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Management of haemothoraces in blunt thoracic trauma: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Haemothorax following blunt thoracic trauma is a common source of morbidity and mortality. The optimal management of moderate to large haemothoraces has yet to be defined. Observational data have suggested that expectant management may be an appropriate strategy in stable patients. This study aims to compare the outcomes of patients with haemothoraces following blunt thoracic trauma treated with either chest drainage or expectant management.

Methods and analysis This is a single-centre, dual-arm randomised controlled trial. Patients presenting with a moderate to large sized haemothorax following blunt thoracic trauma will be assessed for eligibility. Eligible patients will then undergo an informed consent process followed by randomisation to either (1) chest drainage (tube thoracostomy) or (2) expectant management. These groups will be compared for the rate of additional thoracic interventions, major thoracic complications, length of stay and mortality.

Ethics and dissemination This study has been approved by the institution's research ethics board and registered with ClinicalTrials.gov. All eligible participants will provide informed consent prior to randomisation. The results of this study may provide guidance in an area where there remains significant variation between clinicians. The results of this study will be published in peer-reviewed journals and presented at national and international conferences.

Trial registration number NCT03050502.

Strengths and limitations of this study

- First randomised controlled trial designed to clarify the role of chest drainage for blunt traumatic haemothorax.
- The nature of the intervention groups does not allow for blinding.
- This is a single-centre study.

INTRODUCTION

Thoracic injuries are common in patients with blunt polytrauma and are responsible for approximately 25% of all injury-related mortalities.[1] Traumatic injuries to the thorax often result in the accumulation of blood within the pleural space (ie, a haemothorax (HTX)). Traditionally, the management of HTXs has included chest tube placement. Although HTXs are effectively managed with tube thoracostomy (TT), this intervention is associated with a number of potentially serious complications including iatrogenic injury, retained HTXs and empyema in up to 22% of patients.[2–5]

Prior to the ubiquitous use of chest CT, diagnosing quantities of blood <1000 mL was challenging. With the widespread adoption of CT 'pan-scanning', however, significantly more HTXs are being detected. The clinical significance and suboptimal treatment of these small to moderate HTXs remain unknown.[6]

The East American Association of Trauma guidelines suggest that all HTXs should be considered for TT drainage.[7] However, several retrospective studies suggest that many traumatic HTXs can be managed expectantly without TT drainage.[8–12] A prospective observational study also suggests that small to moderate HTXs (<300 cc of blood) can be absorbed without intervention.[5] Classic studies from the 1960s indicate that much larger quantities of blood can be reabsorbed without intervention as well.[13 14] As a result, the management of HTXs remains a clinical dilemma when the volume of blood is moderate to large and the patient is haemodynamically stable.

This study aims to evaluate the rate of additional thoracic interventions after expectant management as compared with upfront pleural drainage in patients with moderate to large volume haemothoraces secondary to blunt trauma.

METHODS AND ANALYSIS

Overview

The study will be a single-centre, dual-arm, parallel randomised controlled trial. Patients

	STUDY PERIOD						
	Enrolment	Allocation	Post-Admission Day			Post-Discharge Followup	
TIMEPOINT	*Within 24hrs*	*Within 24hrs*	*1*	*...*	*D/C*	*30 days*	*90 days*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Randomization		X					
Allocation		X					
INTERVENTIONS:							
Tube Thoracostomy			●	—			
Expectant Management			●	—	●		
ASSESSMENTS:							
Additional thoracic interventions			●	—	—	—	●
Major thoracic complications			●	—	—	—	●
Length of stay			●	—	●		
Mortality					X		

Figure 1 SPIRIT diagram describing schedule of enrolment, interventions and assessments. SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

presenting with HTXs secondary to blunt thoracic trauma that are moderate to large in size will be randomised in a 1:1 ratio to chest drainage or expectant management. We hypothesise non-inferiority of expectant management as compared with pleural drainage in terms of rate of additional thoracic interventions. This study protocol was constructed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidelines.[15] A SPIRIT diagram detailing the timing of screening, randomisation, allocation and assessment is provided in figure 1.

Trial design

HTXs are common among patients with blunt thoracic trauma. They are associated with a range of intrathoracic and extrathoracic injuries with varying severity. The trial described below incorporates this real-world variability and therefore adopts a pragmatic trial design. The explanatory versus pragmatic nature of the trial is summarised visually using the pragmatic explanatory continuum indicator summary (PRECIS-2) wheel (figure 2).[16]

Setting

The study will take place at the Foothills Medical Centre (FMC), a University of Calgary affiliated tertiary care hospital located in Calgary, Alberta, Canada. The FMC is a Trauma Association of Canada (TAC) accredited level 1 trauma centre that provides trauma care to southern Alberta, Southwest Saskatchewan and Southwest British Columbia.

Eligibility criteria

The population will consist of all eligible patients presenting with moderate to large sized HTXs (≥300 cc, as estimated on CT) secondary to blunt thoracic trauma. HTX size will be evaluated using a previously validated formula: $V=d^2\times X\times L$, where V is volume of blood in cubic centimetres (cc), d is the greatest depth of HTX from the chest wall to lung on any CT image in centimetres, X is the thickness of CT slice in centimetres and L is the total craniocaudal length occupied by pleural fluid in centimetres.[5 17] HTX size will be calculated by both a trauma team leader and an attending radiologist. The inclusion and exclusion criteria are designed to identify a population of patients presenting with blunt traumatic HTXs who do not have an urgent clinical indication for TT. These are summarised in table 1.

Consent

Eligibility will be determined by the attending trauma surgeon at the time of initial admission investigations. Informed consent and randomisation will also occur as soon as possible within a 24-hour window from admission (figure 1). This 24-hour window will begin at the time of admission to our institution in an effort to include eligible patients transferred from other regional centres.

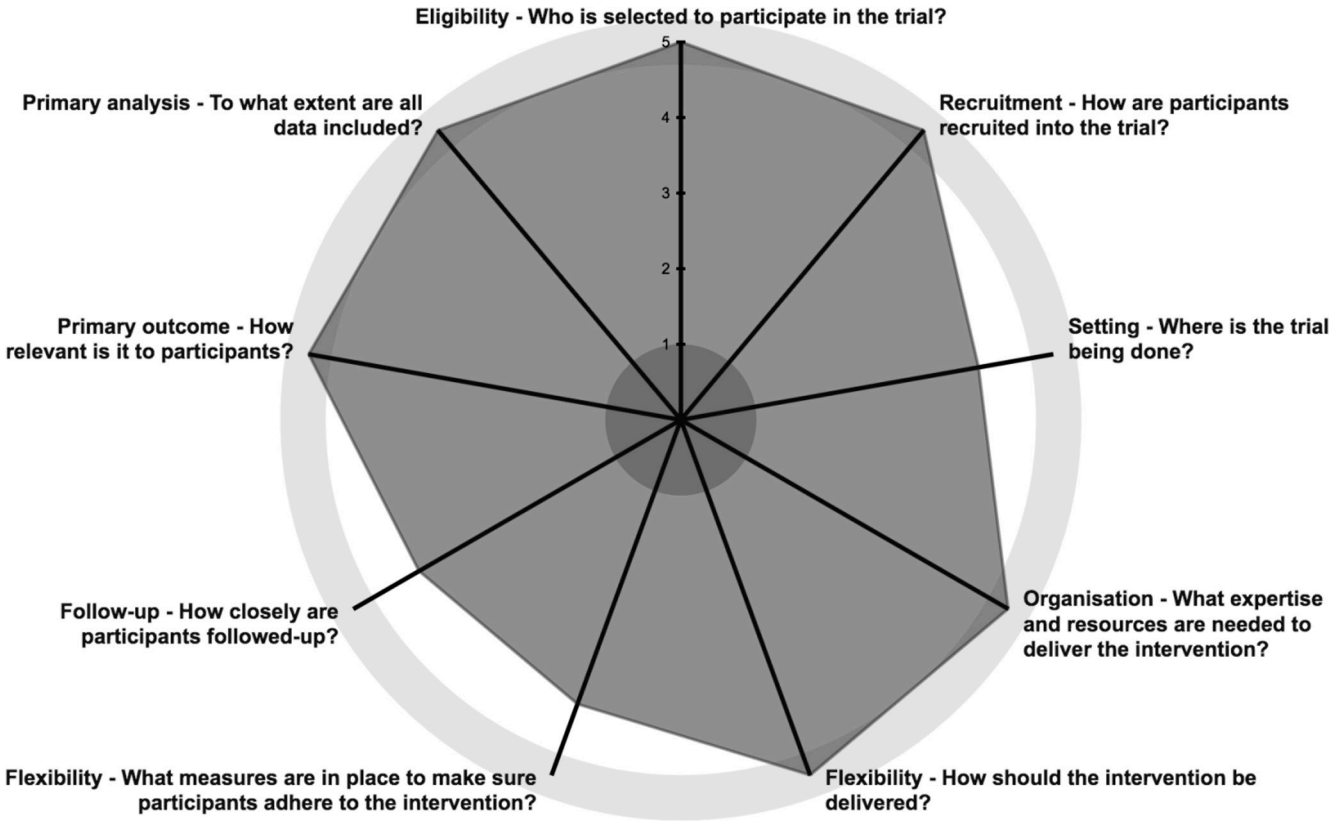

Figure 2 Description of trial design using pragmatic explanatory continuum indicator summary wheel.

The intervention will be applied immediately following randomisation.

Randomisation

Once eligibility has been determined, participants will be randomised using a block randomisation model (block size 4). The randomisation tool is located on a password-protected website. If an eligible patient has bilateral blunt traumatic haemothoraces, randomisation will occur for only one side. The intervention will then be applied to both sides.

Table 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
Age≥18 years	Haemodynamic instability attributed to HTX*
Blunt thoracic injury	Respiratory distress attributed to HTX*
Moderate or large HTX (≥300 cc) detected on CT	Any scenario requiring urgent TT placement*
	Penetrating thoracic injury
	Chest tube already in situ (eg, prior to transfer)
	>24 hours after admission
	Ipsilateral flail chest fracture pattern

*In the judgement of the attending trauma surgeon.
HTX, haemothorax; TT, tube thoracostomy.

Interventions

1. Chest drainage: this group will have an intrapleural catheter placed with the intent of draining all intrapleural blood (HTX). The size and nature of the catheter, manner of placement and timing of removal will be at the discretion of the attending trauma team leader.
2. Observation (expectant management): this group will not have an intrapleural catheter placed on the basis of the HTX, but will undergo standard observation/conservative management by the trauma service. Intrapleural catheters may be placed after enrolment at the attending clinician's discretion. After enrolment, this decision will constitute an outcome variable and require full documentation as to the indications and rationale.

The size and nature of the tube or catheter used for chest drainage will be at the discretion of the attending trauma team leader. Current evidence indicates that the size and nature of the catheter does not impact outcomes in approriate ly selected patients.[18 19] Following chest tube insertion, a standardised protocol will be followed including daily chest X-rays, monitoring of chest tube output and observation for air leak. Again, chest tube removal will be at the discretion of the attending trauma surgeon.

Table 2 Sample data collection

Demographics	Injury severity	Admission physiology
Age	Mechanism of injury	Heart and respiratory rate
Gender	Injury Severity Score	Blood pressure and mean arterial pressure
Comorbid medical conditions	Abbreviated Injury Score	FiO_2/PaO_2 ratio
	Glasgow Coma Score	Arterial blood gases
Resuscitation requirements	**Diagnosis and management of HTX**	**Complications**
PRBC, FFP and platelet transfusion	Presence of HTX on chest X-ray	Retained HTX
Crystalloid administration	Volume estimate of HTX on CT	Empyema
Factor VIIA administration	Presence of pneumothorax	Prolonged air leak
Tranexamic acid administration	Presence of flail chest	Subcutaneous haematoma
Vasopressor administration	Bilateral HTX	Chest tube-related injury
	Details of TT insertion	

FiO_2, fractional inspired oxygen; FFP, fresh frozen plasma; HTX, haemothorax; PaO_2, arterial oxygen pressure; PRBC, packed red blood cell; TT, tube thoracostomy.

Participants allocated to observation can undergo chest drainage or other interventions at the discretion of the attending trauma surgeon if the culinarycondition necessitates a change in management. Chest drainage will depend on clinical features such as worsening pain, increasing oxygen requirements, increasing size or haemodynamic consequences. All participants will receive the institutional/trauma service standard of care for all other treatments other than chest tube placement. This includes methods of pain control, venous thromboembolism prophylaxis, and specialist consultation and management of additional injuries.

Data collection

Data will be collected from both electronic and paper-based medical records by study staff on standardised report forms. Details regarding chest tube size, method of insertion and duration will be recorded for all patients undergoing chest drainage, either following initial randomisation or for those requiring chest drainage following randomisation to observation. A sample of additional recorded data points is included in table 2. After hospital discharge, participants will be assessed for progress and potential complications in a dedicated outpatient trauma clinic approximately 30 and 90 days after randomisation. This outpatient follow-up will include chest X-rays to monitor for radiological resolution. The attendance of blunt injured patients within our trauma clinic has traditionally been very high (>90%). All study documents will be maintained in a secure location in a locked office.

Outcomes

Outcomes will be assessed by the attending trauma surgeon, trauma fellow and other study authors. Assessments will include daily physical examinations, blood tests and chest X-ray. Primary outcomes include the rate of additional thoracic interventions (ie, additional TT insertion, image-guided drainage, video-assisted thoracic surgery or thoracotomy). Secondary outcomes include the rate of empyema, tracheostomy, inhospital mortality, intensive care unit, length of stay (LOS), overall hospital LOS and days of mechanical ventilation.

Sample size

The reported rate of retained HTX after TT is approximately 33%.[6] Using this as a surrogate for failure of the intervention, the rate of success of TT is estimated as 67%. Sample size was then calculated assuming (1) non-inferiority of the expectant management group; (2) significance level (alpha) of 0.05; (3) power (beta) of 90% and (4) an expected difference in event rates of 15%. One hundred and sixty-nine patients will be randomised to each intervention.

Analysis

An intention-to-treat analysis will be used. Descriptive statistics will be used to describe the patients in both treatment arms. Continuous variables will be compared using Student's t-test and the Mann-Whitney U test. The χ^2 test or Fisher's exact test will be used to compare categorical variables. Multivariate analysis will be done to compare mortality rates of the different management received but also to account for other potential confounding variables. All variables with a P value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for mortality and morbidity. Statistical analysis will be performed with STATA.

CONCLUSION

The management of haemothoraces in blunt trauma remains an area of clinical equipoise. This trial aims to compare chest drainage and expectant management in blunt traumatic haemothoraces. This will further clarify the role of expectant management that has been

described in previous observational reports.[8–12] Blunt traumatic haemothorax is a very common condition and the results of this study have the potential to improve the quality of care for trauma patients around the world.

Contributors CGB is the principal investigator and has coordinated all phases of trial design, statistical analysis plan and drafting of the protocol. AKB, CS, SCG, AWK, RL, PBM and MBD contributed to the development of the trial design. DAC and AKB critically appraised the trial design, participated in study coordination and wrote the manuscript. All authors contributed to the writing of the manuscript and agreed with submission of the final version for publication.

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Competing interests None declared.

Patient consent Detail has been removed from this case description/these case descriptions to ensure anonymity. The editors and reviewers have seen the detailed information available and are satisfied that the information backs up the case the authors are making.

Ethics approval Conjoint Health Research Ethics Board at the University of Calgary (REB16-1056).

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