實證醫學討論會

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日期:102.04.15

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Outline

- Analysis
- Asking
- Acquire
- Appraisal
- Apply
- Audit

Step I

Analysis 分析臨床場景(Clinical Scenario)

Clinical Scenario

Patient profile:

- Age: 7-month-old - Gender: Female

Medical history:

- The girl is a patient of acute myeloblastic leukemia, received chemotherapy under TPOG AML protocal since 1 month ago.
- This time, the patient was admitted due to neutropenic fever.
- During the 1st week of admission, vital sign was stable under antibiotic treatment.

Clinical Scenario

- However, on the 8th day of admission, poor activity and appetite were noted. Frequent vomiting was found even under emetics.
- At midnight, conscious level revealed drowsy. Heart rate decreased to 120 beats per minutes. Blood pressure elevated up to 130/100mmHg. Sunset eye and tense fontanel were observed.
- Emergent CT was arranged.

Clinical Scenario

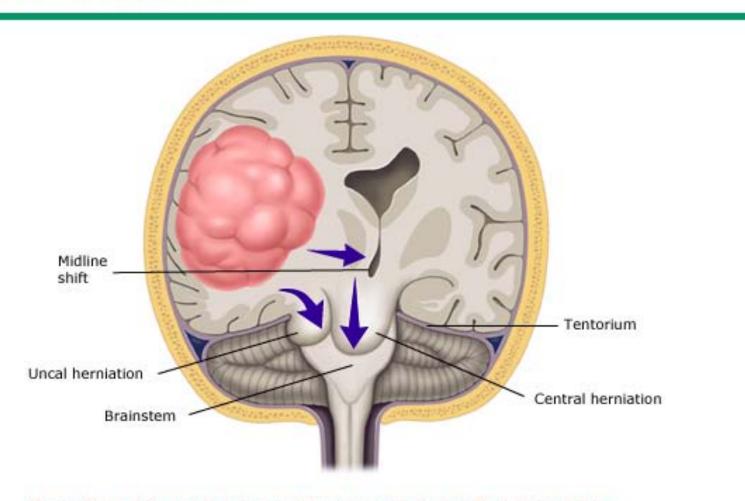
- Under the impression of hydrocephalus with increased intracranial pressure, neurosurgeon was consulted for VP shunt insertion.
- Before the operation, osmotherapy with mannital was arranged. However, even under the maximum dose of mannital, bradycardia was still found. Mild dilatation of bilateral pupil was also noticed.

Step 2

Asking 提出background questions及foreground questions

Background

Transtentorial herniation



Clinical Signs of Central Transtentorial Hemiation with Rostral-Caudal Deterioration



Intracranial hypertension

Caucag of intracranial hyportonoion

Causes of intracranial hypertension				
Traumatic brain injury/Intracranial hemorrhage				
Subdural, epidural, or intraparenchymal hemorrhage				
Ruptured aneurysm				
Diffuse axonal injury	9			
Arteriovenous malformation or other vascular anomalies				
Central nervous system infections (eg, encephalitis, meningitis, abscess)				
Ischemic stroke				
Neoplasm				
Vasculitis				
Hydrocephalus				
Idiopathic intracranial hypertension (pseudotumor cerebri)				
Idiopathic				

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Background

- □ CBF = (CAP JVP) ÷ CVR
 - Cerebral blood flow (CBF)
 - Carotid arterial pressure (CAP)
 - Jugular venous pressure (JVP)
 - Cerebrovascular resistance (CVR)
- CPP = MAP ICP
 - Cerebral perfusion pressure (CPP)
 - adults: 50 to 70 mmHg
 - Children: 50 to 60 mmHg
 - Arterial pressure (MAP)
 - Intracranial pressure (ICP)

Background question

- How to treat intracranial hypertension?
 - Mannitol
 - Hypertonic saline
 - Hyperventilation
 - CSF drainage
 - Barbiturates coma
 - Corticosteroid

Foreground question by PICO

Р	pediatric patient with intracranial hypertension
I	Hypertonic saline
С	mannitol
0	Reducing intracranial pressure

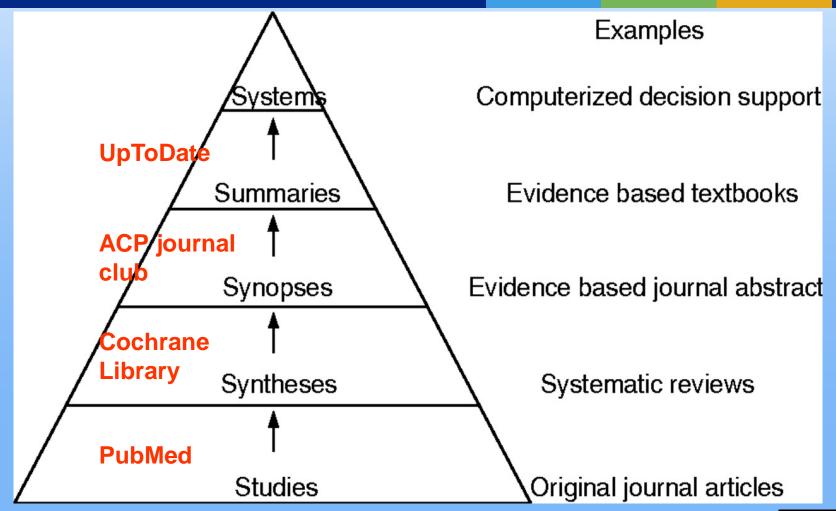
Q: Is hypertonic saline more effective than mannital for intracranial pressure (ICP) control in pediatric patient?

Step 3

Acquire

搜尋資料:包括keywords and search strategy

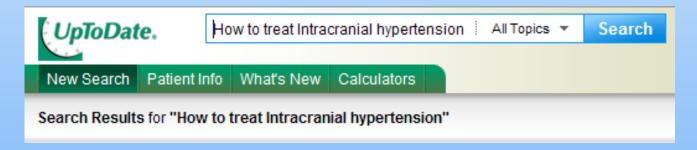
Search strategy: 5S model







Database: UpToDate



Keyword:

Elevated intracranial pressure in children



Article

Elevated intracranial pressure in children

MANAGEMENT

- General measures
- Specific measures
- Mannitol
- Hypertonic saline
- Hyperventilation
- CSF drainage
- Barbiturate coma
- Corticosteroids

EXPERIMENTAL THERAPIES

- Hypothermia
- Indomethacin

CONTRAINDICATED THERAPIES

SUMMARY AND

RECOMMENDATIONS

REFERENCES

GRAPHICS View All

ALGORITHMS

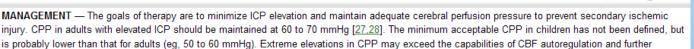
 Management of suspected meningitis in children

DIAGNOSTIC IMAGES

CT findings in elevated ICP

FIGURES

- Intracranial compensation for mass
- · Intracranial pressure volume and ICP
- · Cerebral autoregulation in hypertension
- Transtentorial herniation



The best therapy for elevated ICP is resolution of the underlying cause. Regardless of the cause, ICH is a medical emergency, and treatment should be undertaken as expeditiously as possible. Early neurosurgical consultation should be obtained to assist with management decisions regarding the excision of mass lesions, ICP drainage, and ICP monitoring [1,5,22].

Therapy usually follows a stepwise progression of interventions that have an increasing risk of adverse effects [29].

General measures — Some general measures of therapy for elevated ICP have a low risk of adverse effects and can be used in all patients. The vital signs, including temperature, of all patients should be continuously monitored.

These measures include:

increase ICP.

- Rapid treatment of hypoxia, hypercarbia, and hypotension, since even brief derangements in these parameters can adversely affect outcome [21,22]. Isotonic fluids (eg, 0.9 percent [normal] saline) should be administered to patients to maintain adequate MAP; if this fails, infusions of dopamine or norepinephrine can be initiated [22,28,30].
- Elevation of the head of the bed from 15 to 30 degrees; mild head elevation can lower ICP without adversely affecting MAP or CPP [22.28.31]; elevation greater than 40 degrees may decrease CPP.
- Aggressively treating fever with antipyretics and cooling blankets, since hyperpyrexia increases cerebral metabolism and increases CBF, further elevating ICP [22].
- Controlling shivering in intubated patients with muscle relaxants (eg, vecuronium, rocuronium).
- Administering prophylactic phenytoin or phenobarbital to patients who are at high risk of developing seizures (eg, those who have parenchymal abnormalities, depressed skull fractures, or severe traumatic brain injuries). Seizures are associated with increases in ICP [32]. Breakthrough seizures are best treated with benzodiazepines (see "Management of status epilepticus in children").
- Maintaining adequate analgesia to blunt the response to noxious stimuli [5].







Summary

- How to treat Intracranial hypertension?
 - Mannitol
 - Hypertonic saline
 - Hyperventilation
 - CSF drainage
 - Barbiturates coma
 - Corticosteroid

Summary

Mannitol

- Increasing the osmotic gradient between plasma and parenchymal tissue, resulting in a net reduction in brain water content.
- Decrease ICP and Improve CPP
- Potential side effects
 - Hyperosmolarity
 - hypovolemia
 - electrolyte imbalance
 - acute renal failure
 - may cross the injured BBB at the site of the cerebral lesion and cause an exacerbation of cerebral edema.

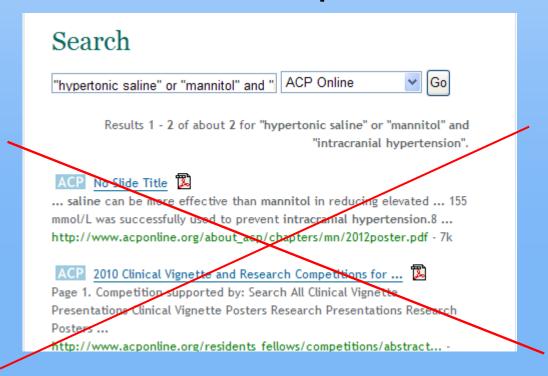


Hypertonic saline

- Establishing an osmotic gradient that reduces brain water content.
- Benefits:
 - does not cause profound osmotic diuresis
 - the risk of hypovolemia as a complication is decreased
 - Restoration of normal cellular resting membrane potential and cell volume
 - inhibition of inflammation
 - enhancement of cardiac output
- Complications:
 - Rebound increased ICP
 - renal insufficiency is associated with serum osmolality >320 mOsm/L
 - Hyperosmolality?
 - osmotic demyelination syndrome (central pontine myelinolysis)?
 - heart failure?
- The optimal dose and form of administration have not been identified.

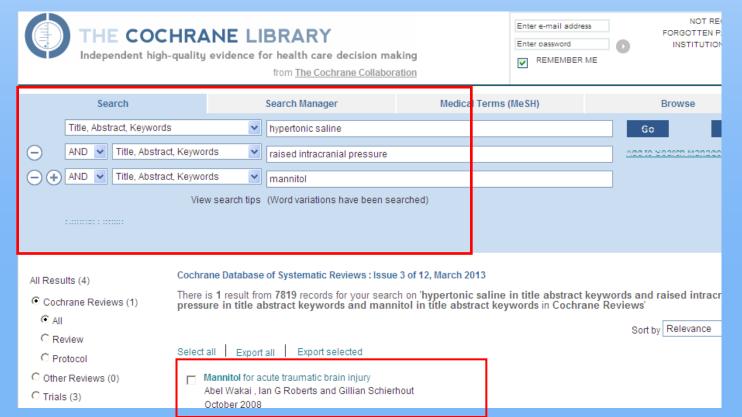


- Database: ACP Journal Club
- Keyword: hypertonic saline or mannitol for increased Intracranial pressure in children





- Database: The Cochrane Library
- Keyword: hypertonic saline and raised intracranial pressure and mannitol





[Intervention Review]

Mannitol for acute traumatic brain injury

Abel Wakai1, Ian G Roberts2, Gillian Schierhout3

Editorial group: Cochrane Injuries Group.

Publication status and date: Edited (no change to conclusions), published in Issue 4, 2008.

Review content assessed as up-to-date: 28 February 2006.

Citation: Wakai A, Roberts IG, Schierhout G. Mannitol for acute traumatic brain injury. Cochrane Database of Systematic Reviews 2007, Issue 1. Art. No.: CD001049. DOI: 10.1002/14651858.CD001049.pub4.

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Syntheses

□Main results

We identified four eligible randomised controlled trials.

One trial compared ICP-directed therapy to 'standard care'

(RR for death =0.83; 95% CI 0.47 to 1.46).

One trial compared mannitol to pentobarbital

(RR for death = 0.85; 95% CI 0.52 to 1.38).

One trial compared mannitol to hypertonic saline

(RR for death = 1.25; 95% CI 0.47 to 3.33).

One trial tested the effectiveness of pre-hospital administration of mannitol against placebo. (RR for death = 1.75; 95% CI 0.48 to 6.38).

□Conclusions

Mannitol therapy for raised ICP may have a beneficial effect on mortality when compared to pentobarbital treatment, but may have a detrimental effect on mortality when compared to hypertonic saline. ICP-directed treatment shows a small beneficial effect compared to treatment directed by neurological signs and physiological indicators. There are insufficient data on the effectiveness of prehospital administration of mannitol.

Studies

- Database: PubMed
- Keyword:
 - "intracranial hypertension" AND mannitol AND "hypertonic saline" AND treatment
- Filters activated: English Abstract, Clinical Trial, Meta-Analysis, Review, Full text available, published in the last 5 years, Humans, (Child: birth-18 years=0)
- Result: 14 articles



Related citations

	Ó	sults: 14 Filters activated: English Abstract, Clinical Trial, Meta-Analysis, Review, Full text available, published in the to 5 years, Humans Clear all
	1.	PRO: osmotherapy for the treatment of acute intracranial hypertension. Grape S, Ravussin P. J Neurosurg Anesthesiol. 2012 Oct;24(4):402-6. doi: 10.1097/01.ana.0000419729.52363.64. Review. PMID: 22955194 [PubMed - indexed for MEDLINE] Related citations
A	2.	Osmotherapy for intracranial hypertension: mannitol versus hypertonic saline. Fink ME. Continuum (Minneap Minn). 2012 Jun;18(3):640-54. doi: 10.1212/01.CON.0000415432.84147.1e. Review. PMID: 22810253 [PubMed - indexed for MEDLINE] Related citations
	3.	Hypertonic saline for treating raised intracranial pressure: literature review with meta-analysis. Mortazavi MM, Romeo AK, Deep A, Griessenauer CJ, Shoja MM, Tubbs RS, Fisher W. J Neurosurg. 2012 Jan;116(1):210-21. doi: 10.3171/2011.7.JNS102142. Epub 2011 Sep 23. Review. PMID: 21942722 [PubMed - indexed for MEDLINE] Related citations
	4.	Hypertonic saline versus mannitol for the treatment of elevated intracranial pressure: a meta- analysis of randomized clinical trials. Kamel H, Navi BB, Nakagawa K, Hemphill JC 3rd, Ko NU. Crit Care Med. 2011 Mar;39(3):554-9. doi: 10.1097/CCM.0b013e318206b9be. PMID: 21242790 [PubMed - indexed for MEDLINE]

No children



Hypertonic saline for treating raised intracranial pressure: literature review with meta-analysis

A review

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Level of evidance

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research	
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non- independent reference standard
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Background

- In 1988 Worthley et al. first reported the use of HTS to reduce ICP in 2 patients who were unresponsive to mannitol.
- Since then, more recent studies have suggested that HTS is possibly more effective than mannitol for the reduction of ICP.
- Also, the side effect profile of HTS appears to be more favorable than that of mannitol.

Background

- Hypertonic saline improves mean arterial pressure and increases circulating blood volume without the delayed hypotensive effect observed with mannitol use.
- Unfortunately, appropriate guidelines for the use of HTS have not been developed; indications for use, dosing, and timing of use still vary widely among institutions.
- Therefore, the present review was undertaken for a better understanding of the efficacy of these 2 treatments of raised ICP.



TABLE 1: Literature search for articles about HTS treatment for ICP

key words used in online PubMed literature search

hypertonic saline and intracranial pressure

hypertonic saline and intracranial hypertension

hypertonic saline and traumatic brain injury

hypertonic saline and subarachnoid hemorrhage

hypertonic saline and neurosurgery

results of search

787 articles located initially*

281 duplicates eliminated

38 excluded due to foreign language

- 127 excluded because unrelated to neurosurgery
 - 134 excluded because unrelated to HTS's effects on cerebral hemodynamics

7 excluded because blood pressure used as primary therapy goal

4 excluded because of lack of ICP monitoring

67 animal studies excluded

88 review/opinion articles excluded

41 studies remained for inclusion

Includes 1 additional study located from review article.



TABLE 2: Literature grouped by study design*

Case Reports	Retro Studies†	Prospective Observational Studies	Prospective RCTs	Prospective Nonrandomized Study
Worthley et al., 1988	Qureshi et al., 1998 ³²	Härtl et al., 1997	Fisher et al., 1992	Oddo et al., 2009
Qureshi et al., 199831	Suarez et al., 1998	Schatzmann et al., 1998	Simma et al., 1998	
Berger et al., 2002	Qureshi et al., 1999	Horn et al., 1999	Schwarz et al., 1998	
Saltarini et al., 2002	Peterson et al., 2000	Khanna et al., 2000	De Vivo et al., 2001	
Einhaus et al., 1996	Larive et al., 2004	Munar et al., 2000	Vialet et al., 2003	
	Ware et al., 2005	Schwarz et al., 2002	Harutjunyan et al., 2005	
	Yildizdas et al., 2006	Tseng et al., 2003	Battison et al., 2005	
	Bentsen et al., 2008	Bentsen et al., 2004	Bentsen et al., 2006	
	Koenig et al., 2008	Al-Rawi et al., 2005	Francony et al., 2008	
	Kerwin et al., 2009	Huang et al., 2006	Ichai et al., 2009	
		Lescot et al., 2006		
		Tseng et al., 2007		
		Rockswold et al., 2009		
		Al-Rawi et al., 2010		
		Bourdeaux & Brown, 2010		

^{*} Retro = retrospective.

[†] No distinction was made between retrospective observational studies and retrospective comparison trials. Prospective studies were considered observational if effects of a treatment were evaluated over time but not compared with another treatment.



Data Extraction

- Its design, objective, number of patients, concentration of HTS used, method of delivery, timing of measurements, main results of the study, and follow-up results.
- The outcomes assessed included ICP, CBF, brain tissue oxygen, brain water content, and GOS score.



Meta-Analysis Method

- Homogeneity-based method of meta-analysis
 - Review Manager for Windows (version 5, Cochrane Collaboration and Update Software) for prospective RCTs.
- Homogeneity between studies
 - the standard Cochran Q statistic and I2 statistic.
- Fixed-effect model
 - merge odds ratio values
 - estimate the overall effect size.
- Overall effect, odds ratio, and confidence interval were presented.

Result

TABLE 3: Studies of HTS versus mannitol*

Authors & Year	Study Design	No. of Pts	Neuro/Mortality Outcome
Ichai et al., 2009	RCT	34	better 1-yr GOS scores in HTS group
Francony et al., 2008	RCT	20	unspecified
Harutjunyan et al., 2005	RCT	32	59% survival in HTS/HES group, 40% survival in mannitol group
Battison et al., 2005	RCT, crossover	9	GOS Score 5 in 3 pts & Score 3 in 6 pts at discharge
Vialet et al., 2003	RCT	20	no difference in mortality rate or 90-day neuro outcome
De Vivo et al., 2001	RCT	30	GOS Score 1 in 22 pts & Score 2 in 8 pts at discharge
Schwarz et al., 1998	RCT, crossover	9	3 pts w/ 2-wk GOS Score 5, other 6 pts w/ GOS Score 3
Oddo et al., 2009	prospective nonrandomized crossover	12	4 pts died
Kerwin et al., 2009	retro crossover	22	unspecified
Yildizdas et al., 2006	retro crossover	67	lower mortality rate & duration of comatose state in HTS group com- pared w/ mannitol group
Ware et al., 2005	retro	13	upper mod disability in 31%; lower mod disability in 8%; 31% died; 31% lost to FU (by 6-mo EGOS score)
Larive et al., 2004	retro crossover	28	21% died; median hospital stay 14 days

^{*} FU = follow-up; mod = moderate; Neuro = neurological; pts = patients.



- 9 of the 12 comparisons between HTS and mannitol, including 7 RCTs, suggested that HTS provides superior control of ICP over mannitol.
 - A greater reduction in ICP after addition of HTS than after mannitol in the minutes to hours after fluid administration was found in 6 trials.
- Outcomes were not consistent among trials.
 - In I RCT consisting of 34 patients, better 1-year GOS scores were seen in the HTS group.
 - Better outcomes were also seen in a retrospective study consisting of 67 patients. The HTS group had a <u>lower mortality rate</u> and <u>shorter duration of comatose state</u> than patients who received mannitol.
 - However, another RCT consisting of 20 patients did not demonstrate any difference in mortality rate or 90-day neurological outcome between the HTS group and the mannitol group, despite showing a better ICP control with HTS.
 - Changes in mean arterial pressure varied between studies after both mannitol and HTS; however, no significant risk of hypotension was seen in any study after either mannitol or HTS.



TABLE 9: Studies in pediatric patients*

Authors & Year	Study Design	Study Description	No. of Pts	Concentration of HTS	Bolus vs Cont Inf	Fluid Administration	Results
Simma et al., 1998	prospective RCT	HTS vs LR in pts w/ GCS score <8; ICP spikes >15 mm Hg treated w/ standard therapies including mannitol	32	268 mmol/L Na (1.5%)	∞nt inf	given over 72 hrs to maintain serum Na at 145–150 mmol/L	no difference in mean ICP btwn groups; 2: more ICP spikes requir- ing intervention in LR group; 3: in- verse correlation btwn serum Na & ICP
Fisher et al., 1992	prospective RCT, crossover	HTS vs NS for intracranial hyper- tension refractory to standard therapies including mannitol	18†	3%	10 ml/kg (6.5–8.5 ml/kg in 3 pts)	given when ICP >15 or CPP <50 mm Hg; 2nd episode treated w/ opposite study fluid (avg of 22 hrs after trauma)	avg ICP < baseline after HTS but not after NS during 2 hrs postinfu- sion; 2: ICP increased in 6 HTS trials
Khanna et al., 2000	prospective ob- servational	HTS for intracranial hypertension refractory to standard therapies including mannitol	10	3%	cont inf	mean enrollment time 3.2 days after admission; infusion titrated to main- tain ICP at <20 mm Hg	decrease in ICP spike frequency up to 72 hrs; 2: inverse correlation btwn serum Na & ICP
Yildizdas et al., 2006	retro	HTS vs mannitol for treatment of cerebral edema determined clinically & radiographically; no ICP monitoring	67	3%	1 ml/kg & cont inf	given for clinical &/or radiographic evi- dence of cerebral edema; infusion given to maintain serum Na in 155– 165 mmol/L range; treatments stopped at GCS score >8	lower mortality rate & duration of co- matose state in HTS group com- pared w/ mannitol group
Peterson et al., 2000	retro	HTS therapy for intracranial hy- pertension & diffuse injury or mass lesion on CT	68	3%	cont inf	infusion titrated to maintain ICP <20 mm Hg over 7 days	ICP <20 mm Hg 92% of time during 7-day period

^{*} Cont Inf = continuous infusion.

[†] Each patient received 1 bolus of each study fluid.

Result

- Two RCTs demonstrated better ICP control with HTS than control fluid (LR or NS) in trauma patients.
- Only I trial compared HTS and mannitol.
 - There was no ICP monitoring in that study
 - The cohort receiving HTS demonstrated a lower mortality and duration of comatose state.
- All 5 pediatric studies supported the use of HTS for reduction of ICP.
- Only I retrospective study demonstrated a better outcome in terms of the mortality rate in patients treated with HTS.

Conclusions

- Majority of the studies showed a more favorable short-term ICP outcome for HTS, no matter what the concentration or administration mode (bolus or continuous drip).
- There has been no report of a serious adverse effect of HTS, which is not surprising because it is given in closely monitored intensive care environments, and hence too quick a rise of Na will be corrected almost immediately.
- HTS appears to have a favorable outcome in all types of intracranial hypertension, no matter the origin.
- There is no consensus on the most optimal concentration, because all concentrations appear to have favorable effects on ICP.

Conclusions

- Multiple studies, including RCTs, show superior effectiveness of HTS compared with mannitol in decreasing ICP.
- However, there is not a clear benefit compared with mannitol in regard to neurological outcome, even though there is a minor positive trend for HTS.
- Furthermore, HTS does not cause the hypotension seen when mannitol is used.

Conclusions

- Any future studies, no matter what the mode of infusion, whether continuous drip or bolus, should monitor serum Na.
- Studies looking into the rebound risk of HTS alone and in comparison with mannitol are also lacking.

Step 4

Appraisal

評讀文獻



■ 評讀文獻的工具 NHS(National Health Service) CASP tools

CRITICAL APPRAISAL SKILLS PROGRAMME
Making sense of evidence about clinical effectiveness



10 questions to help you make sense of a review



- Are the results of the review valid?
 - Screening Questions

I. Did the review address a clearly focused question?	Yes ☑	Can't tell	No 🗌
2. Did the authors look for the appropriate sort	V22 17	Can't tell	No \square
of papers?	Yes 🗹	Carritell	INO [



- Are the results of the review valid?
 - Detailed Questions

3.Do you think the important, relevant studies were included?	Yes ☑	Can't tell	No 🗌
4. Did the review's authors do enough to assess the quality of the included studies?	Yes 🗌	Can't tell ☑	No 🗌
5. If the results of the review have been combined, was it reasonable to do so?	Yes ☑	Can't tell	No 🗌



■ What are the results?

- 6. What are the overall result of the reviews?
- bottom line results: superior effectiveness of HTS compared with mannitol in decreasing ICP.
- 7. How precise are the results?

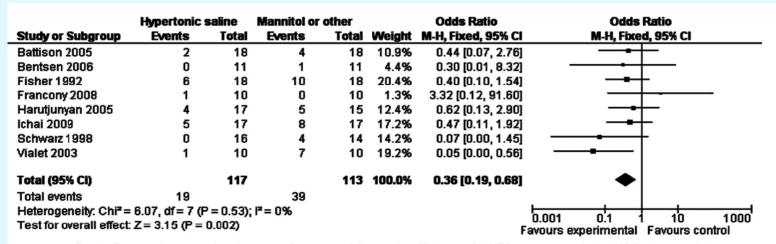


Fig. 1. Forrest plot comparing the rates of treatment failure or insufficiency with HTS versus mannitol or NS for intracranial hypertension. M-H = Mantel-Haenszel.



■ Will the results help locally?

8. Can the results be applied to the local population?	Yes 🗌	Can't tell ☑	No 🗌
9. Were all important outcomes considered?	Yes ☑	Can't tell	No 🗌
11. Are the benefits worth the harms and costs?	Yes ☑	Can't tell	No 🗌

Step 5

Apply

結合醫學倫理方法 將study的結果應用在病人身上



醫療現況

目前病人因為水腦情形導致 腦壓升高,使用高劑量的 mannitol後,IICP的臨床症狀 並未改善並且有持續惡化的 情形。

生活品質

依照目前查詢的文獻顯示, hypertonic saline比mannitol在 控制腦壓有更好的療效,並 有較少的副作用。

病人意願

跟病人家屬討論過目前的情形,建議可使用hypertonic saline做進一步治療,並等待外科手術。

社會經濟脈絡

Hypertonic saline比起mannitol並沒有比較貴,所需要耗費的醫療資源成本也無顯著差異。
Mannitol健保/自費121/139
NaCl 3%健保/自費21/24

Apply

- □跟病人家屬討論過後,我們開始使用3%NaCl 控制腦壓···
- □ 病人臨床上IICP sign無繼續惡化,開刀後水腦 情形也有改善…

Step 6

Audit

自我評估

Audit

- ■提出臨床問題
- ■搜尋最佳證據
- ■嚴格評讀文獻
- ■應用到病人身上
- ■改變醫療行為

Thanks for your listening!