

RESEARCH PROTOCOL

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Enhanced recovery after surgery program in a low and middle-income country:

Feasibility, safety, patient's acceptance, reduction of the length of hospital stay, bed turnover and cost benefits for laparoscopic cholecystectomy at CHUK

By

NYUNDO Martin. MD

**Clinical Associate Professor of Surgery
Senior Consultant General Surgeon**

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Research proposal

Title: Enhanced recovery after surgery program in a low and middle-income country: *Feasibility, safety, patient's acceptance, reduction of the length of hospital stay, bed turnover and cost benefits for laparoscopic cholecystectomy at CHUK*

This research proposal concerns a research project on minimally invasive surgery as new surgical techniques in Rwanda, which will include different studies to conclude into a PhD project in clinical research and public health at the college of medicine and Health Sciences.

This project is part of a laparoscopic surgery program in the Rwandan referral and teaching hospitals to improve the recovery of the patients after surgery especially after laparoscopic cholecystectomy, which will lead to a reduction of hospital of stay and a good bed turnover in surgical department.

1. Principal Investigator: Martin Nyundo, MD, MMed, FCS (Ecsa)

Clinical Associate Professor of Surgery
Senior Consultant General Surgeon

University Teaching Hospital of Kigali (CHUK)

Email: nyundomartin@gmail.com;

Phone: +250 788418727 or +250739952730

2. Research team

- Prof Detry Olivier, General, Hepatobiliary & Laparoscopic Surgeon, University of Liège, Belgium

- Dr. Nifasha Antoine, General and laparoscopic surgeon, CHUK

- Dr. Limgba Augustin, General, Thoracic and Laparoscopic surgeon, KFH/CHUK

- Dr. Urimubabo Christian, General Surgeon, CHUK

- Dr. Gasakure Miguel, General Surgeon, CHUK

- Dr. Nizeyimana Francoise, Head Anesthesiologist, CHUK

- Mr Gasana Magnius, Clinical Psychologist, CHUK

1. Background

Enhanced Recovery After Surgery (ERAS) was started by a group of surgeons from Northern Europe who formed a research group with the aim to explore the ultimate care pathway for patients undergoing colonic resections. In the 1990s Henrik Kehlet had initiated this work with his innovative work on fast track surgery (1) (2), showing that most patients had recovered enough to be discharged 2 days after open sigmoid resections (3), when the length of stay for these operations was 10 days or more in most countries. The ERAS implementation program is a structured systematic implementation program successfully employed internationally in >25 countries. The ambition of the ERAS Society is to disseminate evidence- based principles for perioperative care and to support the development of new knowledge in perioperative medicine and surgical pathophysiology (4).

No single technique or therapy can eliminate postoperative morbidity and mortality. Therefore, it is necessary to resort to multimodal management where several treatments and clinical approaches are combined to reduce in a clinically relevant way the undesirable consequences of surgical aggression, improve patient rehabilitation and reduce postoperative morbidity and overall costs (1)(5)(6)(2).

An enhanced recovery program (ERP) after surgery consists of multimodal and multidisciplinary management to mitigate the surgical stress and the inflammatory response, and their consequences. Postoperative recovery is thereby improved and accelerated. The preoperative period is used to optimize the patient's medical condition (2). Patient education, perioperative instructions and setting achievable expectation, incorporating the patient as a vital component in his/her own wellbeing, and recovery are of utmost importance. Patients need to understand that unless they contribute to the care path presented to them by the ERAS team, optimal surgical outcome and recovery will not be achievable. The patient needs to understand that they have "skin in the game"(7) (8) (9) (10) (11).

Laparoscopic surgery has helped to minimize surgical trauma in an increasing number of surgical procedures and avoids drains. The anesthetist makes preferential use of loco-regional techniques, avoids perioperative fluid overload, and prevents postoperative nausea and vomiting. After surgery, early feeding and mobilization are encouraged and facilitated by a multimodal analgesia strategy that spares opioids and limits their side effects.

ERPs reduce the incidence of medical complications by 50 %, including fewer infectious complications and a possible positive impact on survival after oncologic surgery. Hospital length of stay is shortened (2)^[11]_{SEP} (12) (13) (14) (7) (10).

ERAS has been shown to have important clinical and economic benefits and significant reductions in length of hospital stay and the implementation of ERAS pathways improves clinical outcomes and induces substantial economic gains. ERAS is the current surgical revolution (15) (16).

Cholecystectomy is one of the commonest general surgical operations. Laparoscopic cholecystectomy is currently the most favored approach. As it is associated with less postoperative pain and ileus, it allows early discharge of patients from the hospital (17) (18). Studies from the West have reported that 'day case laparoscopic cholecystectomy' is feasible and safe with success rate of between 69-92 percent (18) (19).

In two randomized groups comparing ambulatory care and overnight stay, the average hospital stay was 3.1 for overnight stay versus 1.7 for ambulatory care (Dirksen) and the ambulatory treatment was less expensive (20) (17). However, careful patient selection is essential in ensuring a high success rate (18).

ERAS is not known in Rwanda and there is no report from any sub African country describing laparoscopic cholecystectomy in ERP. We will conduct a prospective study to assess the feasibility; safety, patients' acceptance, LOS and bed turnover of laparoscopic cholecystectomy in a tertiary care hospital in the ERP.

2. Problem statement

All surgeries, including laparoscopic surgery, represent a major stressor to the patient with possible sequelae for post-operative well being, including decline in functional capacity, cognitive ability, and even cancer spread. Comorbidities such as diabetes, ischemic heart and vascular disease, stroke, and others have a larger impact on postoperative morbidity and mortality than age (21) (10).

ERAS pathways have been successfully implemented in many surgical specialties, including gastrointestinal, hepato-biliary, pancreatic, urologic, gynecologic, and urologic surgery (22) (23) (24).

The strongest evidence so far has been described in patients undergoing open colorectal procedures (6) (25) (26). Combining minimally invasive laparoscopic surgery and ERAS has been shown to have important clinical and economic benefits and significant reductions in length of hospital stay, but its spread remains slow worldwide.

Implementation of ERAS pathways improves clinical outcomes and induces substantial economic gains (15) (16) (2), and is becoming the optimal strategy for many surgeries when technically feasible (27) (28) (10).

Laparoscopic cholecystectomy can be performed as a day-case procedure with a low rate of complications and admissions/readmissions. Patient acceptance in terms of quality of life variables is similar to that for cholecystectomy with an overnight stay. The day care strategy is associated with a reduction in cost (29).

Laparoscopic cholecystectomy in ERAS program should optimize the surgical outcome and improve a quick recovery and decrease the length of hospital stay. At the University Teaching of Kigali, the current practice is to admit patients for laparoscopic cholecystectomy 24 hours prior to surgery and to discharge most patients within two to three days of surgery with a rate of complications around 5%.

Patients overcrowd CHUK and the hospital bed management is a serious challenge. Patients coming far from their homes and with limited financial resources are suffering to get admitted in hospital for elective and none urgent surgeries like cholecystectomy, We believe that ERP can benefit the hospital with a rapid bed turnover rate, and reduces cost for surgery and hospitalization while providing to the patients with quality care and the same time increasing the comfort of the patient in the post-operative period and minimizing the postoperative complications.

The aim of our study is to assess the feasibility and safety of laparoscopic cholecystectomy in the ERP by decreasing the length of stay from 72 hours to 36 hours, hospital bed turnover and evaluate the adverse events and cost related in a tertiary care hospital in Rwanda

3. Research Questions

- Is ERAS protocol implementable in Rwanda Tertiary Hospital?
- Is laparoscopic cholecystectomy feasible, safe and cost-effectiveness in the context of ERP in our settings?
- Is possible to discharge laparoscopic cholecystectomy patients within 36 hours postoperative?

4. Objectives of the study

4.1. General Objective

The general objective of this study is to test the implementation of ERAS protocol in laparoscopic cholecystectomy with the aim of decreasing of the length of hospital stay to 36 hours and assess its safety and patients' acceptance.

4.2. Specific Objectives

1. To assess the level of knowledge and practice of Health care professional about Enhanced recovery after surgery program.
2. To determine the frequency of postoperative adverse events and complications after laparoscopic cholecystectomy (tress, fatigue, nausea and vomiting)
3. To determine the average length of hospital stay and bed turn over after laparoscopic cholecystectomy
4. To determine the rate and reason of overnight and re-admissions
5. To assess the patients' acceptance of ERAS program and the overall satisfaction
6. To determine the patient cost benefit when ERAS is implemented correctly.

5. Research Methodology

5.1. Methods and Settings

This is a prospective and cross sectional study. The study will be conducted in Rwanda at the University Teaching Hospital of Kigali from January to December 2021.

Rwanda is a country of 11.9 million in East Africa. There are approximately 80,000 surgical procedures performed annually in Rwanda, 510 major operations per 100,000 populations (30). Rwanda has 4 main referral hospitals performing surgical operations including laparoscopic procedures. The referral hospitals include: University Teaching Hospital (CHUK), University Teaching Hospital of Butare (CHUB), Rwanda Military Hospital (RMH) and King Faisal Hospital, Kigali (KFH, K)

The University Teaching Hospital of Kigali (CHUK) is the major public, tertiary referral and teaching hospital in Rwanda and it is located in the capital in Kigali. It has 565 beds and 11 operating theaters shared among all surgical services. It provides approximately up to 1600 major operative cases in general surgical services every year including 140 cases of laparoscopic surgeries with 75 cases of laparoscopic cholecystectomies. The CHUK started performing laparoscopic surgery routinely long time before others and currently it performs more than 60% of laparoscopic surgeries performed in the Country in different specialties including general surgery, Urology and Gynecology. Considering the above reason, we selected this hospital to represent others and be the site of our research interest.

This study will be conducted in general surgical unit at the University Teaching Hospital of Kigali (CHUK), it has a capacity of 2 operating rooms with 2 lap towers with complete sets of laparoscopic material and around 40 in patient beds.

The population proportion of laparoscopic cholecystectomy is 5% within a total general surgical population size of 1600 patients per year. A range of 50 to 70 patients will allow to have a confidence level of 95% that the real value is within $\pm 5\%$ of the measured value and have relevant conclusions.

5.2. ERAS pathways

Enhanced recovery after surgery is multimodal and multidisciplinary patient centered care; the patient becomes a true actor of his care. The surgeon, the anesthesiologist and the nurses constitute the trinomial leader. Other specialists are also concerned: physiotherapist, nutritionist, gastroenterologist, etc. (2). This partnership explains the importance of education and enhanced preoperative information during hospitalization (2). The success of this true teamwork requires the concerted writing of protocols, interdisciplinary communication, continuous evaluation of one's practice, and the existence of leadership (31). The team spirit is strengthened (2) (10) (32).

5.2.1. Principal measures (elements) contained in the ERP, irrespective of the specialty (32)

Pre-operative Pre-admission	Intra-operative	Post operative	Post Discharge
<p>1. Patient information and education: Patient optimization (Counseling, smoking, alcohol, pain management plan, pre-habilitation of select patients (e.g., diabetic, hypertensive))</p> <p>2. No bowel preparation</p> <p>3. No premedication</p> <p>4. Initial multimodal medications</p> <p>5. Limited fasting (light meal up to 6 hours preoperative)</p> <p>5. Carbohydrate loading (up to 2 hours preoperative) and Glucose control</p> <p>6. Discharge planning, education and home medication plan</p>	<p>1. Limited fluid intake (Normovolemia)</p> <p>2. Normoglycemia</p> <p>3. Corticosteroids</p> <p>4. Prevention of hypothermia (Normothermia)</p> <p>4. Antibiotic prophylaxis</p> <p>6. Prevention of PONV</p> <p>7. Minimal invasive access</p> <p>8. Multimodal analgesia and Limitation of opioid use,</p> <p>8. No drain or nasogastric tube</p>	<p>1. Multimodal analgesia</p> <p>2. Katamine , IV lidocaine</p> <p>3. NSAIDs for 48 h</p> <p>4. Nausea and vomiting management</p> <p>5. Early mobilization</p> <p>6. No or judicious IV fluid management</p> <p>7. Early re-feeding</p> <p>8. No or rapid removal of the bladder catheter</p> <p>9. Patient/family education (Delirium prevention)</p>	<p>1. Risk management (Monitor for symptoms or changes in health to seek assistance)</p> <p>2. Telephone calls and SMS (Follow-up with surgeon)</p> <p>3. Continue therapy and other activities for recovery as planned</p>

Source: How to implement an enhanced recovery program? Proposals from the Francophone Group for enhanced recovery after surgery (GRACE):

5.2.2. Preoperative evaluation

All the patients include in the ERAS protocol will undergo a preoperative multidisciplinary evaluation performed by the ERAS team. During this evaluation, all information regarding all the step of the ERAS protocol will be given to the patients and all the information regarding the preoperative step to follow, such as smoking quit or alcohol use. Moreover, information about the entire postoperative ERAS step that the patients needed to follow during the hospitalization will be given. Education and discharge plan will be discussed.

5.2.3. Preoperative fasting

All patients will be allowed to take a regular diet until 6 h and Carbohydrate loading or clear fluids until 2 h before surgery. Thromboembolism prophylaxis with low molecular weight heparins will be administered according to patient's comorbidities.

5.2.3. Anaesthesiologic protocol

No premedication will be administered. Two different types of anesthesiology technique will be used: general anesthesia with local infiltration of the surgical incision. In all cases restricted intraoperative fluid administration (6–8 ml/kg/h) and prevention of hypothermia during surgery will be used. Moreover, no opioids will be used during all the perioperative period. Antibiotic prophylaxis will be given in agreement with the hospital protocol. Analgesia and Prevention of PONV will be given. Immediate postoperative monitoring will be performed in the recovery room where the pain numeric rating scale (NRS) will be routinely evaluated by the anesthesiologist or the NPA.

5.2.4. Surgical technique

Laparoscopic approach with a 4-trocar technique will be the first choice when not contraindicated. No Abdominal drainage, no nasogastric tube, when necessary it will be placed immediately after anesthesia and removed upon awakening. A bladder catheter will be placed if indication and be removed immediately after surgery.

5.2.5. Postoperative care

- Analgesia: IV Paracetamol or Katamine administration when necessary.
- No opioids
- Treatment of Nausea and vomiting when necessary

- Pain assessment every 4 hours using pain NRS scale by nursing staff
- If pain not severe: Paracetamol + Ibuprofen or Diclofenac
- Re-feeding
 - Two to 4H after surgery: Liquid diet and mobilization.
 - Withdrawal of intravenous infusions (0.7–1 ml/ kg/h) was obtained during
 - From 8H: light semiliquid meal
 - From the 12H after surgery: a free diet and patient mobilization was further encouraged and increased gradually. All the meals had to be consumed sitting at the table.
- From 24h after surgery: Blood works (FBC and CRP) and Discharge

5.2.6. Discharge & Post discharge

The important criteria for the patient's discharge from the hospital are: Normal vital signs and blood works, absence of complications or symptoms, a digestive function enabling the patient to eat without nausea or vomiting, return of intestinal transit with emission of gas (stool not required), autonomy to move and post-operative pain relief with oral analgesics (2).

After the discharge for all the patients, the surgeon will make follow up on phone on day 3, 5 day and day 7 to detect any signs of complications during the first week. If no complaints the out patient clinic evaluation will be planned at 15 and 30 days from the operation. The patient will be given oral analgesia for at least 48 hours.

5.3. Data collection and analysis

A baseline survey will be conducted to assess the awareness and knowledge of health care professional in charge of perioperative care. From November 2021, we will put in place an ERAS protocol for laparoscopic cholecystectomies. Patients living in Kigali and near Kigali having an easy communication means will be sensitized to adhere to the program.

A multidisciplinary team (Surgeons, Anesthesiologists, nurses, anesthetists and psychologists) will be mobilized to participate in the team. A google sheet questionnaire will be designed to collect information about the awareness and knowledge of perioperative health care professional about ERAS programme and then

a modified ERAS protocol will be put in place and data collection will be done using a coded checklist form and consecutive selection of patients will be done during the study period until we reach at least 50 patients. The operative procedures and instrumentation will be standardized for laparoscopic cholecystectomy, and surgeons who will perform the procedures will be having expertise in laparoscopic cholecystectomy. Reasons for conversion from laparoscopic to open cholecystectomy will be recorded and documented. Emergency patients and patients defined as ASA IV and pediatric patients aged below 16 years will be excluded.

Data will be collected for age, gender, indications for surgery, American Society of Anesthesiology (ASA) class, operative time, adverse events (pain, nausea and vomiting), length of hospitalization, and intra- and post-operative complications. The expenses of surgery and in-hospital care will be calculated and analyzed. On discharge, on day 3 of discharge, day 10, day 15 and day 30 of discharge patient will report outcomes and will be recorded by Surgical Recovery Scale. After discharge, the patients will be called or texted on phone to know about their status and collect information. Data will be recorded using EXCEL. Statistical analysis will be done using SPSS software and the one-way analysis of variance (ANOVA) test, the Chi-square test, and the t Student's test will be used when appropriate for comparisons.

A Univariate analysis will be done to determine variables associated with the length of hospital stay. Pearson's chi square will be calculated to compare variables and..

Continuous variables were presented as mean \pm standard deviation or median (range) when appropriate and categorical variables will be presented as frequency (percentage). A Univariate analysis will be performed through a stepwise linear regression model using length of hospital stay as dependent variable and age, BMI, gender, ASA score, intraoperative infusions, pain, analgesia, nausea, vomiting, 30 days-readmission rates, presence of complications and mortality as independent factors. Variables with significant link will be crossed with outcome variables to draw their correlation overnight, using Multivariate logistic regression A p value < 0.05 will be considered statistically significant.

6. Expected Results

Table 1: Level of awareness and knowledge of ERAS among perioperative care health professionals

Table 2: Baseline characteristics of patients

Table 2: Acceptance rate of patients in ERP

Table 3: Rate of adverse events (Stress, fatigue, pain, nausea and Vomiting)

Table 4: Complications of laparoscopic cholecystectomy

Table 5: The average length of hospital stay

Tableau 6: Cost of laparoscopic cholecystectomy

Table 7: Rate of overnight and readmission

Table 8: Overall satisfaction of patients after laparoscopic cholecystectomy in ERP

Table 9: Comparative analysis of length and independents variables

7. Significance of the study

The results from this study will determine if ERP can be implemented in our settings and laparoscopic cholecystectomy patients are safe to be discharged on one-day post-operative period in a teaching hospital in Rwanda to increase bed turnover and decrease patients hospital costs.

Recommendations will be formulated to encourage surgeons and hospitals in Rwanda to put in place the ERAS protocols and test it for other surgeries. Finally, this study may posit a direction for related future researches

8. Ethical consideration

8.1. Confidentiality

Confidentiality and ethics in this research will be highly considered. The names, identity numbers and identification contact of the patients will be removed from the database and replaced with dummy values (codes).

8.2. Risks of participants

The patients will be closely monitored and any adverse events will be treated using standard approaches. All patients will be discharged using standardized criteria of safe discharge. The patient’s privacy or confidentiality will be respected and reasonable effort will be made to protect the patient’s information while their data will be used for the purpose of this research. Participation will be voluntary and there will be no direct compensation.

8.3. Informed consent

All participants will sign an informed consent during the preoperative evaluation regarding the type of operation and the ERAS protocol application

8.4. Ethical approval

This research proposal will be presented in the UR/IRB and CHUK ethic committee for review and approval.

9. Timeframe of Activity

Activities /Months	Fe 20	M 21	Ap 21	May 21	Jun 21	Jul 21	Aug 21	Sept 21	Oct 21	No 21	De 21	Jan 22	Fe 22	Ma 22	Ap 22
Research proposal	X	X	X	X	X										
Ethics					X										
Data collection						X	X	X	X	X	X				
Data encoding												X			
Data analysis												X	X		
Report writing														X	
Manuscript writing														X	X
Submission for Publication															X

10. Approximated Budget

Item	Description	Cost/unit (FRw)	Qty	No days	Total Cost (FRw)
Access to Journal	Papers that are not open access	80,000	6	-	480,000
Ethical clearance	Ethical fees	150,000	1	-	150,000
Data collection	Incentive for research assistants (Residents)	100,000/ moth	5	6 months	3,000,000
Data encoding	Incentive for data entree (Medical students)	25,000	2	7	350,000
Data analysis	Data clearing and analysis by statistician	50,000	1	7	350,000
PI allowances	Coordination fees for general coordination of the study and cross checking of information	150,000/ Month	6	-	900,000
Communication fees	Call patients for post operative follow up by Research assistants	100,000/ month	6	-	600,000
Report and manuscript	Reporting, IT and printing	500,000	-	-	500,000
Publications	High indexed and per reviewed journal	400,000	2	-	800,000
Total					7,130,000

11. Planning of Activities and related funds

Activities	Q1	Q2	Q3	Q4	Total
	June- September 2021	October – December 2021	January – March 2022	April- June 2022	
General coordination	450,000	450,000	0	0	900,000
Ethical clearance	150,000	0	0	0	150,000
Data collection (Medical files records and post operative follow up by phone calls	1,800,000	1,800,000	0	0	3,600,000
Data Encoding	0	0	350,000	0	350,000
Data analysis	0	0	350,000	0	350,000
Report and Manuscript writing	0	0	500,000	0	500,000
Literature review	0	0	0	480,000	480,000
Submission for Publication	0	0	0	800,000	800,000
Total	2,400,000	2,250,000	1,200,000	1,280,000	7,130,000

12. Conclusion

The minimally invasive surgical procedures proceed towards patient safety without increased fatal complications

The quality of recovery and patient satisfaction are among clinical outcomes should interest the surgeons as indicator of quality of care to patients.

Laparoscopic cholecystectomy combined with ERAS can effectively treat a variety of benign, non-acute gallbladder diseases with shortened waiting time and postoperative hospital stay. ERAS benefits the hospital with a rapid bed turnover rate, and reduces cost for surgery and hospitalization

My study will determine if the ERP is feasible in our context and proposes recommendations in order to improve the quality of recovery of surgical patients and improve the bed turnover in different referral hospitals in Rwanda using enhanced recovery protocols.

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14.

Done at Kigali, on 16th June 2021



NYUNDO Martin, MD