Surgical treatment for chronic subdural haematomas: protocol for a systematic review

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Background

Description of the condition

Chronic subdural haematomas (CSDHs) are among the most common neurosurgical conditions (Gelabert-González 2005, Spain; Han 2009, Korea; Hayashi 2006, Japan; Maurice-Williams 1993, UK; Rohde 2002, Germany; Senturk 2010, Turkey; White 2010, UK). They affect mainly the aged (Adhyaman 2002, UK; Fogelholm 1975, Finland; Maurice-Williams 1993, UK; Mellergard 1996, Sweden), their incidence reaching up to 58.1 per 100,000 in the population 65 years or older (Kudo 1992, Japan). As the world population becomes progressively older (US Census Bureau 2010), the overall incidence is expected to rise. They occur bilaterally in around 19.3% of the cases, are more commonly detected when on the left side, and, for some unknown reason, affect more the male gender (Baechli 2004 Switzerland; Cameron 1978 UK; Fogelholm 1975 Finland; Gelabert-González 2005 Spain; Khadka 2008 Nepal; Krupp 1995 Germany; Kudo 1992 Japan; Lind 2003 New Zealand; MacFarlane 2009 New Zealand; McKissock 1960 UK; Mellergard 1996 Sweden; Miranda 2011 USA; Mori...

According to the classical concept, intracranial subdural haematomas lie between the dura mater and the arachnoid membrane that covers the brain. Actually, the cleavage plane where these blood collections lie is the loose dural border cell layer located in the inner portion of the dura mater (Haines 1993). Chronic subdural haematomas result from bleeding from parasagittal bridging veins caused by trauma of slight or moderate intensity (Trotter 1914). The subdural haematoma becomes covered by a thin membrane in its inner aspect and a thicker outer membrane that contains macrocapillaries (sinusoidal vessels) with increased permeability and endothelial gap junctions that permit the leakage of blood and enlargement of the haematoma (Sato 1975, Yamashima 1983).

Subdural haematomas, are usually classified into acute (within 3 days of trauma), subacute (4 to 20 days) and chronic (after 20 days), while cases with no history of trauma are classified according to the total duration of symptoms (McKissock 1960). They can be classified into these groups according to their morphological aspects seen at surgery, autopsy, computed tomography (CT) or magnetic resonance imaging (MRI) (Frati 2004; Fujisawa 2006; Kenning 2010; Ko 2008; Nomura 1994; Oishi 2001; Senturk 2010; Stanisik 2005; Tanikawa 2001).

Often reported symptoms and signs in adults include headache, mental changes, hemiparesis, papilloedema, depressed consciousness (Cameron 1978, Fogelholm 1975, Gelabert-González 2005, McKissock 1960, Mori 2001), those of increased intracranial pressure being more common among the younger groups (Fogelholm 1975, Liliang 2002). The diagnosis of CSDH is difficult to make based on clinical findings alone, because they are inespecific (Chen 2000). Common symptoms and signs in young children with CSDH include convulsions, vomiting, irritability, lethargy, hyperactive reflexes, enlarged head, full or tense fontanel, sunset eyes and split sutures (Hobbs 2005, Ingraham 1944, Kurschel 2007, McLaurin 1971, Raimondi 1987).
CSDH is not a benign disease, its surgical or overall mortality ranging from 0% to 32% (Baechli 2004; Choudhury 1994; McKissock 1960; Miranda 2011; Ramachandran 2007; Rohde 2002; Sambasivan 1997; van Havenbergh 1996), and recurrence rate from 0.36% to 33.3% (Sambasivan 1997; Tanikawa 2001). In children, mortality due to subdural hematoma is higher during the first year of life, declining as they become older (Raimondi 1987).

Early surgeons preferred craniotomy and removal of the haematoma membranes to avoid recurrence. However, LaLonde (LaLonde 1948) stated that removal of the membrane is not necessary to cure the disease and a study suggested that simple evacuation of the subdural haematoma through trephine or burr hole craniostomy is superior to craniotomy with membranectomy (Svien 1964). It has been observed that following adequate drainage of the haematoma, the membranes decrease in vascularity, cellularity, and eventually disappear (Carlton 1983; Collins 1965; Markwalder 1986; Moyes 1965).

As a general rule, adopted by most surgeons, asymptomatic recollections of haematoma detected by imaging methods and showing no signs of cerebral compression, are not considered true surgical recurrences and are not subjected to new surgical drainage. The decision to reoperate is based on the presence of symptoms and clinical or imaging signs of cerebral compression. The postoperative CT detection of persistent fluid collections in cases who are improving is not considered indication for reoperation by many surgeons who follow these patients until complete cure is reached (Camel 1986; Ernestus 1997; Hueng 2011; Kenning 2011; Miller 1988; Misra 2010). The definition of recurrence that will be adopted in the present review and used by most authors is that of a postoperative recollection of haematoma requiring reoperation.

There are various techniques to open the skull in order to remove subdural haematomas, including twist drill craniostomies (usually made with drills measuring 3 to 5 millimeters in diameter), burr hole craniostomies (usually made with drills measuring between 9 and 22 millimeters in diameter), craniectomies (opening larger than 30 millimeters in diameter), craniotomies (raising a bone flap) (Weigel 2003). While some surgeons make one burr hole, others prefer to make two over the same haematoma (Han 2009; Kansal 2010; Taussky 2008). Some surgeons irrigate the subdural space to wash out of the blood collection while some others avoid irrigation because it may introduce air and cause recurrence (Kitakami 1995; Kubo 2001; Oishi 2001). These and other aspects of the treatment are subject to disagreements among surgeons. The many doubts regarding the
surgical treatment of chronic subdural haematomas require a systematic review analyzing the evidences available (Avezaat 1999; Lega 2010; Rabow 2001).

**Description of the intervention**

Any of the surgical techniques used to treat CSDHs.

**How the intervention might work**

The surgical interventions on CSDHs aim to evacuate their contents, relieving the pressure on the brain, leading to recovery from the symptoms and avoiding mortality, recurrence and complications.

**Why it is important to do this review**

Many studies report on different types of surgical interventions to treat chronic subdural haematomas. This review will analyze their effectiveness and safety.

**Objectives**

To assess the effects on mortality, morbidity, recurrence and other complications of the surgical procedures used in the treatment of patients with CSDHs. The review will address whether one kind of surgical procedure is more effective than other surgical or non-surgical procedures in reducing mortality, morbidity, recurrence and other complications.

**Methods**

**Criteria for considering studies for this review**

**Types of studies**

All randomized controlled trials comparing one kind of surgical procedure with other kind of surgical procedure or with non-surgical treatment will be considered in this review. Trials where non-randomized cohorts are amalgamated with randomized subjects will be excluded if the results of
the randomized subjects cannot be separated out. Published, unpublished and ongoing randomized trials with reported data will be included.

**Types of participants**

Patients of any age or gender, with chronic subdural hematomas.

Patients with other subdural collections (hygromas, effusions and empyemas) and those with CSDH secondary to cranial procedures will be excluded.

**Types of interventions**

Any type of surgical treatment for chronic subdural haematoma.

**Types of outcome measures**

**Primary outcomes**

- Recurrence. We will consider recurrence the postoperative recollection of haematoma requiring reoperation.
- Death at final follow-up.

**Secondary outcomes**

- Neurological functional status as described in the included studies at final follow-up. It will include the results of commonly employed scales such as the Modified Rankin Scale (Table 1), Glasgow Coma Scale (Table 2), Glasgow Outcome Scale (Table 3), Markwalder Grading Scale (Table 4), Bender Grading System (Table 5), Children’s Coma Scale (Table 6), Children’s Outcome Scale (Table 7), and other commonly reported signs such as hemiparesis, dysphasia or mobility and type of health care facility required.
- Complications of the treatment, including infections, seizures and others described in the included studies.

**Search methods for identification of studies**

The search will not be limited by language or publication status.
**Electronic searches**

We will search the following electronic databases:

1. Cochrane Injuries Group Specialised Register (latest version);
2. Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library) (latest version);
3. MEDLINE (PubMed) (1946 to date);
4. Embase Classic + Embase (OvidSP) (1947 to date);
5. LILACS;

The search strategy for MEDLINE ([Appendix 1](#)) will be adapted for the other databases.

**Searching other resources**

- We will search the reference lists of the identified relevant studies for additional citations;
- We will contact specialists in the field and authors of the included trials for unpublished data.

**Data collection and analysis**

Data collection and analysis will be done according to the Cochrane methodology.

**Selection of studies**

Selection of studies will be done by two review authors, independently. One of the authors is specialized in the area (neurosurgery). Disagreements will be resolved by discussion and, when necessary, through arbitration by a third author. Titles and abstracts will be examined, and obviously irrelevant reports will be excluded. Full texts of all the potentially relevant reports will be retrieved and examined for compliance of studies with eligibility criteria.

**Data extraction and management**
Data extraction will be done by two review authors. All relevant data will be extracted, including participants, setting, study design, study duration, sequence generation, allocation sequence concealment, blinding, total number of participants, diagnostic criteria, age, sex, country, co-morbidities, socio-demographics, total number of intervention groups, specific interventions, intervention details, outcomes and time points, number of participants allocated to each intervention group, missing participants, summary data of results for each intervention group (2x2 table for dichotomous data; means and standard deviations for continuous data), estimate of effect with confidence interval and p value, subgroup analyses, funding source, and correspondence with the authors when required.

**Assessment of risk of bias in included studies**

Assessment of risk of bias (systematic errors) in included studies, necessary for the evaluation of the internal validity of their results, is an essential step in systematic reviews. We will use the domain-based 'Risk of Bias' tool contained in the Revue Manager, which includes random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective outcome reporting and other sources of bias (Higgins 2011).

**Measures of treatment effect**

For dichotomous data of outcomes we will use preferably the risk ratio (RR).

In meta-analysis for continuous data of outcomes, we will use the weighted mean difference (or weighted difference in means) or the standardized mean difference.

In meta-analysis for ordinal outcomes, the results may be divided in dichotomous outcomes with an ordering of the categories. When the number of categories is large, the data may be analyzed as continuous outcomes. For measurement scales data, a particular form of ordinal outcome, preferably validated scales will be used.

**Unit of analysis issues**

We expect to include clinical trials of simple parallel groups where participants are individually or block randomized to one of two intervention groups, and a single measurement for each outcome from each
participant is collected and analyzed. Studies based on minimization method will also be considered for inclusion. Whenever possible, we will do intention-to-treat analyses of the data.

**Dealing with missing data**

Dealing with missing data due to attrition or exclusion from the analysis may be a very difficult task. We will contact the original investigators to try to obtain the lacking information. For the secondary outcomes, when the data are missing at random we may make an available case analysis. As to the primary outcomes, if the losses are not excessive, we will attempt intention-to-treat analyses, imputing replacement values. If the losses are substantial, we will perform an available case analysis.

Sensitivity analyses will be performed to evaluate the various possibilities and we will address the potential impact of the missing data on the review in the Discussion section.

**Assessment of heterogeneity**

Our review should include studies on the various surgical interventions for chronic subdural haematomas. Metanalysis will be considered for two or more comparable studies on interventions delivered in the same or in similar ways. In these cases the degree of heterogeneity will be evaluated.

The presence of statistical heterogeneity among studies included in a metanalysis will be detected by a poor overlap of the confidence intervals shown in the forest plot and by the inconsistency index ($I^2$). In the presence of any significant heterogeneity, an analysis of the studies for clinical or methodological diversities will be performed.

In case of considerable variation in results throughout the studies and inconsistency in the direction of effect, the validity of the final result of a meta-analysis will be weakened. However, its presentation will be very useful to show the differences and similarities among the results of the various studies.

In the presence of significant effects of small studies in a metanalysis due to between-study heterogeneity, the fixed- and random-effects estimates of the intervention effect will be compared. In such cases, an investigation of the cause of the heterogeneity will be carried out, including participant population diversity and the methodological quality of the studies.
**Assessment of reporting biases**

The authors will be contacted for the research protocols. We will compare the protocols and the methods section of the studies with the results for eventual differences in the reported outcomes.

When 10 or more studies are included in a meta-analysis, funnel plot asymmetry test will be applied to assess reporting biases.

**Data synthesis**

The data from all included studies will be analyzed in the systematic review. When two or more studies are clinically comparable, the results of them will be combined statistically in a meta-analysis to increase power and improve precision.

**Subgroup analysis and investigation of heterogeneity**

Subgroup analysis will be considered for studies that include both very young children (infants and toddlers) and adults, because of known differences between them. We may consider subgroup analysis on studies that have reported this type of analysis. It may also be used to investigate the reasons for heterogeneity. In general, subgroup analyses will be avoided because of their observational nature.

**Sensitivity analysis**

During the conduction of the review, sensitivity analysis may be considered, for example, to compare different assumptions about missing outcomes in intention-to-treat analyses.

**Acknowledgements**

We are grateful to Mrs. Maria Eduarda S. Puga, MSc, librarian, for her kind assistance in preparing the initial search strategy, including LILACS database.

We are grateful to Ms Deirdre Beecher, Information Specialist of the Cochrane Injuries Group, for preparing the current search strategy on PubMed.
Contributions of authors

Protocol written by Henrique S. Ivamoto and reviewed by Alvaro N. Atallah and Herani Pinto Lemos Jr.

Declarations of interest

There are no conflict of interests.

Additional tables

Table 1. Modified Rankin Scale

Modified Rankin Scale (originally designed and validated for stroke patients)
Grade Findings
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 perform 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  Death
Ref: Banks 2007

Table 2. Glasgow Coma Scale

Glasgow Coma Scale
Type of response    Score    Response
Eye opening          4        Spontaneous
                     3        To speech
Best verbal response 5        Orientated
Table 3. Glasgow Outcome Scale

Glasgow Outcome Scale

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Relate when death occurs (date).</td>
</tr>
<tr>
<td>Vegetative state</td>
<td>Unawareness with only reflex responses, with periods of eye opening. Necessary to state when this outcome has been assessed, because recovery may occur.</td>
</tr>
<tr>
<td>Severe disability</td>
<td>Conscious but dependent for daily support by reason of mental and/or physical disability. Patients have some disability such as dysphasia, hemiparesis or epilepsy and/or deficits of memory or personality but are able to look after themselves, do shopping and travel by public transport. May be able to work under special arrangements.</td>
</tr>
<tr>
<td>Moderate disability</td>
<td>Resumption of normal life with the capacity to work even if pre-injury status has not been achieved. Some of these patients have neurological or psychological deficits.</td>
</tr>
</tbody>
</table>

According to Jennett, moderate disability or good recovery are usually considered as satisfactory or “good” outcome, while severe disability or vegetative state are considered unsatisfactory or “poor” outcome. Studies have shown that most patients have reached their final point on the 5-point outcome scale by six months, and for this reason many studies are based on outcome at six months. Because some authors consider that these categories are too broad, the upper three levels (good, moderate and severe disabilities) may be divided into an upper and lower degree of disability, resulting in a total of eight levels.

Refs: Jennett 1975; Jennett 1981; Jennett 2005

The relationship between Glasgow Outcome Scale and neuropsychological measures after brain injury has been evaluated (Clifton 1993).

Table 4. Markwalder grading system

Markwalder grading system for CSDH
Grade Findings
0  Patient neurologically normal
1  Patient alert and oriented; mild symptoms such as headache; absent or mild neurological deficit, such as reflex asymmetry
2  Patient drowsy or disoriented with variable neurological deficit, such as hemiparesis.
3  Patient stuporous but responding appropriately to noxious stimuli; severe focal signs, such as hemiplegia
4  Patient comatose with absent motor responses to painful stimuli; decerebrate or decorticate posturing
Ref: Markwalder 1981b

Table 5. Bender grading system

Table 7. Bender grading system (for subdural haematomas)

Grade Findings
1  Fully alert and conscious, normal mental functions, few or no focal signs
2  Drowsy or lethargic, organic mental syndrome, focal neurological signs
3  Very drowsy or stuporous, conspicuous organic mental syndrome, pronounced focal signs
4  Coma or signs of herniation
Ref: Bender 1974

Table 6. Children’s Coma Scale (Raimondi & Hirschauer)

Children’s Coma Scale (Raimondi & Hirschauer)
Type of response Score Response
4  Pursuit
3  Extraocular muscles (EOM) intact, reactive pupils
2  Fixed pupils and EOM impaired
1  Fixed pupils and EOM paralysed
3  Cries.
Verbal response 2  Spontaneous respiration
1  Apneic
4  Flexes and extends
Motor response 3  Withdraws from painful stimuli
2  Hypertonic
1  Flaccid
Total maximum score assignable = 11. Minimum score = 3.

Table 7. Children's Outcome Scale (Raimondi & Hirschauer)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Excellent recovery.</td>
</tr>
<tr>
<td>II</td>
<td>Moderate, but nondisabling deficit.</td>
</tr>
<tr>
<td>III</td>
<td>Either a severe motor or cognitive deficit.</td>
</tr>
<tr>
<td>IV</td>
<td>Vegetative.</td>
</tr>
<tr>
<td>V</td>
<td>Death.</td>
</tr>
</tbody>
</table>

Categories I and II are considered “good outcome”. Categories III and IV are considered “poor outcome”.

References

Adhiyaman 2002


Avezaat 1999


Baechli 2004


Banks 2007


Becker 1990

Bender 1974


Caldarelli 2002


Camel 1986


Cameron 1978


Carlton 1983


Cenic 2005


Chen 2000


Choudhury 1994


Clifton 1993

Collins 1965


Ernestus 1997


Fogelholm 1975


Forster 2010


Frati 2004


Frim 2008


Fujisawa 2006


Gade 1990

Gelabert-González 2005


Haines 1993


Han 2009


Hayashi 2006


Higgins 2011


Hobbs 2005


Hueng 2011


Ingraham 1944


Jennett 1975

**Jennett 1977**


**Jennett 1981**


**Jennett 2005**


**Kansal 2010**


**Kaplan 1938**


**Kenning 2010**


**Kenning 2011**


**Khadka 2008**


**Kitakami 1995**

Ko 2008


Krupp 1995


Kubo 2001


Kudo 1992


Kurschel 2007


LaLonde 1948


Langfitt 1978


Lega 2010

Liliang 2002

Lind 2003

Litofsky 1992

MacFarlane 2009

Markwalder 1981b

Markwalder 1986

Maurice-Williams 1993

McKissock 1960

McLaurin 1971
**McLaurin 1990**


**Mellergard 1996**


**Miller 1988**


**Miranda 2011**


**Misra 2010**


**Mori 2001**


**Moyes 1965**


**Nomura 1994**


**Oishi 2001**

**Rabow 2001**


**Raimondi 1987**


**Ram 1993**


**Ramachandran 2007**


**Rohde 2002**


**Sambasivan 1997**


**Santarius 2004**


**Santarius 2009**


**Sato 1975**

**Senturk 2010**


**Stanisik 2005**


**Suzuki 1998**


**Svien 1964**


**Tanikawa 2001**


**Taussky 2008**


**Teasdale 1974**


**Torihashi 2008**

Trotter 1914


US Census Bureau 2010


van Havenbergh 1996


Vinchon 2001


Weigel 2003


White 2010


Yamashima 1983


Sources of support

Internal sources
Personal expenses, Brazil

External sources

- No external source of financial support.

Appendices

1 MEDLINE (PubMed) Search strategy

((((((("Hematoma, Subdural, Chronic"[Mesh]) OR "Intracranial Hemorrhage, Traumatic"[Mesh:noexp]) OR "Hematoma, Subdural, Intracranial"[Mesh]) OR "Hematoma, Subdural"[Mesh:noexp])) OR (((haematoma*[Title/Abstract]) OR hematoma*[Title/Abstract])) AND (((traumatic subdural*[Title/Abstract])) OR (chronic subdural*[Title/Abstract]))) AND (((((("Surgical Procedures, Operative"[Mesh:noexp]) OR "Neurosurgical Procedures"[Mesh:noexp]) OR "Craniotomy"[Mesh]) OR (surgery[Title/Abstract])) OR (surgical procedure*[Title/Abstract]))) OR (((craniotomy[Title/Abstract]) OR craniostomy[Title/Abstract]) OR drainage[Title/Abstract])) OR (percutaneous subdural tapping[Title/Abstract])) OR (surgical treatment*[Title/Abstract])) OR (((drain*[Title/Abstract]) AND irrigation[Title/Abstract])) AND (((closed system[Title/Abstract]) OR continuous[Title/Abstract]) OR catheter[Title/Abstract]))) AND ((("Comparative Study"[Publication Type]) OR "Randomized Controlled Trial"[Publication Type]) OR "Controlled Clinical Trial"[Publication Type])) OR (((randomized[Title/Abstract]) OR randomised[Title/Abstract]) OR placebo[Title/Abstract]) OR randomly[Title/Abstract]) OR trial[Title/Abstract]) OR study[Title/Abstract]) OR group[Title/Abstract])) NOT ("Animals"[Mesh]) NOT ("Animals"[Mesh] AND "Humans"[Mesh])))