy should not be closer than 2.5 cm from the midline, early postoperative pressure dressing
Post-traumatic hydrocephalus	CSF flow abnormality	Deterioration, need for CSF diversion	Superior and medial margin of the craniotomy should not be closer than 2.5 cm from the midline; CSF diversion required
Postoperative neurological deterioration due to decompression	Distortion of the white matter tracts	Failure to achieve benefits of decompression	Excessively large decompression
Syndrome of the trephined	Sinking scalp flap due to lack of support and sub-atmospheric pressure causes changes in blood flow and fluid shifts	Multiple new symptoms, delayed deterioration, and failure to hold the gains of initial improvement	Early cranioplasty (ASAP), pull up with external fixator if cranioplasty cannot be done
Postoperative infection	Greater propensity for wound breakdown and CSF leaks	Greater mortality, increase in duration of hospital stay, delay in cranioplasty	Prophylactic antibiotics
Paradoxical herniation	Subatmospheric negative intracranial pressure under the sinking flap and removal of CSF, typically by lumbar puncture.	Deterioration in sensorium and new neurological deficits	Intravenous hydration, Trendelenburg position, blood patch, and early (ASAP) cranioplasty
A higher chance for injury with trivial trauma	Unprotected cranial contents when cranioplasty is delayed	Severe injuries or death	Hinge cranioplasty, early cranioplasty

Evidences before the RCT trials

Still few randomized trials



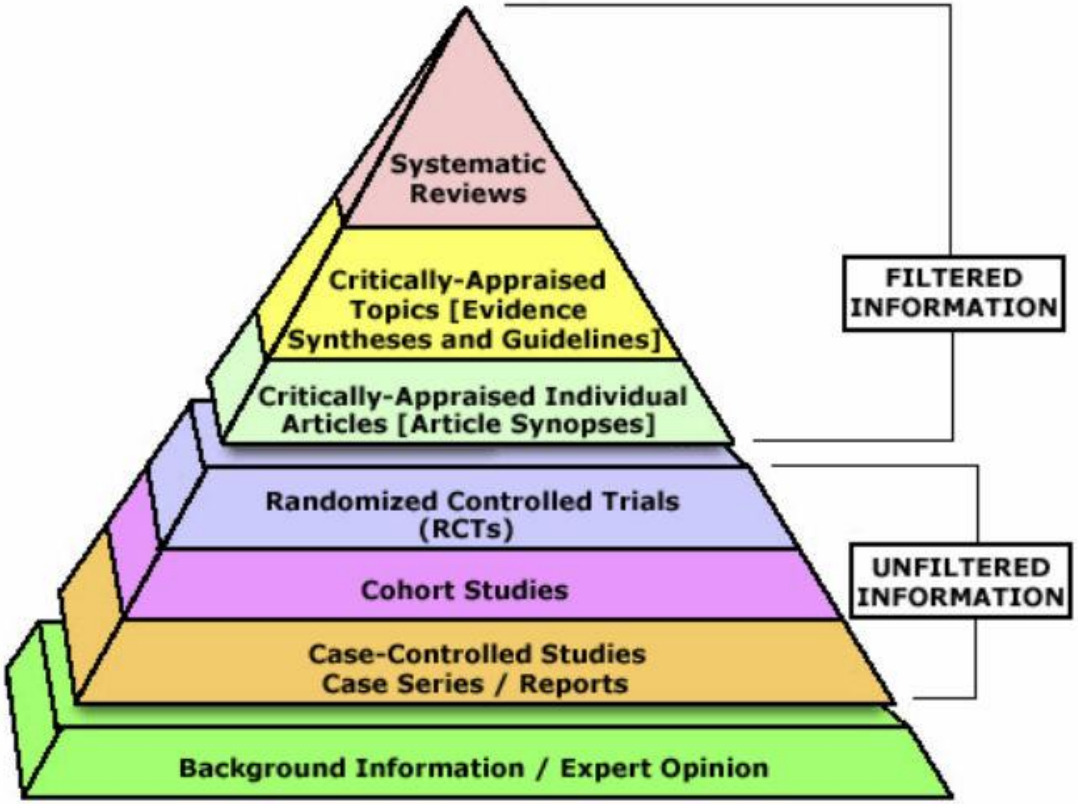
Few evidences to support the **routine use of 2nd DC** to reduce **favourable outcomes** in adults with severe TBI and refractory high ICP

No randomized **historical controls**

May be empirically useful

when maximal medical management has failed to control ICP

Evidence-Based Medicine Pyramid



Systematic Review or Meta-analysis

Table 8 Meta-analysis of Recent Literature Review (past 10 years) of DC for Severe TBI

Study author	Study year	# Patients	Study type	Mortality %	% e-GOS 6–8	FTP crani. %	Complication rate %	% time to DC < 24 h
Timofeev	2006	49	Retro	18	61	16	N/A	56
Aarabi	2006	50	Retro	28	40	98	84	98
Williams	2009	171	Retro	22	56	N/A	36	50
Qui	2009	37	Retro	27	57	100	30	100
Honeybul	2010	147	Retro	18	40	50	77	25
Chibbaro	2010	147	Prospe	23	67	88	23	100
Cooper	2011	73	Prospe	19	30	0	49	100
Nirula	2013	264	Retro	29	N/A	N/A	N/A	N/A
Gouello	2014	60	Retro	28	67	97	13	33
Present study		31	Retro	6	71	100	45	74
Totals	2006–2016	1029	8 retro 2 prospe	23	53	66	45	61

Association of FTP craniectomy with good to excellent outcome (e-GOS of 6–8). Odds Ratio (O.R.) = 0.43, 95 % confidence interval (CI) 0.31–0.60, p = 0.001, z-statistic 4.74

Retro = retrospective; Prospe = prospective; e-GOS 6–8 = good outcome; FTP crani = unilateral frontotemporoparietal craniectomy; DC = decompressive craniectomy

Systematic Review

Evidence-Based Review of Moderate to Severe Acquired Brain Injury | 2013

(ERABI)

ERABI Research
–Toronto/Otawa
– London group

Acute Interventions for Acquired Brain Injury

Levels of Evidence	Level 1a	Level 1b	Level 2	Level 3	Level 4	Level 5	Conflicting
Elevating the head by 30 degrees improves intracranial and cerebral perfusion pressures.			X				
Propofol may help to reduce ICP and the need for other ICP and sedative interventions when used in conjunction with morphine			X				
Infusions of propofol greater than 4mg/kg per hour should be undertaken with extreme caution						X	
Sodium lactate is more effective than mannitol for the management of acute elevations in ICP.		X					
High dose mannitol results in lower mortality rates and better clinical outcomes compared with conventional mannitol.			X				
Early out of hospital administration of mannitol does not negatively affect blood pressure.			X				
Mannitol is effective in lowering intracranial hypertension only when initial ICP values are abnormally elevated.					X		
Midazolam has no effect on ICP.			X				
There is conflicting evidence regarding midazolam effect on MAP and CPP							X
Bolus opioid administration resulted in increased ICP.	X						
The evidence regarding the effects of opioid infusion on ICP levels is conflicting.							X
Remifentanil results in faster arousal compared to hypnotic based sedation.			X				
The use of tromethamine, a weak base and buffer that crosses the blood brain barrier, can offset the deletrious effects of prolonged hyperventilation and lead to better outcomes than hyperventilation alone.			X				
Hyperoxia can counteract the deleterious effects of hyperventilation for the control of ICP following brain injury.					X		
Hyperventilation below 34 torr arterial CO_2 can cause an increase in regionally hypoperfused tissue					X		
Cerebrospinal fluid drainage decreases intracranial pressure in the short term.		X					

	1A	1B	2	3	4	5	conflicting
The efficacy of phentobarbital over conventional ICP management measures has not yet been proven.							X
There is no difference between thiopental and pentobarbital in the control of elevated ICP.			X				
Pentobarbital is not better than mannitol for the control of elevated ICP.			X				
Barbiturate therapy may cause reversible leucopenia, granulocytopenia and systemic hypotension.					X		
A combination of barbiturate therapy and hypothermia may result in improved clinical outcomes up to one year post injury					X		
Standard trauma craniectomy is more effective than limited craniectomy in lowering elevated ICP and leading to better GOS outcome at six months.			X				
Decompressive craniectomy reduces elevated ICP but does not significantly improve clinical outcomes post ABI in children.		X					
Resection of a larger bone flap results in greater decreases in ICP reduction after craniectomy, better patient outcome and leads to fewer post surgical complications.				X			
Hypertonic saline reduces ICP more effectively than mannitol.	X						
Hypertonic saline results in similar clinical outcome and survival when compared with treatment with Ringer's lactate solution up to six months post injury.		X					
Use of hypertonic saline in the ICU, with children, results in a lower frequency of multiple early complications and a shorter ICU stay compared with Ringers's lactate.		X					
Saline solution results in decreased rates of motrality compared with albumin.		X					
Hypertonic saline reduces elevated ICP refractory to conventional ICP management measures.					X		
Hypertonic saline may be useful as a component of a resuscitation algorithm by increasing cerebral oxygenation.					X		
Continuous rotational therapy does not worsen intracranial pressure in severe brain injury patients.					X		
Prone position may increase oxygenation and CPP in ABI patients with acute respiratory insufficiency.					X		
There is conflicting evidence regarding hypothermia's effect on							X

Meta-analysis

SCIENTIFIC REPORTS

OPEN

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Decompressive craniectomy in the management of intracranial hypertension after traumatic brain injury: a systematic review and meta-analysis

Danfeng Zhang, Qiang Xue, Jigang Chen, Yan Dong, Lijun Hou, Ying Jiang & Junyu Wang

2017.08

Danfeng Zhang, Qiang Xue, Jigang Chen, Yan Dong, Lijun Hou, Ying Jiang & Junyu Wang

We aim to perform a systematic review and meta-analysis to examine the prognostic value of decompressive craniectomy (DC) in patients with traumatic intracranial hypertension. PubMed, EMBASE, Cochrane Controlled Trials Register, Web of Science, http://clinicaltrials.gov/ were searched for eligible studies. Ten studies were included in the systematic review, with four randomized controlled trials involved in the meta-analysis, where compared with medical therapies, DC could significantly reduce mortality rate [risk ratio (RR), 0.59; 95% confidence interval (CI), 0.47–0.74, $P < 0.001$], lower intracranial pressure (ICP) [mean difference (MD), −2.12 mmHg; 95% CI, −2.81 to −1.43, $P < 0.001$], decrease the length of ICU stay (MD, −4.63 days; 95% CI, −6.62 to −2.65, $P < 0.001$) and hospital stay (MD, −14.39 days; 95% CI, −26.00 to −2.78, $P = 0.02$), but increase complications rate (RR, 1.94; 95% CI, 1.31–2.87, $P < 0.001$). No significant difference was detected for Glasgow Outcome Scale at six months (RR, 0.85; 95% CI, 0.61–1.18, $P = 0.33$), while in subgroup analysis, early DC would possibly result in improved prognosis ($P = 0.04$). Results from observational studies supported pooled results except prolonged length of ICU and hospital stay. Conclusively, DC seemed to effectively lower ICP, reduce mortality rate but increase complications rate, while its benefit on functional outcomes was not statistically significant.

ICP/mortality rate ↓
Complications ↑
Functional outcome =

Mortality and 6-mo outcome

Study or Subgroup	DC Events	DC Total	NON-DC Events	NON-DC Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.2.1 early-surgery						
Hutchinson 2016	54	201	92	188	69.9%	0.55 [0.42, 0.72]
Qiu 2009	10	37	21	37	15.4%	0.48 [0.26, 0.87]
Taylor 2001	3	13	6	14	4.2%	0.54 [0.17, 1.72]
Subtotal (95% CI)		**251**		**239**	**89.6%**	**0.54 [0.42, 0.68]**
Total events	67		119			
Heterogeneity: Chi² = 0.18, df = 2 (P = 0.91); I² = 0%						
Test for overall effect: Z = 5.06 (P < 0.00001)						
1.2.2 late-surgery						
Cooper 2011	14	73	15	82	10.4%	1.05 [0.54, 2.02]
Subtotal (95% CI)		**73**		**82**	**10.4%**	**1.05 [0.54, 2.02]**
Total events	14		15			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.14 (P = 0.89)						
Total (95% CI)		**324**		**321**	**100.0%**	**0.59 [0.47, 0.74]**
Total events	81		134			
Heterogeneity: Chi² = 3.73, df = 3 (P = 0.29); I² = 20%						
Test for overall effect: Z = 4.60 (P < 0.00001)						
Test for subgroup differences: Chi² = 3.53, df = 1 (P = 0.06), I² = 71.7%						

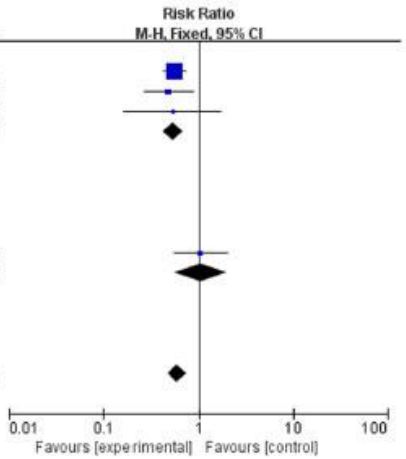


Figure 2. Forest plots for the effect of DC versus NON-DC on overall mortality. DC, Decompressive Craniectomy.

Mortality +

Study or Subgroup	DC Events	DC Total	NON-DC Events	NON-DC Total	Weight	Risk Ratio M-H, Random, 95% CI
2.2.1 early-surgery						
Hutchinson 2016	115	201	123	188	34.1%	0.87 [0.75, 1.02]
Qiu 2009	16	37	25	37	22.8%	0.64 [0.42, 0.99]
Taylor 2001	6	13	12	14	16.0%	0.54 [0.29, 1.01]
Subtotal (95% CI)		**251**		**239**	**72.8%**	**0.74 [0.56, 0.99]**
Total events	137		160			
Heterogeneity: Tau² = 0.03; Chi² = 3.66, df = 2 (P = 0.16); I² = 45%						
Test for overall effect: Z = 2.02 (P = 0.04)						
2.2.2 late-surgery						
Cooper 2011	41	73	34	82	27.2%	1.35 [0.98, 1.88]
Subtotal (95% CI)		**73**		**82**	**27.2%**	**1.35 [0.98, 1.88]**
Total events	41		34			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.82 (P = 0.07)						
Total (95% CI)		**324**		**321**	**100.0%**	**0.85 [0.61, 1.18]**
Total events	178		194			
Heterogeneity: Tau² = 0.08; Chi² = 11.13, df = 3 (P = 0.01); I² = 73%						
Test for overall effect: Z = 0.97 (P = 0.33)						
Test for subgroup differences: Chi² = 7.29, df = [illegible]						

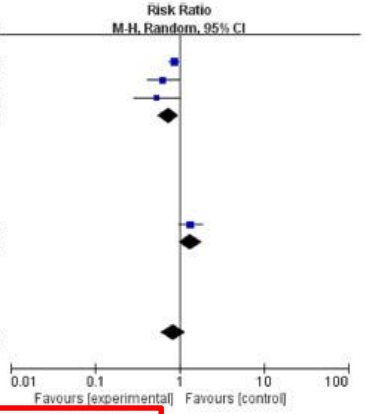


Figure 3. Forest plots for the effect of DC versus NON-DC on GOS scores at 6 months. DC, Decompressive Craniectomy; GOS, Glasgow Outcome Scale.

GOSE 6mo −

ICP /ICU stays / Complications

ICP +

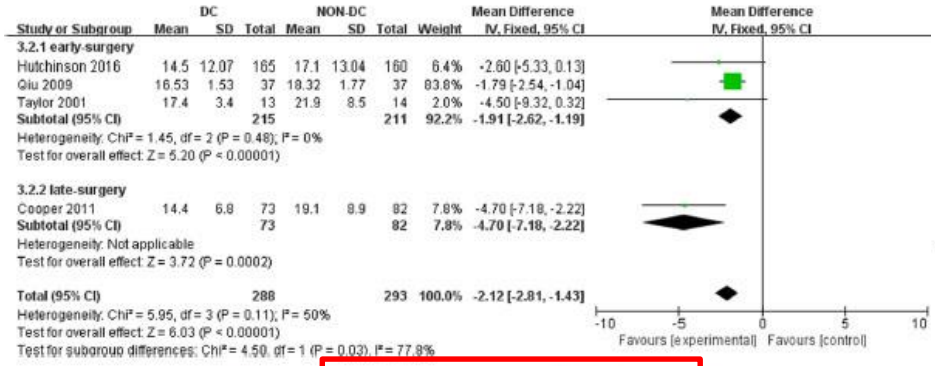


Figure 4. Forest plots for the effect of DC versus NON-DC on ICP reduction. DC, Decompressive Craniectomy; ICP, Intracranial Pressure.

ICU and hospital stays +

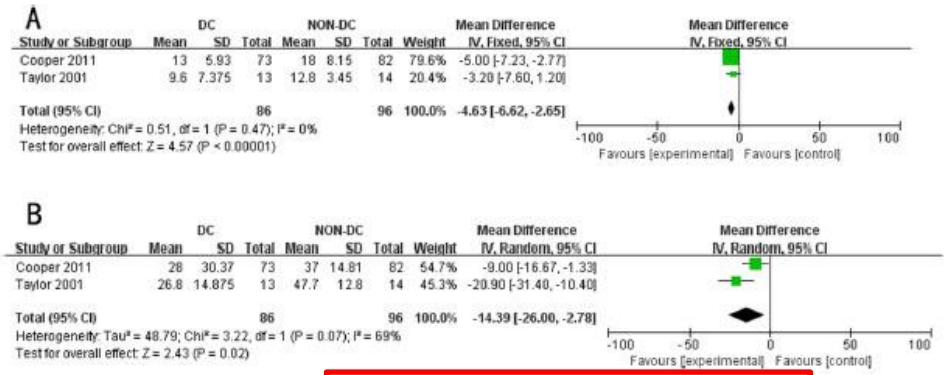


Figure 5. Forest plots for the effect of DC versus NON-DC on length of ICU and hospital stay. (A) length of ICU stay; (B) Length of hospital stay. DC, Decompressive Craniectomy; ICU, intensive care unit.

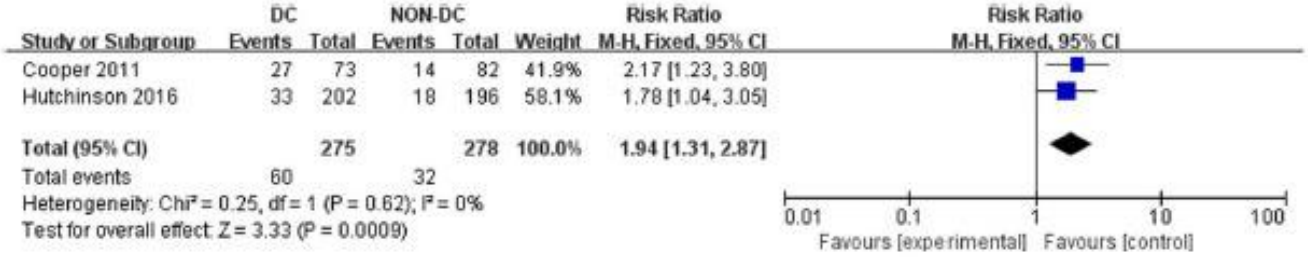


Figure 6. Forest plots for the effect of DC versus NON-DC on complications. DC, Decompressive Craniectomy.

Complications −

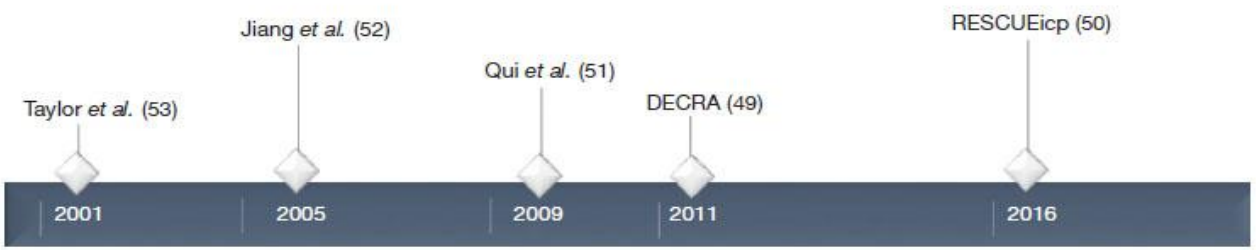
Randomized Controlled Trials (RCT's)

DECRA trial
RESCUEicp trial
STITCH trial
RESCUE_ADH trial

RCT for DC in TBI

Randomized controlled trials for decompressive hemicraniectomy

Study	Type of craniectomy	Treatment groups	Follow up	Conclusions
Hutchinson *et al.* 2016 (50) (RESCUEicp)	Unilateral frontotemporoparietal DC	1. Surgical (N=202) 2. Medical (N=196)	6 mo	Decreased mortality rate, higher morbidity rate with surgical group
Cooper *et al.* 2011 (49) (DECRA)	Bifrontotemporoparietal DC	1. Surgical and standard care (N=73) 2. Standard care alone (N=82)	6 mo	Surgical group had less ICU time and less high ICP. Extended GCS of surgical patients was worse than standard care alone and had a greater risk of unfavorable outcome
Qui *et al.* 2009 (51)	Unilateral DC *vs.* unilateral temporoparietal	1. Unilateral DC (N=37) 2. Unilateral temporoparietal DC (N=37)	1 yr	Improved outcome in larger DC with higher rate of complications
Jiang *et al.* 2005 (52)	Unilateral frontotemporoparietal *vs.* temporoparietal DC	1. Unilateral frontotemporoperietal (N=245) 2. Temporoparietal DC (N=241)	6 mo	Greater mortality in temporoparietal DC
Taylor *et al.* 2001 (53)	Bitemporal craniectomy without dural opening	1. Medical management (N=14) 2. Medical management + DC (N=13)	6 mo	Early decompression results in lower ICP and improved outcome ★



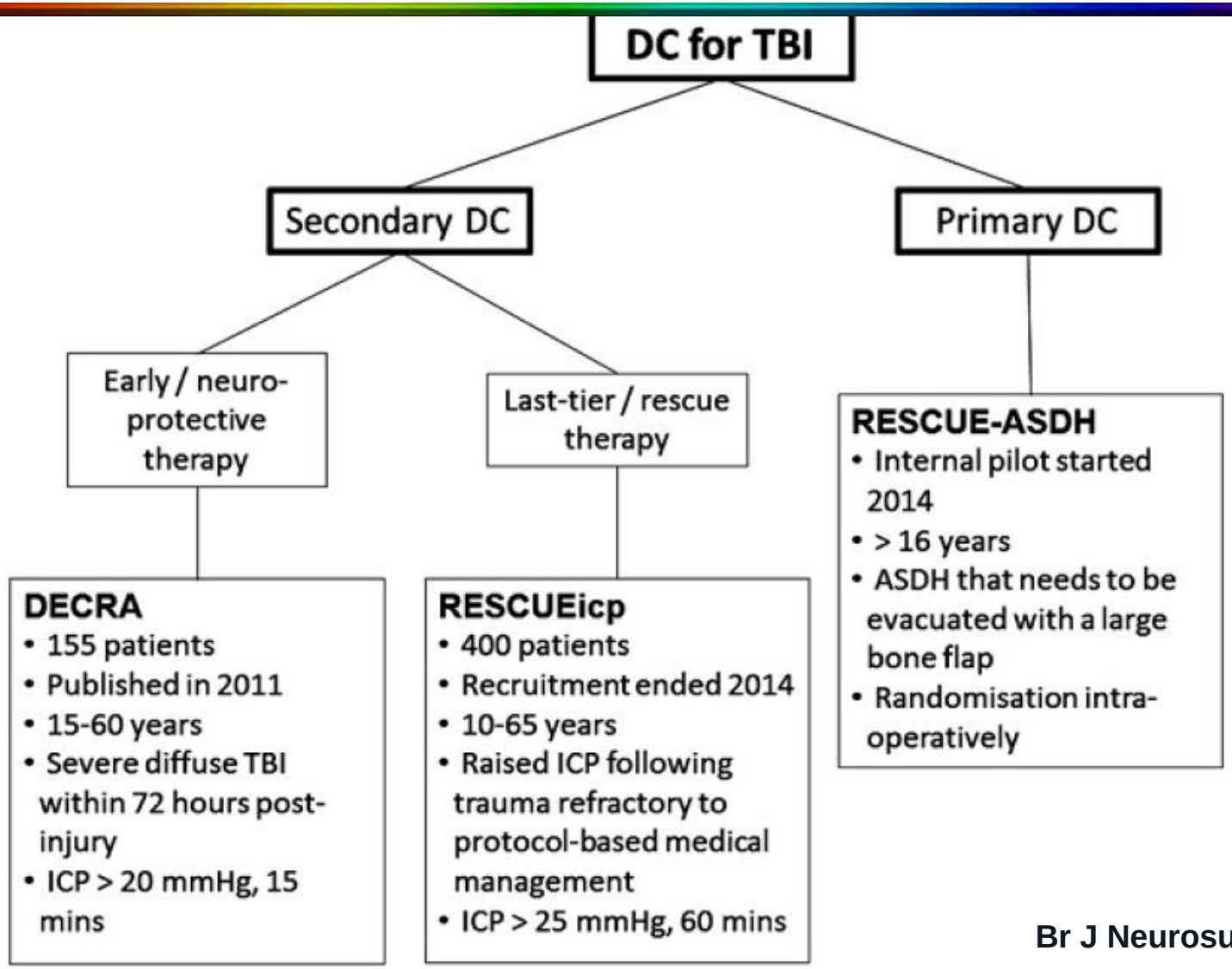
ICP/outcome → ICP/ICU stay → Mortality ↓ Complications ↑

Definitions

- **Primary DC**; large part of skull(bone flap) out after evacuating hematoma in early phase after head injury

- **Secondary DC**; DC undertaken pts who managed in ICU with ICP monitoring
  → as a part of tiered therapeutic protocols
  life-saving Tx aim to control ICP(<25mmHg) and CPP

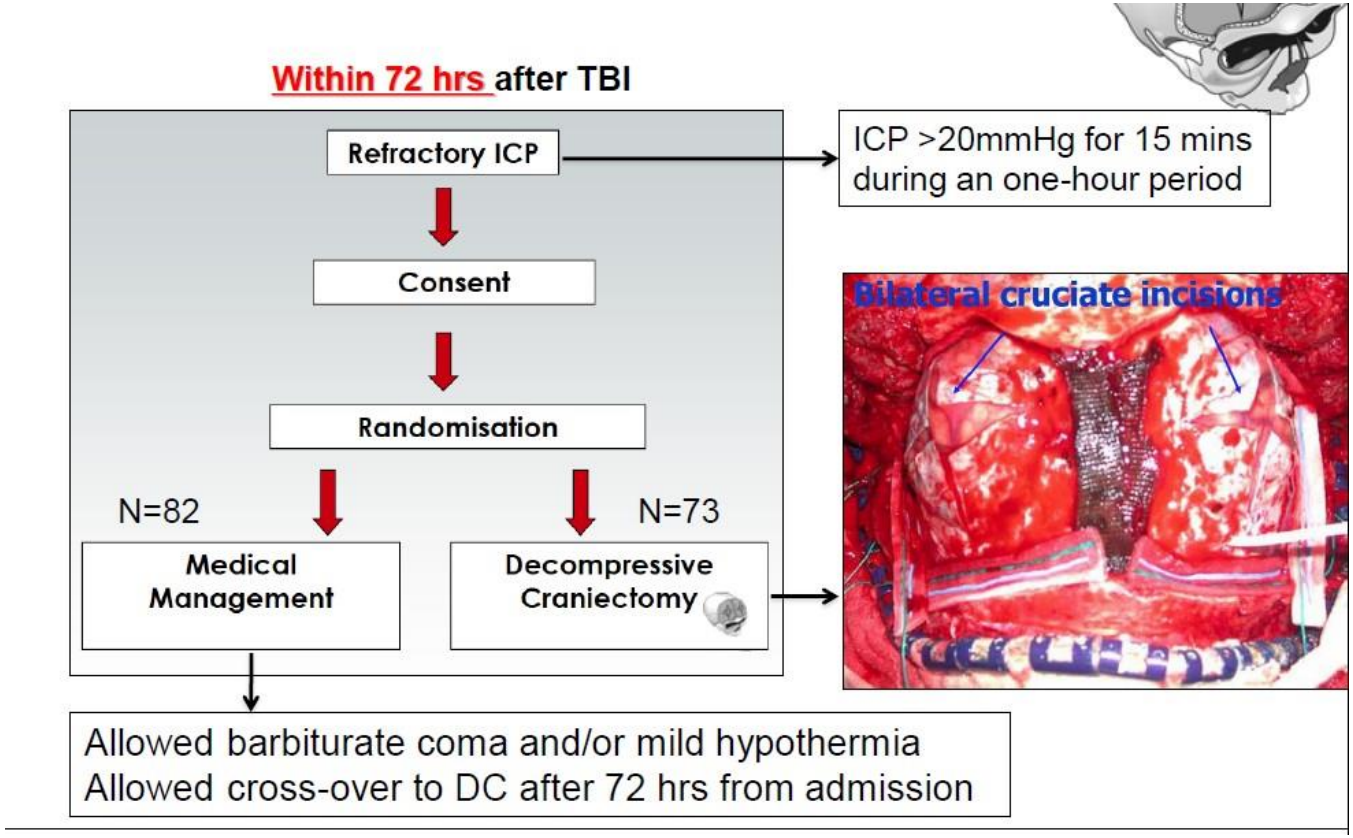
Decompressive Craniectomy



Br J Neurosurg 2016

I. DECRA trial(Australia group)

- 2002-2010 in **Australia, New Zealand and Saudi Arabia**
  155 pts with diffuse TBI



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 21, 2011 VOL. 364 NO. 16

Decompressive Craniectomy in Diffuse Traumatic Brain Injury

D. James Cooper, M.D., Jeffrey V. Rosenfeld, M.D., Lynnette Murray, B.App.Sci., Yaseen M. Arabi, M.D., Andrew R. Davies, M.B., B.S., Paul D'Urso, Ph.D., Thomas Kossmann, M.D., Jennie Ponsford, Ph.D., Ian Seppelt, M
and th

BACKGROUND

It is unclear wi
in patients wi
pressure.

METHODS

From Decemb
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RESULTS

Patients in the
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craniectomy gr
greater risk of
P=0.02). Rates
and the standa

CONCLUSIONS

In adults with
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unfavorable o
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ACTRN012605000009617.)

- **DCE(73) vs Standard Care(82)**

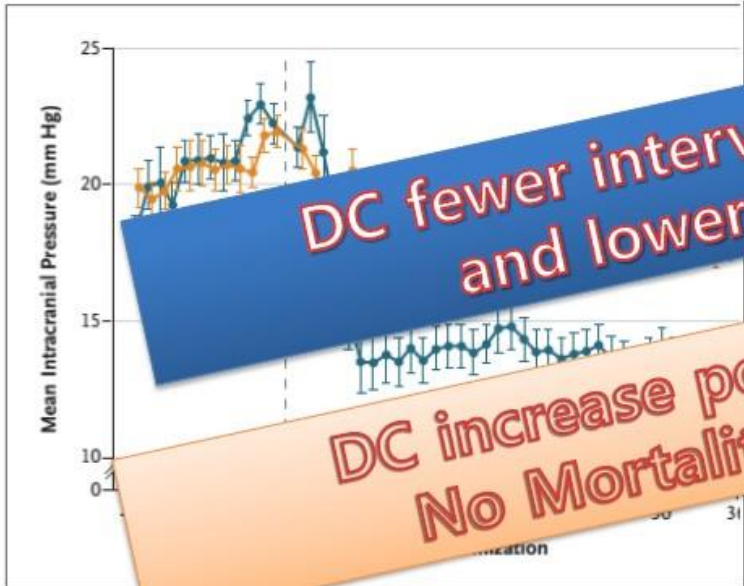

Figure 1. Intracranial Pressure before and after Randomization.
Shown are the mean measurements of intracranial pressure in the two study groups during the 12 hours before and the 36 hours after randomization. The I bars indicate standard errors.

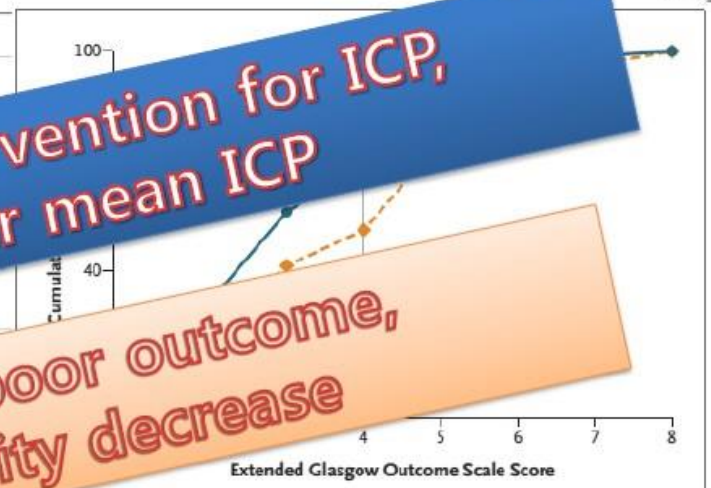

Figure 2. Cumulative Proportions of Results on the Extended Glasgow Outcome Scale.
In this study, an unfavorable outcome was defined as a composite of death, vegetative state, or severe disability, corresponding to a score of 1 to 4 on the Extended Glasgow Outcome Scale, as indicated by the vertical line. According to this measure, an unfavorable outcome occurred in 70% of patients in the craniectomy group and 51% of those in the standard-care group (P=0.02). The cumulative proportion is the percentage of all scores that are lower than the given score.

DC fewer intervention for ICP, and lower mean ICP

DC increase poor outcome, No Mortality decrease

cal
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tracranial hy-
ny decreased
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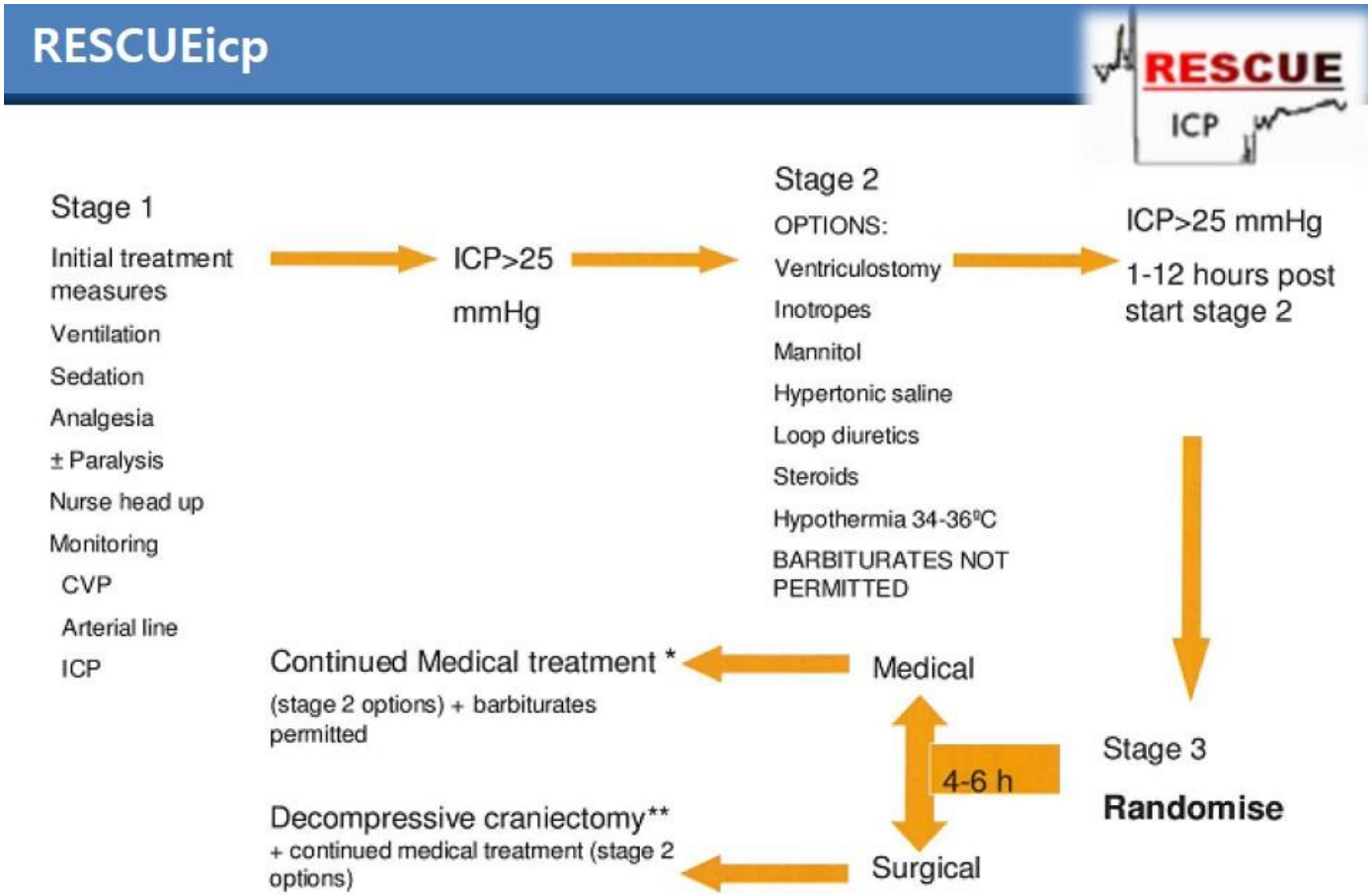
cal Research

Council of Australia and others; DECRA Australian Clinical Trials Registry number, ACTRN012605000009617.)

II. RESCUEicp Trial(Cambridge group)



** Large sample; 400 pts
Ended on 31 Mar 2014 and followed up
Primary end points in 2016

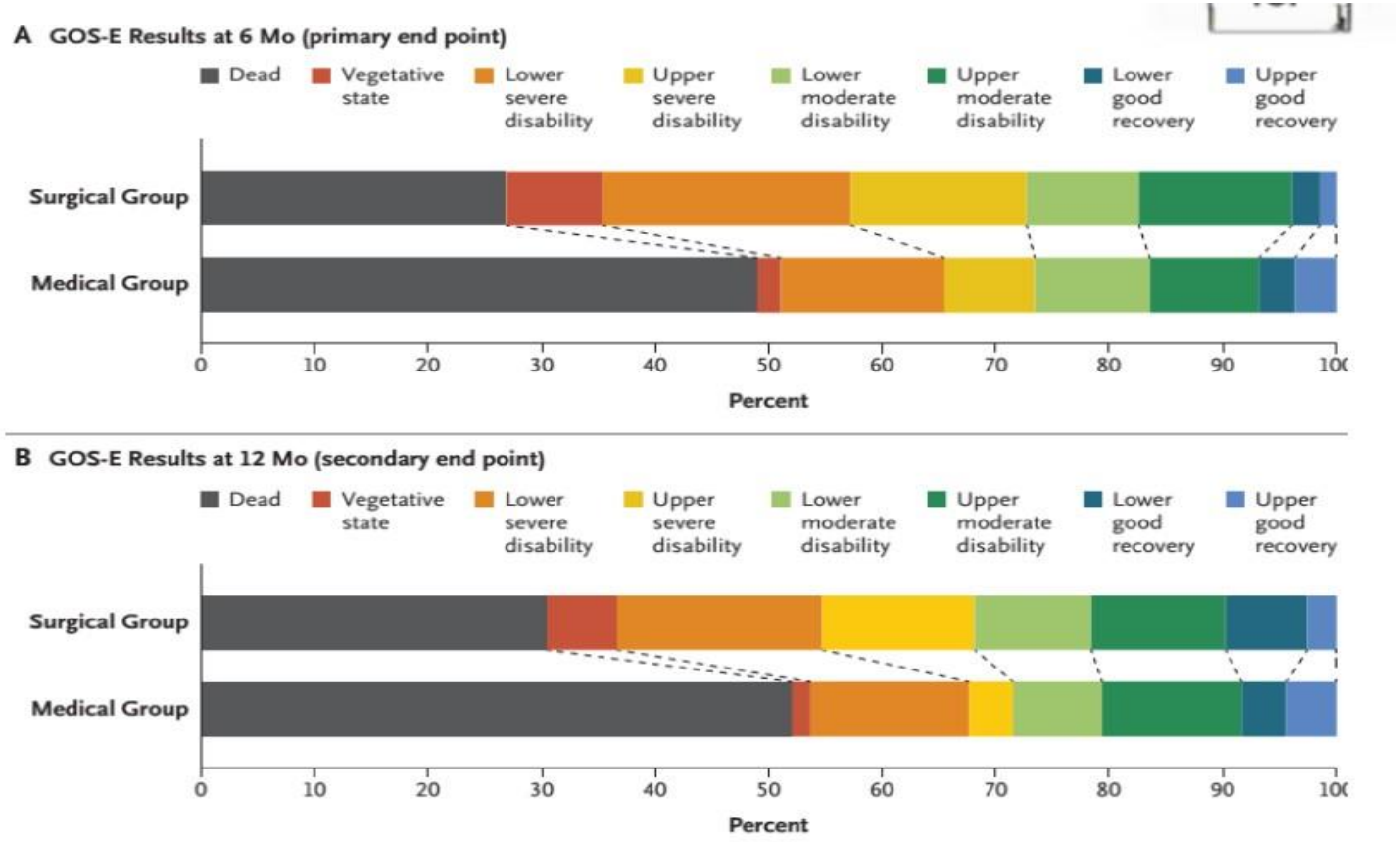
Published Article

ORIGINAL ARTICLE

Trial of Decompressive Craniectomy for Traumatic Intracranial Hypertension

P.J. Hutchinson, A.G. Kolias, I.S. Timofeev, E.A. Corteen, M. Czosnyka, J. Timothy, I. Anderson, D.O. Bulters, A. Belli, C.A. Eynon, J. Wadley, A.D. Mendelow, P.M. Mitchell, M.H. Wilson, G. Critchley, J. Sahuquillo, A. Unterberg, F. Servadei, G.M. Teasdale, J.D. Pickard, D.K. Menon, G.D. Murray, and P.J. Kirkpatrick, for the RESCUEicp Trial Collaborators*

NEJM, 2016



Values in RESCUEicp

- Rapid surgery after randomization
- Allow for provider discretion in clinical decision making within certain limits
  - method of decompression
  - bifrontal (63%), unilateral (37%)
- 37% got surgery / 9% barbiturate
- **DCE lower mortality, but it may not ensure a return to normal functioning.**

DECRA vs. RESCUEicp

	DECRA	RESCUEicp
International multicenter	Australian	British
N	155/3478	398/2008
Years	2002-2010 Apr 2011	2004-2014 Sep 2016
Aim of study	**Early, Neuroprotective**	**Last tier, "rescue" therapy**
Randomization	<72hr	Any time
ICP	20mmHg, 15min	25mmHg, 1-12hr
Primary DC before Randomization	Not allowed	Allowed
Surgery	Bilateral	Bilateral and Unilateral
Real Practice	**Less common**	**More common**
Follow up	6 months	24 months
T-ICH	**excluded**	**included**

III. STITCH(Surgical Trial in T-ICH)

- **Mendelow et al in 2015**

  -multi-center, randomized, parallel group trial

  - hematoma evacuation within 12 hours vs. conservative Tx

  - randomized within 48hours of TBI/T-ICH 10cc ⬆

  - GOS at 6mo

- **Results**

  - total 170 pts were randomized, 31/59 center world-wide

  - 82 pts with complete f-up after initial conservative Tx. To surgery

    40/82 pts→ unfavorable outcome

    Absolute benefit of 10.5%

- **Limitations**

  - small sample size→ premature termination

IV. RESCUE-ASDH trial

- Miller et al; 2/3 of 48 pts with evacuation of ASDH **have raised ICP in post-operative periods**
  → Half of the pts with raised ICP leading herniation & death
  → still showing higher mortality

- Willberg et al; 40% of 101 comatose pts underwent craniectomy **maintaining ICP<20mmHg**
  → 43% of pts have **raising uncontrollable ICP**

- DC vs craniotomy; **retrospective cohort study** of 91pts operated ASDH
  → morbidity 0.75(DC) < 0.90(craniotomy)

British Neurotrauma Group

BNTRC

National Institute for Health Research

RESCUE-ASDH

Randomised **E**valuation of **S**urgery with **C**raniectomy for patients **U**ndergoing **E**vacuation of **A**cute **S**ubdural **H**aematoma

Issue 3, April 2015

RECRUITMENT

- Currently **11** UK centres are open to recruitment and another **10** centres are in set-up.
- The study has recruited **29** patients to date with **16** patients randomised (**R**) and another **13** patients being followed up in an observational cohort (**O**).

OPEN SITES

Site	Date opened	R Cohort	O Cohort
Cambridge	Sept 2014	**6**	**3**
Southampton	Oct 2014	3	4
Plymouth	Dec 2014	1	1
Liverpool	Oct 2014		5
Leeds	Nov 2014	2	
Sheffield	Dec 2014	1	
Middlesbrough	Feb 2015	2	
Birmingham	March 2015		
Royal London	March 2015	1	
St Mary's London	March 2015		
Manchester	March 2015		

SITES in SET UP

Sites initiated & awaiting R&D sign off	Sites awaiting initiation visit	Sites going through R&D review
King's College London	Preston	Newcastle
Bristol	Coventry	St George's London
Oxford	Nottingham	
Cardiff	Brighton	

THANK YOU FOR YOUR HARD WORK AND CONTINUOUS SUPPORT!

RESCUE-ASDH

- **Inclusion Criteria**

  Adult head injured patients(>16 years)

  ASDH on CT scan

  Surgeons feels that **hematoma needs to evacuated** (craniotomy or DC; bone flap at least 11cm)

- **Exclusion criteria**

  Bilateral ASDH

  Prev. enrolled RESCUEicp study

  Severe pre-existing physical or mental disability

RESCUE-ASDH

- **The primary outcome**

  Extended Glasgow Outcome Scale(**GOSE**) at **12mo** post-injury

- **The secondary outcome**

  GOSE at 6 months

  QOL(EQ-5D) at discharge from the ICU/from NS ward

  Length of stay in ICU

  Serious **adverse events** and **surgical complications**

  Re-admission within 1-yr F-up

  Re-operating within 2 weeks after randomization

  Incidence of **hydrocephalus**

  Therapy intensity levels//Economic evaluation

RESCUE-ASDH

- **Analysis**

  "intention-to-treat" basis with proportional odds model

  ~35% in favorable outcome in surgical evacuation of ASDH

  Sample size of 990 pts(495 each arm; 10% drop out)

  8% absolute difference in **favorable outcome**(90%, 2-SD <0.05)

- **Internal pilot study in UK started in Autumn 2014**

  1yr recruitment

  64 pts from 15 UK sites

  57 pts observational study cohort

  21 centers are now open in UK

http://www.rescueasdh.org/contact-us (further information)

Guidelines supported by RCT’s

Brain Trauma FOUNDATION

Concussion Coma Guidelines Research News About Contact Donate

Guidelines for the Management of Severe TBI, 4th Ed.

Back to All Guidelines

To view the Executive Summary of the Guidelines click here.

To view the complete Guidelines, including methods and detailed evidence review, click here.

A searchable index of Guideline recommendations can be found below.

To view the Guidelines on Neurosurgery's website, click here.

Search Guidelines for the Management of Severe TBI, 4th Ed. Submit

Online published
Neurosurgery, September 21, 2016

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VI. Indications for Intracranial Pressure Monitoring

VII. Intracranial Pressure Monitoring Technology

VIII. Intracranial Pressure Thresholds

IX. Cerebral Perfusion Thresholds

X. Brain Oxygen Monitoring and Thresholds

XI. Anesthetics, Analgesics, and Sedatives

XII. Nutrition

XIII. Antiseizure Prophylaxis

XIV. Hyperventilation

XV. Steroids

**28 evidence-based recommendations
14 new
14 not changed

Topics Included in This Edition

The topics are organized in three categories that are specific to severe TBI in adults: treatments, monitoring, and thresholds.

Treatments

1. Decompressive Craniectomy
2. Prophylactic Hypothermia
3. Hyperosmolar Therapy
4. Cerebrospinal Fluid Drainage
5. Ventilation Therapies
6. Anesthetics, Analgesics, and Sedatives
7. Steroids
8. Nutrition
9. Infection Prophylaxis
10. Deep Vein Thrombosis Prophylaxis
11. Seizure Prophylaxis

Monitoring

12. Intracranial Pressure
13. Cerebral Perfusion Pressure
14. Advanced Cerebral Monitoring

Thresholds

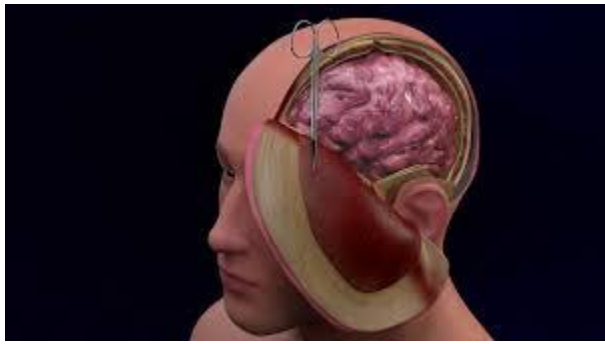
15. Blood Pressure
16. Intracranial Pressure
17. Cerebral Perfusion Pressure
18. Advanced Cerebral Monitoring

Treatment Guidelines

1. **Decompressive Craniectomy (new)**
2. Prophylactic Hypothermia
3. Hyperosmolar Therapy
4. **Cerebrospinal Fluid Drainage (new)**
5. **Ventilation Therapies (←hyperventilation)**
6. Anesthetics, Analgesics, and Sedatives
7. Steroids
8. Nutrition
9. Infection Prophylaxis
10. Deep Vein Thrombosis Prophylaxis
11. Seizure Prophylaxis

Decompressive Craniectomy --New

Recommendations



- ✓ Level I – insufficient evidence
- ✓ **Level IIA**

(1) **Bi-frontal DC**

* Diffuse injury(without mass lesion)

** **ICP >20 mmHg // >15min** for 1 hour non responder to **1st tier Tx.**

→ Not recommend to improve 6mo-GOSE

→ lower ICP // lower ICU stay

(2) **Large F-T-P DC**;

less than 12 x 15 cm or **15 cm diameter**

→ larger flap can reduce mortality & improve neurologic outcome

→ As the **results of the DECRA trial**

Guidelines from Extracted Evidences

Table 1-1. Quality of the Body of Evidence (Depressive Craniectomy)

COMPONENTS OF OVERALL QUALITY – Class 1 and 2								
Topic	**Number of Studies**	**Meta-Analysis**	**Number of Subjects**	**Class of Studies**	**Consistency (High, Moderate, Low)**	**Directness (Direct or indirect)**	**Precision (High, Moderate, Low)**	**Quality of Evidence (High, Moderate, Low, or Insufficient)**
DC vs. initial medical management[14]	1 RCT	NA	155	1	NA	Direct	Low	Moderate
Larger DC vs. smaller DC[15,16]	2 RCTs	No: Different outcomes	560	2	Moderate	Direct	Moderate	Moderate
COMPONENTS OF OVERALL QUALITY – Class 3								
DC vs. craniotomy[17,18]	2 Obser-vational	No	174	3	Moderate	Direct	Low	Insufficient
Timing of DC[19,20]	2 Obser-vational	No	160	3	Low	Direct	Low	Insufficient

Abbreviations: DC=decompressive craniectomy, NA=not applicable, RCT=randomized controlled trial.

Summary

1. **Evidence** guided decompressive craniectomy for TBI is **still challenging**

2. **Systematic reviews or meta-analysis** showed

   Standard craniectomy > limited craniectomy(level 2)

   Large bone flap; ICP reduction+better outcome+few Cx(level 3)

3. **Large randomized controlled trials** mentioned that

   DECRA;gain on **ICP control + ICU stays** but **no functional gain**

   RESCUEicp;lower **ICP** + **decrease mortality**/**high morbidity** rate

   STITCH; **high unfavorable outcome** / **absolute benefit 10.5%**

   RESCUEASDH; Primary DC for pts with ASDH is **being evaluated**

Conclusion

21st century has been marked by efforts to develop evidence base for DC following TBI

Current evidence suggests

1. **Early (neuroprotective) bi-frontal DC** is **not superior to medical Tx in diffuse TBI**
2. **Secondary DC as a last-tier therapy** for severe & refractory high ICP is subject of the RESCUEicp study
3. **Primary DC for pts with ASDH is being systemically evaluated** in the context of the RESCUE-ASDH trial

In the view of evidence, number of **complications** with DC

→ indiscriminate use of DC for TBI is not appropriate


Thank You For Attention !!