British Neurosurgical Trainee Research Collaborative

BNTRC

Advancing Research through Collaboration

Protocol for a prospective multi-centre audit of chronic subdural haematoma management and outcome in the United Kingdom and Ireland

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Contents

Abstract

Background: Chronic subdural haematoma (CSDH) is a common condition especially prevalent in old age. Evacuation of a CSDH is one of the commonest neurosurgical procedures. CSDH evacuation aims to provide symptomatic improvement with minimum morbidity, however the optimal peri-operative management, surgical technique, post-operative care and the role of adjuvant therapies remain controversial.

Aim: We propose a prospective multi-centre audit in order to establish current practices, outcomes and national benchmarks for future studies.

Methods: Neurosurgical units (NSU) in the United Kingdom and Ireland will be invited to recruit patients to this audit. All adult patients aged 16 years and over with a primary or recurrent CSDH will be eligible for inclusion.

Audit standards and outcome measures: The proposed outcome measures are: (1) clinical recurrence requiring re-operation within 60 days; (2) modified Rankin scale (mRS) score at discharge from NSU; (3) morbidity and mortality in the NSU; (4) destination at discharge from NSU; (5) length of stay in the NSU. Audit standards have been derived from published systematic reviews and a randomised controlled trial. The proposed standards are: clinical recurrence rate <20%; unfavourable mRS (4-6) at discharge from NSU <30%; mortality rate in NSU <5%; morbidity rate in NSU <10%. Data will be entered into a secure online database and analysed by the study's management group.

Conclusions: The audit will determine the contemporary management and outcomes of patients with CSDH in the United Kingdom and Ireland. It will inform national guidelines, clinical practice and future studies in order to improve the outcome of patients with CSDH.

Introduction

Chronic subdural haematoma (CSDH) is a condition commonly encountered in neurosurgical practice (incidence of 58 per 100,000 per year in population over 70).[1] As the population ages this is predicted to increase. However, despite its prevalence current evidence concerning its treatment is based predominantly on retrospective studies. More robust, prospective trials are required if further improvements in the morbidity and mortality of this patient population are to be achieved.[2-4]

Treatment variables

Treatment of CSDHs aims to relieve neurological impairment and symptoms attributable to the collection, but the optimal and most reliable clinical management strategy to achieve this remains controversial. The patient's pathway from identification of a CSDH to eventual discharge incorporates various treatment measures, each of which should be subject to consideration of its value. For example, operative evacuation of the haematoma is the gold standard of treatment for symptomatic patients, but should the operative technique include one burr hole or two, or should a mini-craniotomy be performed? Other adjunctive measures include subdural drain use, postoperative bed rest and postoperative high flow oxygen. Utilisation of these measures varies from case to case and centre to centre and is perhaps dependent on surgeon's preference.[5,6]

Such variety in practice reflects the generalized lack of an evidence-based approach in this area.[2,3,a]

The paucity of class I evidence amongst the CSDH literature is startling and more prospective trials are needed. To determine the priorities for study, it is imperative to elucidate the current breadth and heterogeneity of practice. We intend to understand this further by auditing treatment practices and outcomes in the United Kingdom (UK) and Ireland against recommendations derived from existing published literature.

A study by trainees

Due to their direct involvement in the care of this patient group from an early stage, neurosurgical trainees are well placed to take an active role in a national audit of practice coordinated by the British Neurosurgical Trainees Research Collaborative (BNTRC).

Aim

We intend to perform a prospective multi-centre audit of contemporary practice and outcomes in the management of patients treated for CSDH in the UK and Ireland.

[a] For a further review of the literature the reader is referred to the study proposal paper in press[7]

Methods

The study proposal was presented at the launch meeting of the BNTRC at the Royal College of Surgeons of England in October 2012 and at the British Neurosurgical Research Group meeting in March 2013. It has been reviewed and approved by the Academic Committee of the Society of British Neurological Surgeons and is supported by the Society of British Neurological Surgeons (SBNS).

Center Eligibility

Any hospital which provides acute neurosurgical services in the UK and Ireland is eligible to participate. Each participating centre will be invited to nominate a consultant audit lead and a trainee who will ultimately coordinate the audit. This is a national audit approved by the SBNS. Local audit registration is also encouraged.

Patient Eligibility

Patient inclusion:

- Adults aged 16 years or over.[b] No upper age limit.
- Any patient with a primary or recurrent CSDH confirmed on cranial imaging referred to a participating NSU for management.

Patient exclusion:

- Patients with other pathologies identified either at operation, or during subsequent management (eg, vascular malformations, subdural empyema).

[b] Chronic subdural collections in the paediatric population are more likely to represent an alternative pathology.

Audit Timeline

Pilot phase

Initially data collection will be piloted in 3 units as a means of testing the online data collection tool.

Main audit

Upon confirmation of successful data collection at the three pilot sites, local trainee investigators from other NSUs will be invited to commence data collection. The main data collection phase will run for a provisional period of 3 months (subject to adequate participation).

Outcome measures

1. R*ecurrence*

Clinically significant recurrence is defined as the occurrence of symptoms and signs attributable to a radiologically confirmed ipsilateral CSDH necessitating re-operation within 60 days.

2. *Modified Rankin scale score*

Modified Rankin scale (mRS) score as an objective quantitative measure of functional outcome. We intend to collect this data at the point of discharge. The use of the mRS as a measure of functional outcome at discharge has been validated by studies such as the randomized controlled trial (RCT) by Santarius *et al* which investigated the utility of post-operative closed subdural drainage in patients with CSDH and found that

favourable mRS scores (0-3) at discharge and at 6 months were observed significantly more in patients who had a drain sited compared to those who did not.[8] After adjustment for confounding factors, the use of a drain was predictive of mRS at discharge.[8]

3. In-NSU morbidity

Morbidity is defined as any adverse event occurring during inpatient stay in the NSU.

4. *Destination of discharge*

Although we acknowledge this may be influenced by local practice and resources the destination of discharge will serve as a surrogate marker for functional outcome.

5. *Length of stay in NSU*

Although we acknowledge this may be influenced by local practice and resources the length of stay will serve as a surrogate marker for functional outcome.

6. In-NSU *mortality*

Mortality is defined as any death occurring from admission until discharge from the NSU. We have elected to collect in-NSU mortality data due to its relative ease of collection compared to 30-day mortality. In their comprehensive systematic review, Weigel *et al* established mortality rates based on the same definition, thus a potential for comparison of this data also exists.

Audit Standards

We have devised a number of audit standards based on existing published literature, outlined below. Weigel *et al* published a comprehensive evidence-based review in 2003.[2] Ducruet *et al* published a robust systematic review more recently in 2012.[3] Other important studies, such as a RCT of the use of subdural drains in CSDH by Santarius *et al* have also been taken into account when devising the following audit standards.[8] There are no robust UK data which can be used in order to set an audit standard for destination following discharge. Due to regional differences in resources, setting a standard for length of stay on the basis of a single-centre study is not appropriate. The audit will provide national benchmarks for discharge destination and length of stay.

1. Clinical recurrence rate <20%

The systematic review by Weigel *et al* identified a recurrence rate of 12.1% (based on summarised data from studies of BHC, 0-29%).[2] The recent systematic review by Ducruet *et al* observed a recurrence rate of 11.7% (based on a meta-analysis of BHC studies, range 2-31%).[3] Pooled outcomes from the RCT by Santarius *et al* observed 6 month recurrence rates of 16.7%. The trial also observed that median time to recurrence was 15.5 days (IQR 4-46) in the drain group and 8 days (IQR 5-12) in the non-drain group.[8] Therefore, it would be reasonable to allow a 2 month period following index admission for identification of recurrences.

2. In-hospital morbidity rate <10%

The systematic review by Weigel *et al* identified a morbidity rate of 3.8% (relative percentage based on summarised data from studies of BHC, 0-9%).[2] The recent systematic review by Ducruet *et al* observed a complication rate of 9.3% (based on a meta-analysis of BHC studies, range 0-25%).[3]

3. Unfavourable mRS at discharge <30%

Pooled outcome data from the RCT by Santarius *et al* suggest that the rate of unfavourable mRS at discharge was 24.5% (47/192).[8] The recent systematic review by Ducruet *et al* observed a favourable outcome in 84.9% (based on a meta-analysis of BHC studies, range 58-90%).[3] We therefore suggest that a reasonable rate of unfavourable mRS at discharge would be less than 30%.

4. In-hospital mortality rate <5%

The systematic review by Weigel *et al* identified an in-hospital mortality rate of 3% (relative percentage, based on summarised data from studies of BHC, 0-32%).[2] The recent systematic review by Ducruet *et al* observed a mortality rate of 3.7% (based on a meta-analysis of BHC studies, range 0-13).[3]

Data

Data Collection

Data collection will be piloted in three units. On successful completion of the pilot, local trainee investigators will commence recruitment in all participating units. We anticipate an overall recruitment rate of ten patients per unit per month.

Patients will be identified daily by on-call teams, at handovers, from on-call databases or from the emergency theatre log book. Patient demographics and baseline characteristics including medical co-morbidities and relevant medication history, together with details of pre-, intra- and post-operative management described in table 1 will be collected. A minimum data set including baseline characteristics and proposed management will also be collected for patients referred but not transferred to the NSU.

Data on CSDH recurrence requiring reoperation within 60 days of index admission will be determined. Should a patient be re-admitted within 60 days with a recurrence, the data collector will be required to update the electronic proforma for that patient (ie one proforma per patient during the audit). Modified Rankin scale at discharge (for comparison to admission mRS), destination at discharge (home/local hospital/rehabilitation/other), length of stay and all cause in-hospital mortality will also be recorded.

Any unit routinely collecting long term functional outcome data, including mortality, will be encouraged to submit this data to the national audit.

Management of patients on anticoagulant or antiplatelet agents
Use of steroids
Type of operation (eg, BHC, TDC and craniotomy)
Number of burr holes (if performed)
Use of intra-operative irrigation
Use of post-operative drain and time before removal
Implementation of post-operative head down tilt
Period of post-operative bed rest
Use of post-operative high flow oxygen
Post-operative imaging

Table.1 Data collection will include aspects of management

Data will be collected into a secure web-based database in accordance with the Caldicott guidelines and the data protection act[c]. The secure database will be accessible to data collectors via the British Neurosurgical Trainees Association (BNTA) website (www.e1v1m1.co.uk). Participating NSUs will also be requested to keep a paper copy of each data sheet. Any trainee and their respective consultant collecting data will be acknowledged as a study collaborator. Invitations to the writing group of any subsequent paper reporting results will be made based on data collection.

[c] Competitive quotes are currently being sought for this facility.

Data Analysis

At the end of the study period, the collated anonymised data will be compared to standards established from the best available published literature as described above using one-sample tests.

Data will be tested for distribution and differences in outcome groups will be statistically compared using: unpaired t-tests, Mann-Whitney U tests and Chi-squared as appropriate. The impact of variables on outcome will be investigated with a multivariable logistic regression model or a cox regression model as appropriate. Odds ratios and 95% confidence interval will be reported. Funnel plots will be used to compare outcomes between units and identify any wide variations.

The report of this audit will be prepared in accordance to guidelines set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational studies.[9]

Future directions

We will identify areas of clinical uncertainty as judged by a lack of consistency between units, and formulate hypotheses that can be subjected to a future prospective randomized trial. We will be able to prepare guidelines based on the current practice in the UK and Ireland that, when validated by prospective studies could form the basis of best practice.

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Appendix 1 BNTRC Chronic Subdural Haematoma Audit – Data Collection Proforma

Trainee name: _____ **NSU**:_____

Patient Demographics:

Hosp No._____ **Sex**: M / F **Age**:_____years

Patient Transferred to NSU for Management: Yes [ ] No [ ] *(if no directed to new page-see last section)*

Date of admission to NSU: *DD/MM/YEAR*

Clinical Details:

Has the patient previously undergone evacuation of ipsilateral CSDH?
Yes [ ] *Date:DD/MM/*YEAR Method of primary evacuation: BHC [ ] TDC [ ] Craniotomy [ ]
No [ ]

History of head injury in preceding 3 months: Yes **[ ]** No [ ]

Residence: Independent [ ] Carers [ ] Residential home [ ] Nursing home [ ]

Mobility: Independent [ ] Stick [ ] Zimmer [ ] Wheelchair [ ] Bed-bound [ ]

mRS at time of admission: 0 [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ]

Symptoms: *Cognitive impairment* [ ] *Seizures* [ ] *Incontinence* [ ]
Gait Disturbance [ ] *Dysphasia* [ ] *Hemiparesis* [ ] *- power UL* ___/5
Headache [ ] *Facial droop* [ ] *- power LL* ___/5

Pre-op INR:_____ **Pre-op platelet count:** _____

Pre-admission anticoagulants: Yes [ ] : *Aspirin* [ ] *dypiridamole* [ ]
No [ ] *Warfarin* [ ] *clopidogrel* [ ]
*Other*_____
duration discontinued pre-op _____days _____hrs

Preoperative blood products/haematological treatment:
Yes [ ] *Platelet T/F* [ ] *Vit K* [ ] *FFP* [ ] *Beriplex* [ ] *Other* [ ] _____ No [ ]

GCS pre-op:_____ E = ____ V=____ M=____

Significant Co-morbidities:
Diabetes [ ] Dementia [ ] COPD/Resp disorder [ ] Cerebrovascular dis [ ]
Ischaemic heart dis [ ] Arrhythmia [ ] Epilepsy [ ] CSF Shunt [ ] Malignancy [ ]
Metalic heart valve [ ] Other_____

Pre-op Radiology:

Haematoma Site: Right: [ ] Left: [ ] Bilateral: [ ]

Maximal thickness: _____mm (Rt) _____mm (Lt)

Maximal midline shift:_____mm

Density of haematoma: Hypodense [ ] Isodense [ ] Hyperdense [ ] Mixed [ ]

Membranes evident on CT: Yes [ ] No [ ]

Non-surgical treatment:

Pharmacological management employed as primary treatment: Yes [ ] No [ ]

Name of steroid:_____ **Initial daily dose:**_____mg **Duration:**_____**days**

Pharmacological management employed as adjuvant treatment: Yes [ ] No [ ]

Name of steroid:_____ **Initial daily dose:**_____mg **Duration:**_____days

Patient received no pharmacological or surgical treatment: [ ]

Operation:

Operation as primary treatment: Yes [ ] - *unilateral* [ ] No [ ]
- *bilateral* [ ]

Type of operation: - Burr hole Evacuation [ ] - Twist Drill Craniostomy [ ]
- Craniotomy [ ] - *Size* _____*cm x* _____*cm*
- Other [ ] _____

Date of Operation: _____ **Grade of Surgeon:**_____

Anaesthetic: General [ ] Local [ ]

Number of burr holes: 1 [ ] 2 [ ] 3 [ ] > 3 [ ]

Colour of fluid: Clear [ ] Straw [ ] Engine oil [ ] Fresh blood [ ] Mixture [ ]

Use of Intra-op Irrigation: Yes [ ] No [ ]

If more than one burr hole made, did they communicate on irrigation: Yes [ ] No [ ]

Use of drain: Yes [ ] No [ ] **Type of drain**: Jacques catheter [ ] other [ ] _____

If drain used, which burr hole inserted (if more >1 burr hole): Frontal burr hole [ ] Posterior burr hole [ ]
Other [ ] _____

Site of drain: Subdural [ ] Subgaleal [ ]

Post-op:

Flat bed rest: Yes [ ] if yes duration _____hrs No [ ]

Use of high flow oxygen: Yes [ ] if yes duration _____hrs No [ ]

Duration of Drain in-situ: _____days

Time postoperative mobilization allowed: Immediate [ ] <12hrs [ ] 12-24hrs [ ] 24-48hrs [ ] >48hrs [ ]

Antiplatelet/Anti-coagulant agents re-commenced: - Not applicable [ ] - <1 week post-op [ ]
- ≥1 week post-op [ ] - Left to discretion of GP/ Physician [ ]

Post-op Imaging:

Date of 1st post-op scan (if performed):_____

Indication for scan: - Routine post-op check [ ] - Clinical concern [ ]

Evidence of subdural air: - Yes [ ] - No [ ]

Size of collection: - Maximal thickness ____mm

Evidence of midline shift: - Yes [ ] - *Maximal thickness ____mm* - No [ ]

Outcome:

Re-collection necessitating further operation: Yes [ ] No [ ]

Date/s of further operations for re-collection: _____ _____ _____

Type of re-operation: Burr hole [ ] Twist drill [ ] Craniotomy [ ] - *Size _____cm x _____cm*
Other_____

Return to theatre for other reason (specify): _____

Post-op complications (1° op) – Procedure related: Site infection [ ] Seizure [ ] New neuro deficit [ ]

Post-op complications (1° op) - General: Pneumonia [ ] Arrhythmia [ ] VTE [ ] MI [ ]

In-NSU mortality: Yes [ ] No [ ] **Date of death**:___/___/_____ **Cause of death**:_____

Place of Discharge: As pre-op [ ] Local Hospital [ ] Neuro-rehabilitation [ ]
Nursing home [ ] Residential home [ ] Other [ ] _____

Length of stay on NSU: _____days

mRS at discharge: 0 [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ]

Patients not managed in NSU:

GCS at referral:_____ E = V= M=

Significant Co-morbidities:

Diabetes	[ ]	Dementia	[ ]
COPD/Resp disorder	[ ]	Cerebrovascular dis	[ ]
Ischaemic heart dis	[ ]	Arrhythmia	[ ]
Epilepsy	[ ]	CSF Shunt	[ ]
Malignancy	[ ]	Other_____	
Metallic heart valve	[ ]		

Reason for not transferring patient:

A. Neurosurgical intervention deemed not to be in patient's best interest due to significant comorbidities or poor pre-morbid status.

B. Neurosurgical intervention deemed futile due to poor neurological status

C. Small collection not sufficient to explain patient's symptoms

D. Small collection patient felt to be asymptomatic

E. Patient on anti-platelets – will be admitted for elective drainage when off antiplatelets for a suitable period of time.

F. Other, please specify_____

Oral steroids advised: Yes [ ] No [ ]

Appendix 1 Guidance notes for completing proforma

Demographics

We would like to know your name and unit to ensure appropriate accreditation. The patient's personal details should remain anonymous but their hospital number will be collected to ensure complete data collection.

If the patient is not managed at the NSU you will be directed to another short section where we hope to collect some data on these cases.

Should a patient present with a clinically significant re-collection for the first time during the audit window a proforma should be completed for this presentation. A new proforma should also be completed for those patients presenting for a second time with a clinically significant re-collection within the 60 day window following discharge (ie a new proforma should be completed for each presentation).

With regards to method of evacuation, BHC refers to burr hole craniostomy and TDC refers to twist drill craniostomy.

Clinical details

If the patient has undergone drainage of an ipsilateral CSDH previously but the precise date is not known the approximate date can be inserted as the first day of a particular month or the first day and first month of a particular year (eg 01/04/2011 – if the operation was known to be undertaken in April 2011 but the precise date is unknown).

The trainee is expected to calculate the modified Rankin scale score when the patient presents to the NSU. The modified Rankin scale is included in this document as Appendix 2 to facilitate this process.

The pre-operative INR and platelet count refers to the last haematological values available before the operation is commenced.

Non-surgical treatment

Primary treatment refers to the pharmacological agents being used as a first line treatment as a means of avoiding the need for operation (no plan to operate when pharmacological agents commenced).

Adjuvant therapy refers to pharmacological therapy (ie steroids) that were commenced with the ultimate intention of proceeding to theatre in the near future and/or commenced post-operatively.

Operation

Number of burr holes refers to the number of burr holes made for each haematoma drainage. In cases of bilateral drainage please record the greatest number of burr holes made on a particular side.

Post-op

To qualify as flat bed rest the patient should have been specifically nursed flat post-operatively. To qualify for high-flow oxygen use the oxygen should have been employed as a means of facilitating recovery from the CSDH postoperatively (eg as a means of reducing intracranial air), not for the management of respiratory co-morbidity.

Patients not managed in NSU

The trainee lead in each unit should ideally monitor the referral database for such referrals and record the data as appropriate.

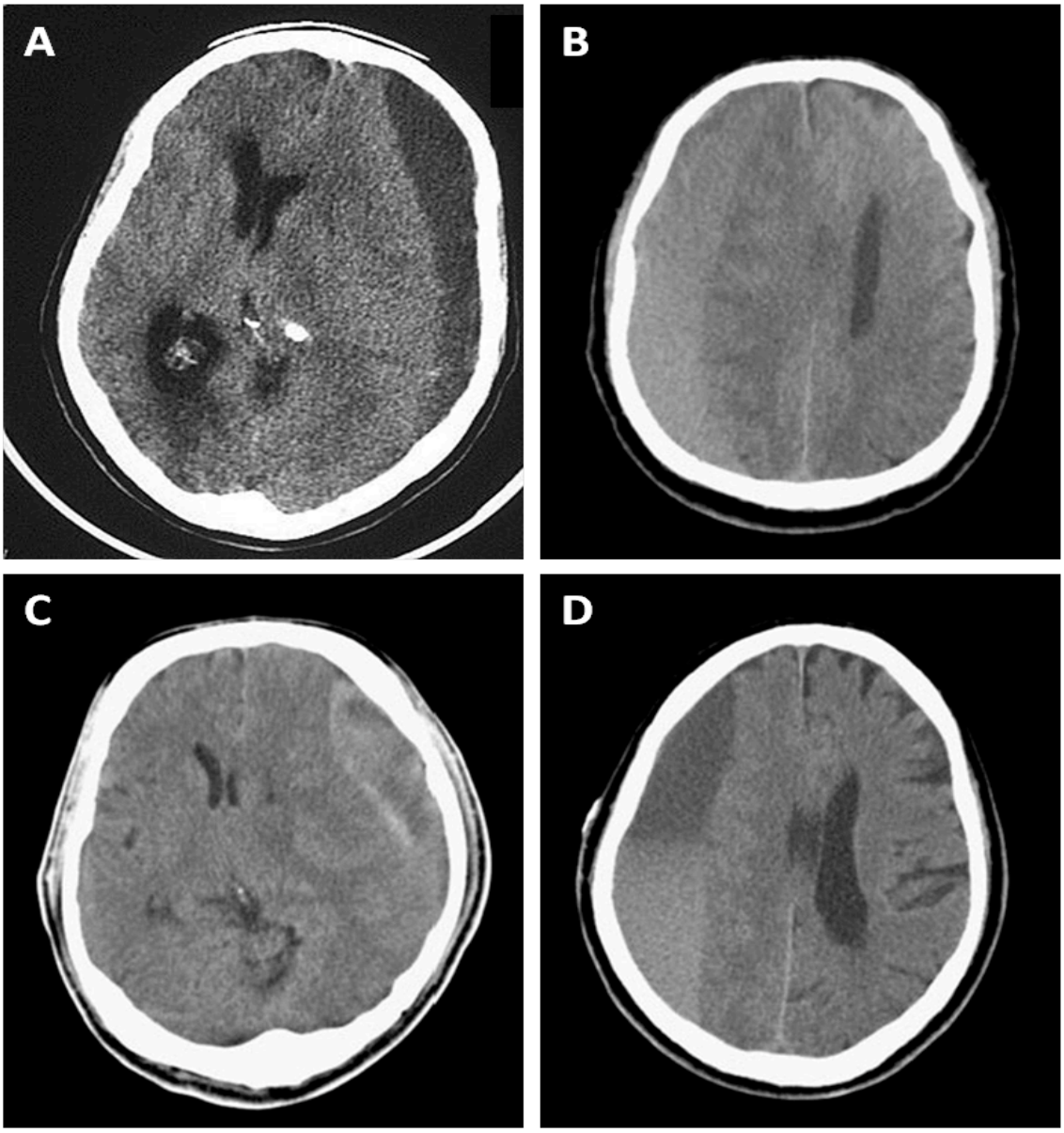
Appendix 2

Modified Rankin Scale

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

Appendix 3

Examples of CSDHs on CT



CT scans illustrating examples of **A** hypodense, **B** isodense, **C** & **D** mixed density chronic subdural haematoma collections.