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Task-sharing spinal anaesthesia care in three rural Indian hospitals: a non-inferiority randomised controlled clinical trial

Nandakumar Menon,[1] Regi George,[2] Raman Kataria,[3] Ravi Manoharan,[2] Meredith B. Brooks ,[4,5] Alaska Pendleton,[6,7] Veena Sheshadri,[1] Sudarshana Chatterjee,[3] Wesley Rajaleelan,[1,8] Jithen Krishnan,[1] Simone Sandler,[6] Saurabh Saluja,[6,9] David Ljungman,[6,10] Nakul Raykar,[6,11] Emma Svensson,[6,12] Isaac Wasserman,[6,13] Anudari Zorigtbaatar ,[6,14] Gnanaraj Jesudian ,[15] Salim Afshar,[6,16] John G Meara,[6,16] Alexander W Peters,[6,9] Craig D McClain [6,17]

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AWP and CDM are joint senior authors.

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For numbered affiliations see end of article.

Correspondence to
Dr Craig D McClain; craig.mcclain@childrens.harvard.edu

ABSTRACT

Background Task-sharing of spinal anaesthesia care by non-specialist graduate physicians, termed medical officers (MOs), is commonly practised in rural Indian healthcare facilities to mitigate workforce constraints. We sought to assess whether spinal anaesthesia failure rates of MOs were non-inferior to those of consultant anaesthesiologists (CA) following a standardised educational curriculum.

Methods We performed a randomised, non-inferiority trial in three rural hospitals in Tamil Nadu and Chhattisgarh, India. Patients aged over 18 years with low perioperative risk (ASA I & II) were randomised to receive MO or CA care. Prior to the trial, MOs underwent task-based anaesthesia training, inclusive of remotely accessed lectures, simulation-based training and directly observed anaesthetic procedures and intraoperative care. The primary outcome measure was spinal anaesthesia failure with a non-inferiority margin of 5%. Secondary outcome measures consisted of incidence of perioperative and postoperative complications.

Findings Between 12 July 2019 and 8 June 2020, a total of 422 patients undergoing surgical procedures amenable to spinal anaesthesia care were randomised to receive either MO (231, 54.7%) or CA care (191, 45.2%). Spinal anaesthesia failure rate for MOs (7, 3.0%) was non-inferior to those of CA (5, 2.6%); difference in success rate of 0.4% (95% CI=0.36–0.43%; p=0.80). Additionally, there were no statistically significant differences observed between the two groups for intraoperative or postoperative complications, or patients' experience of pain during the procedure.

Interpretation This study demonstrates that failure rates of spinal anaesthesia care provided by trained MOs are non-inferior to care provided by CAs in low-risk surgical patients. This may support policy measures that use task-sharing as a means of expanding anaesthesia care capacity in rural Indian hospitals.

Trial registration number NCT04438811.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The Lancet Commission on Global Surgery report in 2015 highlighted the lack of workforce across all specialties working within surgical systems. The World Federation of Societies of Anaesthesiologists has recommended a goal of 5 anaesthesia providers per 100 000 population to meet minimal workforce numbers. In the vast majority of low-income and middle-income countries (LMICs), the actual number of providers is well below this standard leading to little or no access to necessary surgical care. These disparities are even more exaggerated in rural locations, where there are few if any physician anaesthesia providers. There are no studies looking at comparison of clinical outcomes between trained physician anaesthetists and non-subspecialty trained anaesthesia providers in LMICs.

BACKGROUND

Task-sharing, the delivery of healthcare tasks by non-traditional cadres of healthcare workers, is a strategy advocated by the WHO to accelerate the delivery of universal health coverage. Task-sharing seeks to address the global shortage of healthcare workers, estimated to reach 18 million by 2030.[1] In perioperative care, the disparity of specialist workforce provision is particularly marked–with low-income nations estimated to have 0.7 surgical and anaesthesia physician providers per 100 000 population, approximately 30 times below minimum targets. Anaesthesia providers account for only a quarter of the global perioperative workforce.[2] Globally, over 5 billion people lack access to surgical and anaesthesia care, with severe workforce shortages playing a major contributing

WHAT THIS STUDY ADDS

⇒ Based on a partnership with a network of rural Indian hospitals, we developed a three-phase training programme to train medical officers (MOs, non-specialty trained physicians) in three rural Indian hospitals to perform spinal anaesthesia safely and effectively. After undergoing and passing the described training programme, patients were randomised to receive spinal anaesthesia from a specialty trained consultant anaesthetist or one of the trained MOs. This was designed as a non-inferiority trial to determine if the MOs could administer a spinal anaesthetic comparable in safety and efficacy to a specialty trained consultant anaesthetist. This is the first, to our knowledge, randomised controlled trial looking at clinical outcome differences between specialty trained physician anaesthetists and non-specialty trained anaesthesia providers anywhere.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This work contributes new evidence and strategies for addressing the severe lack of surgical care workforce across LMICs. Given the significant lack of adequate anaesthesia workforce personnel, this study describes a model that can not only help increase safe and effective provision of anaesthetic care in remote locations but also demonstrates that, when compared with specialist physician delivery, the safety and efficacy are the same after successful completion of the described training. The implications of this work are (1) demonstration that task-sharing in anaesthesia in LMICs is not only a good idea in the abstract but also can be accomplished in a manner that provides evidence-based safety and quality and (2) the described approach to training and care is scalable (within India and beyond—other Asian nations, Sub-Saharan Africa, South and Central America and high-income countries with large remote and rural populations) and has the potential to offer improved surgical and anaesthesia care to the billions of people currently lacking access across the world.

factor.[3] Given the severity of the workforce shortage, task-sharing is considered one of the few viable options to deliver universal access to surgical and anaesthesia care in the Sustainable Development Goals era.[4]

In India, as in many other countries, healthcare worker density is significantly lower in rural areas than in cities. An estimated 68% of citizens live in rural areas with access to only 22% of the healthcare workforce.[3] Community health centres (CHCs) provide secondary-level care, inclusive of 30 inpatient beds and one operating theatre, for a population range of 80 000 to 120 000.[5] National standards mandate the provision of at least one consultant anaesthesiologist (CA) per centre.[5] The fourth and most recent, District Level Household and Facility Survey, conducted from 2012 to 2014, found provision of anaesthesia services were markedly deficient, ranging from 0% of surveyed CHCs having an anaesthesiologist in Meghalaya to 50% in Goa (the highest reported percentage).[6] This unmet need is likely to contribute to the high mortality and morbidity of conditions amenable to surgical care observed in the Indian population.[7–9]

To mitigate the constraint of specialist providers, the de facto standard of care in many nations is task-sharing of anaesthesia provision, which is estimated to occur in as many as 119 countries, across all World Bank income groups.[10] In India, medical officers (MOs), who are non-specialist medical graduate physicians, have a precedent of delivering anaesthesia care in rural hospitals.[11] Medical officers are incentivised to work in non-urban healthcare settings in a number of ways, including subsidised medical education at government medical colleges or as a mandatory requirement to fulfil prior to postgraduate specialisation.[12] Therefore MOs represent a latent and potentially scalable solution to the anaesthesia workforce constraint in India. However, the practice of task-sharing anaesthesia care with MOs remains contentious, particularly among professional societies for anaesthesiology in India and, therefore, adoption of this strategy remains heterogenous. Concerns centre on the lack of a validated educational curriculum with appropriate credentialing, the paucity of research into the clinical safety of task-sharing and the difficulty of providing a comparable standard of care to specialist providers.[13]

Among the modalities of anaesthesia delivery, spinal anaesthesia–the injection of a local anaesthetic agent into the subarachnoid space delivering neuraxial analgesia–is potentially advantageous for task-sharing given its safety profile, low-cost and efficacy.[14] Spinal anaesthesia, unlike general anaesthesia, can be administered without the concomitant loss of consciousness or airway reflexes.[15 16] Spinal anaesthesia is also considered relatively cost-efficient to deliver in comparison to volatile or intravenous general anaesthesia.[17] It is routinely used for surgical procedures where the primary incision is below the umbilicus, including caesarean section, anorectal procedures, appendectomies, lower limb surgery, inguinal and femoral hernia repairs.[18]

In this study, we hypothesised that a three-part educational programme, consisting of online didactic lectures with examinations, on-site simulation training and directly observed clinical skills under the supervision of consultant anaesthesiologists, would result in medical officers developing a level of proficiency in providing spinal anaesthesia care that was non-inferior to CAs.

METHODS

Study design

This was a multicentre, randomised controlled, non-inferiority trial to assess the spinal anaesthesia failure rate of patients who received MO-delivered anaesthesia for emergency and elective surgery in comparison to CAs. This study was conducted in three rural hospitals in India: ASHWINI Gudalur Adivasi Hospital (Tamil Nadu), Tribal Health Initiative (Tamil Nadu) and Jan Swathya Sahyog (Chhattisgarh).

Participants

MOs selected to participate in the trial were Indian medical graduates (MBBS) who had completed a compulsory rotatory residential internship and received Medical Council

of India registration but had not undergone specialist training. Exclusion criteria for MOs included any recent suspension from clinical practice and plans to change work sites or specialise before the expected end date of the trial. All four MOs had pre-existing experience of working in rural hospital environments. CAs had completed postgraduate training in anaesthesia and had experience working in rural environments. Patients selected were between 18 and 65 years old, graded I–II ASA Physical Status Classification System,[19] with a Body Mass Index (BMI) less than 35, undergoing a procedure amenable to spinal anaesthesia and able to provide written consent. Exclusion criteria included patient refusal, contraindications to spinal anaesthesia: allergy, coagulopathy (pathological or secondary to anticoagulation use), sepsis, hypovolaemia, raised intracranial pressure, pre-existing lumbar spine pathology, infection overlying the lumbar area or unknown planned duration of surgery.[20] All participants including MOs, CAs and patients gave written informed consent prior to enrolment into the study.

Procedures

The MOs received a three-phase, 5–6-month clinical educational programme in spinal anaesthesia training prior to participating in the trial. Phase 1 consisted of a 10 module online didactic course on spinal anaesthesia with 10 postmodule and a final postcourse multiple choice question examinations on the OpenPediatrics platform (Boston, MA, USA). MOs were required to successfully complete each online module and pass each examination with a minimum score of 88% before proceeding to phase 2. Phase 2 included on-site simulation training on anaesthesia emergencies that used 'Airway Larry' Airway Management Trainer Torsos (Nasco, Fort Atkinson, WI, USA) and the SimMon Medical Simulation App (Denmark) on tablet devices.[21] To standardise and facilitate the delivery of anaesthesia simulation training, senior clinicians underwent a 3-day train-the-trainers simulation course at Boston Children's Hospital (Boston, MA, USA) and then assumed roles of simulation educators in their respective hospitals. A range of clinical scenarios were practised that represented an array of anaesthetic emergencies. Phase 3 consisted of directly supervised clinical training delivered by CAs. Each MO performed a minimum of 50 supervised spinal anaesthesia cases, which has been demonstrated to correlate to a 90% success rate among anaesthesia residents.[22–24] Training was also provided for basic and advanced airway techniques, with MOs required to log 20 cases requiring bag-mask ventilation and 20 cases requiring invasive ventilation techniques under CA supervision. These additional airway skills were taught to improve clinical skills but not demonstrate competency. To further evaluate clinical performance, each medical officer kept a logbook of cases and underwent a directly observed practical skills evaluation every 10th case and a global assessment every 20th case.

Randomisation and masking

Patients presenting for surgery at the three hospital sites were first evaluated by a CA to confirm eligibility for participation in the study. Those determined to meet all inclusion criteria and none of the exclusion criteria were then referred to the study coordinator. The study coordinator obtained informed written consent from study participants who were then enrolled into the trial to receive spinal anaesthesia care from either an MO or a CA. The study coordinator was also in charge of allocation, with randomisation occurring at the time of enrolment using random number generation, Excel (Microsoft Windows). Enrolment occurred up to 1 week prior to procedure to support planning of clinical service provision. The study proceeded on a per-protocol basis, and as such, any patients who did not undergo their planned surgical procedures for any reason did not affect the randomisation assignment of other participants in the trial. At all times, a CA was available in the facility to assist with any unexpected patient issues or safety risks, and all members of the care team were empowered to request a CA evaluate a patient in the MO arm at any time. All unsuccessful attempts at delivering spinal anaesthesia (as defined below) in both groups either had further spinal attempts by CAs or converted to general anaesthesia as deemed most clinically appropriate by CAs. All patients were continually monitored for adverse events, irrespective of success or failure of spinal anaesthesia procedure. Clinical teams were not masked due to the nature of the trial; however, both patients and the statistician were masked during trial implementation.

Outcomes

The primary outcome measure was spinal anaesthesia failure, indicated by a provider requiring more than three attempts to access the lumbar intrathecal space with free flow of cerebrospinal fluid or inadequate surgical anaesthesia requiring perioperative conversion to general anaesthesia. Each attempt was counted by individual spinal needle puncture of the dermal skin overlying the lumbar area. Secondary outcomes were the occurrence of intraoperative complications and postoperative complications. These were assessed at postoperative review 1, occurring at 72 hours postoperatively or prior to discharge, whichever occurred first, and again at postoperative review 2, occurring between 10 and 14 days after the procedure. Intraoperative complications included direct assessment of sustained hypotension, bradycardia, desaturations, high spinal anaesthesia, apnoea, hypothermia, local toxicity and cardiac arrest. Postoperative complications included direct assessment of headache, epidural haematoma, spinal abscess, meningitis and neurological deficit. Research nurses who served as impartial data collectors directly observed each spinal procedure and the conduct of anaesthesia care. Research nurses independently determined failure, intraoperative complications and postoperative complications. Patient-reported measures of intraoperative pain and absolute category rating of care delivered were also obtained

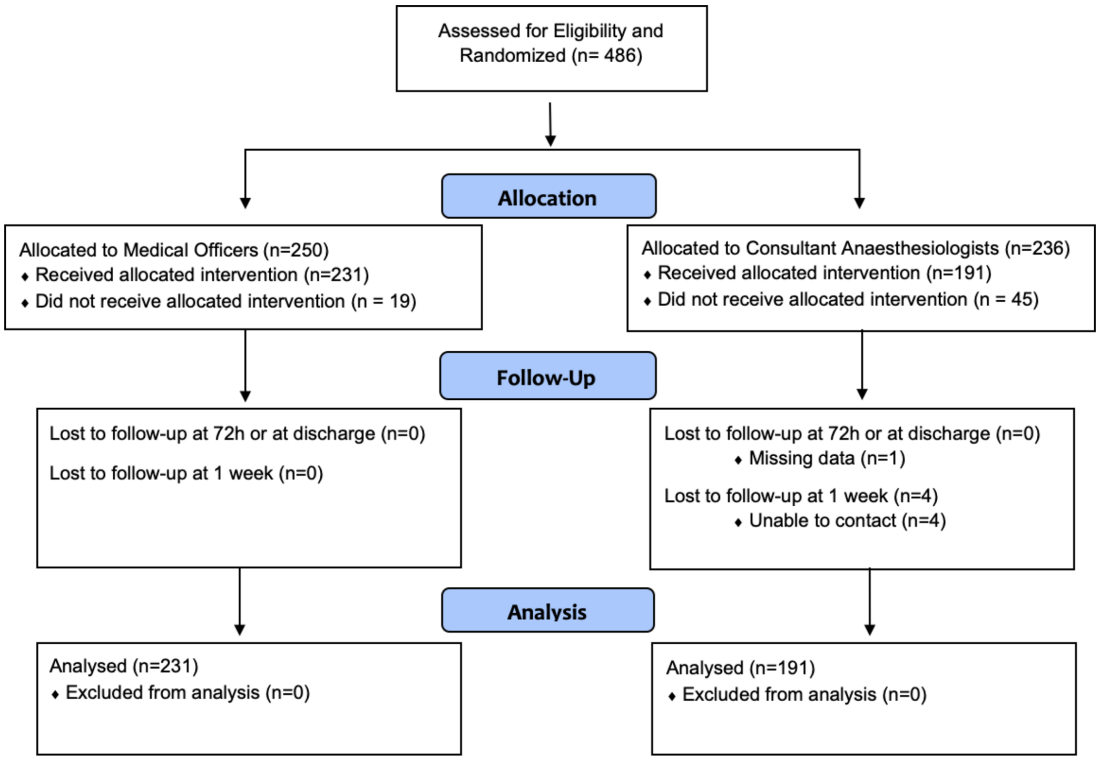

Figure 1 CONSORT flow diagram of patients included in the study.

postoperatively. Data collection was performed on paper data capture sheets and then transcribed onto the digital Research Electronic Data Capture forms (REDCap 2018 Vanderbilt University, Nashville, TN) web-based application.

Statistical analysis

Appraisal of published literature on spinal anaesthesia failure rates demonstrated significant heterogeneity of reported failure rates ranging from 1% to 19.5%.[25–29] One publication assessed spinal anaesthesia failure rates in rural Indian hospitals, reporting a failure rate of 5.7%.[30] Following consultation with CAs in India, a presumed failure rate of 4% was deemed most appropriate in the rural clinical setting. The sample size for the clinical trial was calculated on a presumed spinal anaesthesia failure rate of 4% in the control group. A non-inferiority margin was set at 5% based on published estimates for competencies of anaesthesia clinical trainees that estimate a failure rate below 10% as indicative of competency.[22–24] The sample size was powered at 80% with an alpha of 5%. Based on these determinants, a minimum of 191 eligible patients were required in each arm of the trial. Power calculations were performed using the SSI module in STATA (STATACORP 2017). Patient characteristics, spinal anaesthesia failure rates and incidence of postoperative complications were analysed with T-test and Wilcoxon rank sum for continuous variables, and χ squared and Fisher's exact tests for discrete variables. Descriptive statistics and statistical calculations were performed in SAS V.9.4 (Cary, NC, USA).

Table 1 Characteristics of medical officers and consultant anaesthesiologists

	Medical officers	Consultant anaesthesiologists
Total	4	3
Gender (% female)	75%	25%
Postgraduate clinical practice (median years)	3.75	32

Role of funding sources

Funding for the clinical education programme and clinical trial was obtained from a research grant awarded by the Centre for Global Health Delivery-Dubai, Harvard Medical School (027562-746846-0307; Dubai, UAE). Funds were used to subsidise clinical time, purchase training materials, patient monitoring, and fund the salaries of research nurses and data collectors. Expenses incurred for research meetings and travel to hospital sites were funded by a grant from the Boston Children's Hospital Global Health Programme (Downs India Fund; Grant number - N/A; Boston, MA, USA). The funders of this study had no role in study design, subject participation, data collection, data analysis, data interpretation or writing of the report. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Table 2 General characteristics of clinical participants

Characteristic	Medical officers	Consultant anaesthesiologists	P value
N	231	191	N/A
Age, mean (SD)	37.2 (13.6)	34.9 (13.0)	0.0800*
Age, median (IQR)	34 (25–47)	30 (25–45)	0.0909†
Gender			
Female	152 (65.8%)	131 (69.0%)	0.4937
Male	79 (34.2%)	59 (31.1%)	
BMI, median (IQR)	21.0 (18.4–24.0)	20.7 (19.0–23.3)	0.8978†
ASA classification score (%)			
1	180 (79.0%)	140 (73.3%)	0.1752
2	48 (21.1%)	51 (26.7%)	
3+	0 (0.0%)	0 (0.0%)	
Comorbidities (%)			
Haematological	5 (2.2%)	3 (1.6%)	0.7339‡
Genitourinary	1 (0.4%)	1 (0.5%)	1.0000‡
Cardiac	9 (3.9%)	4 (2.1%)	0.2863
Renal	1 (0.4%)	0 (0%)	1.0000‡
Endocrine	7 (3.0%)	0 (0%)	0.0178‡
Respiratory	1 (0.4%)	0 (0%)	1.0000‡
Metabolic	0 (0%)	1 (0.5%)	0.4526‡
Autoimmune	2 (0.9%)	0 (0%)	0.5033‡
Infectious	1 (0.4%)	0 (0%)	1.0000‡
Gastrointestinal	0 (0%)	1 (0.5%)	0.4526‡
Neurological	1 (0.4%)	0 (0%)	1.0000‡
Current medication (%)			
Antiplatelets	0 (0%)	0 (0%)	N/A
Anti-coagulants	0 (0%)	0 (0%)	N/A
Beta-blockers	2 (0.9%)	2 (1.1%)	1.0000‡
Case type (%)			
Emergency	28 (12.2%)	33 (17.3%)	0.1435
Elective	201 (87.8%)	158 (82.7%)	0.1435

Please note where totals are below 422; information was not available to the research nurse or incompletely filled on the data-capture sheet.
*T-test.
†Wilcoxon rank sum test.
‡Fisher's exact test, otherwise χ^2 test.
ASA, American Society of Anesthesiologists; BMI, Body Mass Index; N/A, not applicable.

RESULTS

Between 12 July 2019 and 8 June 2020, a total of 486 patients were enrolled in the study. Of those enrolled, 250 (51.4%) were randomised to MOs and 236 (48.6%) to CAs. A total of 64 (13.2%) enrolled participants did not undergo the primary intervention due to scheduling and clinical factors (figure 1). Randomisation continued until the pre-determined number of evaluable participants per study arm was met; this left a final cohort of 422 evaluable patients enrolled in the study with 231 (54.7%) of cases randomised to MOs and 191 (45.2%) to CAs.

Four MOs and three CAs were recruited to participate in the study. At the commencement of the trial, MOs had a median of 3.75 years of postgraduate clinical experience compared with a median of 32 years among CAs (table 1). Comparing patient characteristics between MOs and CAs (table 2), the mean age of patients enrolled was 37 years and 35 years, respectively, with similar gender distributions. Mean BMI was 21.8 and 21.5 in the respective arms. 320 participants (76%) had healthy physiological status (ASA 1 score) which did not differ significantly between the trial cohorts. The remaining 99 participants

Table 3 Primary outcome measure: failure to deliver spinal anaesthesia

Primary outcome	N	Medical officers (n=231)	Consultant anaesthesiologists (n=191)	% between-group difference (95% CI)	P value
Failure to deliver spinal anaesthesia in all cases	422	7 (3.0%)	5 (2.6%)	0.4 (0.36 to 0.44)	0.7997
Failure to deliver spinal anaesthesia in emergent cases	61	1 (3.6%)	2 (6.1%)	−2.5 (−2.92 to −2.08)	1.0000*
Failure due to inaccessibility of intrathecal space	422	7 (3.0%)	5 (2.6%)	0.4 (0.36 to 0.44)	0.7997
Failure due to conversion to general anaesthesia	422	0 (0.0%)	0 (0.0%)	–	–

*Fisher's exact test, otherwise χ^2 test.

(24%) had mild to moderate systemic disease (ASA 2 score), mostly with haematological (2%), cardiac (3%) and endocrine (2%) comorbidities. However, there was no significant difference in comorbidities between the groups, with 48 of these in the MO arm (21.1%) and 51 in the CA arm (26.7%). 359 procedures (85%) were elective while the remaining 61 (15%) were for medical emergencies. This case mix was similarly distributed in both the arms, with 28 emergency cases (12.2%) in the MO arm and 33 emergency cases (17.3%) in the CA arm. The breakdown of case type was similar in each arm. For the MO cohort, the distribution was abdominal (hernias, appendectomies, etc) 41 (17.7%), perineal (pilonidal cysts, haemorrhoids, etc) 27 (11.7%), lower extremity (amputations, fractures, etc) 11 (4.8%), genitourinary (urethral stricture, orchiectomy, etc) 24 (10.4%) and obstetrics and gynaecology (C-section, tubal ligation, hysterectomy, etc) 128 (55.4%). For the CA cohort, the distribution was abdominal—40 (20.9%), perineal—19 (10%), lower extremity—7 (3.7%), genitourinary—9 (4.7%) and obstetrics and gynaecology—116 (60.7%).

There was no statistically significant difference in the primary outcome–delivery of spinal anaesthesia into the intrathecal space in three or fewer attempts (table 3). MOs were unsuccessful in 7 (3.0%) patients, while the CAs were unsuccessful in 5 (2.6%) patients, with a difference in success rate of 0.4% (CI=0.36–0.43%; p=0.7997). Differences in intraoperative pain management were also non-significant between trial arms, with supplementary local anaesthesia given to 16 (6.9%) of MO cases and 11 (5.8%) of CA cases. Patient-reported experiences of pain were higher in MO arm (12, 5.3%) compared with CA (4, 2.1%); however, this did not attain statistical significance (p=0.0927).

Secondary outcomes included intraoperative and postoperative complications, as well as patients' experience of pain during the procedure (tables 4 and 5). The most common intraoperative complication in both groups was hypotension (2.2% in MO arm, 3.2% in CA arm) and bradycardia (0.9% and 1.1%), however, without significant differences (p=0.5559 and p=1.0000, respectively). There were no significant differences in all postoperative complications between the MO and the CA patient groups (1.3% and 1.1%, p=1.0000) either at 72 hours after the procedure or at the time of discharge (table 5A). Two patients that had headaches each in the CA and MO groups both recovered well with conservative management. No participants in either group suffered infectious complications or neurological injuries (table 5A). All participants were contacted during the second week postoperatively, either in-person or by telephone, and there were no further complications reported during this extended postoperative period (table 5B). There were no noted harms or unintended consequences in either group per CONSORT.

DISCUSSION

Spinal anaesthesia delivered by trained MOs was non-inferior to that delivered by CAs in three rural hospitals in

Table 4 Intraoperative complications

Secondary outcomes	Medical officers (n=231)	Consultant anaesthesiologists (n=191)	P value
Hypotension	5 (2.2%)	6 (3.2%)	0.5559*
Bradycardia	2 (0.9%)	2 (1.1%)	1.0000*
High spinal	1 (0.4%)	0 (0%)	1.0000*
Apnoea	0 (0%)	0 (0%)	N/A
Desaturation	0 (0%)	0 (0%)	N/A
Hypothermia	1 (0.4%)	0 (0%)	1.0000*
Local anaesthesia toxicity	0 (0%)	0 (0%)	N/A
Cardiac arrest	0 (0%)	0 (0%)	N/A

*Fisher's exact test.
N/A, not available.

Table 5 (A) Spinal complications identified at postoperative review 1. (B) Spinal complications identified at postoperative review 2

Secondary outcomes	Medical officers (n=231)	Consultant anaesthesiologists (n=191)	P value
(A)			
Any complications following surgery	2 (0.9%)	2 (1.1%)	1.0000*
Headache	2 (0.01%)	2 (0.01%)	1.0000*
Meningitis	0 (0%)	0 (0%)	N/A
Spinal haematoma	0 (0%)	0 (0%)	N/A
Spinal abscess	0 (0%)	0 (0%)	N/A
Neurological deficit	0 (0%)	0 (0%)	N/A
Other	0 (0%)	0 (0%)	N/A
(B)			
Any complications following surgery	0 (0%)	0 (0%)	N/A
Postdural puncture headache	0 (0%)	0 (0%)	N/A
Meningitis	0 (0%)	0 (0%)	N/A
Spinal haematoma	0 (0%)	0 (0%)	N/A
Spinal abscess	0 (0%)	0 (0%)	N/A
Neurological deficit	0 (0%)	0 (0%)	N/A
Other	0 (0%)	0 (0%)	N/A

*Fisher's exact test.
N/A, not available.

India. Furthermore, the incidence of anaesthetic-related complications was not statistically different between the two arms of the trial, including both the intraoperative and postoperative care periods. This study demonstrates that with proper training, spinal anaesthesia care may be effectively task-shared for low-risk patients in a rural healthcare setting to facilitate the delivery of obstetric and surgical care, a core component of universal health coverage. We believe this to be the first randomised controlled trial in anaesthesia care task-sharing in a low-income and middle-income country (LMIC) and, as such, the first to assess the efficacy of task-shared anaesthesia care in low-resource healthcare settings. These findings are likely to be generalisable to other comparable healthcare settings within and outside of India.

Published evidence evaluating clinical outcomes related to task-shared anaesthesia care is rare. A Cochrane review of the clinical outcomes of anaesthesia task-sharing between physician and non-physician providers only identified one study in an LMIC nation, Haiti, with the rest occurring in the USA. Paucity of data and the potential for confounding, given a lack of randomisation, led authors of the review to determine inconclusive recommendations.[31] Comparatively, evidence on the clinical outcomes of task-shared surgical care is more readily available, including both cohort and experimentally designed trials.[32–36] We believe the opacity of evidence relating to anaesthesia task-sharing is of concern, given its ubiquitous practice globally. Furthermore, the lack of credible research prevents meaningful, evidence-based policy to scale these measures, with issues on clinical efficacy and safety left largely unanswered. We, therefore, believe this study adds significantly to the existing body of literature and would highlight the need for further investment in similar clinical trials.

Task-sharing of anaesthesia care can alleviate the immense clinical demand for anaesthesia services and workforce provision. In India, the anaesthesia workforce consists of 16 500 specialist physicians, representing a density of 1.27 providers per 100 000 population (2017 values).[37] In order to meet minimum global targets for anaesthesia care, the workforce would have to expand fourfold. Additionally, an increase in anaesthetic provider density alone is unlikely to solve the issue of delivering anaesthesia care in rural areas. In Canada, the USA and Australia with CA provider densities of 12.42, 20.82 and 23.09 per 100 000 population respectively, task-sharing of anaesthesia care is still required to enhance workforce capacity, particularly, in rural areas.[37] Furthermore, demand-side pressures are significant, with an estimation that the Indian population requires 3646 surgical procedures per 100 000 population annually,[38] creating a clear burden of unmet need should anaesthesia services continue to be inaccessible. We interpret these realities and are broadly in support of task-sharing of anaesthesia care under appropriate safeguards and clinical training.

The foremost concern of task-sharing, particularly, in procedural care, centres on the safety of such approaches and the need to maintain quality of care. We believe this study may facilitate regional and national policy measures on the practical viability of task-sharing. There have been historic central government-led efforts to expand the

anaesthesia workforce in India through task-sharing with the introduction of the Life Saving Anaesthesia Skills course in 2002 for medical officers. This programme provides 6 months of clinical training in anaesthesia (regional and general) for medical officers to conduct anaesthesia at obstetric first referral units in India. However, a review of this programme found deficiencies in the quality of clinical training and post-accreditation monitoring was deemed weak.[39] Furthermore, we note that anaesthesia-related obstetric complications, particularly related to general anaesthesia, are a significant contributor to maternal mortality with an estimated one in seven maternal deaths during or after a caesarean section in LMICs accredited to poor quality anaesthesia care.[40]

Given these issues, we believe it is critically important how we monitor, ascertain competency and revalidate physicians who have been trained in task-shared anaesthesia care. The success of this approach will rely on the collaborative partnerships employed to deliver high-quality clinical training and effectively monitor performance. The governance of task-sharing programmes are likely best fulfilled by anaesthesiologists themselves with ongoing assessment of clinical outcomes and periodic revalidation of skills. We note that task-sharing of anaesthesia care may prove divisive among anaesthesia professional societies in India.[41] However, the stark severity of the workforce shortages faced in rural India should allay some concerns on the dilutive effect of such programmes. Further, we also highlight the counterfactual and the current situation in rural India, where anaesthesia task-sharing occurs out of necessity on an ad hoc basis with variable supervision and no professional regulation or guidance. To facilitate consensus building, we would advocate for broad-based stakeholder engagement with the aim of reaching a mutually acceptable process for the adoption of task-sharing programmes. We would advocate strongly for inclusion of robust anaesthesia education within standard undergraduate medical school curriculums to help introduce and familiarise future students and medical officers with basic concepts of perioperative care. We would also advocate for the need to clearly define the scope of practice that may be undertaken by trained MOs, as well as the clinical risk profile of patients to mitigate legitimate concerns among specialist anaesthesia providers. Auditing of care delivered against the WHO-WFSA standards of care may provide a useful framework with which to assess quality of care and compliance to international best practices.[42]

The strength of this study lies in the experimental design that enables robust analysis of outcome measures to critically appraise the performance of medical officers who have undergone standardised training in spinal anaesthesia care delivery. We hope this study will help inform evidence-based policy on the viability of anaesthesia task-sharing programmes in rural health centres. Another key strength was the creation of a multimodal training programme that was tailored for and delivered by rural Indian healthcare facilities under the supervision of CAs. Medical graduates in India are often required to spend 1 year in a rural healthcare facility, termed the 'rural bond.' During this period, MOs are often informally trained in aspects of anaesthesia to support delivery of surgical services. Therefore, the provision of a task-sharing educational programme may standardise these efforts and provide accreditation controls to maintain the quality of care. A further key strength was the follow-up of patients at two postoperative timepoints with a minimal loss to follow-up rate. This may relate to the strength of healthcare worker networks within the local programmes and the high penetration of mobile phone devices in the populations served.

Our study had a number of limitations, most notably, there was a segment of patients who were enrolled into the trial but did not complete their procedure and, thus, could not be considered as evaluable. There were a disproportionate number of participants who did not complete their procedure in the CA cohort compared with the MO cohort. Contributing factors were competing clinical priorities for anaesthesiologists and the cancellation or delay of procedures based on clinical reasons and scheduling conflicts. Although there was unequal retention during the time from enrolment and randomisation to completion of the procedure, randomisation continued until the minimal number of evaluable participants was met in each arm, ensuring appropriate power to conduct the primary outcome analysis. Additionally, we were not able to capture an accurate eligibility number in the CONSORT flow diagram as patients were pre-operatively screened for suitability based on the booked surgical procedure and clinical characteristics with only those deemed eligible then reviewed by research nurses.

It is also worth noting this study focused on the clinical outcomes related to the delivery of spinal anaesthesia alone. We recognise that anaesthesia care is a broad spectrum of skills and that when spinal anaesthesia failure occurs, it often requires the delivery of general anaesthesia. There were three key reasons for not training MOs to deliver general anaesthesia: (i) the lack of pre-existing practice of general anaesthesia task-sharing in our partner hospitals and the raised risk profile did not demonstrate clinical equipoise, (ii) the rarity of general anaesthesia performed in rural surgical facilities would limit the opportunity to effectively train medical officers in this skill, and (iii) the funding and time constraints of this study. Ketamine general anaesthesia is widely available in rural Indian facilities and can be delivered without advanced airway techniques. Future iterations of this training curriculum could include training with ketamine general anaesthesia if deemed appropriate by partner clinical sites. Another limitation noted was while the study was powered to detect differences in spinal anaesthesia failure rates, it was underpowered to detect major adverse anaesthetic events, owing to the rarity of these (the majority are less than 1% risk). Therefore, should this educational programme be scaled further, we would advocate for the continued reporting of adverse events to assess long-term safety in a larger cohort of patients.

In summary, this study is the first randomised controlled trial exploring anaesthesia care task-sharing in a low-income and middle-income nation. It provides evidence in support of efforts to scale the anaesthesia workforce in rural health facilities, through task-sharing with standardised educational training of medical officers. The future success of task-sharing programmes will be determined by the degree of engagement with anaesthesiologists, the quality of clinical instruction and the regulation of training programmes with continued auditing of adverse events. We conclude that validated task-sharing programmes which are tailored for delivery in rural Indian hospitals and CHCs empower rural networks to proactively manage their specialist provider constraints and deliver essential care services to rural populations. Effective task-sharing is a credible solution to overcoming human resource constraints which preclude the delivery of universal access to anaesthesia care to rural Indian populations and can be delivered without adverse events in lower-risk patient groups.

Equitable partnership

This study was a partnership between several Indian surgeons and anaesthesiologists who live and work in the rural hospitals that were the primary study locations, and an international group of physicians and researchers at the Programme for Global Surgery and Social Change at Harvard Medical School. The study came about as a response to issues identified by Indian surgeons and anaesthesiologists published in the Karad Consensus Statement on surgical system strengthening in rural India. Equitable distribution of work, responsibilities, accountability and credit has been prescribed throughout the process of study conceptualisation, design, data collection, data analysis and writing/editing of manuscript. These principles were maintained throughout the entire process by the entire research team. Eight of the first 10 authors of this study are from India, including the first author. Seven of the authors are women with a mix of high-income country and LMIC background. The breakdown of LMIC authors include early, mid and late career authors. The data have been shared with all authors and will be available to any interested party if requested. The results of the study are currently informing a larger, structured education offering in partnership with an Indian University (Martin Luther Christian University in Shillong, India). PGSSC will ensure that funding for open access is available. Neither patients nor the general public were involved in the study design as it was not appropriate.

Author affiliations
[1]ASHWINI Gudalur Adivasi Hospital, Gudalur, Tamil Nadu, India
[2]Tribal Health Initiative, Sittilingi, Tamil Nadu, India
[3]Jan Swasthya Sahyog, Bilaspur, Chhattisgarh, India
[4]Boston University School of Public Health, Boston, Massachusetts, USA
[5]Department of Global Health, Harvard Medical School, Boston, Massachusetts, USA
[6]Program in Global Surgery and Social Change, Harvard Medical School, Boston, Massachusetts, USA
[7]Department of Vascular and Endovascular Surgery, University of Rochester, Rochester, New York, USA
[8]Department of Anesthesia and Perioperative Medicine, University of Ottawa, Ottawa, Ontario, Canada
[9]Department of Surgery, Weill Cornell Medical College, New York, New York, USA
[10]Department of Surgery at the Institute of Clinical Sciences, University of Gothenburg, Goteborg, Sweden
[11]Department of Surgery, Brigham and Women's Hospital, Boston, Massachusetts, USA
[12]Department of Clinical Sciences Lund, Lund University, Lund, Sweden
[13]Department of Otolaryngology - Head and Neck Surgery, Massachusetts Eye & Ear Infirmary, Boston, Massachusetts, USA
[14]Faculty of Medicine and Health Sciences, McGill University, Montreal, Quebec, Canada
[15]Karunya Rural Community Hospital, Coimbatore, Tamil Nadu, India
[16]Department of Plastic and Oral Surgery, Boston Children's Hospital, Boston, Massachusetts, USA
[17]Department of Anesthesiology, Critical Care and Pain Medicine, Boston Children's Hospital, Boston, Massachusetts, USA

X Meredith B. Brooks @meredithbbrooks, Saurabh Saluja @newvernacular, Anudari Zorigtbaatar @anudari.zorigtbaatar, John G Meara @JohnMeara, Alexander W Peters @alexpeters and Craig D McClain @mcc_craig

Contributors NM – study concept and design, funding acquisition, data curation and analysis, methodology, local project manager, project administration, writing and editing of manuscript; RG – conceptualisation, data collection, local administration; RK – conceptualisation, data collection, local administration, writing and editing manuscript; RM – data collection and writing; MB – formal analysis, methodology, validation, writing and editing; AP – data collection and curation, data analysis, project administration, writing and editing of manuscript; VS – data collection, local administration, writing and editing manuscript; SC – conceptualisation, data collection, local administration, writing and editing manuscript; WR – local administration, data collection and curation, writing and editing manuscript; JK – conceptualisation, data collection, local administration, writing and editing manuscript; SS – data collection/curation, editing manuscript; SaS – conceptualisation, funding acquisition; DL – data collection and curation, project administration, editing manuscript; NR – funding acquisition, writing and editing of manuscript; ES – conceptualisation, data collection, local administration, writing and editing manuscript; IW – data collection/curation, analysis, project administration, writing and editing manuscript; AZ – data collection and curation, editing manuscript; GJ – study concept, editing manuscript; SA – study concept, project administration, editing manuscript; JM – study concept, funding acquisition, project administration, writing and editing manuscript; AWP – data collection and analysis, project administration, writing and editing of manuscript; CMcC – initial study concept and design, funding acquisition, methodology, data analysis, project manager, writing, editing, and submission of manuscript; guarantoor, and corresponding author.

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Ethics approval This study involves human participants. Ethical approval was obtained from Harvard Medical School (Boston, MA, USA; IRB17-1376 for the clinical trial and IRB17-0624 for the training program) with local ethical approval obtained from institutional review boards of each participating hospital – (1) ASHWINI (20170218-01), (2) Sittilingi Tribal Health Initiative (THI1005) and Jan Swasthya Sahyog People's Health Support Group (JSS, no reference number). The trial was performed in accordance with the Declaration of Helsinki and Good Clinical Practice guidance and researchers were trained in Human Subjects Research (Biomedical) with Collaborative Institutional Training Initiative. The trial was registered with ClinicalTrials.gov (NCT04438811) and approved by the Indian Council of Medical Research (Proposal ID: 2019-7622). A data safety monitoring board (DSMB) was convened to monitor the study throughout the clinical trial phase of the study. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. De-identified data is available upon written request for 12 months following publication of the manuscript. Requests should be addressed to Dr. CMcC at craig.mcclain@childrens.harvard.edu. Reuse of the data must be agreed upon by Dr. CMcC in discussion with the authors.

ORCID iDs
Meredith B. Brooks http://orcid.org/0000-0001-8431-5517
Anudari Zorigtbaatar http://orcid.org/0000-0002-5050-8967
Gnanaraj Jesudian http://orcid.org/0000-0002-7444-5892
Craig D McClain http://orcid.org/0000-0002-3462-9638

REFERENCES

1 WHO. WHO | global strategy on human resources for health: workforce 2030. 2017. Available: http://www.who.int/hrh/resources/globstrathrh-2030/en/ [accessed 05 Feb 2021]
2 Holmer H, Lantz A, Kunjumen T, *et al*. Global distribution of surgeons, anaesthesiologists, and obstetricians. *Lancet Glob Health* 2015;3:S9–11.
3 Meara JG, Leather AJM, Hagander L, *et al*. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *Lancet* 2015;386:569–624.
4 Ulisubisya MM. The critical condition of anaesthesia provision in low-income and middle-income countries. *Lancet Glob Health* 2016;4:e597–8.
5 Government of India DG of, Welfare M of H& F. *Indian Public Health Standards (IPHS) Guidelines for Community Health Centres*. 2012.
6 District Level Household & Facility Survey. Available: http://rchiips.org/DLHS-4.html [Accessed 06 Feb 2021].
7 Roy N, Khajanchi MU. A hospital too far—access to surgical facilities in India. *Lancet Glob Health* 2015;3:e587–8.
8 Dare AJ, Ng-Kamstra JS, Patra J, *et al*. Deaths from acute abdominal conditions and geographical access to surgical care in India: A nationally representative spatial analysis. *Lancet Glob Health* 2015;3:e646–53.
9 Mansourati M, Kumar V, Khajanchi M, *et al*. Mortality following surgery for trauma in an Indian trauma cohort. *Br J Surg* 2018;105:1274–82.
10 Federspiel F, Mukhopadhyay S, Milsom PJ, *et al*. Global surgical, obstetric, and anesthetic task shifting: A systematic literature review. *Surgery* 2018;164:553–8.
11 Mavalankar D, Callahan K, Sriram V, *et al*. Where there is no anesthetist – increasing capacity for emergency obstetric care in rural India: An evaluation of a pilot program to train general doctors. *Intl J Gynecology & Obste* 2009;107:283–8.
12 Rao M, Rao KD, Kumar AKS, *et al*. Human resources for health in India. *Lancet* 2011;377:587–98.
13 Law TJ, Lipnick M, Joshi M, *et al*. The path to safe and accessible anaesthesia care. *Indian J Anaesth* 2019;63:965–71.
14 Schnittger T. Regional anaesthesia in developing countries. *Anaesthesia* 2007;62 Suppl 1:44–7.
15 Pelland A, George R. Safe obstetric anaesthesia in low- and middle-income countries. *BJA Educ* 2017;17:194–7.
16 Ariyo P, Trelles M, Helmand R, *et al*. Providing Anesthesia Care in Resource-limited Settings: A 6-year Analysis of Anesthesia Services Provided at Médecins Sans Frontières Facilities. *Anesthesiology* 2016;124:561–9.
17 Schuster M, Gottschalk A, Berger J, *et al*. A retrospective comparison of costs for regional and general anesthesia techniques. *Anesth Analg* 2005;100:786–94.
18 American Society of Regional Anesthesia and Pain Medicine. Regional anesthesia for surgery. Available: https://www.asra.com/page/41/regional-anesthesia-for-surgery [Accessed 13 Feb 2021].
19 American Society Of Anesthesiologists. ASA physical status classification system | american society of anesthesiologists (ASA). standards and guidelines. 2019. Available: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system [Accessed 06 Feb 2021].
20 NYSORA. Spinal anesthesia. Available: https://www.nysora.com/techniques/neuraxial-and-perineuraxial-techniques/spinal-anesthesia/ [Accessed 13 Feb 2021].
21 Sheshadri V, Wasserman I, Peters AW, *et al*. Simulation capacity building in rural Indian hospitals: a 1-year follow-up qualitative analysis. *BMJ Simul Technol Enhanc Learn* 2021;7:140–5.
22 Mohamed Ali H, Taha MY, Ahmed Aswa AR, *et al*. Learning curve for spinal anesthesia as a basic skill in the training program of the anesthesia resident in faculty of medicine, Cairo University. *Egypt J Anaesth* 2020;36:112–7.
23 Kopacz DJ, Neal JM, Pollock JE. The regional anesthesia "learning curve". What is the minimum number of epidural and spinal blocks to reach consistency? *Reg Anesth* 1996;21:182–90.
24 Drake EJ, Coghill J, Sneyd JR. Defining competence in obstetric epidural anaesthesia for inexperienced trainees. *Br J Anaesth* 2015;114:951–7.
25 Kinsella SM. A prospective audit of regional anaesthesia failure in 5080 Caesarean sections. *Anaesthesia* 2008;63:822–32.
26 Levy JH, Islas JA, Ghia JN, *et al*. A retrospective study of the incidence and causes of failed spinal anesthetics in A university hospital. *Anesth Analg* 1985;64:705–10.
27 Han JU, Kim BG, Yang C, *et al*. Prospective randomized comparison of cerebrospinal fluid aspiration and conventional popping methods using 27-gauge spinal needles in patients undergoing spinal anaesthesia. *BMC Anesthesiol* 2020;20:32.
28 Fettes PDW, Jansson J-R, Wildsmith JAW. Failed spinal anaesthesia: mechanisms, management, and prevention. *Br J Anaesth* 2009;102:739–48.
29 Ashagrie HE, Ahmed SA, Melesse DY. The incidence and factors associated with failed spinal anesthesia among parturients underwent cesarean section, 2019: A prospective observational study. *Int J Surg Open* 2020;24:47–51.
30 Tiwari M, Tiwari P, Chhabra B. Failed spinal anaesthesia: an immediate second spinal is a valid option in rural India. *J Evol Med Dent Scie* 2013;2:5395–401.
31 Lewis SR, Nicholson A, Smith AF, *et al*. Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients. *Cochrane Database Syst Rev* 2014;2014.
32 Beard JH, Ohene-Yeboah M, Tabiri S, *et al*. Outcomes After Inguinal Hernia Repair With Mesh Performed by Medical Doctors and Surgeons in Ghana. *JAMA Surg* 2019;154:853–9.
33 Ashley T, Ashley H, Wladis A, *et al*. Outcomes After Elective Inguinal Hernia Repair Performed by Associate Clinicians vs Medical Doctors in Sierra Leone: A Randomized Clinical Trial. *JAMA Netw Open* 2021;4:e2032681.
34 Wilson A, Lissauer D, Thangaratinam S, *et al*. A comparison of clinical officers with medical doctors on outcomes of caesarean section in the developing world: meta-analysis of controlled studies. *BMJ* 2011;342:d2600.
35 van Duinen AJ, Kamara MM, Hagander L, *et al*. Caesarean section performed by medical doctors and associate clinicians in Sierra Leone. *Br J Surg* 2019;106:e129–37.
36 Pereira C, Bugalho A, Bergström S, *et al*. A comparative study of caesarean deliveries by assistant medical officers and obstetricians in Mozambique. *BJOG* 1996;103:508–12.
37 Kempthorne P, Morriss WW, Mellin-Olsen J, *et al*. The WFSA Global Anesthesia Workforce Survey. *Anesth Analg* 2017;125:981–90.
38 Bhandarkar P, Gadgil A, Patil P, *et al*. Estimation of the National Surgical Needs in India by Enumerating the Surgical Procedures in an Urban Community Under Universal Health Coverage. *World J Surg* 2021;45:33–40.
39 Review of training mbbs doctors in anaesthesia for emergency obstetric care final report. Available: https://www.researchgate.net/publication/320267994_REVIEW_OF_TRAINING_MBBS_DOCTORS_IN_ANAESTHESIA_FOR_EMERGENCY_OBSTETRIC_CARE_FINAL_REPORT [accessed 04 Mar 2021]
40 Sobhy S, Zamora J, Dharmarajah K, *et al*. Anaesthesia-related maternal mortality in low-income and middle-income countries: A systematic review and meta-analysis. *Lancet Glob Health* 2016;4:e320–7.
41 Lipnick MS, Bulamba F, Ttendo S, *et al*. The Need for a Global Perspective on Task-Sharing in Anesthesia. *Anesth Analg* 2017;125:1049–52.
42 Gelb AW, Morriss WW, Johnson W, *et al*. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. *Can J Anaesth* 2018;65:698–708.