

OPERATIONAL RESEARCH PROTOCOL

(15-01-2016)

Victoria Hospital Wynberg

STUDY COUNTRY: South Africa

STUDY SITE: Victoria Hospital Wynberg (VHW)
Mitchell's Plain Hospital (MPH)

STUDY TITLE: *A qualitative evaluation of Laparoscopic Cholecystectomies performed in 2 non-tertiary hospitals in a developing country*

COLLABORATING PARTNERS/INDIVIDUALS AND AFFILIATIONS:

Victoria Hospital Wynberg:

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Background:

Gallstone disease accounts for a high number of emergency and elective surgical admissions to South African hospitals. A high proportion of patients suffering from symptomatic or complicated gallstones require cholecystectomy (surgical removal of the gall bladder) as definitive treatment for which the standard of care is laparoscopic (LC), as opposed to open cholecystectomy (OC).

Modern South African surgeons are required to have basic competency in minimally invasive surgery (MIS) and should be able to perform LC independently once their training has been completed and they have left their academic tertiary hospital, as this is likely to be the most common MIS procedure that they will perform in their practice.

There are, however, very few structured MIS training modules incorporated into South African surgical residencies. There are even fewer post-qualification MIS fellowships available to newly qualified surgeons in this country. This results in a

wide range of MIS competency at training completion amongst South African surgeons.

It is not known whether this variation in training and differences in competency at completion of surgical residency influences the safety and outcomes of LC performed in non-tertiary hospitals. Very few data from developing countries exist to address this question.

Study Objectives:

The outcomes of a basic MIS procedure, LC, performed in 2 non-tertiary centres in a local health setting will be assessed to determine whether there is a role for structured MIS training during surgical residency and whether there is a need for post qualification MIS fellowship training for newly qualified South African surgeons.

Methods:

Study design

Retrospective review of hospital folders

Study population and time frame

All patients undergoing LC at VHW and MPH from 01/01/2015 to 31/12/2015. Patients who had cholecystectomies for reasons other than symptomatic or complicated gallstone disease will be excluded.

Data Collection

Theatre logbooks will be reviewed to identify patients who underwent cholecystectomy within the study period. Hospital folders will then be retrieved and data variables will be entered into a password-protected database.

The following variables will be included:

Patient demographics

- Age
- Gender
- Population group

Operating surgeon

- Level of training

Preoperative assessment

- Diagnosis
- Date of first consultation
- Number of emergency presentations prior to surgery

- Number of admissions prior to surgery
- Preoperative biliary intervention if applicable

Operative data

- Indication for surgery
- Date of surgery
- Procedure planned (OC or LC)
- Procedure performed (LC or OC)
- Reason for change in planned procedure if applicable
- Duration of procedure

Postoperative assessment

- Specific post operative complications
- Referral to tertiary centre if applicable
- Reason for referral to tertiary centre if applicable

Statistical analysis:

Statistical analysis will be performed using STATA 10 (College Station, TX, USA). Univariate and multivariate analysis will be performed. All databases will be security encoded to protect patient confidentiality.

Informed consent:

Informed consent was obtained for all patients prior to undergoing a surgical procedure. No additional consent will be obtained for this study, as it is 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 any patient identifiers.

Risk/Inconveniences:

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

Specific patient benefits:

The findings of this analysis would help us assess whether the standard of care in the participating hospitals is acceptable for this procedure, and whether the clinicians providing this care would benefit from further training.

Feedback and dissemination of information:

The results of this study will be made known to the nurses, doctors and hospital managers in the government system. This will help evaluate the current standard of care and may help advocate for any changes that may be necessary to improve the

service to patients within this system.

Attempts will be made to publish this analysis in a national or international journal.

Implications of the research for national policy and practice:

There are currently very few data evaluating MIS competency of surgeons in developing countries. This study may help to identify a need for further MIS training in surgical residents as well as recently qualified surgeons.

Ethics approval:

Pending

Funding:

No funding

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