Effects of Trauma Life Support Training Programs on Patient Outcomes: A Pilot Cluster Randomised Trial

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Keywords

Role of study sponsor and funders

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 tertiary care hospitals across metropolitan areas in India. We included adult trauma patients and residents managing these patients. Two hospitals were randomised to ATLS®, two to PTC, and three to standard care. The feasibility outcomes were consent rate, lost to follow up rate, pass rate, missing data rates, and differences in distribution between observed and data extracted from medical records. We conducted community consultations in parallel with the pilot trial. **Ethics and dissemination** We obtained ethical approval from all participating hospitals. **Results** Between April 2022 and February 2023 we included 376 patients and 21 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 rate ranged from 0 to 98. Data collected through observations were similar to data extracted from medical records, but there was more missing data in the extracted data. **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]. 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[2–4].

The proprietary Advanced Trauma Life Support® (ATLS®) and the low-cost alternative Primary Trauma Care (PTC) are the most established trauma life support training programmes with physicians trained in over 80 countries[5,6]. Observational studies indicate that these programmes may improve patient outcomes[7], but there is no high quality evidence from controlled trials to support this[2–4].

Several systematic reviews call for trials in settings where these programmes are not routinely taught. We performed a pilot study to assess the feasibility of conducting a cluster randomised controlled trial comparing ATLS® and PTC with standard care, and to estimate probable effect sizes and the intracluster correlation coefficient needed for the sample size calculations of a full-scale trial.

Methods

Trial Design

We piloted a three-armed cluster randomised controlled trial. The protocol was published[8]. There were two intervention arms, ATLS® and PTC training, and one standard care arm. 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 standard care arm). This design allowed us to assess outcomes both as final values and as change from baseline.

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.

Eligibility Criteria for Cluster and Participants

Clusters

We included Indian tertiary care hospitals that admitted more than 400 adult patients with trauma each year, with operation theatres, X-ray, CT, and ultrasound facilities, and blood bank available around the clock. Most surgical and emergency medicine departments in India organise their physicians in units. Each unit typically consists of at least three faculty members and three to twelve residents, and is assigned a specific day of the week when they manage the emergency department. 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 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 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 eligible hospital selected the units for training. We randomised on the hospital level to avoid contamination between intervention arms and the standard care arms.

Patient Participants

Adults (15 years or older) who 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 XX of the International Classification of Disease version 10 (ICD-10) codebook as reason for presenting.

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 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.

Intervention

In each intervention arm the residents in one or two units 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. 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, according to the standard ATLS® curriculum[5]. The PTC training was conducted in New Delhi, according to the standard PTC curriculum[6]. We did not modify or adapt the delivery or content of these programs during this pilot study.

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 feasibility as well as participant outcomes. The feasibility outcomes were: - Consent rate. For both patients and residents this was equal to the percentage of participants who consented to be included, 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 percentage 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 percentage of residents that passed 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.

The primary patient participant outcome was all cause mortality within 30 days from the time of arrival to the emergency department, measured and compared across trial arms as both final values and as change from baseline.

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. 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 these units were approached to consent to training if their hospital was randomised to either of the intervention arms. The training was conducted approximately one month after the study started.

Sample size

We did not conduct a formal power calculation for this pilot study, as the primary aim was to assess feasibility. The time period was dictated by budget and time constraints.

Allocation

We used simple randomisation implemented using sealed envelopes to allocate sites to trial arms.

Blinding

It was not possible to blind investigators or participants to interventions.

Data Collection

Each participating hospital had a dedicated research officer who collected the data for a total duration of four months. The research officers collected data by observing the care delivered, interviewing the participants, and by extracting data from hospital records. The research officers collected data of all trauma patients who presented to the participating units during their duty hours. Admitted patient participants 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 30 days.

Variables

The research officers collected data on demographics, time of injury to arrival at the participating hospital, time to recording vital signs, vital signs, times to and management details including imaging and surgery, and details of any injury sustained.

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 will be published separately.

Data monitoring

Weekly meetings with the core team and research officers took place. We conducted one interim analysis, 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. We did not use a data monitoring committee.

Statistical Methods

We analysed all pilot data, including both feasibility and participant outcomes, using descriptive statistics. We did not perform any formal hypothesis tests during the analysis of this pilot's data[9]. Quantitative variables are summarised as mean +/- standard deviation, median, interquartile range and range. Qualitative variables are presented as absolute numbers and percentages. We used an empty generalised linear mixed model to estimate the intracluster correlation coefficient.

We compared patient participant outcomes in all possible combinations of trial arms. 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.

Ethics and Dissemination

We were granted research ethics approval from each participating hospital.

Results

Between the study period of April 2022 to 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 1. 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.
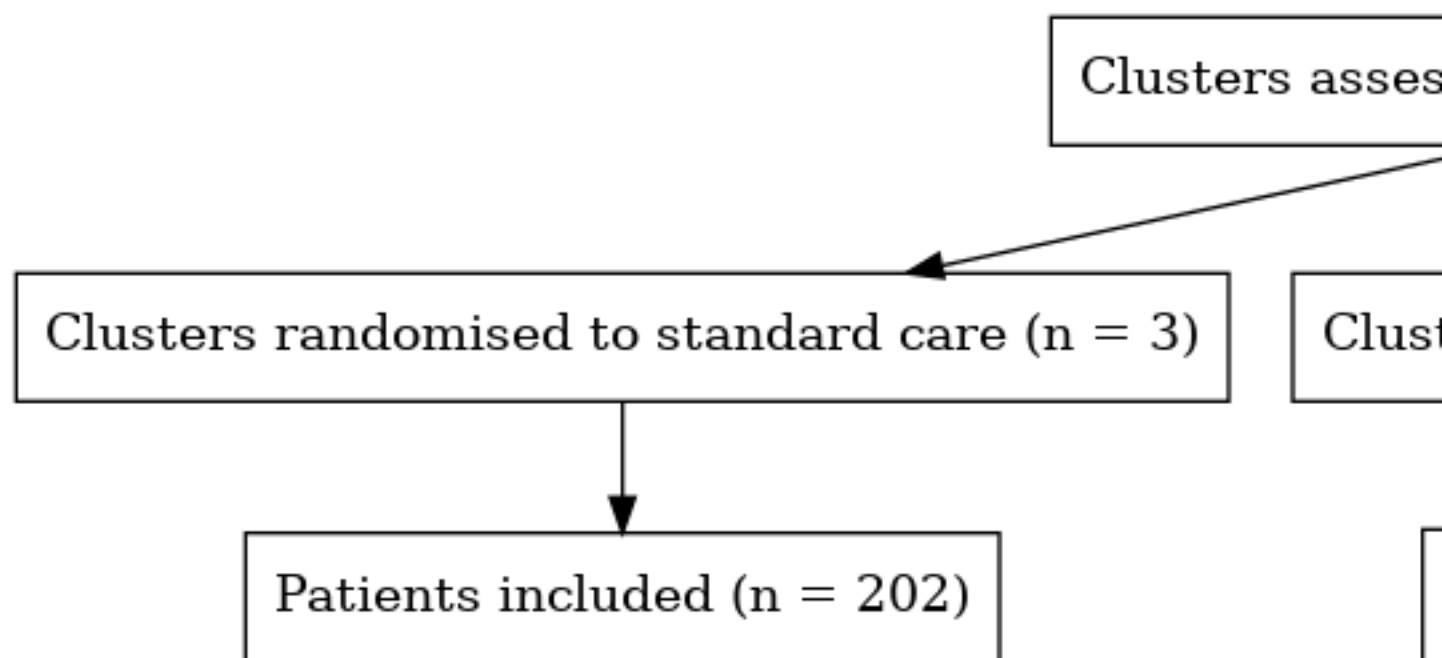

Figure 1: Study flow diagram. Abbreviations: ATLS, Advanced Trauma Life Support; PTC, Primary Trauma Care.

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Feasibility Outcomes

. 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 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

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%)	90
Female	6 (38%)	13 (23%)	5 (12%)	24
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: 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

through observation or interview, are shown in Table **??**(tab:observed-vs-retrospective). Overall, the data were similarly distributed, but there were considerably more missing values in extracted data compared to observed data.

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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).

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, across trial arms and both before and after training.

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[10,11]. 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 research 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[12–16]. 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[12–15], whereas one study from China that included 820 patients found a significant reduction in mortality, from 20 to 15%, after implementing ATLS®[16].

Several controlled trials, including at least two randomized controlled trials[17,18], show that ATLS® is associated with improved provider skills[2]. Observational evidence indicates that PTC also leads to improved provider skills[4]. 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

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 research 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.

Analysis level of feasibility outcomes

We had planned to analyse feasibility outcomes on both an overall and individual cluster level, but we only analysed them on an overall level.

Supplementary material

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