





BMJ Open Stockholm score of lesion detection on computed tomography following mild traumatic brain injury (SELECT-TBI): study protocol for a multicentre, retrospective, observational cohort study

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ABSTRACT

Introduction Mild traumatic brain injury (mTBI) is one of the most common reasons for emergency department (ED) visits. A portion of patients with mTBI will develop an intracranial lesion that might require medical or surgical intervention. In these patients, swift diagnosis and management is paramount. Several guidelines have been developed to help direct patients with mTBI for head CT scanning, but they lack specificity, do not consider the interactions between risk factors and do not provide an individualised estimate of intracranial lesion risk. The aim of this study is to create a model that estimates individualised intracranial lesion risks in patients with mTBI who present to the ED.

Methods and analysis This will be a retrospective cohort study conducted at ED hospitals in Stockholm, Sweden. Eligible patients are adults (≥15 years) with mTBI who presented to the ED within 24 hours of injury and performed a CT scan. The primary outcome will be a traumatic lesion on head CT. The secondary outcomes will be any clinically significant lesion, defined as an intracranial finding that led to neurosurgical intervention, hospital admission ≥48 hours due to TBI or death due to TBI. Machine-learning models will be applied to create scores predicting the primary and secondary outcomes. An estimated 20 000 patients will be included.

Ethics and dissemination The study has been approved by the Swedish Ethical Review Authority (Dnr: 2020-05728). The research findings will be disseminated through peer-reviewed scientific publications and presentations at international conferences.

Trial registration number NCT04995068.

INTRODUCTION

With over 60 million annual cases worldwide,¹ traumatic brain injury (TBI) is one of the most common reasons behind emergency department (ED) visits.² The vast majority are mild TBI (mTBI) with an admission Glasgow Coma Scale

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This will be the first study to assess the interactions between risk factors, both in terms of synergism and antagonistic effects, to provide an individualised estimate of intracranial lesion risk following mild traumatic brain injury.
- ⇒ An estimated 20 000 patients will be included, allowing for robust conclusions and the opportunity to analyse presumed risk factors that are very rare.
- ⇒ Machine-learning models will be applied to create scores predicting the primary and secondary outcomes.
- ⇒ Data collectors will not be blinded to outcome data.

(GCS) of 13–15,³ of whom 5%–10% develop an intracranial lesion that might require medical or surgical management.^{4,5}

Several decision aids have been developed to identify patients in whom a head CT should be performed. These include the Canadian CT Head Rule (CCHR),⁵ New Orleans Criteria (NOC),⁶ National Institute of Health and Care Excellence (NICE) guidelines,⁷ CT in Head Injury Patients (CHIP) Prediction Rule,⁸ the National Emergency X-Radiography Utilisation Study II (NEXUS II) criteria⁹ and the Scandinavian Neurotrauma Committee (SNC) guidelines,^{10,11} all of which allow for more selective use of CT scanning in patients with mild TBI. The Brain Injury Guidelines (BIG) and the Mild TBI Risk Score have also been developed to help determine which patients are suitable for discharge once the CT has been performed,^{12,13} and hence, do not primarily focus on stratifying the risk of lesion detection.

While the above-described algorithms have a high sensitivity for identifying those with intracranial lesions, they share some flaws. To begin, they have low specificity,¹⁴ resulting in CT overuse with unnecessarily high radiation exposure, ED overcrowding and higher costs.^{15 16} For example, in a recent prospective, multicentre, external validation of the CHIP Prediction Rule, NOC, CCHR and NICE guidelines, 82% of patients who presented to the ED with a mild TBI underwent a CT scan and 8% had a traumatic intracranial finding. While the sensitivity ranged from 73% to 99%, specificity ranged from only 4% (NOC) to 61% (NICE).¹⁴ These findings were corroborated in another prospective validation of CCHR, NOC and NEXUS II, where 93% of patients underwent CT scanning and specificity ranged from 16% (NOC) to 52% (NEXUS II).¹⁷ Another important limitation is the lack of interaction assessments between risk factors, both in terms of synergism and antagonistic effects, to better estimate intracranial lesion risk. In addition, some novel parameters are not present or detailed specifically in the present guidelines, for example, warfarin versus direct oral anticoagulants or which specific 'neurological deficits' that are high risk. Lastly, the available decision aids do not provide an individualised probability of lesion development. This can be contrasted to the HEART score, which provides risk stratification for major cardiac events in patients with chest-pain,¹⁸ CHA₂DS₂-VASc, which gives an annual risk of stroke in those with atrial fibrillation,¹⁹ and Wells score to predict deep vein thrombosis.^{20 21}

Objective

The aim of this study is to create a model that estimates individualised intracranial lesion risks in patients with mTBI who present to the ED.

METHODS AND ANALYSIS

Study setting

This will be a retrospective cohort study of adults with mTBI in the ED setting. We will focus on information available to the ED physician when making the decision of whether to perform a head CT scan or not. Thus, the model will incorporate predictors from the patient's history, physical examination and laboratory results. The study will follow the Transparent Reporting of a multi-variable prediction model for Individual Prognosis or Diagnosis guidelines,²² and has been registered at ClinicalTrials.gov (NCT04995068).

Study population

The study will include all patients who sought ED care for a mTBI at the Karolinska University Hospital Huddinge, Karolinska University Hospital Solna, Stockholm South General Hospital, Norrtälje Hospital, Danderyd's Hospital and Söder-
tälje Hospital. Together these hospitals serve a catchment area of more than 2 million people in Stockholm, Sweden. All hospitals share the same prehospital TBI management protocol,²³ and adhere to the SNC guidelines for initial

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Adult (≥ 15 years) Presented within 24 hours of TBI between 2010 and 2020 GCS 13–15 at presentation to the emergency department
Exclusion criteria	No CT scan performed Patient from another region in Sweden or another country Penetrating TBI Secondary transfer from other ED Medical record missing Already performed CT scan for other TBI within 30 days
.ED, emergency department; GCS, Glasgow Coma Scale; TBI, traumatic brain injury.	

management of minimal, mild and moderate head injuries.¹¹ The Karolinska University Hospital Solna, S:t Görans Hospital and Stockholm South General Hospital also have the capabilities to sample the brain biomarker S100B, thus adhering to the updated SNC guidelines from 2013.¹⁰ Included patients will be adults (≥15 years) with mTBI (GCS 13–15) who presented to the ED within 24 hours of injury between 2010 and 2020 (table 1). Inclusion years will depend on the availability of digital hospital charts, which became centralised during the 2010s throughout the Stockholm Regional Council, but the focus will be on the last 6 years (2015–2020) when data will be available from all hospitals. Patients have been identified by a systemwide search in the electronic medical records software for International Classification of Diseases, Tenth revision (ICD-10) codes for intracranial injury (S06X) and fracture of skull and facial bones (S02X), as well as the ED admissions codes for 'head injury'.

Data collection

Clinical variables will be retrospectively collected by, or closely supervised by, trained physicians using standardised review protocols. Review will be conducted by members of the direct care team at the different study hospitals. Clinical data will be collected from the health record software TakeCare (CompuGroup Medical Sweden AB, Farsta, Sweden), while imaging data will be collected from the radiological management software Sectra Picture Archiving and Communication System (Sectra AB, Linköping, Sweden). The data will be entered into anonymised case report forms (CRF) (online supplemental additional file 1) in the electronic data capture system REDCap,²⁴ which can be accessed by the authors AFS and EPT. We will not be able to blind assessors from outcome data.

The primary outcome will be any traumatic lesion on head CT, defined as a cerebral haematoma, subdural haematoma, epidural haematoma, subarachnoid haemorrhage, intraventricular haemorrhage, diffuse axonal injury, depressed skull fracture, traumatic infarction or sinus thrombosis. The secondary outcome will be any clinically significant lesion, defined as a traumatic intracranial finding that led to neurosurgical intervention, hospital admission ≥48 hours due to the TBI or death due

to TBI. We will use the 48-hour cut-off to exclude overnight admissions for minor CT findings that did not result in any further treatment. Due to the retrospective nature of the study, each patient has already been assessed at their index ED visit by a physician who decided the need for a head CT in accordance with the SNC guidelines,¹⁰ and the results of the CT scans have been interpreted by site faculty radiologists (including a board certified radiologist).

Online supplemental additional file 1 details the CRF that will be used to collect inputs for the model. The candidate variables have been chosen due to their previously demonstrated relationship to intracranial lesion risk in the mTBI decision rules CCHR,⁵ NOC,⁶ NICE guidelines,⁷ CHIP Prediction Rule,⁸ NEXUS II criteria,⁹ SNC guidelines,^{10 11} BIG,¹² the Mild TBI Risk score,¹³ as well as others which we believe have clinical grounds to be predictive.

Statistics

An estimated 20 000 patients will be included, which represents all patients treated between 2015 and 2020 who fulfil the inclusion criteria. This means that even in an extreme case of modelling predictors with a total of 100 degrees of freedom, there will still be around 200 patients per predictor parameter. The model will also identify the most important predictors early on, leading to a large sample size for estimating coefficients. A separate statistical analysis plan, together with pilot results, will be published following completion of the first 5000 patients. This will help us to better estimate how many patients are needed to adequately assess the clinical impact of presumed risk factors that are more rare (eg, dual antiplatelet therapy and ventriculoperitoneal shunt).

In order to identify relevant predictors, a regularised regression approach will be attempted. Cross-validation will be used for variable selection. Missing data might be imputed if it is missing at random or completely at random, assuming that the missing rate is within reasonable bounds. We already know that there will be missing S100B values from certain hospitals, and two parallel might will be developed: a 'core' model with variables available at all hospitals, and an additional model with S100B data from the hospitals that use extended laboratory testing. Interaction terms will be used when clinically or statistically motivated. Area under the receiver operating characteristic curve will be used to assess model performance. The dataset will be randomly divided into a derivation and a validation dataset, allowing for internal validation. Overfitting will be avoided by using regularised regression, which will eliminate poorly performing predictors. Furthermore, the validation set will give a non-biased estimate of the final score's performance internally.

Ethics and dissemination

The study has been approved by the Swedish Ethical Review Authority (Dnr: 2020-05728) who waived the need for informed consent. Each hospital in the Stockholm Region will certify that local regulations are adhered to. The research findings will be disseminated through

publications in international, peer-reviewed scientific publications and presentations at conferences.

Patient and public involvement statement

Patients and members of the public were not involved in the design of this study.

DISCUSSION

Potential clinical benefits

While there are several guidelines to help direct patients with mTBI for CT scanning, this will be the first study to provide an individualised estimate of intracranial lesion risk following mTBI, including those with a clinically significant lesion. The large cohort will allow us to analyse presumed risk factors that are very rare, such as intraventricular shunts and haemostatic disorders. In addition, novel parameters that are not present or detailed specifically in the present guidelines will be included, for example, warfarin versus direct oral anticoagulants or which specific 'neurological deficits' that are high risk. Applying a machine-learning algorithm on a large sample size will also allow us to explore the combined effects of predictive or protective factors, both in terms of synergism and antagonistic effects. Together, we believe this will allow us to increase model specificity, without compromising sensitivity, compared with previous decision tools.

Study limitations

There are some limitations to bear in mind. As all patients do not undergo a CT scan, there will be those with undiagnosed intracranial lesions. In one study, 0.8% of elderly patients with TBI who did not undergo a head CT were diagnosed with intracranial bleeding within 6 weeks, as compared with 0.6% of patients with an initial negative CT scan.²⁵ This also means that we will only be able to determine SNC guideline compliance with regard to overtriage, but not undertriage, which might impact the characteristics of the study population. Thus, the derived model will not be applicable to patients with mTBI who have not undergone CT scans. However, to mitigate this, the Swedish National Patient Register²⁶ will be used to detect if any excluded patient was diagnosed with an intracranial lesion within 30 days of their index ED visit. This will also allow us to calculate the incidence of delayed intracranial haemorrhage among the patients with initial normal CT scans. The imperfect reference standard bias, introduced with differential testing depending on the emergency physician CT request, might also inflate the strength of association between predictor variables which are commonly used to determine the need for CT in the SNC guidelines (such as loss of consciousness or anti-coagulation use).^{10 11} Lastly, the model will be developed based on patients seeking medical care in Stockholm, Sweden. This means that the generalisability of the data outside of Stockholm can be questioned, and the score will need to undergo prospective validation in other

regions prior to potential clinical implementation. Assessors will also not be blinded to outcome data.

Trial status

Patient recruitment was commenced on 1 September 2021 and the study is estimated to be completed by 31 December 2023.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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Variable list

Patient ID

Hospital

- ☐ Danderyds Sjukhus
☐ Karolinska Universitetssjukhuset Solna
☐ Karolinska Universitetssjukhuset Huddinge
☐ Norrtälje Sjukhus
☐ S:t Görans Sjukhus
☐ Södertälje Sjukhus
☐ Södersjukhuset
 (Hospital where the emergency department was located)

1 Sex

- ☐ Male ☐ Female

2 Age

(Years)

3 Date of trauma

(YYYY-MM-DD (if unknown, leave blank))

Time of trauma

(HH:MM (if unknown, leave blank))

4 Emergency department admission date

(YYYY-MM-DD (if unknown, leave blank))

Emergency department admission time

(HH:MM (if unknown, leave blank))

5 Time from injury to emergency department admission

- ☐ 0-3 hours
☐ 3-6 hours
☐ 6-12 hours
☐ 12-24 hours
☐ Unknow

6 Doctor assessment date

(YYYY-MM-DD (if unknown, leave blank))

Doctor assessment time

(HH:MM (if unknown, leave blank))

7 Date of discharge from emergency room

(YYYY-MM-DD (if unknown, leave blank))

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Time of discharge from emergency room

(HH:MM (if unknown, leave blank))

8 Comorbidities

- ☐ None of the below
☐ Dementia
☐ Alcoholism
☐ Liver cirrhosis
☐ Chronic renal impairment
☐ Intraventricular shunt
☐ Anticoagulation treatment
☐ Antiplatelet treatment
☐ Bleeding disorder
 (Select all that apply)

If "anticoagulation treatment" = yes, specify type(s)

- ☐ Warfarin
☐ Apixaban (Eliquis)
☐ Rivaroxaban (Xarelto)
☐ Dabigatran (Pradaxa)
☐ Edoxaban (Lixiana)
☐ LMWH (low-molecular-weight heparin)
☐ Other
 (Select all that apply)

If "antiplatelet treatment" = yes, specify type(s)

- ☐ ASA (Trombyl)
☐ Clopidogrel (Plavix)
☐ Ticagrelor (Brilique)
☐ Prasugrel (Effient)
☐ Dipyridamole (Persantin)
☐ Ticlopidine (Ticlid)
☐ Eptifibatide (Integrilin)
☐ Other
 (Select all that apply)

If "bleeding disorder" = yes, specify type

9 Trauma mechanism

- ☐ Low energy fall (same level)
☐ High energy fall (> 1 meter or > 5 steps)
☐ Motor vehicle accident (not motorcycle)
☐ Motorcycle accident
☐ Bicycle accident
☐ Pedestrian hit by traffic
☐ Other traffic accident
☐ Shot by gun
☐ Stabbed by sharp object
☐ Struck by blunt object
☐ Blast injury (e.g. explosion)
☐ Other
☐ Unknown

10 Multitrauma

- ☐ Yes ☐ No
 (Defined as radiology ordered for body part other than brain / cervical spine due to suspicion of traumatic injury)

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If "multitrauma" = yes, specify	<input type="checkbox"/> Thorax <input type="checkbox"/> Abdomen <input type="checkbox"/> Spine (thoracic or lumbar) <input type="checkbox"/> Upper Extremity <input type="checkbox"/> Lower Extremity (Select all that apply)
11 GCS = 15 before injury	<input type="radio"/> Yes <input type="radio"/> No ("No" means that the patient was GCS 14 or below prior to injury (e.g. dementia))
12 GCS on emergency department admission	<input type="radio"/> GCS = 15 <input type="radio"/> GCS = 14 <input type="radio"/> GCS = 13 (GCS when the physician performed the first assessment of the patient)
GCS eye score	<input type="radio"/> 4 (eyes open spontaneously) <input type="radio"/> 3 (eyes open to verbal command) <input type="radio"/> 2 (eyes open to pain) <input type="radio"/> Unknown
GCS verbal score	<input type="radio"/> 5 (orientated to time, person, place) <input type="radio"/> 4 (confused) <input type="radio"/> 3 (inappropriate words) <input type="radio"/> Unknown
GCS motor score	<input type="radio"/> 6 (obeys command) <input type="radio"/> 5 (moves to localised pain) <input type="radio"/> 4 (flex to withdraw from pain) <input type="radio"/> Unknown
13 Deterioration in GCS after first assessment	<input type="radio"/> Yes <input type="radio"/> No (Deteriorated in GCS after initial assessment of GCS)
14 Intoxicated	<input type="radio"/> Yes <input type="radio"/> No (Intoxicated on assessment (e.g. alcohol))
If "intoxicated" = yes, specify substance(s)	<input type="checkbox"/> Alcohol <input type="checkbox"/> Central stimulants (e.g. amphetamines, cocaine, LSD, ecstasy) <input type="checkbox"/> Anxiolytics (e.g. benzodiazepines) <input type="checkbox"/> Cannabis <input type="checkbox"/> Opioids <input type="checkbox"/> Other <input type="checkbox"/> Unknown (Select all that apply)
15 Pupillary status	<input type="radio"/> Normal <input type="radio"/> Unilateral dilation <input type="radio"/> Bilateral dilation (If not detailed, choose "normal")
If abnormal pupillary status - reactive to light?	<input type="radio"/> Yes <input type="radio"/> No

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16	Post-traumatic neurological deficit	<input type="checkbox"/> None of the below <input type="checkbox"/> Weakness in extremity <input type="checkbox"/> Numbness in extremity <input type="checkbox"/> Diplopia (double-vision) <input type="checkbox"/> Blurry vision <input type="checkbox"/> Dysphasia (problems with speech) <input type="checkbox"/> Dizziness / loss of balance <input type="checkbox"/> Loss of coordination <input type="checkbox"/> Other (Select all that apply. Do NOT check if patient had impairment prior to injury (e.g. already paralyzed patient))
	If "other deficit" = yes, specify	_____
17	Other worrisome factors	<input type="checkbox"/> None of the below <input type="checkbox"/> Amnesia <input type="checkbox"/> Confirmed loss of consciousness <input type="checkbox"/> Suspected loss of consciousness (e.g. if patient is unsure) <input type="checkbox"/> Vomiting <input type="checkbox"/> Persistent headache <input type="checkbox"/> Seizure <input type="checkbox"/> Scalp wound that needed suturing (excl. face) <input type="checkbox"/> Suspected open or depressed skull fracture <input type="checkbox"/> Sign(s) of skull base fracture (Select all that apply)
	If "amnesia" = yes, specify type(s)	<input type="radio"/> Retrograde (can't recall entire traumatic event) <input type="radio"/> Anterograde (can't remember new information) <input type="radio"/> Combined retrograde and anterograde <input type="radio"/> Unknown / missing
	If "loss of consciousness" = yes, specify if it was due to the head injury (i.e. not syncope / fainting)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
	If "vomiting" = yes, specify amount	<input type="radio"/> Once <input type="radio"/> More than once <input type="radio"/> Unknown / missing
	If "sign(s) of skull base fracture" = yes, specify	<input type="checkbox"/> Racoon-eyes (bruising around eye - "black eye", "brillenhematoma") <input type="checkbox"/> Battle's sign (bruising of the mastoid process behind ear) <input type="checkbox"/> Rhinorrhea (CSF-leak from nose) <input type="checkbox"/> Otorrhea (CSF-leak from ear) <input type="checkbox"/> Anosmia (loss of smell) <input type="checkbox"/> Hematotympanon (blood behind ear drum) <input type="checkbox"/> Deafness <input type="checkbox"/> Nystagmus <input type="checkbox"/> Facial nerve paralysis <input type="checkbox"/> Other
	If "other sign(s) of skull base fracture" = yes, specify	_____
18	Lab sampled	<input type="radio"/> Yes <input type="radio"/> No

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Date of lab sampling (first test)

(YYYY-MM-DD)

Time of lab sampling (first test)

(HH:MM)

S100B

(µg/L)

PK(INR)

APT-time

(seconds)

Hemoglobin (Hb)

(g/L)

Platelet count

(150 x 10⁹/L)

Serum ethanol

(mmol/L)

Alcohol promille level (breathalyzer)

(promille)

19 Date of CT scan

(YYYY-MM-DD)

Time of CT scan

(HH:MM)

20 Intracranial lesion on CT

☐ Yes ☐ No

If "intracranial lesion on CT" = yes, specify type(s)

- ☐ Cerebral contusion
 - ☐ Traumatic subarachnoid haemorrhage
 - ☐ Epidural hematoma
 - ☐ Acute subdural hematoma
 - ☐ Chronic subdural hematoma
 - ☐ Intraventricular hematoma
 - ☐ Diffuse axonal injury
 - ☐ Sinus thrombosis
 - ☐ Traumatic infarct
 - ☐ Skull fracture (neurocranium, not face)
- (Select all that apply)

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If "skull fracture" = yes, specify type(s)

- ☐ Linear fracture with impression
☐ Linear fracture without impression
☐ Crush fracture with impression
☐ Crush fracture without impression
☐ Other

If "intracranial lesion on CT" = yes, specify management

- ☐ None (sent home from emergency department)
☐ Admission < 48 hours due to TBI ("overnight observation")
☐ Admission > 48 hours due to TBI
☐ Paus or reversal of anticoagulants or antiplatelets
☐ Intubated due to TBI
☐ Transfer to neurosurgical department
☐ Death due to TBI
 (Select all that apply)

If patient was admitted due to TBI, specify amount of days in hospital

Follow-up CT performed

☐ Yes ☐ No

If "follow-up CT performed" = yes, specify reason(s)

- ☐ Decided on admission regardless of neurology
☐ Decreased consciousness
☐ Increased headache
☐ New neurological abnormality
☐ Vomiting
☐ Other
☐ Unclear / unknown

If "follow-up CT performed" = yes, specify if the lesion progressed

☐ Yes ☐ No

21 Re-admission within 30 days with CT-verified intracranial lesion

☐ Yes ☐ No