OPERATIONAL RESEARCH STUDY PROTOCOL

(03/08/2009)

Médecins sans Frontières-South Africa, MSF-Brussels

STUDY COUNTRY: Central Africa Republic, South Sudan, Ivory Coast, Pakistan, Democratic Republic of Congo, Chad, Haiti, Somalia, Niger, Burundi, Sierra Leone, Mali, Indonesia.

STUDY-SITE: Batngafo, Kabo, Bor, Bangolo, Dargai, Lubutu, Bongor, Iriba, Masisi, Kirotshe, Gonaives, Guri-El, Dakaro, Bo, Tombouctou, Asmat

STUDY-TITLE: Operative Mortality in Resource-limited Settings: the MSF experience in 13 Countries

COLLABORATING PARTNERS/ INDIVIDUALS AND AFFILIATIONS *

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BACKGROUND

It has been estimated that over 230 million major surgical procedures are performed worldwide annually. The greatest burden of unmet need is in poor-income countries where only 3.5% of procedures are performed. (1) Little data exist documenting the feasibility and safety of operations performed in resource-limited settings. Some studies reported intra-operative mortality as high as 5-10% (2-4) and concern has been raised about the safety of surgical delivery in these settings. Similarly, high anesthesia-related mortality rates have been reported in a number of resource-limited settings, from one in 504 deaths in a central hospital in Malawi to one in 133 in a teaching hospital in Togo. (5, 6)

Most surgical programs in developed countries subscribe to outcomes-based programs to monitor and improve the quality of surgical care. For example in the US, a national database system to collect and report risk-adjusted event data for surgical services, the National Surgery Quality Improvement Program (NSQIP), represents 70,000 surgeons throughout the country and compares individual hospital mortality and morbidity against national norms. Participating hospitals must agree to keep a standardized database and meet mimimum case standards. (7)

In resource-limited countries, these types of national programs to monitor and improve surgical quality improvement do not yet exist. However, increasingly the safety of international surgical care is being re-examined. In 2007, the WHO launched the safe surgery saves lives project aimed at "improving the safety of surgical care around the world by ensuring adherence to proven standards of care in all states." The WHO safety checklist is a tool created to improved compliance with standards and decreased complications and has been shown to decrease mortality. (8)

In addition to government providers, a multitude of other actors deliver surgical care in resource-limited settings such as humanitarian organizations, non-governmental organizations, missionary groups, and other volunteer groups. Services are provided in a variety of ways: surgical camps, independent hospitals, and collaborative efforts within government structures and health care systems. Surgical standards and protocols vary or are non-existent in some cases. Very little data on the safety of surgical programs in resource-limited settings exist mostly because of there is a lack of resources to collect data and no centralized database exists to compare programs to one another. Long term outcome data is particularly challenging to collect because patients do not always return once their surgical procedure is completed. In these settings, operative mortality can be a crude proxy for safe delivery of operative care.

Médecins Sans Frontières (MSF) is an international humanitarian medical organization which provides surgical care in response to acute need from natural disaster, conflict, or unacceptably high morbidity. MSF has provided surgical care in resource-limited settings for over 30 years.

STUDY OBJECTIVES

The main objective of our study was to report operative mortality from 17 programs in 13 countries from 2001-2008. Secondary objectives were to describe the types of MSF surgical programs, the patient characteristics, types of surgical disease, and procedures provided. .

METHODS

Study design and period

- The is a retrospective analysis of data prospectively collected between Jan 2001-Dec 2008.

Study population

- All undergoing surgical procedures during the study period at 17 surgical sites

Data collection

An electronic database (EXCEL) was used for routine monitoring and evaluation of patients undergoing surgical procedures in 17 MSF surgical projects. The following variables will be

included in the analysis: age, gender, surgical pathology, type of intervention, emergency intervention, ASA score, and operative mortality.

Statistical analysis

Statistical analysis will be performed using STATA 10 (College Station, TX, USA). Univariate and mulivariate analysis will be performed. All databases are security encoded

Informed consent

- Informed consent was obtained for all patients prior to undergoing a surgical procedure. No additional informed consent was obtained for this study as this was a retrospective analysis of routinely collected data.

Confidentiality of data

- All data and related forms will be held in strict confidence as is the current practice. No names or identifying information will be used in any publication or presentation. The data does not have patient identifiers

Risks/inconveniences

- There are no specific risks for the patients linked to this analysis.

Specific patient Benefits:

The findings of this analysis would help us to assess the effectiveness of current management strategies and advocate for change where appropriate.

FEEDBACK AND DISEMINATION OF INFORMATION

- The results of this study will be made known to the nurses, clinical officers, and doctors working at each of the study sites. This will help evaluate our current management strategies and consider/advocate for possible improvements.

- In order to disseminate the information gained, attempts will be made to publish the studies in regional or international peer reviewed journals.

IMPLICATIONS OF THE RESEARCH FOR NATIONAL POLICY AND PRACTICE

There is very limited information known on the operative mortality of surgical projects in resource-limited settings. The information from this study would help improve basic knowledge on the subject, the effectiveness of current management and possible ways forward in improving the latter.

A better understanding of the risk factors of operative mortality will help MSF improve its programs.

COLLABORATIVE PARTNERSHIP

Médecins Sans Frontières (MSF) collaborates with the Ministry of Health in each country with surgical projects. Some of the projects have since closed; these findings will be shared with relevant partners wherever possible.

ETHICAL APPROVAL:

FUNDING

- The study is funded by the MSF Brussels operational center.

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