Journal of Critical Care 36 (2016) xxx–xxx

Contents lists available at ScienceDirect

Journal of Critical Care

journal homepage: www.jccjournal.org

Evaluation of a critical care outreach service in a middle-income country: A stepped wedge cluster randomized trial and nested qualitative study☆,☆☆,★,★★,☆☆☆,☆☆☆☆

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ARTICLE INFO

Available online xxxx
Keywords:
Critical care outreach
Stepped wedge randomized controlled trial
Hospital mortality
Cardiopulmonary resuscitation
Length of stay
Health service evaluation

ABSTRACT

Purpose: This trial evaluates implementation of critical care outreach in a middle-income country.
Materials and methods: Critical care outreach delivered by a team of intensive care nurses was implemented across general hospital wards in an Iranian university hospital. The order of implementation was randomized with wards stratified by predicted mortality rates. Effectiveness was evaluated using a stepped wedge cluster randomized controlled trial design, comparing outcomes between patients admitted before and after implementation. The primary outcomes were inhospital mortality and cardiopulmonary resuscitation. A nested qualitative study explored challenges to implementation and contextualized the trial outcomes.
Results: Between July 2010 and December 2011, 13 wards were sequentially randomized to implement the critical care outreach: 7802 patients were admitted before implementation and 10 880 after implementation. There were 370 deaths (4.74%) among patients admitted before implementation and 384 deaths (3.53%) after implementation. Adjusting for clustering and temporal trends, the odds ratio for mortality was 1.03 (95% confidence interval, 0.68-1.53). Results for other outcomes were broadly similar. Focus groups revealed a lack of endorsement of the intervention by management and ward nurses.
Conclusions: This pragmatic evaluation of critical care outreach in a middle-income country did not show a reduction in mortality or other outcomes.

1. Introduction

1.1. Scientific background

Demand for intensive care beds is increasing in lower income and middle-income countries [1,2]. Critical care outreach, comprising a system for identifying acutely ill patients in general wards and an outreach team, is widely implemented in developed countries [3-7]. However, systematic reviews of randomized controlled trials have not found robust evidence that it reduces mortality, cardiac arrest, unplanned intensive care admissions, or length of stay [8-10]. It has been suggested that the policy was not evidence based [11,12]. Apart from one before-and-after study, it is unevaluated in middle-income countries [13].

1.2. Explanation of rationale

Hospital managers decided to implement critical care outreach (CCO) across the general hospital wards of Shariati Hospital, Tehran. They agreed to a randomized roll-out, allowing robust evaluation as a stepped wedge cluster randomized controlled trial [14].

☆ The research was carried out in Shariati Hospital which is affiliated to Tehran University of Medical Sciences, Tehran, Iran. UK address for reprints. Reprints will not be ordered.

☆☆ Funding: This study supported by Digestive Disease Research Institute affiliated to Tehran University of Medical Sciences. KH and TM acknowledge financial support for the submitted work from the National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care for West Midlands. KH also acknowledge financial support from the Medical Research Council Midland Hub for Trials Methodology Research (grant no. G0800808).

★ Trial registration: The trial was registered on July 7, 2015, on the Iranian Registry of Clinical Trials (registration no. IRCT201107187053N1; www.irct.ir).

★★ Ethical approval: This research was approved by the Institutional Review Board of Tehran University of Medical Sciences and Digestive Diseases Research Institute in accordance with Iranian Ministry of Health and Medical Education guidelines.

☆☆☆ Competing interests: The author(s) declare that they have no competing interests.

☆☆☆☆ Authors' contributions: AJ conceived the trial, participated in its design, led its coordination, and helped to draft the manuscript. KH helped design of the trial, developed the methods, carried out the statistical analysis, and wrote the first draft of the manuscript. TM contributed to the design of the trial and the interpretation of the results and helped draft the manuscript. All authors read and approved the final manuscript.

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http://dx.doi.org/10.1016/j.jcrc.2016.07.018
0883-9441/

1.3. Aim

This trial assessed the effects of CCO on hospital mortality and cardiopulmonary resuscitation. Secondary aims were to assess effects on length of stay and intensive care admissions.

2. Methods

Between July 2010 and December 2011, Shariati Hospital implemented and sequentially randomized CCO across 13 wards as an unblinded stepped wedge cluster randomized trial. Outcomes were compared between admissions before (unexposed) and after each ward implemented CCO (exposed).

2.1. Trial design

The trial was implemented in periods of 4 weeks: baseline data collection for 3 periods (12 weeks), roll-out of the intervention to 2 wards every 2 periods (6 steps of 8 weeks each), and postintervention data collection for 3 periods (12 weeks). This was a total of 18 periods (72 weeks) (Supplementary Fig. 1). Each ward also had 8-week transition phase of implementation, during which ward staff were trained to adopting the intervention.

2.2. Rationale for the trial design

Randomization was at the cluster level to avoid issues of contamination. Because it was necessary to implement CCO sequentially in wards rather than introduce it to all wards at the same time, we randomized the roll-out sequence. This allowed us to evaluate implementation as a stepped wedge cluster randomized trial.

2.3. Participants and setting

Shariati Hospital is a university and public teaching hospital with 800 beds, in 29 wards including 5 intensive care units (47 beds). It admits 20 000 patients annually. All 13 adult general wards (general medical wards, orthopedics, hematology, obstetrics, pulmonary, urology, surgery, and maxillofacial wards) served by 3 of the 5 intensive care units were selected for the new CCO team.

There were no patient exclusion criteria, everyone admitted to the 13 wards over the duration of the trial was classified as belonging to 1 of the 3 exposure groups (unexposed, transition phase, and exposed). Those admitted before the ward was randomized to implement the intervention were unexposed, those admitted after were exposed, and those admitted when the ward was undergoing training were in the transition phase.

2.4. Intervention

Critical care outreach was intended to respond to the needs of acutely ill patients and to share skills between intensive care and general ward staff. Implementation was overseen by a committee including representatives of management, nursing, and medical teams. The CCO team included 6 experienced intensive care nurses who before the trial were introduced to the ward staff and underwent 3 months of additional training in patient monitoring and clinical management (Supplementary Appendix 1). Training of the critical care team included theory and management protocols followed by full-time practical training. The week the ward crossed over to the intervention, ward nurses began 8 weeks of training on assessment, identification, and management of acutely ill patients (Supplementary Appendix 2).

The committee chose a single parameter system using routinely measured vital signs for ward staff to use to identify acutely ill patients for the CCO team. This was simple, avoided calculations, and minimized false alerts [15]. Eligibility criteria included physiological criteria listed in Supplementary Appendix 3 (respiratory rate, oxygen saturation, pulse, blood pressure, temperature, urinary output, and change in consciousness), ward staff concern, recent discharge from intensive care, or patients actively identified by the CCO team. Eligible patients showing no improvement after 30 minutes were referred to the CCO team. The CCO team assessed these patients using a composite scoring system (Supplementary Appendix 4). The CCO team managed all high-risk patients (score >5) and determined who should care for moderate-risk patients (score 3-5). Ward staff managed all low-risk patients (score <3). Patients under CCO care were immediately evaluated by a team member and then either directly cared for by the CCO team or by ward staff under their instruction. Stable patients were discharged from CCO after 72 hours. Patients who remained acutely ill and hemodynamically unstable or whose conditions caused concern were transferred to the intensive care unit.

Before randomization to the intervention arm (unexposed) wards, usual care continued. Ward nurses cared for acutely ill patients under the supervision of ward physicians. Physicians could request transfer to intensive care, but this was largely based on their individual judgment, rather than using scoring systems or formal referral criteria.

2.5. Outcomes

Primary outcomes were inhospital mortality and number of patients undergoing cardiopulmonary resuscitation (both expressed per patient). Secondary outcomes were length of stay and intensive care unit admission.

2.6. Data collection procedures

Data collection procedures were developed specifically for this evaluation. An independent data team was notified daily of new admissions to the study wards and on the same day reviewed patient records to collect information on patients' age, sex, reason for admission (medical, scheduled or unscheduled surgery, or ward transfer) and data required for the Simplified Acute Physiology Score (SAPS) II [16]. No additional investigations were undertaken; any missing SAPS II data items were assumed to be normal.

Mortality and length of stay data were obtained from the hospital electronic information systems. Data on cardiopulmonary resuscitation and admissions to the intensive care unit were obtained from nursing office and CCO team records by the CCO team in exposed wards and by the independent data team in unexposed wards. For these outcomes, data collection was, therefore, not blind to exposure status. Where there was uncertainty, outcome data were rechecked by reviewing patient records.

2.7. Sample size

The sample size for this study was for the most part fixed by its design. That is to say, we used an opportunity to make a randomized evaluation of an intervention which was going to be rolled-out. Our study size was, therefore, constrained by the duration that it would take to roll-out the intervention to all wards. However, as preliminary power calculations suggested that this amount of data might only be able to detect larger differences, we added the 12 weeks preperiod and 12 weeks postperiod worth of data (calculations showed that any additional data had no material impact on power). Over the 72 weeks of the trial, 23 000 admissions to the wards were expected. We used Hussey and Hughes methods to calculate the minimum detectable effect based on the mortality rate (primary outcome) in those unexposed to the intervention and the magnitude of the intracluster correlation (ICC) of mortality rates [17]. With estimated inhospital mortality of 3.5%, ICC from 0.01 to 0.05, and an average cluster size of 1770, the study design would have 80% power (at 5% significance) to detect a decrease in mortality to 2.35 (a 35% relative risk reduction). This effect size is moderate to

Please cite this article as: Jeddian A, et al, Evaluation of a critical care outreach service in a middle-income country: A stepped wedge cluster randomized trial and nested qualitative study, J Crit Care (2016), http://dx.doi.org/10.1016/j.jcrc.2016.07.018