

APEROLD study: acute peritonitis in the oldest nonagenarian patients with acute abdomen. Which is the fate?

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Abstract

This is a prospective, multicenter, observational study whose objective is to investigate the impact of emergency abdominal surgery *versus* nonoperative therapy on the outcomes of nonagenarians. All consecutive patients aged 90 years or older admitted to the surgical department for acute secondary peritonitis and undergoing urgent or emergency surgery or nonoperative management

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Ethics approval and consent to participate: this study will be conducted in accordance with the Declaration of Helsinki. All participating centers receive the study protocol and relevant documents to request approval according to local ethical guidelines.

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will be invited to participate. They can choose to consent or decline for a 30-day data collection period.

The primary aim of this study is to evaluate early and late outcomes: 30-day and 1-year survival rates, clinical course and postoperative complications rate, and 1-year functional status. The secondary aim is to investigate which factors contribute to the choice of surgical intervention over nonoperative management, as well as the accuracy of risk scoring systems in predicting poor outcomes or functional loss: P-POSSUM score, American Society of Anesthesiologists (ASA) score, APACHE II score, Charlson's Comorbidity Index (CCI), Flemish version of the Triage Risk Screening Tool (fTRST), and the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) calculator.

According to our experience, the time is ripe for large multicenter trials to establish an ultimate scoring system for statistical probability of survival or treatment success, with the ultimate goal of obtaining evidence to guide the management of the emergency in people older than 90 years.

Introduction

Background

Improvement in living conditions and an increase in life expectancy led to a rise in the median age of the population, especially in industrial countries.¹ As a result of the growing number of elderly, the nonagenarian population is growing progressively, and consequently, more nonagenarian patients have access to emergency departments with surgical or clinical pathologies.^{2,3} Today, there are no guidelines focusing on the treatment of the subgroup of nonagenarians, who are often treated on a case-by-case basis, depending on experience and outcomes in "younger" patients.⁴ In addition, it is known that emergency department physicians report feeling less comfortable dealing with older, more complex patients, and this may be the reason that discharge diagnoses in the emergency department are more likely to be inaccurate in older adults.⁵

It has been shown that increasing age is an independent predictive factor of postoperative morbidity and mortality, and when compared to younger patients, emergency abdominal surgery in nonagenarians is a higher-risk procedure for operative complications with increased morbidity and mortality rates.^{4,6} Nearly 50% of these patients undergoing emergency procedures die within 1 year after surgery.⁷ Although there is a huge variation in individual

health status with aging, patients over 90 years of age generally present a syndrome of physiological decline that makes them particularly vulnerable to unfavorable outcomes and deterioration in physical status after surgical stress. This status is defined as frailty, which is known as an independent risk factor for postoperative morbidity and mortality.^{9,10} Therefore, coexisting chronic diseases and polytherapy have a synergistic effect of reducing the ability to deal with surgical emergencies and affecting outcomes.

Patients with acute secondary peritonitis are typically critically ill patients requiring appropriate treatment without delay, as well as the goal of effective therapy of intra-abdominal infections (IAIs) requiring early recognition, fluid resuscitation, antimicrobial therapy, and source control.¹¹

In therapeutic decision-making, emergency surgeons have the crucial role of balancing benefits and surgical risk to select patients who may benefit from surgical procedures in an emergency setting and evaluate whether the treatment should be conducted with curative or palliative intent. For patients aged over 90, it is important to determine which individuals benefit from surgical treatment by considering different factors: the high frequency of concomitant diseases and limited functional reserves, the higher rate of postoperative complications with increased morbidity and mortality, and the request of intensive therapies, longer recovery, rehabilitation, and institutionalized care.^{4,12}

Even if there are clear indications for the intervention, it should always be considered if surgery can determine a real improvement in the quality of residual life or whether the statistical probability of surviving or the success of the treatment is so low as to be considered unacceptable. Accurate data regarding the risks and benefits of surgical intervention and surgical outcomes are required to assess the “futility in emergency surgery” that plays a crucial role in managing such vulnerable patients.^{13,14} Therefore, stratification of perioperative risk appears useful in emergency surgery, and the decision-making process can be supported by the use of frailty screening tests such as Clinical Frailty Scale (CFS) or the most common scoring systems also used in elective surgery such as American Society of Anesthesiologists (ASA), Acute Physiologic Assessment and Chronic Health Evaluation II (APACHE II), Physiological and Operative Severity Score for the enumeration of morbidity and mortality (POSSUM) and Portsmouth-POSSUM (P-POSSUM), Charlson’s Comorbidity Index (CCI), American College of Surgeons National Surgical Quality Improvement Program risk calculator (ACS NSQIP), and Flemish version of the Triage Risk Screening Tool (fTRST) (*Appendix A*).¹⁵⁻²¹

Few studies described postoperative outcomes in very elderly patients undergoing emergency abdominal surgery, and these are largely performed on patients younger than nonagenarians. Portinari *et al.* conducted a retrospective cohort study to assess the 30-day survival of nonagenarian patients undergoing non-traumatic emergency abdominal surgery.⁴ They reported 27/85 patients (31.8%) died within 30 days, and most of them (92.6%) experienced medical complications. Moreover, the study showed a quick decline in survival over the first 30 postoperative days, followed by a gradual reduction during the rest of the first year. In the surviving nonagenarians, functional status worsened, and 64.2% of patients did not return to their original housing situation or were institutionalized. P-POSSUM is commonly used in general and emergency surgery to predict postoperative morbidity and mortality.²² Nonetheless, there are several doubts about the accuracy of this score in predicting 30-day mortality, as shown by this study and similar findings obtained by Racz *et al.*, who found POSSUM and P-POSSUM scoring systems were not reliable predictors of in-hospital mortality.⁷ They showed that over-

all in-hospital postoperative mortality was acceptable (15.2%), while nearly 50% of patients who underwent emergency surgery died within the first year after surgery. Pelavski *et al.* found higher mortality during the first 26 days after surgery, with a significant decrease during the rest of the first postoperative year.²² Perregaard *et al.* similarly found that emergency abdominal surgery in ninety-year-olds is a high-risk procedure with a high short- and medium-term mortality rate, with an overall 30-day mortality rate after emergency surgery of 34%, which rises to 54% within the first year.²³ They also showed that elderly patients with a low ASA class and a good performance status had a good survival rate after surgery. Thus, considering the possibility of offering more conservative treatments in nonagenarian patients with acute secondary peritonitis, it would be desirable to assess the real impact of surgery and its benefits on the long-term outcomes of these patients and find easily obtainable factors that best predict morbidity and mortality.

Objectives

The collected information will be used to investigate the impact of emergency abdominal surgery *versus* nonoperative management on the outcome of people older than 90 years.

The primary aim is to evaluate early and late outcomes in patients aged 90 years with acute peritonitis undergoing surgery or nonoperative management: 30-day and 1-year survival rates, clinical course and postoperative complications rate, and 1-year functional status.

The secondary aim is to investigate which factors can contribute to the choice of surgical intervention instead of nonoperative management and the accuracy of risk scoring systems in predicting poor outcomes or functional loss: P-POSSUM score, American Society of Anesthesiologists (ASA) score, APACHE II score, Charlson’s Comorbidity Index (CCI), Flemish version of the Triage Risk Screening Tool (fTRST), and the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) calculator. (*Appendix A*)

Materials and Methods

Population, eligibility, and exclusion criteria

All consecutive patients 90 years old or older admitted to the surgical department for acute secondary peritonitis and undergoing urgent or emergency surgery or nonoperative management will be invited to participate and can choose to consent or decline for a 30-day data collection period.

In order to be eligible to participate in this study, a subject must meet the following criteria: i) aged 90 years or older; ii) diagnosis of acute secondary peritonitis undergoing urgent or emergency surgery or nonoperative management. Subject exclusion criteria: i) aged 89 years or younger; ii) elective surgery.

Sample size calculation

According to the literature, emergency surgery in nonagenarians is a risk procedure with high short-term mortality; the estimated overall 30-day mortality after surgery at each participating center is 31-35%.

Applying a root mean square percentage error (rMSPE) of 13%, the inclusion of 200 patients treated with abdominal emergency surgery for acute peritonitis should be sufficient to analyze primary study objectives.

Outcomes

Primary outcome parameter: number of nonagenarian patients with acute secondary peritonitis undergoing urgent or emergency surgery or nonoperative management in 1 month.

Secondary outcome parameters: patient characteristics (age, sex, weight, height, BMI, smoking, comorbidities, previous abdominal surgery, pharmacotherapy, functional status, living situation, ADL/IADL); hospital admission (clinical status, arterial blood gas, blood tests, ECG); etiology of secondary acute peritonitis (small bowel obstruction, small bowel perforation, colonic obstruction [not malignant], perforated diverticulitis, perforated peptic ulcer or gastric cancer, acute cholecystitis, acute appendicitis, obstructed abdominal wall hernia with or without bowel infarction, colorectal cancer perforation-obstruction, bowel infarction, splenic abscess, other) (Table 1).

The study will be designed as a prospective, multicenter, observational study.

Data collection and data entering

All patient data will be entered anonymously by or under the supervision of the treating physicians. No patient-identifiable data will be collected, and the data collected will be on comorbidities and treatment/operation. The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of human beings according to current legislation and to the Helsinki Declaration (64th Assembly Fortaleza, Brazil, October 2013).

Table 1. Secondary outcome parameters.

Secondary outcome
Patient features
Age
Sex
Weight
Height
BMI
Smoke
Comorbidities
Previous abdominal surgery
Pharmacotherapy
Functional status
Living situation
ADL/IADL
Hospital admission
Clinical status
Arterial blood gas
Blood tests
ECG
Etiology of secondary acute peritonitis
Small bowel obstruction
Small bowel perforation
Colonic obstruction (not malignant)
Perforated diverticulitis
Perforated peptic ulcer or gastric cancer
Acute cholecystitis
Acute appendicitis
Obstructed abdominal wall hernia with or without bowel infarction
Colorectal cancer perforation - obstruction
Bowel infarction
Other

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. A designated collaborator at each participating site will be provided with REDCap project server login details, allowing them to securely submit data to the REDCap system.

A detailed case report form (CRF) is created from the REDCap database and provided to the invited centers. The CRF includes info points with definitions and guidelines that aid in adequate scoring of the listed parameters (*Appendix B*).

Ethics statement and regulatory approval

This study will be conducted in accordance with the Declaration of Helsinki. All participating centers will receive the study protocol and relevant documents so they can request approval according to local ethical guidelines.

Conclusions

In conclusion, we agree that the time is ripe for large multicenter trials to establish an ultimate scoring system for the statistical probability of survival or treatment success, with the ultimate goal of obtaining evidence to guide the management of the emergency in people older than 90 years. This study is intended as a “call to participants” in order to gather data on the effects of emergency abdominal surgery *versus* nonoperative therapy on the outcomes of nonagenarians and to use this data to enhance the scoring system in this population subsection.

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Online supplementary material:

Appendix A. Risk prediction score.

Appendix B. Case report form (CRF).