

Feasibility of a Cluster Randomised Trial on the Effect of Trauma Life Support Training: A Pilot Study in India

Trauma life support training Effectiveness Research Network (TERN) collaborators

Trial registration

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

Corresponding author

Martin Gerdin Wärnberg, MD, PhD (MGW) 

Department of Global Public Health
Karolinska Institutet
171 77 Stockholm
Sweden

martin.gerdin@ki.se

+46 708 53 95 98 (mobile)figure

Authors (in alphabetical order by last name)

Debojit Basak, MS 

Project Research Scientist, Institute of Post Graduate Medical Education and Research, Kolkata, India.

Johanna Berg, MD (JB) 

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Emergency Medicine, Department of Internal and Emergency Medicine, Skåne University Hospital, Malmö, Sweden.

Shamita Chatterjee, MBBS, MS (SC) 

Department of Surgery, Institute of Post Graduate Medical Education and Research, Kolkata, India.

Li Felländer-Tsai, MD, PhD (LFT) 

Division of Orthopaedics and Biotechnology, Department of Clinical Science Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Sweden.

Department of Reconstructive Orthopedics, Karolinska University Hospital, Stockholm, Sweden.

Geeta Ghag (GG), MBBS, MS 

Department of Surgery, HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai, India.

Catherine Juillard, MD, MPH (CJ) 

Division of General Surgery, Department of Surgery, David Geffen School of Medicine at UCLA, Los Angeles, California, United States of America.

Monty Khajanchi, MBBS, MS (MK) 

Seth G. S. Medical College and K.E.M. Hospital, Mumbai, India.

Tamal Khan, MSc (TK)

Senior Research fellow, All India Institute of Medical Sciences, New Delhi, India.

Vipul Nandu, MBBS, MS (VN) 

Department of Surgery, HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai, India.

Nobhojit Roy, MBBS, MS, PhD (NR) 

Program for Global Surgery and Trauma, The George Institute of Global Health, New Delhi, India.

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Rajdeep Singh, MBBS, MS (RS) 

Department of Surgery, Maulana Azad Medical College, New Delhi, India.

Kapil Dev Soni, MBBS, MD (KDS) 

Critical and Intensive Care, JPN Apex Trauma Center, All India Institute of Medical Sciences, New Delhi, India.

Lovisa Strömmer, MD, PhD (LS) 

Division of Surgery and Oncology, Department of Clinical Science, Intervention and Technology (CLINTEC), and Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Non-author contributors

Anirban Chatterjee (AC)

Department of Orthopaedic Sciences, Medica Superspecialty Hospital, Kolkata, India.

Marie Hasselberg (MH)

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Debabrata Kundu (DK)

Department of Surgery, Medical College Kolkata, Kolkata, India.

Anurag Mishra (AM)

Department of Surgery, Maulana Azad Medical College, New Delhi, India.

Arun Prasad (AP)

Department of Surgery, Indraprastha Apollo Hospitals, New Delhi

Harris Solomon (HS)

Department of Cultural Anthropology and the Duke Global Health Institute, Duke University, Durham, USA.

Megha Tandon (MT)

Department of Surgery, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India.

Keywords

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

Word Count

2836

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

Objective 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.

Design A pilot pragmatic three-armed parallel, cluster randomised, controlled trial between April 2022 and February 2023. Patient follow up was 30 days.

Setting Tertiary care hospitals across metropolitan areas in India.

Participants Adult trauma patients and residents managing these patients.

Interventions ATLS® or PTC training for residents in the intervention arms.

Main Outcomes and Measures The outcomes were consent rate, lost to follow up rate, pass rate, missing data rates, differences in distribution between observed and data extracted from medical records as well as all cause and in-hospital mortality at 30 days from the time of arrival to the emergency department.

Results Two hospitals were randomised to ATLS[®], two to PTC, and three to standard care. We included 376 patients and 22 residents. The percentage of patients who consented to follow up was 77% and the percentage of residents who consented to training was 100%. The lost to follow up rate was 14%. The pass rate was 100%. The missing data was overall low for key variables. Data collected through observations were similar to data extracted from medical records, but there was more missing data in the extracted data. Twenty-two (16%) patients died within 30 days in the standard care arm, one (4%) patient in the ATLS[®] arm, and three (5%) 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 will be feasible, especially if such a trial would use data and outcomes available in medical records.

Trial Registration ClinicalTrials.gov (reg. no NCT05417243)

Strengths and limitations of this study

- Prospective data collection with direct observations by dedicated research officers.
- Lack of a priori defined success criteria and thresholds for the feasibility outcomes.
- Use of sealed envelopes potentially compromised allocation concealment.
- Participating centers' heterogeneity may affect the study estimates and bias the results.

Introduction

Trauma, defined as the clinical entity composed of physical injury and the body's associated response, causes 4.3 millions deaths every year¹. Several trauma life support training programs have been developed to improve the early management of patients in hospital by providing a structured framework to assessment and treatment²⁻⁴.

The proprietary Advanced Trauma Life Support® (ATLS®) and the low-cost alternative Primary Trauma Care (PTC) are two widely established trauma life support training programmes with over a million physicians trained in over 80 countries^{5,6}. Observational studies indicate that these programmes may improve patient outcomes⁷⁻²¹, but there is no high quality evidence from controlled trials to support this^{2-4,22-24}.

Several studies, including at least two randomised studies^{25,26}, show that ATLS® is associated with improved knowledge and skills among providers². Observational evidence suggests that PTC also leads to improved provider skills⁴. The missing link is then whether these improved knowledge and skills translate into measurably improved patient outcomes.

Systematic reviews call for controlled trials in settings where these programmes are not routinely implemented²⁻⁴, because conducting such effectiveness trials in settings where they are part of the standard of care is not possible. Many settings without routinely implemented trauma life support training are in low- and middle income countries, where trial logistics can be more challenging.

We therefore conducted a pilot study to assess the feasibility of a cluster randomised controlled trial comparing the effect of ATLS® and PTC with standard care on outcomes in adult trauma patients.

Methods

Protocol Deviations

Protocol deviations are mentioned where relevant in this manuscript, but a list of all deviations is also included as Supplementary Material S1 for completeness.

Trial Design

We piloted a three-armed cluster randomised controlled trial²⁷. There were a standard care arm and two intervention arms, ATLS® and PTC training. We planned to collect 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 standard care arm). The actual data collection period varied across clusters depending on the timing of the training, to ensure a minimum of three months of data collection after the training in the intervention clusters. We included the one month lead to be able to evaluate the feasibility of comparing patient outcomes both as absolute differences between the intervention phases, and as differences in change from baseline. In the published protocol, we also aimed to estimate probable effect sizes

and other measures needed for the sample size calculations of a full-scale trial²⁷, but we revised this aim in the light of current guidance on the conduct and reporting of pilot trials²⁸.

Study Setting

We conducted this pilot study in seven tertiary hospitals across metropolitan areas in India, where neither ATLS®, PTC, nor any other established trauma life support training program is routinely taught. Details about each cluster is included as Supplementary Table S1. Originally, we intended to include six hospitals as clusters, but decided to include a seventh when they expressed interest and as we had the budget to accommodate this. These seven hospitals were a convenience sample of hospitals in India that fulfilled the inclusion criteria, and with existing connections to the research team.

Eligibility Criteria for Cluster and Participants

Hospitals

We included tertiary care hospitals in metropolitan areas in India that admitted more than 400 adult patients with trauma each year, and that had operation theatres, X-ray, CT, and ultrasound facilities, and blood bank available around the clock.

Clusters

We defined a cluster as one or more units of physicians providing trauma care in the emergency department of Indian tertiary care hospitals. To be eligible, units could have no more than 25% of their physicians trained in either ATLS®, PTC, or similar training programs before the start of the pilot study. 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. The principal investigator at each hospital selected the units for training. We randomised on the hospital level to avoid contamination between intervention arms and the standard care arms.

Residents

We trained 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 from the time of the training. Consent was sought from the residents in each of the intervention groups before they underwent the ATLS® or PTC training. In the published protocol, we stated that only surgical residents would be trained. However, in some of the participating hospitals, emergency medicine residents performed the initial resuscitation and management of trauma patients, and we therefore decided to train them instead.

Patients

We included persons who were 15 years or older and presented to the emergency department at participating hospitals with a history of trauma when a designated unit was on duty. History of trauma was defined as having any of the external causes of morbidity and mortality listed in

block V01-Y36, chapter 20 of the International Classification of Disease version 10 (ICD-10) codebook as reason for presenting.

Standard Care

Standard care varies across hospitals in India, but most surgical and emergency medicine departments in India organise their physicians in units. These units include both faculty members and residents, who are assigned a specific day of the week when they are posted in the emergency department. In the emergency department, trauma patients are initially assessed by either surgical or emergency medicine residents who also 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. We did not collect data on how standard care varied between the participating hospitals.

Intervention

In each intervention arm the residents in one or two units were trained in either ATLS® or PTC at the beginning of the three month intervention phase. For the purpose of this pilot study, our target was to train a minimum of 75% of residents in each unit. We did not train the units' faculty, because 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 and the PTC training was conducted in New Delhi. Both trainings were conducted according to their respective standard curriculum^{5,6}, and we did not modify or adapt the delivery or content of these programmes during this pilot study.

The provider courses of both programmes are two days, and they teach how to assess, resuscitate and stabilize trauma patients and how to adapt to needs of different patient populations. The teaching is based on case discussions and skill stations. There are some important differences between the two programmes. The ATLS course include more on the inter-hospital transfer of patients and includes a greater emphasis on the trauma team⁵. The PTC course on the other hand focuses on trauma care in the low resource setting⁶. The ATLS® programme is run by the American College of Surgeons and participants pay a fee to take a course, whereas the PTC programme is run by the UK Charity PTC Foundation and is free of charge.

Feasibility outcomes

Our feasibility outcomes were:

- Consent rate of patients and residents. This was equal to the percentage of patients or residents who consented to be included, out of the total number of eligible patients or residents.
- Lost to follow up rate. This applied only to patients and was equal to the percentage of patients who did not complete 30 day follow up, out of all included patients.
- Missing data rate. This applied to each outcome and variable and was equal to the percentage of missing values.

- Differences in distributions between directly observed data and data extracted from medical records. Distribution refers to summary statistics and directly observed data refers to data collected by project officers while observing the delivery of care. This outcome applied to all variables that could be reasonably expected to be present in the medical records, but we decided to only extract this data from a convenience sample of patients to reduce the workload of the project officers collecting data.
- Pass rate. This applied only to residents in the intervention arms and was equal the percentage of residents who passed the training programme, out of the total number of trained residents.

We did not prespecify criteria to judge whether to continue with the full scale trial.

Sample size

We wanted to include at least two clusters per arm to avoid drawing conclusions based on single centers, and we wanted to train at least two units per intervention cluster to be able to evaluate the logistics of sending residents for training. We did not conduct a formal power calculation for this pilot study, as the purpose was to assess the feasibility of the trial logistics and research methods. We anticipated that the numbers of patients included per cluster were anticipated would vary between clusters depending on the volume of patients at each hospital.

Participant Timeline and Inclusion

Patients

Arriving patients were screened for eligibility and consented, if conscious. Unconscious patients were consented by the patient's representative. This proxy consent was reaffirmed by the patient, on regaining consciousness. Patients who did not regain consciousness were included based on their representative's consent. We followed up patients at 24 hours after arrival at the emergency department, and at 30 days after arrival at the emergency department. The follow up period for each patient was therefore one month.

Residents

Participating units were screened for eligibility once hospitals confirmed their participation. All residents in these units were approached to consent to training if their hospital was randomised to either of the intervention arms. The protocol stated that residents would be approached for consent before the hospitals were randomised, but this proved not to be feasible, and we therefore asked residents for consent after the hospitals were randomised but before training. The training was conducted approximately one month after the study started in that hospital. Initially, we planned to use simple random sampling to select the units to be trained in each intervention hospital, but for pragmatic reasons we decided to leave the decision on which units to train to the site principal investigator. The number of residents trained in each intervention cluster varied because the size of the units varied.

Allocation and blinding

We used simple randomisation implemented using sealed envelopes to allocate sites to trial arms. It was not possible to blind investigators, residents or patients to the intervention. We did not blind the data analysts.

Data Collection

The planned data collection period was four months, but the actual data collection period varied across clusters depending on the timing of the training, to ensure a minimum of three months of data collection after the training in the intervention clusters. A research officer collected data on all patients who presented on the days and shifts when participating residents were assigned to trauma care. The research officers observed care and interviewed residents and patients, and also extracted data from the hospital records. We followed up admitted patients for their complications and other in-hospital outcome measures. Patients who were not admitted or who were discharged before the end of the study were followed up telephonically for mortality outcomes and quality of life outcomes.

Variables

The research officers collected data on demographics, vital signs, management details including imaging and surgery, and details of any injury sustained. All injuries were coded according to the International Classification of Diseases version 10 (ICD-10). Based on these ICD-10 codes, we calculated the Injury Severity Score (ISS) using the R package `icdpicr`²⁹. The ISS is a widely used measure of injury severity and ranges from 0 to 75, with a cutoff of 16 often being used to define major trauma, and 75 representing unsurvivable trauma. We also collected data on potential outcomes for the full-scale trial, including mortality within 30-days and in-hospital, complications and health related quality of life (using the EQ-5D-3L). We did not calculate an EQ-5D-3L index score, because there is currently no Indian value set available for the EQ-5D-3L³⁰. We also attempted to collect data on cause of death. A list of variables is available in Supplementary Table S2.

Patient and public involvement

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. The results of these consultations are published separately³¹. We initially planned to distribute periodic surveys to residents and follow them up after 30 days after training, but we changed this to interviews after the end of the study period as we thought this would provide richer data (not published).

Data monitoring

We conducted weekly online meetings to monitor the study and data collection. We conducted one interim analysis approximately halfway through the study, and decided to complete the study as residents and patients were consenting to be included in the study and key variables including mortality outcomes could be collected. We did not use a data monitoring committee.

Statistical Methods

We used the R version 4.5.0 (2025-04-11) Statistical Software for all analyses³². We analysed all data, including the feasibility outcomes, using descriptive statistics and did not perform any formal hypothesis tests³³. Initially, we planned to analyse feasibility outcomes both on an overall and individual cluster levels, but the sample sizes in individual clusters were too small to generate meaningful results. Quantitative variables are summarised as median and interquartile range. Qualitative variables are presented as absolute numbers and percentages. Additional analyses performed according to the original protocol are available as additional online material³⁴.

Ethics and Dissemination

We were granted research ethics approval from the institutional ethics committees at each participating hospital. For each participating hospital, the approvals were HBTMC/266/SURGERY for Dr R N Cooper Municipal General Hospital in Mumbai, IEC(II)/OUT/134/2022 for Seth GS Medical College and KEM Hospital in Mumbai, ICC/214/22/20/05/2022 for Lokmanya Tilak Municipal Medical College and General Hospital, CREC/2022/FEB/1(ii) for MEDICA Superspeciality Hospital in Kolkata, MC/KOL/IEC/NON-SPON/1217/11/21 for Medical College, Kolkata, NRSMC/IEC/93/2021 for Nilratan Sircar Medical College & Hospital in Kolkata, and finally IEC-03/2022-2332 for the Postgraduate Institute of Medical Education and Research, Chandigarh.

Results

We included 376 trauma patients from seven clusters between April 2022 and February 2023. The period of data collection and the number of patients included per month per cluster is shown in Figure 1. Due to an error in the data uploading process, data was only available for one and three months for two clusters respectively. The standard care arm included 202 patients, the ATLS® arm included 44 patients, and the PTC arm included 130 patients. We trained a total of 22 residents, seven in ATLS®, and 15 in PTC.

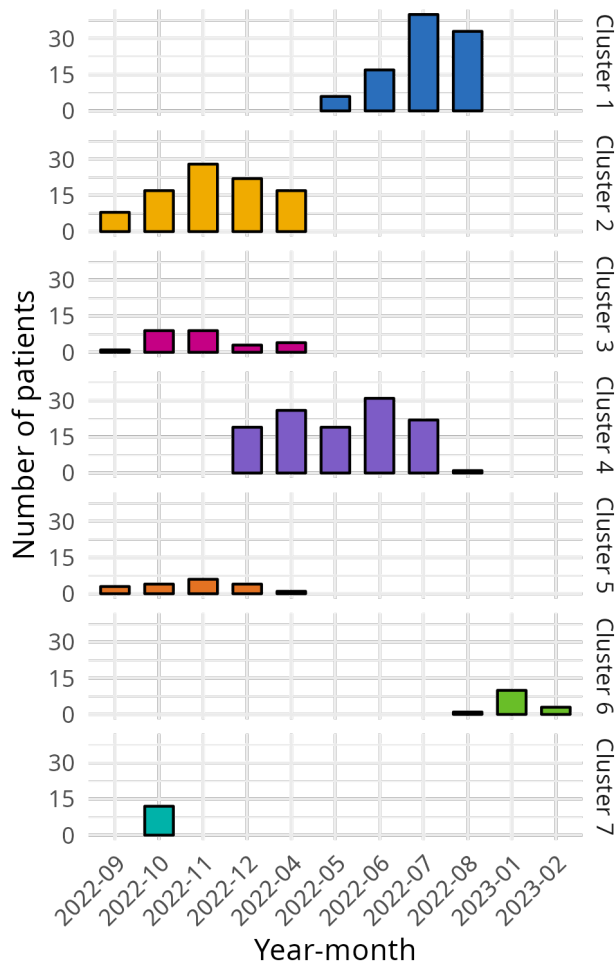


Figure 1: Number of patients included per cluster per month. Due to an error in the data uploading process, data was only available for one and three months for two clusters respectively.

The study flow diagram is shown in Figure 2 and patient sample characteristics across trial arms are shown in Table ?? . Extended patient sample characteristics are shown in Supplementary Table S2. Overall, the number of females were 86 (23%), the median (IQR) age was 33 (24, 46) years, and the median ISS (IQR) was 4 (1, 8). These prognostic factors differed between the trial arms. A total of 32 (10%) patients died within 30 days after arrival to the emergency department, and 29 (8%) patients died in hospital.

After training, a total of 22 (16%) patients in the standard care arm died within 30 days, compared to 1 (4%) patients in the ATLS® arm and 3 (5%) patients in the PTC arm. The corresponding figures for in-hospital mortality were 19 (12%)%, 1 (4%)%, and 3 (4%)% for the standard care, ATLS® and PTC arms respectively.

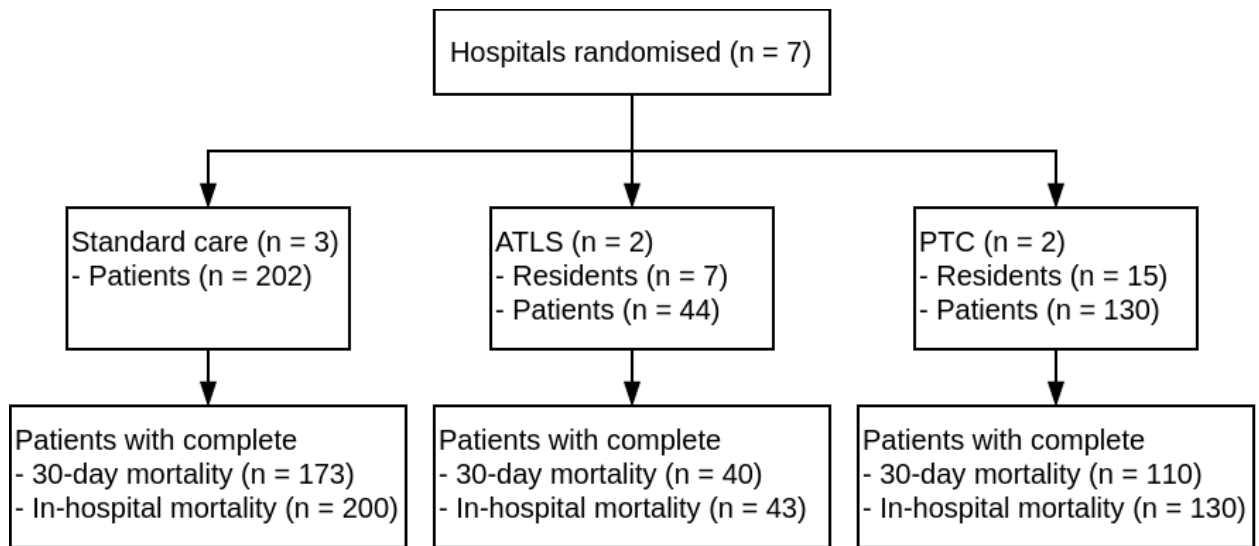


Figure 2: Study flow diagram. Abbreviations: ATLS, Advanced Trauma Life Support; PTC, Primary Trauma Care.

Characteristic	Standard care N = 202	ATLS N = 44	PTC N = 130	Overall N = 376
Age, years, median (IQR)	35 (25, 47)	40 (30, 57)	30 (22, 38)	33 (24, 46)
Elderly (Age ≥ 65 years), n (%)	15 (7%)	6 (14%)	5 (4%)	26 (7%)
Sex, n (%)				
Male	160 (79%)	33 (75%)	97 (75%)	290 (77%)
Female	42 (21%)	11 (25%)	33 (25%)	86 (23%)
Dominating injury type, n (%)				
Penetrating	13 (6%)	3 (7%)	1 (1%)	17 (5%)
Blunt	189 (94%)	41 (93%)	129 (99%)	359 (95%)
Blunt multisystem trauma, n (%)	2 (1%)	2 (5%)	6 (5%)	10 (3%)
Severe traumatic brain injury, n (%)	10 (5%)	1 (2%)	5 (4%)	16 (4%)
Missing	1	0	0	1
Shock (SBP ≤ 90 mmHg), n (%)	4 (2%)	2 (5%)	4 (3%)	10 (3%)
Missing	7	3	4	14
Respiratory rate, breaths per minute, median (IQR)	20 (18, 22)	21 (20, 24)	21 (20, 24)	20 (19, 23)
Missing	7	0	5	12
Oxygen saturation, %, median (IQR)	98 (97, 99)	98 (97, 99)	98 (98, 99)	98 (97, 99)
Missing	1	1	0	2
Heart rate, beats per minute, median (IQR)	86 (80, 96)	87 (73, 100)	90 (76, 104)	86 (78, 100)
Missing	1	1	1	3
Systolic blood pressure, mmHg, median (IQR)	123 (112, 135)	124 (113, 131)	122 (111, 136)	123 (112, 135)
Missing	7	3	4	14
Glasgow Coma Scale, median (IQR)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)
Missing	2	1	0	3
Injury Severity Score, median (IQR)	1 (1, 8)	4 (1, 5)	4 (1, 8)	4 (1, 8)
Missing	37	5	35	77
In-hospital mortality, n (%)	21 (11%)	1 (2%)	7 (5%)	29 (8%)
Missing	2	1	0	3

Characteristic	Standard care N = 202	ATLS N = 44	PTC N = 130	Overall N = 376
30 day mortality, n (%)	23 (13%)	1 (3%)	8 (7%)	32 (10%)
Missing	29	4	20	53

Abbreviation: ATLS = Advanced Trauma Life Support; PTC = Prehospital Trauma Care; SBP = systolic blood pressure

Missing data counts are only shown for variables with missing values. The absence of a count indicates complete data.

Outcomes

The percentage of patients who consented to follow up was 77% and the lost to follow up rate was 14%. The missing data rate ranged from 0 to 50%, with details for selected variables shown in Table ?? and in Supplementary Table S2. The variables with the maximum amount of missing data were in the cost of treatment, also reported in Supplementary Tables S2.

The differences in distributions between directly observed data and data extracted from medical records, for selected variables that were collected through observation or interview, are shown in Table ??. Overall, the data were similarly distributed, but there were considerably more missing values in the data extracted from medical records compared to the directly observed data.

The percentage of residents who consented to training was 100% and the pass rate was 100%.

Characteristic	Directly observed N = 55	Medical records N = 55
Age, years, median (IQR)	34 (27, 48)	34 (25, 50)
Missing	0	22
Sex, n (%)		
Female	10 (18%)	6 (18%)
Male	45 (82%)	27 (82%)
Missing	0	22
Dominating injury type, n (%)		
Blunt	52 (95%)	29 (91%)
Penetrating	3 (5%)	3 (9%)
Missing	0	23
Respiratory rate, breaths per minute, median (IQR)	21 (18, 24)	18 (16, 20)
Missing	0	37
Oxygen saturation, %, median (IQR)	98 (98, 99)	98 (97, 100)
Missing	0	29
Heart rate, beats per minute, median (IQR)	85 (80, 98)	87 (84, 93)
Missing	0	19
Systolic blood pressure, mmHg, median (IQR)	123 (112, 136)	118 (110, 128)
Missing	1	18

Discussion

We show that it is feasible to conduct and collect data for a cluster randomised controlled trial comparing ATLS[®] with PTC and standard care. Missing data were low for key variables, including the primary outcome and many secondary outcomes. Some variables, especially the cost of treatment (reported in Supplementary Table S2) had very high missing data rates and may not be feasible to include in a full-scale trial, or require different data collection methods. The missing data was substantially higher when data was extracted from medical records instead of being directly observed, but the data were similarly distributed, indicating that data collected from medical records is reliable even if it is less complete. To improve completeness of data extracted from the medical records, a full scale trial should limit the number of variables extracted from the medical records and the importance of having these registered should be emphasised to the participating hospitals.

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^{35,36}. 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%, which is comparable to previous trials. Following up patients after discharge is notoriously

challenging in the setting of this study, and the full scale trial might need to focus on in-hospital mortality as the primary outcome.

During the course of this pilot study we deviated from the protocol in several ways. We have reported these deviations where appropriate in the methods section, and provide a list as Supplementary material S1. The most important deviation was the revision of the aim of this pilot study, because we initially planned to estimate potential effect sizes and other measures to help sample size calculations for a full scale trial, in addition to the feasibility outcomes. However, current guidance advice against using pilot studies to estimate effect sizes, as the usefulness of these estimates is questionable^{28,37}. We therefore decided to only report patient outcomes descriptively. Another important deviation from the protocol was the training of emergency medicine residents. We initially planned to train only surgical residents, but trauma management routines varied between participating hospitals, and we decided to adapt to local routines. The full scale study will need to accommodate this variation as part of the protocol.

There are some important limitations of this pilot study and therefore additional lessons to be learned and factored into the design of the full-scale trial. First, the volumes of patients included at some of the participating hospitals were lower than expected. A careful assessment of patient volumes as part of the screening process will be needed for the full-scale trial. Second, data on complications and cause of death were almost universally missing. To collect data on these variables will require other methods, as these were not explicitly described in the medical records and autopsy reports are not readily available. Third, we did not collect in-depth data on the standard care at each hospital. This data should be collected as part of the screening process for the full-scale trial. Fourth, we used sealed envelopes for randomisation, which increases the risk of bias and errors. The full scale trial should use a computer-generated randomisation system. Fifth, we did not blind the data analysts, but recommend doing so in the full scale trial. Fifth, we assessed a very large number of potential outcomes, and the full scale trial should focus on the most relevant outcomes. Finally, because of a data uploading error, there was only limited data available from two clusters. At the time of data collection, network issues and other technical issues were a challenge in some of the clusters, and this can be mitigated in the full scale trial by using a more robust data collection system with local offline backups.

Previous studies on the effect of ATLS® or PTC training on patient outcomes are observational or quasi-experimental without a control group, with heterogeneous results⁸. Most studies have found that these programmes are associated with improved outcomes, although not all studies have found significant effects^{7,9,10,12,14–18,20,21}. In contrast, some studies have found that these programmes may be associated with increased mortality^{13,19}. We found fewer deaths in the intervention arms compared to the standard arm. This difference may have resulted from the randomisation process with a small number of heterogeneous clusters, highlighting the importance of taking varying cluster sizes into account when designing the full scale trial.

A full scale trial remains ethical after this pilot study, considering that it was never powered to detect meaningful differences in clinical outcomes. In addition, educating physicians in trauma life support through programmes like ATLS® and PTC is considered standard care in many settings, but this approach has been criticised for being costly and for propagating outdated practices^{wiles_atls_2015?}. Several systematic reviews call for trials in settings where these programmes are not routinely implemented^{2–4}, and in recognition of their wide use and high

face validity, a stepped-wedge design in which all clusters receive the intervention but at randomised time points may be the best option.

Our study represents the first published attempt to pilot a controlled trial of the effect of trauma life support training on patient outcomes, and we conclude that conducting a full-scale cluster randomised trial should be feasible after incorporating the lessons of this pilot study.

Contributorship statement

MGW conceived of the study, performed the analysis and drafted and revised the manuscript. AG, AM, CJ, DKV, HS, JB, KDS, LFT, LS, MH, MK, NR, PB, PP, RS, SD, and VK contributed to the design of the study. MGW, DKV, KDS, and MK drafted the first version of the protocol. AG, HS, and SD drafted the first version of the patient and public involvement activities. JB and PP drafted the first versions of the data management sections and wrote the data management plan. PB and PP drafted the first versions of the statistical analysis section. AG, AM, CJ, DKV, HS, JB, KDS, LFT, LS, MH, MGW, MK, NR, PB, PP, RS, SC, SD, and VK contributed to the refinement of the protocol. DB, JB, SC, LFT, GG, MK, TK, CJ, NR, RS, KDS, LS and VP interpreted the results and revised the manuscript. AR, AC, C, DK, GG, MK, MT, VK and VP are representatives of participating hospitals.

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 code for analysis is released publicly. The final anonymized dataset is available from the corresponding author on request.

References

1. GBD 2019 Diseases and Injuries Collaborators. [Injuries—level 1 cause](#). *The Lancet* **396**, (2020).
2. 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).
3. Jayaraman, S. *et al.* [Advanced trauma life support training for hospital staff](#). *Cochrane Database of Systematic Reviews* (2014).
4. Kadhun, M. *et al.* [Are primary trauma care \(PTC\) courses beneficial in low- and middle-income countries - a systematic review](#). *Injury* **51**, 136–141 (2020).
5. American College of Surgeons, C. on T. *Advanced trauma life support® student course manual*. (American College of Surgeons, 2018).
6. Foundation, P. T. C. *Primary trauma care course manual for trauma management in locations with limited resources*. (Primary Trauma Care Foundation, 2018).
7. Vestrup, J. A. *et al.* [Impact of advanced trauma life support training on early trauma management](#). *The American Journal of Surgery* **155**, 704–707 (1988).
8. 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).
9. Ali, J. *et al.* [Trauma outcome improves following the advanced trauma life support program in a developing country](#). *The Journal of Trauma: Injury, Infection, and Critical Care* **34**, 890–899 (1993).
10. Olden, G. D. J. van *et al.* [Clinical impact of advanced trauma life support](#). *The American Journal of Emergency Medicine* **22**, 522–525 (2004).
11. 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).
12. 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).
13. Drimousis, P. G. *et al.* [Advanced Trauma Life Support certified physicians in a non trauma system setting: Is it enough?](#) *Resuscitation* **82**, 180–184 (2011).
14. Noordin, S. *et al.* [Evolution of trauma management at a tertiary care hospital: A cohort study](#). *International Journal of Surgery* **9**, 75–78 (2011).

15. Hashmi, Z. G. *et al.* Hospital-based trauma quality improvement initiatives: First step toward improving trauma outcomes in the developing world. *Journal of Trauma and Acute Care Surgery* **75**, 60–68 (2013).
16. 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).
17. Magnone, S. *et al.* Impact of ATLS Guidelines and Trauma Team Introduction on 24 Hours Mortality in Severe Trauma in a Busy Italian Metropolitan Hospital: A Case Control Study. *Turkish Journal of Trauma and Emergency Surgery* (2015).
18. Bellanova, G. *et al.* In a Mountain Trauma Center. *Ann. Ital. Chir.* (2016).
19. 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).
20. Kamau, C. *et al.* Impact of advanced trauma life support training on 30-day mortality in severely injured patients at a Kenyan tertiary center: A retrospective matched case-control study. *International Journal of Emergency Medicine* **17**, 153 (2024).
21. Kumar, S. *et al.* Evaluating the Impact of Advanced Trauma Life Support (ATLS) Training in Reducing Preventable and Potentially Preventable Deaths: A Mixed-Methods Cohort Study. *Cureus* **17**, e81681 (2025).
22. 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).
23. Putra, A. B. *et al.* Impact of Advanced Trauma Life Support Training for Improving Mortality Outcome: A Systematic Review and Meta-analysis. *The New Ropanasury Journal of Surgery* **8**, (2023).
24. McIver, R. *et al.* Effect of trauma quality improvement initiatives on outcomes and costs at community hospitals: A scoping review. *Injury* **55**, 111492 (2024).
25. 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).
26. 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).
27. 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).
28. Teresi, J. A. *et al.* Guidelines for Designing and Evaluating Feasibility Pilot Studies. *Medical care* **60**, 95–103 (2022).

29. Black, A. *et al.* [Icdpicr: 'ICD' programs for injury categorization in r.](#) (2022).
30. Jyani, G. *et al.* [Development of an EQ-5D Value Set for India Using an Extended Design \(DEVINE\) Study: The Indian 5-Level Version EQ-5D Value Set.](#) *Value in Health* **25**, 1218–1226 (2022).
31. David, S. *et al.* [Patient-reported outcomes relevant to post-discharge trauma patients in urban India.](#) (2024).
32. R Core Team. [R: A language and environment for statistical computing.](#) (R Foundation for Statistical Computing, 2024).
33. Lee, E. C. *et al.* [The statistical interpretation of pilot trials: Should significance thresholds be reconsidered?](#) *BMC Medical Research Methodology* **14**, (2014).
34. Wörnberg, M. [Additional Online Material - Feasibility of a Cluster Randomised Trial on the Effect of Trauma Life Support Training: A Pilot Study in India.](#) (2025).
35. 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).
36. 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).
37. Eldridge, S. M. *et al.* [How big should the pilot study for my cluster randomised trial be?](#) *Statistical Methods in Medical Research* **25**, 1039–1056 (2015).