A Pilot Multicenter Cluster Randomized Trial to Compare The Effect of Trauma Life Support Training Programs on Patient and Provider Outcomes

Trauma life support training Effectiveness Research Network (TERN) collaborators

Trial registration

This pilot study was registered with ClinicalTrials.gov (reg. no NCT05417243).

Keywords

Trauma management, Accident and emergency medicine, Education and training.

Role of study sponsor and funders

The funding sources had no role in the design of this study nor during its execution, analyses, interpretation of the data, or decision to submit the results.

Abstract

Introduction Trauma life support training programmes aim to improve trauma outcomes but there is no evidence from controlled trials to show that they work. We conducted a pilot study to assess the feasibility of conducting a cluster randomised controlled trial comparing the effect of Advanced Trauma Life Support® (ATLS®) and Primary Trauma Care (PTC) with standard care on patient outcomes. **Methods and analysis** We piloted a pragmatic three-armed parallel, cluster randomised, controlled trial in India, where neither of these programmes are routinely taught. We recruited tertiary hospitals and included trauma patients and residents managing these patients. Two hospitals were randomised to ATLS®, two to PTC, and three to standard care. The primary outcome was all cause mortality at 30 days from the time of arrival to the emergency department. We conducted community consultations in parallel with the pilot trial. **Ethics and dissemination** We obtained ethical approval from all participating centres. **Results** Between April 2022 and February 2023 we included 376 patients and 21 residents from 7 centres. The percentage of patients who consented to follow up was 78% and the resident recruitment rate was 100%. The lost to follow up rate was 14%. 22 (16%) patients died within 30 days in the standard care arm, 1 (3.8%) patients in the ATLS® arm, and 3 (4.9%) patients in the PTC arm. **Conclusions** Conducting a full-scale cluster randomised controlled trial comparing the effects of ATLS®, PTC, and standard care on patient outcomes should be feasible after incorporating key lessons from this pilot.

Introduction

Trauma, defined as the clinical entity composed of physical injury and the body's associated response, causes 4.3 millions deaths every year[1]. Almost 10% of the global burden of disease is due to trauma and trauma is the top contributor to the burden of disease in children and adults aged 10 to 49 years[2].

Trauma care is time sensitive and early management of life or limb threatening conditions is crucial. Several trauma life support training programs have been developed to improve the early management of patients as they arrive at hospital by providing a structured framework to assessment and treatment[3–5].

The proprietary Advanced Trauma Life Support® (ATLS®) is the most established trauma life support training program and more than one million doctors in over 80 countries have been trained in the programme[6]. Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs[5].

The free Primary Trauma Care (PTC) program is the most widely spread alternative programme. The goal of PTC is to improve trauma care in LMIC[7]. Like ATLS®, doctors in over 80 countries have been trained in PTC, and the programme has been endorsed by the World Health Organization (WHO), among other international organizations including several professional societies[7].

There are observational studies indicating that trauma life support training programmes may improve patient outcomes[8], but there are no randomised trials[3–5]. We performed a pilot study aiming to assess the feasibility of conducting a cluster randomised controlled trial comparing ATLS® and PTC with standard care.

Methods

Trial Design

We piloted a three-armed cluster randomised controlled trial. There were two intervention arms, ATLS® and PTC training, and one control arm, standard care. We collected data for four months in all three arms, first during a one month observation phase and then during a three month intervention phase (or continued observation in the control arm). This design allowed us to assess outcomes both as final values and as change from baseline.

Our study is a pilot study because its objectives involves estimating quantities, such as the probable effect sizes, proportion of participants with the outcome (if binary), and the intracluster correlation coefficient, needed for the sample size calculations of a full-scale trial[9]. This pilot study also establish how many participants that can be enrolled, as well as likely drop out rates, and the feasibility of collecting primary and secondary outcomes.

Study Setting

We conducted this pilot in seven Indian tertiary hospitals, where neither ATLS®, PTC, nor any other trauma life support training program is routinely taught. The seven hospitals were Seth G. S. Medical College and K.E.M. Hospital, Mumbai; Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai; HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai; Medica Superspecialty Hospital, Kolkata; Medical College Kolkata, Kolkata; Sir Nil Ratan Sircar Medical College & Hospital, Kolkata; Postgraduate Institute of Medical Education & Research, Chandigarh.

Eligibility Criteria for Participants and Clusters

There were two groups of participants: patients and resident doctors.

Patient Participants

Adults (15 years or older) who presented to the emergency department at participating hospitals with a history of trauma. History of trauma is here defined as having any of the external causes of morbidity and mortality listed in block V01-Y36, chapter XX of the International Classification of Disease version 10

(ICD-10) codebook as reason for presenting. We explored intervention effects across the following clinical subgroups: men, women, blunt multisystem trauma, penetrating trauma, shock, severe traumatic brain injury, and elderly, as defined by Hornor et al[10].

Resident Doctor Participants

Resident doctors doing their speciality training in surgery or emergency medicine managing trauma patients in the emergency department and who were expected to remain in the participating hospitals for at least one year. To facilitate administration each surgical department is divided into units, which manage the out-patient and emergency departments, operating rooms etc on different days each week. One or two, out of typically six, units' residents were selected from each hospital. One unit consists of at least three faculty and three to twelve residents.

To be eligible, units had to have a maximum of 25% of the doctors trained in either ATLS®, PTC, or similar training programs before the start of the pilot. Those residents who had received training in the last five years were considered as trained. The figure of 25% was decided through consensus in the research team, to balance feasibility and contamination of results.

Consent was sought from the residents in each of the intervention groups before they underwent the ATLS® or PTC training. We did not ask for consent from residents at the units in the control hospitals as their practice was not affected by this pilot and we did not collect any personal identifiable data on them.

Clusters

Indian tertiary care hospitals that admit more than 400 adult patients with trauma each year. We randomised on the cluster (hospital) level to avoid contamination between intervention and control arms. To be eligible for inclusion hospitals had to provide the following services round the clock: operation theatres, X-ray, CT, and ultrasound facilities, and blood bank. In addition the baseline admission rate had to be more than 35 adult patients with major trauma per month.

Interventions

In each intervention arm one or two units', out of typically six, residents per hospital providing emergency care to trauma patients were trained in either ATLS® or PTC. For the purpose of this pilot study, our target was to train a minimum of 75% of residents in each unit. If residents dropped out or changed units after training but before data collection was completed we planned to conduct additional training if needed to meet the 75% criterion, but this was not required. We did not train the units' faculty, as they are typically not directly involved in the initial management of trauma patients.

The ATLS® training was conducted in an ATLS® certified training centre in Mumbai, according to the standard ATLS® curriculum[6]. The PTC training was conducted in New Delhi, according to the standard PTC curriculum[7]. These courses were conducted over a period of 2.5 to 3 days. The residents certified "pass" were considered as trained in respective courses.

The control group provided standard care with no intervention.

Modifications

Both ATLS® and PTC are standard training programs with fixed curricula[6,7]. We did not modify the delivery or content of these programs during this pilot.

Adherence

The intervention was the training in either ATLS® or PTC and resident participants were required to adhere to, i.e. participate in, the training, to be eligible for passing. We did not consider adherence to training contents during care delivery as adherence to the trial intervention.

Standard Care

Standard care varies across hospitals in India, but trauma patients are initially managed by casualty medical officers, surgical residents, or emergency medicine residents. They are mainly first- or second-year residents who resuscitate patients, perform interventions and refer patients for imaging or other investigations. Compared with other settings where a trauma team approach is adopted, nurses and other healthcare professionals are only involved to a limited extent during the initial management.

Outcomes

Our pilot study included both participant and feasibility outcomes. Prior to deciding on these participant outcomes we searched the Core Outcome Measures in Effectiveness Trials (COMET) Initiative's database but were unable to identify appropriate core outcome sets for our populations of participants.

The primary participant outcome was all cause mortality within 30 days from the time of arrival to the emergency department. The primary outcome and most secondary outcome were assessed and compared both as final values and as change from baseline. All outcomes that pertain to the individual participant level are detailed in Supplemental Material 1. We decided to include a large number of outcomes, including some more exploratory, so that we could test their feasibility and relevance.

We also assessed the following feasibility outcomes, which pertained both to overall study population as well as to the individual cluster level:

- Recruitment rate. For both patients and residents this was equal to the proportion of participants enrolled, out of the total number of eligible participants, over the course of the pilot study.
- Lost to follow up rate. This applied only to patients and was equal to the proportion of patients that did not complete 30 day follow up, out of all enrolled patients, over the course of the pilot study.
- Pass rate. This applied only to residents in the intervention arms and equal the proportion of residents that pass the training programme, out of the total number of trained residents, over the course of the pilot study.
- Missing data rate. This applied to each outcome and variable and was equal to the proportion of missing data, over the course of the pilot study.
- Differences in distributions of observed and extracted data. This applied to each outcome and variable and compared the distributions of data collected by observations versus extracted from hospital records. For quantitative variables this was be the difference in means, standard deviations, medians, interquartile ranges, and ranges. For qualitative variables this was the differences in absolute counts and percentages, across categories.

Participant Timeline

Patients

Patients were screened for eligibility as they arrived at the emergency department. Eligible patients were approached in the emergency department to consent to follow up, if they were conscious. If they were unconscious a patient representative was approached to consent to follow up. Once the patient was conscious we approached the patient to affirm the patient representative's consent. We followed up patients at discharge, at 24 hours after arrival at the emergency department, and at 30 days after arrival at the emergency department.

Residents

Participating units were screened for eligibility once hospitals confirmed their participation. All residents in eligible units were approached to consent to training if their hospital was randomised to either of the intervention arms. Training was conducted approximately one month after the study started.

Sample size

Given budget and time constraints, including the rotation of units in the emergency departments in Indian hospitals (which often happen on a six months basis) the feasible data collection period was four months. We assumed that each of the units saw 2-4 trauma patients per week and based on that estimated that if we selected a minimum of one unit per hospital then each hospital would enrol 8-16 patients per month and 32-64 patients during the four months of this pilot. With a 20% attrition rate we expected each hospital to enrol 26-51 patients, coming to a total sample size of between 156 and 306 patients for this pilot study.

Recruitment

To ensure adequate recruitment we only approached hospitals that stated that the their volumes were high enough to allow us to reach the sample size goals detailed above. Patients were enrolled by a dedicated project officer as they arrived at the emergency department. The recruitment period was four months. Recruitment was monitored weekly through online conferences. No financial or non-financial incentives were provided to trial investigators or participants for enrolment.

Allocation

Sequence generation

We used simple randomisation to allocate sites to trial arms. We prepared seven sealed envelopes from which one representative from each pilot site selected one in a common meeting. The content of the envelopes dictated what trial arm (ATLS®, PTC, or standard care) each hospital was allocated to. There were two hospitals in each of the intervention arms and three hospitals in the control arm.

Concealment Mechanism

We did not conceal the sequence.

Implementation

The random allocation sequence was generated by MGW. Clusters were enrolled by the project's core team. Patient participants were enrolled if they presented during the project officers shift. Resident participants were enrolled if they were in the units selected for training. The principal investigator at each hospital selected the units for training. For patient participants consent for follow up was sought after randomisation from patients or patient relatives as appropriate. For resident participants consent was also sought after randomisation.

Blinding

It was not possible to blind investigators or participants to interventions. We did not blind the data analysts during this pilot, but we plan to blind the data analysts during the full-scale trial.

Data Collection

Data collection started one month before the training was delivered, to establish a baseline. Each participating hospital had a dedicated project officer who collected the data.

Because participating residents were assigned designated days for trauma care for a period of 6 months, data were collected during those particular days and shifts when these trained doctors were in the emergency department. The project officers collected data both by observing the care delivered and by interviewing the participants, and by extracting data from hospital records.

Data collection continued for three months after training. The research officers collected data of all trauma patients who presented to the participating units during their duty hours. Those patients who were admitted were followed up for complications and other in-hospital outcome measures, for example length of stay.

Patients who were not admitted were followed up telephonically for mortality outcomes and quality of life outcomes. The follow up period was be 30 days. The project officers made at most three attempts to reach a participant or participant representative telephonically, after which the data were recorded as missing.

The project officer administered the study information and informed consent (consent was sought only for data collection including follow up) to the patient, or the patient's representative as appropriate, once the patient was stabilised. They will continue to collect data once they have received the consent.

Details of data of those patients/relatives not willing to give consent were not included in the analysis. The number of patients who opt out from data collection was collected.

Variables

The project officers collected data on demographics, time of injury to arrival at the participating hospital, time to recording vital signs, vital signs, and times to and management details including imaging and surgery. Details of any injury sustained were collected and coded using ICD 10 and the Abbreviated Injury Scale (AIS). For ICD 10 coders underwent the WHO online ICD 10 training module and for AIS they were accredited. Based on AIS we calculated the Injury Severity Score (ISS) and the New ISS (NISS). Supplemental Material 2 contains a full variable list, with definitions.

Patient and public involvement

In this study, we conducted community consultations to collect inputs from patients, their caregivers, patient groups, and resident doctors to be used in the selection of outcome measures and implementation of the full-scale trial; following the Guidance for Reporting Involvement of Patients and the Public (GRIIPS 2)[11]. The results of these consultations will be reported in a separate publication.

Data management

We used the online data collection tool KoboToolbox[12], accessible only over a virtual private network (VPN), for each participating hospital to upload pseudonymised data to secure servers. Data validation techniques such as restricted values or values within a specific range were used to avoid ambiguous data entries and ensure the validity of the data. Ambiguous responses and errors were resolved after discussion with the core team during weekly meetings. An instruction manual or codebook for data variables was prepared to ensure consistency in data entry. This manual was referred to during the project data collection and variable descriptions were visible for each variable in the online data collection tool. Pseudonymised data were stored at the centralised server. The data were only accessible by the project's principal investigator or by delegation by the project principal investigator.

Data monitoring

Weekly meetings with the core team and project officers took place. We conducted an interim analysis on October 12, 2022, and decided to complete the study as participants were consenting to be included in the study and key variables including mortality outcomes could be collected. No outcomes were dropped. We did not use a data monitoring committee in the pilot study due to its limited scope.

Statistical Methods

We analysed all pilot data using descriptive statistics. Quantitative variables are summarised as mean +/- standard deviation, median, interquartile range and range. Qualitative variables are presented as absolute numbers and percentages. Feasibility outcomes are summarised both on the overall sample level as well as on the individual cluster level. We used an empty generalised linear mixed model to estimate the intracluster correlation coefficient.

We compared participant outcomes in three combinations of trial arms: ATLS® versus PTC, ATLS® versus standard care, and PTC versus standard care. In each combination we compared both differences in final

values and differences in change from baseline. For the intervention arms the change from baseline was calculated as the difference between the one month period of data collection before the training was undertaken and the three month period after the training. For the control arm the data collection period was four months and the difference from baseline was calculated as the difference between the first one month and the following three months.

Within each combination of trial arms we had planned to conduct subgroup analyses of men, women, blunt multisystem trauma, penetrating trauma, shock, severe traumatic brain injury, and elderly. These subgroups were however too small to allow for meaningful analyses, and are therefore reported descriptively only.

We calculated both absolute and relative differences for each comparison, along with 75, 85, and 95% confidence intervals. We used an empirical bootstrap procedure with 1000 draws to estimate these confidence intervals. We did not perform any formal hypothesis tests during the analysis of this pilot's data[13]. We also compared the data collected through observations and interviews with the data collected from hospital records, to assess the feasibility of collecting data from hospital records in the full-scale trial.

Ethics and Dissemination

We were granted research ethics approval from each participating hospital. The approval numbers were IEC(II)/OUT/134/2022 for King Edward Memorial Seth G. S. Medical College and K.E.M. Hospital, Mumbai; IEC/214/22 for Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai; HBTMC/266/SURGERY for HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai; CREC/2022/FEB/1(ii) for Medica Superspecialty Hospital, Kolkata; Medical College Kolkata, Kolkata; NRSmC/IEC/93/2021 for Sir Nil Ratan Sircar Medical College & Hospital, Kolkata; and PGI/IEC/2022/000/003 for Postgraduate Institute of Medical Education & Research, Chandigarh.

The protocol was published in BMJ Open[14] and was registered with ClinicalTrials.gov (reg. no NCT05417243). Amendments to the protocol after publication were determined by the core research group and updated on ClinicalTrials.gov.

The final anonymized dataset and code for analysis are released publicly. Authorship follows the International Committee of Medical Journal Editors (ICMJE) guidelines.

Results

Between April 2022 and February 2023, we enrolled 376 trauma patients from 7 participating centres. The ATLS® arm enrolled 44 patients, the PTC arm 130 patients, and the standard care arm 202 patients. We trained a total of 21 residents, 6 in ATLS®, and 15 in PTC.

The study flow diagram is shown in Figure 1 and patient sample characteristics across trial arms are shown in Table 3. Overall, the number of females were 86 (23%), the median (IQR) age was 33 (24, 46) years, and the median ISS (IQR) was 1 (0, 4). A total of 32 (9.9%) patients had the primary outcome of mortality at 30 days after arrival to the emergency department.

```
## Table printed with `knitr::kable()`, not {gt}. Learn why at
## https://www.danieldsjoberg.com/gtsummary/articles/rmarkdown.html
## To suppress this message, include `message = FALSE` in code chunk header.
```

```
## Table printed with `knitr::kable()`, not {gt}. Learn why at
## https://www.danieldsjoberg.com/gtsummary/articles/rmarkdown.html
## To suppress this message, include `message = FALSE` in code chunk header.
```

```
## Table printed with `knitr::kable()`, not {gt}. Learn why at
## https://www.danieldsjoberg.com/gtsummary/articles/rmarkdown.html
## To suppress this message, include `message = FALSE` in code chunk header.
```

Table 1: Patient sample characteristics

Characteristic	**ATLS**, N = 16	**PTC**, N = 57	**Standard care**, N = 41	**Overa
Age, years	46 (31, 61)	30 (22, 38)	32 (23, 46)	33
Elderly	3 (19%)	3 (5.3%)	3 (7.3%)	9
Sex				
Male	10 (63%)	44 (77%)	36 (88%)	9(
Female	6 (38%)	13 (23%)	5 (12%)	2
Other	0 (0%)	0 (0%)	0 (0%)	(
Unknown	0 (0%)	0 (0%)	0 (0%)	(
Dominating injury type				
Penetrating	2 (13%)	0 (0%)	3 (7.3%)	5
Blunt	14 (88%)	57 (100%)	38 (93%)	10
Blunt multisystem trauma	1 (6.3%)	3 (5.3%)	0 (0%)	4
Severe traumatic brain injury	0 (0%)	3 (5.3%)	4 (9.8%)	7
Shock	1 (6.7%)	0 (0%)	0 (0%)	1
Missing	1	1	3	
Respiratory rate, breaths per minute	21.5 (20.0, 24.0)	21.0 (19.0, 23.0)	20.0 (18.0, 21.0)	20.0 (
Missing	0	3	4	
Oxygen saturation, %	98.00 (96.00, 99.00)	98.00 (97.00, 98.00)	98.00 (97.75, 99.00)	98.00 (
Missing	1	0	1	
Heart rate, beats per minute	94 (76, 104)	90 (79, 104)	86 (80, 96)	88
Missing	0	1	1	
Systolic blood pressure, mmHg	128 (113, 149)	123 (115, 136)	126 (117, 130)	124
Missing	1	1	3	
Glasgow Coma Scale	15.00 (15.00, 15.00)	15.00 (15.00, 15.00)	15.00 (15.00, 15.00)	15.00 (
Missing	1	0	0	
Injury Severity Score	3 (1, 10)	4 (0, 9)	1 (0, 4)	2
In-hospital mortality	0 (0%)	4 (7.0%)	2 (4.9%)	6
Missing				
30 day mortality	0 (0%)	5 (10%)	1 (2.6%)	6
Missing	2	8	3	

Table 2: Patient sample characteristics

Characteristic	**ATLS**, N = 16	**PTC**, N = 57	**Standard care**, N = 41	**Overa
Age, years	46 (31, 61)	30 (22, 38)	32 (23, 46)	33
Elderly	3 (19%)	3 (5.3%)	3 (7.3%)	9
Sex				
Male	10 (63%)	44 (77%)	36 (88%)	9(
Female	6 (38%)	13 (23%)	5 (12%)	2
Other	0 (0%)	0 (0%)	0 (0%)	(
Unknown	0 (0%)	0 (0%)	0 (0%)	(
Dominating injury type				
Penetrating	2 (13%)	0 (0%)	3 (7.3%)	5
Blunt	14 (88%)	57 (100%)	38 (93%)	10
Blunt multisystem trauma	1 (6.3%)	3 (5.3%)	0 (0%)	4
Severe traumatic brain injury	0 (0%)	3 (5.3%)	4 (9.8%)	7
Shock	1 (6.7%)	0 (0%)	0 (0%)	1
Missing	1	1	3	
Respiratory rate, breaths per minute	21.5 (20.0, 24.0)	21.0 (19.0, 23.0)	20.0 (18.0, 21.0)	20.0 (
Missing	0	3	4	
Oxygen saturation, %	98.00 (96.00, 99.00)	98.00 (97.00, 98.00)	98.00 (97.75, 99.00)	98.00 (
Missing	1	0	1	
Heart rate, beats per minute	94 (76, 104)	90 (79, 104)	86 (80, 96)	88
Missing	0	1	1	
Systolic blood pressure, mmHg	128 (113, 149)	123 (115, 136)	126 (117, 130)	124
Missing	1	1	3	
Glasgow Coma Scale	15.00 (15.00, 15.00)	15.00 (15.00, 15.00)	15.00 (15.00, 15.00)	15.00 (
Missing	1	0	0	
Injury Severity Score	3 (1, 10)	4 (0, 9)	1 (0, 4)	2
In-hospital mortality	0 (0%)	4 (7.0%)	2 (4.9%)	6
Missing				
30 day mortality	0 (0%)	5 (10%)	1 (2.6%)	6
Missing	2	8	3	

Table 3: Patient sample characteristics

Characteristic	**ATLS**, N = 16	**PTC**, N = 57	**Standard care**, N = 41	**Overa
Age, years	46 (31, 61)	30 (22, 38)	32 (23, 46)	33
Elderly	3 (19%)	3 (5.3%)	3 (7.3%)	9
Sex				
Male	10 (63%)	44 (77%)	36 (88%)	9(
Female	6 (38%)	13 (23%)	5 (12%)	2
Other	0 (0%)	0 (0%)	0 (0%)	(
Unknown	0 (0%)	0 (0%)	0 (0%)	(
Dominating injury type				
Penetrating	2 (13%)	0 (0%)	3 (7.3%)	5
Blunt	14 (88%)	57 (100%)	38 (93%)	10
Blunt multisystem trauma	1 (6.3%)	3 (5.3%)	0 (0%)	4
Severe traumatic brain injury	0 (0%)	3 (5.3%)	4 (9.8%)	7
Shock	1 (6.7%)	0 (0%)	0 (0%)	1
Missing	1	1	3	
Respiratory rate, breaths per minute	21.5 (20.0, 24.0)	21.0 (19.0, 23.0)	20.0 (18.0, 21.0)	20.0 (
Missing	0	3	4	
Oxygen saturation, %	98.00 (96.00, 99.00)	98.00 (97.00, 98.00)	98.00 (97.75, 99.00)	98.00 (
Missing	1	0	1	
Heart rate, beats per minute	94 (76, 104)	90 (79, 104)	86 (80, 96)	88
Missing	0	1	1	
Systolic blood pressure, mmHg	128 (113, 149)	123 (115, 136)	126 (117, 130)	124
Missing	1	1	3	
Glasgow Coma Scale	15.00 (15.00, 15.00)	15.00 (15.00, 15.00)	15.00 (15.00, 15.00)	15.00 (
Missing	1	0	0	
Injury Severity Score	3 (1, 10)	4 (0, 9)	1 (0, 4)	2
In-hospital mortality	0 (0%)	4 (7.0%)	2 (4.9%)	6
Missing				
30 day mortality	0 (0%)	5 (10%)	1 (2.6%)	6
Missing	2	8	3	

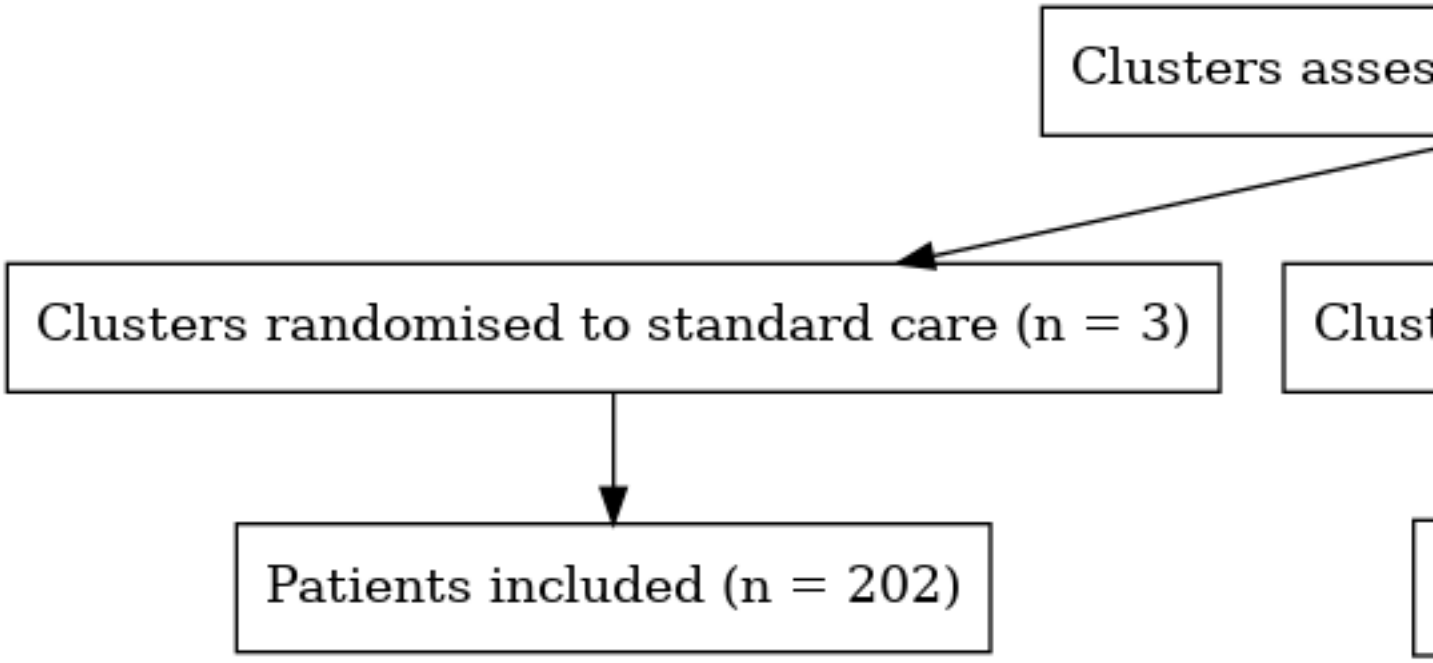

Figure 1: Study flow diagram. Abbreviations: ATLS, Advanced Trauma Life Support; PTC, Primary Trauma Care.

Patient Participant Outcomes

After training, a total of 22 (16%) patients in the standard care arm had the primary outcome, compared to 1 (3.8%) patients in the ATLS® arm and 3 (4.9%) patients in the PTC arm. The absolute change from baseline in the primary outcome (95% CI) in the standard care arm was 13.4 (3, 20)% units, in the ATLS® arm 3.8 (0, 20.98)% units, and in the PTC arm -5.1 (-16.57, 4.76)% units. The relative change from baseline in the primary outcome (95% CI) in the standard care arm was 6.15 (2.62, 10.91), in the ATLS® arm , and in the PTC arm 0.49 (0, 2.31).

The absolute risk difference between the standard care and ATLS® arms (95% CI) was 12.2 (-8.05, 23.3)% units, between the standard care and PTC arms (95% CI) 11.1 (-5.3, 22.33)% units, and between the ATLS® and PTC arms (95% CI) -1.1 (-22, 11.22)% units. The relative risk in the standard care arm compared with the ATLS® arm (95% CI) was 4.21 (1.36, 15.71), in the standard care arm compared with the PTC arm (95% CI) 3.27 (0.61, 18.82), and in the ATLS® arm compared with the PTC arm (95% CI) the relative risk was 0.78 (0, 4.44). The absolute and relative differences in changes from baseline comparing the three arms are shown in Supplementary materials, along with data on all secondary outcomes.

Resident Participant Outcomes

A total of 21 residents were trained during this pilot study. Overall their median confidence in managing trauma patients was 10 (IQR 10-10) on a 10 point Likert scale with 10 being most confident. In the pre training period, the median confidence in the stadard care arm was 10 (IQR 10-10), compared to 10 (IQR 10-10) in the ATLS and 10 (IQR 10-10) in the PTC arm. In the post training period, the corresponding figures were 10 (IQR 10-10) in the standard care arm, 10 (IQR 10-10) in the ATLS and 10 (IQR 10-10) in the PTC arm.

Feasibility Outcomes

. Out of 21 potentially eligible residents, 21 (100%) participated in the study. The lost to follow up rate was 14, with 53 out of 376 patients not completing 30 day follow up. Among residents the pass rate, after two

Table 4: Differences in distributions between observed and extracted data, for selected variables that were collected through observation or interview.

Characteristic	**Directly observed**, N = 55	**Retrospective**, N = 55
Age, years	34 (29, 48)	34 (24, 50)
Missing	0	21
Sex		
Female	10 (18%)	6 (18%)
Male	45 (82%)	27 (82%)
Missing	0	22
Dominating injury type		
Blunt	52 (95%)	29 (91%)
Penetrating	3 (5.5%)	3 (9.4%)
Missing	0	23
Respiratory rate, breaths per minute	21.0 (18.0, 23.5)	18.0 (16.0, 20.0)
Missing	0	37
Oxygen saturation, %	98.00 (98.00, 99.00)	98.00 (97.25, 99.75)
Missing	0	29
Heart rate, beats per minute	85 (80, 98)	87 (84, 93)
Missing	0	19
Systolic blood pressure, mmHg	123 (112, 136)	118 (110, 128)
Missing	1	18

attempts, was 100%. The missing data rate ranged from 0 to 98, with details for selected variables shown in Table **??**(tab:sample-characteristics). The differences in distributions between observed and extracted data, for selected variables that were collected through observation or interview, are shown in Table **??**(tab:observed-vs-retrospective). Overall, there were considerably more missing values in extracted data compared to observed data.

```
## Table printed with `knitr::kable()`, not {gt}. Learn why at
## https://www.danieldsjoberg.com/gtsummary/articles/rmarkdown.html
## To suppress this message, include `message = FALSE` in code chunk header.
```

Discussion

We show that conducting a cluster randomized controlled trial comparing ATLS® with PTC and standard care is feasible in this setting. Missing data were low for key variables, including the primary outcome and many secondary outcomes. Some variables had very high missing data rates and may not be feasible to include in a full-scale trial.

We found that the ATLS® arm had lower 30-day mortality compared to the PTC and standard care arms. We also found that the PTC arm had lower mortality than the standard care arm. These findings indicate a large potential effect of training physicians in trauma life support, but it is important to note that this pilot study was not powered to detect any differences in outcomes. The arms differed considerably in sample size, with the ATLS® arm having the smallest sample size. This difference resulted from the randomisation process with a small number of heterogeneous clusters.

The primary patient participant outcome, all-cause 30-day mortality, was missing in 14% of patients. This may appear high, especially compared to for example the CRASH-2 and REACT-2 trials, which report missing primary outcome in less than 0.01% of patients[15,16]. Like many other trauma trials, both CRASH-2 and REACT-2 used in-hospital mortality as their primary outcome measure, whereas we attempted to follow up patients after discharge. Our missing data rate for in-hospital mortality was only 1%, comparable to previous trials.

During the course of this pilot we deviated from the protocol in multiple ways, and provide a detailed list as Supplementary material. Some key limitations of this pilot and therefore lessons to be learned and factored into the design of the full-scale trial include the lower than expected enrolment rates of some centres, centre specific management routines, and difficulties in collecting data on complications and cause of death. We minimised the impact of the lower than expected enrolment rates by including a seventh centre, but on-site observations of patient volumes are likely to be needed for the full-scale trial. We decided to be pragmatic in selecting which residents to train and how to structure the data collection depending on how and by whom patients were initially managed, but this flexibility will need to be built into the full-scale trial protocol. Finally, we found that data on complications and cause of death were hard to identify and therefore the full-scale trial will need to include longer training of project officers.

Previous studies on the effect of in-hospital trauma life support training on patient outcomes are observational or quasi-experimental without a control group, with heterogeneous results[17–21]. Studies from Trinidad and Tobago, El Salvador, Rwanda, and Cambodia found no significant effect on patient mortality after implementing in-hospital trauma life support training[17–20], whereas one study from China that included 820 patients found a significant reduction in mortality, from 20 to 15%, after implementing ATLS®[21].

Several controlled trials, including at least two randomized controlled trials[22,23], show that ATLS® is associated with improved provider skills[3]. Observational evidence indicates that PTC also leads to improved provider skills[5]. The missing link is then how, and if, these improved skills translate into improved patient outcomes. As trauma care providers we assume, and probably rightly so, that we deliver better care if we train. The question is then how we should train, especially considering the costs associated with some of the programs offered.

We conclude that a full-scale cluster randomised trial should be feasible after incorporating the lessons of this pilot, and that this full-scale trial should, regardless of its outcome, influence how we train trauma care providers in the future.

Contributorship statement

Competing Interests

Several authors are ATLS® and/or PTC instructors.

Funding

Doctors for You through grants awarded to Karolinska Institutet by the Swedish Research Council (grant number 2020-03779) and the Laerdal Foundation (grant number 2021-0048).

Data Sharing Statement

The final anonymized dataset and code for analysis are released publicly.

Protocol Deviations

Trial Registration

We intended to also register our trial with Clinical Trials Registry - India but because of time constrains we had to initiate the study before registration was finalised, and Clinical Trials Registry - India only allow prospective registration.

Outcomes across subgroups

Because of small numbers in the pre-specified subgroups we decided to report only descriptive data on these subgroups.

Number of Participating Centres

We ended up recruiting seven centres instead of six and therefore assigned two centres each to the intervention arms and three centres to the control arm.

Resident Participants

Emergency medicine in addition to surgery.

Periodic suverys to residents

We did not distribute periodic surveys to the participating residents but discussed challenges and suggestions that they had regarding the scheduling or implementation of the training programs.

Follow up of residents

We stated that resident participants would be followed up 30 days after training, if they are in the intervention arms, or 30 days after the study started, if they are in the control arm, but the intervention period was three months.

Data collection from records

We decided to record data from records only for a subset of patients to reduce the project officers' workload.

Selection of units for training

We planned to use simple random sampling to select units if there were more than two eligible units in a hospital but instead the hospital principal investigator decided which units to train.

Timing of resident consent

We had initially planned to ask residents for consent before randomisation, but the units were only finalised after the hospitals had been randomised, and residents were therefore approached for consent afterwards.

Supplementary material

References

1. GBD 2019 Diseases and Injuries Collaborators. Injuries—level 1 cause. *The Lancet* **396**, (2020).

2. Vos, T. *et al.* Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: A systematic analysis for the global burden of disease study 2019. *The Lancet* **396**, 1204–1222 (2020).

3. Mohammad, A. *et al.* Educational and clinical impact of advanced trauma life support (ATLS) courses: A systematic review. *World Journal of Surgery* **38**, 322–329 (2013).

4. Jayaraman, S. *et al.* Advanced trauma life support training for hospital staff. *Cochrane Database of Systematic Reviews* (2014).

5. Kadhum, M. *et al.* Are primary trauma care (PTC) courses beneficial in low- and middle-income countries - a systematic review. *Injury* **51**, 136–141 (2020).

6. American College of Surgeons, C. on T. *Advanced trauma life support® student course manual*. (American College of Surgeons, 2018).

7. Foundation, P. T. C. *Primary trauma care course manual for trauma management in locations wih limited resources*. (Primary Trauma Care Foundation, 2018).

8. Jin, J. *et al.* Effectiveness of quality improvement processes, interventions, and structure in trauma systems in low- and middle-income countries: A systematic review and meta-analysis. *World Journal of Surgery* **45**, 1982–1998 (2021).

9. Hemming, K. *et al.* How to design efficient cluster randomised trials. *BMJ* j3064 (2017).

10. Hornor, M. A. *et al.* Quality benchmarking in trauma: From the NTDB to TQIP. *Current Trauma Reports* **4**, 160–169 (2018).

11. Staniszewska, S. *et al.* GRIPP2 reporting checklists: Tools to improve reporting of patient and public involvement in research. *BMJ* j3453 (2017).

12. Kobo. KoboToolbox.

13. Lee, E. C. *et al.* The statistical interpretation of pilot trials: Should significance thresholds be reconsidered? *BMC Medical Research Methodology* **14**, (2014).

14. Gerdin Wärnberg, M. *et al.* A pilot multicentre cluster randomised trial to compare the effect of trauma life support training programmes on patient and provider outcomes. *BMJ Open* **12**, e057504 (2022).

15. Roberts, I. *et al.* The CRASH-2 trial: A randomised controlled trial and economic evaluation of the effects of tranexamic acid on death, vascular occlusive events and transfusion requirement in bleeding trauma patients. *Health Technol Assess* **17**, (2013).

16. Sierink, J. C. *et al.* Immediate total-body CT scanning versus conventional imaging and selective CT scanning in patients with severe trauma (REACT-2): A randomised controlled trial. *The Lancet* **388**, 673–683 (2016).

17. Ariyanayagam, D. *et al.* The impact of the ATLS course on traffic accident mortality in trinidad and tobago. *West Indian Medical Journal* **41**, 72–74 (1992).

18. Cioè-Peña, E. *et al.* Development and implementation of a hospital-based trauma response system in an urban hospital in san salvador, el salvador. *Trauma* **19**, 118–126 (2016).

19. Petroze, R. T. *et al.* Can focused trauma education initiatives reduce mortality or improve resource utilization in a low-resource setting? *World Journal of Surgery* **39**, 926–933 (2014).

20. Van Heng, Y. *et al.* Non-doctors as trauma surgeons? A controlled study of trauma training for non-graduate surgeons in rural cambodia. *Prehospital and Disaster Medicine* **23**, 483–489 (2008).

21. Wang, P. *et al.* Comparison of severe trauma care effect before and after advanced trauma life support training. *Chinese Journal of Traumatology (English Edition)* **13**, 341–344 (2010).

22. Ali, J. *et al.* Teaching effectiveness of the advanced trauma life support program as demonstrated by an objective structured clinical examination for practicing physicians. *World Journal of Surgery* **20**, 1121–1126 (1996).

23. Ali, J. *et al.* Comparison of performance of interns completing the old (1993) and new interactive (1997) advanced trauma life support courses. *The Journal of Trauma: Injury, Infection, and Critical Care* **46**, 80–86 (1999).