PaedSurg Africa

Paediatric Surgery across Sub-Saharan Africa: A Multi-Centre Prospective Cohort Study

Protocol Overview

PaedSurg Africa Research Collaboration

PaedSurg Africa is a multi-centre research collaboration constituting surgeons and allied health professionals undertaking neonatal and paediatric surgery (PS) across sub-Saharan Africa (SSA) - an area heavily neglected in global health prioritisation. Such research collaboratives are being increasingly utilised as a highly effective and efficient method of collecting large volume prospective data in a short period of time. Utilising a similar methodology, GlobalSurg collected data on 10,745 patients in just 2-weeks from 375 centres around the world[1]. All research collaborators will be co-authors of published results.

Paediatric Surgery in Sub-Saharan Africa

In 2015, the Lancet Commission on Global Surgery (LCoGS) highlighted that 5 billion people worldwide do not have access to safe, affordable surgical care[2]. The same year, the World Health Assembly (Resolution 68/31) incorporated 'emergency and essential surgery and anaesthesia care' within 'Universal Health Coverage'[3]. In concordance with this, plans have arisen to exponentially scale up access to surgical care in low- and middle-income countries (LMICs).

SSA has the highest unmet need for surgical care in the world at 41 million cases/ year (29% of the worlds unmet need)[2]. Up to 50% of the population in SSA are children[4]. It is estimated that 2.6 million children are born with a congenital anomaly in SSA each year[4,5]. Hence, in order for the world to achieve the LCoGS goal of 80% coverage of surgical care by 2030, there must be a focus on scaling up PS care in SSA where a significant proportion of the burden of surgical disease lies.

To date there has been limited data published on neonatal and PS in SSA. Nwomeh et al undertook a systematic review and meta-analysis of neonatal surgery in SSA and identified just 13 prospective studies and 38 retrospective studies between 1995 – 2014[6]. The results highlighted poor outcomes with mortality rates of over 50% for conditions such as gastroschisis, which has mortality rates consistently under 4% in high-income countries[6,7]. Similarly, the limited literature on PS in SSA highlights significantly poorer outcomes for common conditions such as appendicitis, intussusception and inguinal hernia[8-13].

Surgery has largely been overlooked in global health prioritisation and funding, likely because of the perception of prohibitive cost and complexity of care. Conversely, recent health economic studies have amply demonstrated the overall cost-effectiveness of PS procedures; for instance investing in a paediatric inguinal hernia repair is similar to administering a tetanus vaccine or treating a patient with malaria in terms of disability-adjusted life years (DALYS)/ US$[14].

This study aims to form the largest prospective cohort study of PS across SSA. This information is vital to advocate for enhanced children's surgical services both at country level via 'National Health Strategic Plans' and at an international level. We aim to identify context-appropriate interventions to improve the outcome of five common neonatal and general paediatric surgical conditions. The conditions are: gastroschisis, anorectal malformation (ARM), appendicitis, inguinal hernia and intussusception.

Aim:

To compare the outcomes of five common neonatal and paediatric surgical conditions between SSA and HICs.

Objectives:

1) To undertake the first multi-centre prospective cohort study across SSA to compare outcomes of common paediatric surgical conditions with benchmark data from HICs.

2) To identify context appropriate interventions and peri-operative factors associated with an improved outcome.

3) To form a research collaboration of paediatric surgeons and allied health professionals across SSA; this aims to enhance research capacity and create the infrastructure for ongoing collaborative research and interventions to improve outcome.

4) To raise awareness and provide advocacy for neonatal and paediatric surgical care within global health prioritisation, planning and funding.

Methodology

Authorship

We will ask publishing journals to make all co-authors PubMed citable. Articles will be published under 'PaedSurg Africa Research Collaboration'. At the end of the article co-authors will be listed under the following headings:

- Lead investigators: collaborators who have contributed to the study protocol, data analysis and write-up of the manuscript.
- Country leads: collaborators who have recruited several sites in their country to contribute to the study.
- Local investigators: collaborators who have gained ethical approval for the protocol in their centre and collected data at their site including patient identification, data completion and follow-up of mortality and complications. The study invites up to three local investigators per institution.

Data collection tool

Prospective data will be collected utilising the free, user-friendly, secure database, REDCap[15]. The tool includes a Smartphone app that allows offline data collection. Data collection sheets that can be printed for written data collection and later uploaded will also be provided. Data collection will be for any continuous 1-month period between October to December 2016. A pilot study will be run in August 2016 at 3 institutions in SSA.

Conditions studied:

The 5 conditions selected are common congenital or acquired neonatal and paediatric surgical conditions with low morbidity and mortality in HICs. Consequently surgical interventions for these conditions carry high avertable DALYs and cost-effectiveness ratios, as saving the life of a neonate or child with minimal long-term disability can permit a lifetime of labour and income for their family and their country's economy. Limited, mostly retrospective, individual institutional studies suggest significantly poorer outcomes of these conditions in SSA.

Patient data and outcome measures:

Primary outcome will be all cause in-hospital mortality. For patients hospitalised for > 30-days, a 30-day mortality will be utilised.

Secondary outcomes will include post-operative complications.

Data will be collected on: patient demographics, referral source, duration from onset of condition to presentation, pre-operative resuscitation, intervention and outcome.

Validation:

At 5% of collaborating centres, one research collaborator will be asked to identify patients and upload the study data independent to the other research collaborator(s). This data will be collected on a separate REDCap validation database and the inputted data will be cross-checked with that entered into the main database. The database will be programmed to only permit datasets to be submitted if a minimum of 90% of the data has been completed.

Questionnaire data:

A short questionnaire will be undertaken by all research collaborators at the time of project sign up regarding the facilities and resources available at their institution.

Estimated population:

Estimated patient numbers per centre during a 1-month study period are: 1-2 gastroschisis[16-18], 1-2 anorectal malformations[19-23], 11 appendicitis[24,25], 14 inguinal hernias[11,14,26-30], 1 intussusception[13] (29 patients per centre). We aim to include a minimum of 50 centres, which would generate 1450 patients. Estimates were calculated using the mean number of patients presenting per month to all institutions from SSA who have published data on these conditions. There is no minimum amount of patients required to participate in the study.

Data Analysis

Mortality and morbidity outcomes in SSA will be compared to benchmark data from HICs and significant differences determined using Chi-Squared analysis.

Multi-level, multivariate logistic regression analysis will be utilised to identify context appropriate interventions and peri-operative factors associated with improved outcomes. For example: does availability of air enema reduction significantly reduce mortality from intussusception in the SSA context and if so, by how much? Data will be adjusted for confounding factors such as delay in presentation. $P<0.05$ will be deemed significant.

Ethics:

We have received full ethical approval for the project by the Kings College London Ethics Committee. Research collaborators in SSA will be required to receive approval for the project at their own centres according to local ethical regulations and provide evidence of this in order to submit data. In some institutions the study may require audit approval rather than ethics approval because it involves using data obtained as part of usual patient care and will be anonymised at the point of data entry; this was the case for the GlobalSurg Research Collaborative, which has a similar methodology[1].

If no formal ethics or audit committee exists, collaborators must provide written consent from the Director of the Hospital or Head of Surgical Department. All data will be anonymous and remain confidential. Data will not be identifiable at individual surgeon, institution or country level.

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