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The criteria of "inoperability"

Stefano Romagnoli, Laura Paparella, Paolo Boninsegni

Department of Anesthesiology and Intensive Care, Azienda Ospedaliero-Universitaria Careggi, Florence, Italy

Abstract

In the literature, the term "inoperable" mainly refers to two specific clinical aspects: cancer staging and technical difficulty/impossibility in performing. In light of this clarification, the statement "the patient cannot be anesthetized" has no medical foundation. On the contrary, the physicians have to carefully stratify the perioperative risk and optimize the patients' preoperative clinical status. In order to perform a precise risk stratification, the European Society of Cardiology and the European Society of Anaesthesiology have joined and published the guidelines for the perioperative cardiovascular management of patients scheduled to undergo non-cardiac surgery. The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) represents the most complete and accurate prediction tool so far. It includes 21 preoperative factors relating to demographics, comorbidities and procedures able to predict outcomes based on preoperative risk factors such as death, cardiac complications, pneumonia, and acute kidney injury. The present article will address aspects related to common aspects concerning modifiable and non-modifiable that should be addressed in every patient to whom elective surgery has been scheduled.

Introduction

Before analyzing the topic in detail, the definition of "inoperable" in this specific context requires clarification. In the literature, the term "inoperable" mainly refers to two specific clinical aspects: non-operability due to cancer staging; and neoplastic reasons or technical difficulty/impossibility in performing surgery (*e.g.* severe aortic calcification in cardiac surgery). No specific clinical conditions identify a patient as "inoperable". Just as the statement "the patient cannot be anesthetized" has no medical foundation, the term "inoperable patient" is similarly without basis.

In modern perioperative medicine, the definition of "inoperability" may be identified with an extremely high perioperative risk of death. As such, the physician has a responsibility to stratify the perioperative risk, optimize the patients' preoperative clinical status and postoperative program (from intensive care unit (ICU) admission to rehabilitation), and collect all necessary information to be shared with relevant parties (patient, surgeons, the anesthesiologist, and the cardiologist). The present article will address the most commonly recommended tools for risk evaluation and stratification.

Corresponding author: Stefano Romagnoli, Department of Anesthesiology and Intensive Care, Azienda Ospedaliero-Universitaria Careggi, Largo Brambilla 3, 50139 Firenze, Italy. Tel. +39.335.6100535.
E-mail: stefano.romagnoli@unifi.it

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Preoperative evaluation for non-cardiac surgery

An important aspect of preoperative risk assessment is the identification of procedures and/or patients' clinical conditions that elevate the risk of complications, and the subsequent implementation of strategies that mitigate these risks. Each year, an increasing number of elderly patients with cardiovascular disease undergo non-cardiac surgery. These patients require careful perioperative management to minimize their perioperative risk. Perioperative cardiovascular complications are the strongest predictors of morbidity and mortality following major non-cardiac surgery [1].

Two main steps are crucial to this end: first, clinical risk assessment including a detailed medical history and a physical examination; and, second, surgical classification into one of three levels of risk (Tables 1 and 2).

A Joint Task Force of the European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA) involving two key perioperative components (cardiologists and anesthesiologists) has recently published the revised guidelines for the perioperative cardiovascular management of patients scheduled to undergo non-cardiac surgery [2]. These guidelines represent the official position of the ESC and the ESA on various aspects of perioperative cardiac care, including the requirement (or not) for preoperative testing.

Preoperative risk assessment

Estimating perioperative risk and correctly communicating this risk to patients is crucial. The decision to undergo surgery requires a complex consideration of risks, short- and long-term benefits, and possible alternative therapies [3]. Moreover, the importance of risk estimation may vary from case to case. While in some instances the potential for benefit from surgery is clearly high (*e.g.* curative surgery for cancer), there may be others where accurate risk quantification is extremely important, especially when risk is elevated and alternative therapies exist (*e.g.*, surgery *vs* radiation therapy).

Table 1. Classes of recommendation and levels of evidence applied in the 2014 Guidelines.

Class of recommendation	Definition
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy
Class IIb	Usefulness/efficacy is less well established by evidence/opinion
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful
Level of evidence	**Definition**
Level A	Data derived from multicenter randomized clinical trials or meta-analyses
Level B	Data derived from a single randomized clinical trial or large non-randomized studies
Level C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Table 2. Revised Cardiac Risk Index (Lee Criteria).

1. History of ischemic heart disease
2. History of congestive heart failure
3. History of cerebrovascular disease (stroke or transient ischemic attack)
4. History of diabetes requiring preoperative insulin use
5. Chronic kidney disease (creatinine >2 mg/dL)
6. Undergoing suprainguinal vascular, intraperitoneal, or intrathoracic surgery

Risk for cardiac death, nonfatal myocardial infarction, and nonfatal cardiac arrest: 0 predictors = 0.4%, 1 predictor = 0.9%, 2 predictors = 6.6%, ≥3 predictors = >11%

Importantly, morbidity and mortality occur in a relatively small proportion of surgical patients. For instance, the United Kingdom has an overall perioperative mortality rate of 2%. However, 80% of these deaths occur in a small subset of high-risk surgical procedures. This subgroup constitutes only 12% of the surgical population [4], and perioperative risk stratification is hence important for the early identification of these individuals.

Several preoperative scoring systems have been developed to estimate the risks of mortality or complications after surgery. The ESC/ESA guidelines recommend one of the following two clinical risk indices for preoperative cardiac risk stratification (Class I recommendation) [2]: The Lee cardiac risk index [1] (Table 3), and the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) [5] (Figure 1 a,b).

The Lee index incorporates six equally weighted components: coronary artery disease, heart failure, cerebrovascular disease, renal insufficiency, diabetes mellitus, and high-risk surgical procedures. Unfortunately, most perioperative risk stratification methods are designed to predict a certain type of event – typically death or specific complications – and the prognostic accuracy of a risk-stratification tool is not necessarily transferable across different postoperative events. The Lee index or 'revised cardiac risk' index was designed to predict major cardiac complications after

non-cardiac surgery. While it allows for good discrimination between patients with varying risks of cardiac complications, however, the index is a poor predictor of postoperative mortality [6]. In addition, some of its components, such as diabetes mellitus, may warrant elimination, as they provide minimal associated prognostic information [7].

The ACS NSQIP has significantly improved precision in quantifying postoperative complications and probability of death. The program collects high-quality, standardized clinical data on preoperative risk factors and postoperative complications from more than 500

Table 3. Surgical risk estimate according to type of surgery or intervention* [2].

Low-risk (<1%)	Intermediate-risk (1-5%)	High-risk (>5%)
Superficial surgery	Intraperitoneal: splenectomy, hiatal hernia repair, cholecystectomy	Aortic and major vascular surgery
Breast	Carotid symptomatic (CEA or CAS)	Open lower limb revascularization or amputation or thromboembolectomy
Dental	Peripheral arterial angioplasty	Duodeno-pancreatic surgery
Endocrine (thyroid)	Endovascular aneurysm repair	Liver resection
Eye	Head and neck surgery	Esophagectomy
Reconstructive	Neurological and orthopedic: major (hip and spine surgery)	Repair of perforated bowel
Carotid asymptomatic (CEA or CAS)	Urological and gynecological: major	Adrenal resection
Gynecology: minor	Renal transplant	Total cystectomy
Orthopedic: minor (meniscectomy)	Intra-thoracic: non major	Pneumonectomy
Urological: minor (transurethral resection of the prostate)		Pulmonary or liver transplant

CAS, carotid artery stenting; CEA, carotid endarterectomy. *Surgical risk estimate is a broad approximation of 30-day risk of cardiovascular death and myocardial infarction that takes into account only the specific surgical intervention, without considering the patient's comorbidities.

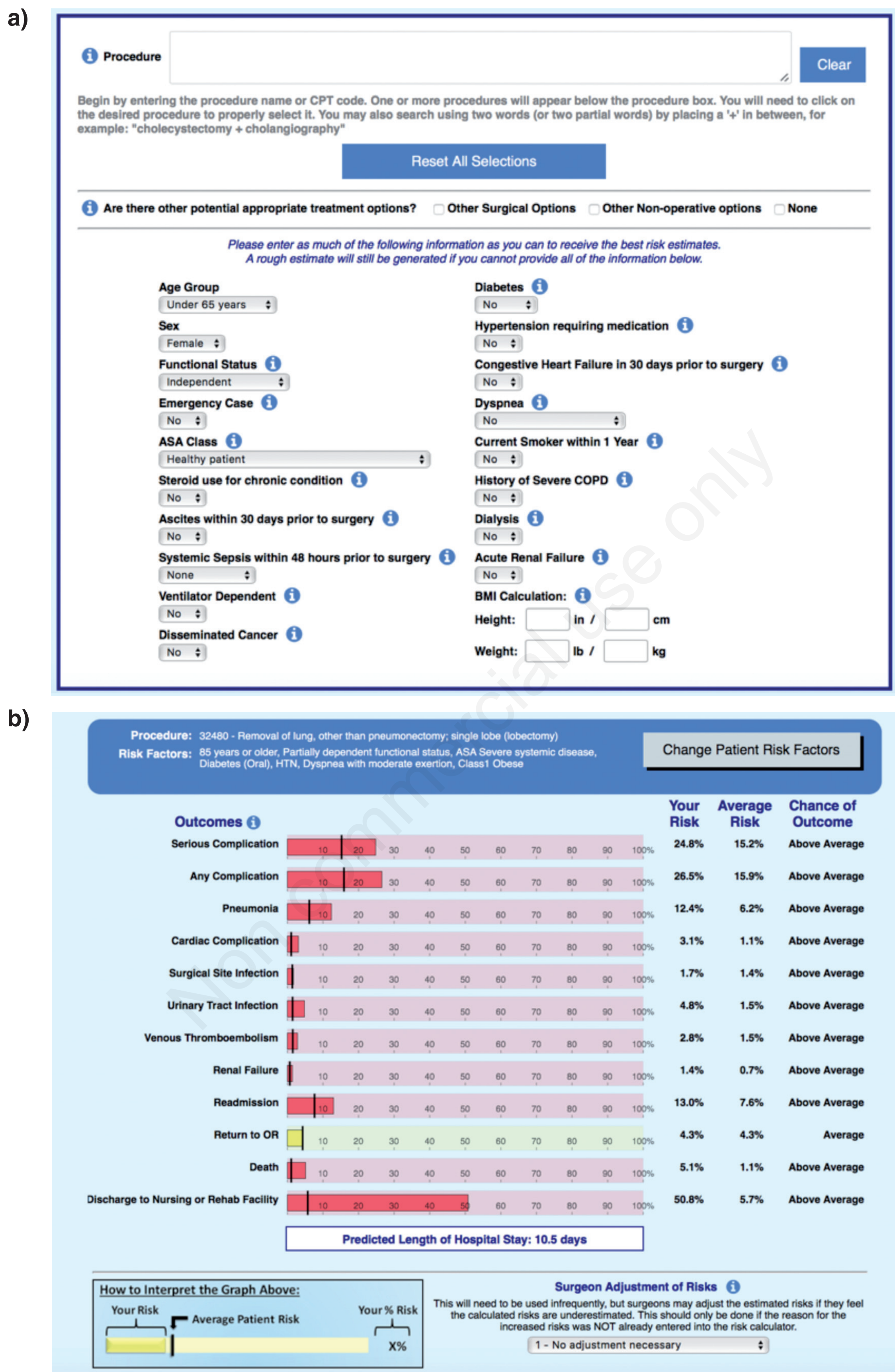

Figure 1. American College of Surgeons National Surgical Quality Improvement Program (NSQIP). a) Items; b) final analysis showing the post-operative complication risks for the analyzed patient.

hospitals in the USA. Using standardized clinical data from 393 hospitals, a web-based tool was developed (http://riskcalculator.facs.org) to allow surgeons to easily enter 21 preoperative factors relating to demographics, comorbidities and procedures. Regression models were developed to predict eight outcomes based on preoperative risk factors [8]. These models are able to predict a range of postoperative events, such as death, cardiac complications, pneumonia, and acute kidney injury, with good accuracy [8]. While clearly the best tool, nevertheless, the ACS NSQIP risk calculator has two notable limitations: first, the prediction models were derived from a very large multicenter observational dataset that is yet to undergo external validation, especially in settings outside the United States; and, second, it incorporates the American Society of Anesthesiologists Physical Status (ASA-PS) classification system, which has limited interrater reliability [9].

Closely related to perioperative risk assessment is the assessment of preoperative functional capacity on the basis of metabolic equivalents (METs). The evaluation of functional capacity is highly emphasized in perioperative risk assessment. In both the American College of Cardiology and American Heart Association clinical practice guidelines and the ESC/ESA guidelines, a patient's estimated functional capacity is a key determinant in whether further specialized preoperative cardiac testing is recommended [2,10]. The importance of functional capacity is derived from the results of studies of preoperative exercise stress testing or cardiopulmonary exercise testing (CPET). Patients with objective exercise testing scores of more than 4-6 METs have low perioperative risk [11]. For simplicity, however, physicians typically estimate patients' functional capacity by enquiring about their daily level of activity.

Clinical risk factors (Table 4), perioperative risk evaluation tools and METs are effective instruments for perioperative risk evaluation. The selective and individualized preoperative screening of patients scheduled for non-cardiac surgery is mandatory. Not every patient with cardiovascular disease requires detailed preoperative cardiac evaluation. For instance, patients with stable cardiovascular disease undergoing low- or intermediate-risk surgery do not require additional preoperative cardiac assessment. On the other hand, patients with a known or high risk of cardiac disease scheduled for high-risk non-cardiac surgery should undergo cardiac assessment by a multidisciplinary expert team. In addition, based on the surgical risk estimation according to the type of surgery or intervention and the clinical risk factors according to the revised cardiac risk index, specific, tailored flowcharts have been proposed by the ESC/ESA Joint Task Force [2] for additional preoperative tests.

When risk is particularly high, a careful and precise evaluation is mandatory to ensure that patient consent occurs in full knowledge of the facts. In select cases, where a patient is deemed to be at very high risk, consideration might be given to canceling the planned surgery and opting for alternative non-operative or less-invasive treatments.

Table 4. Clinical risk factors according to the revised cardiac risk index [1].

Ischemic heart disease (angina pectoris or previous myocardial infarction*)
Heart failure
Stroke or transient ischemic attack
Renal dysfunction (serum creatinine>170 Φmol/L or creatinine > 2.0 mg/dL or creatinine clearance < 60 ml/min/1.73m^2)
Diabetes mellitus requiring insulin therapy

*According to universal definition of myocardial infarction [14].

Patients consenting to intervention should have a reasonable understanding of the nature of the options available to them, along with the potential risks and outcomes of each option. Nonetheless, a recent review of the available literature indicates that patients undergoing surgery are often poorly informed about their condition and treatment, and real autonomous decisions remain difficult to obtain [3].

Moreover, the total risk associated with an operation must be conceptualized as consisting of two mutually exclusive components: intrinsic risk and modifiable risk. The total risk is simply the risk that can be expected for a specific patient undergoing a given operation, and can be quantified and predicted based on historical observations of previous patients in similar situations. This kind of risk can be efficiently estimated using the ACS NSQIP. Some portion of the total risk – namely, 'modifiable' risk – may be reduced or totally eliminated: for instance, smoking cessation has been shown to reduce the risk of complications [12]. Yet an amount of risk will nevertheless remain (intrinsic risk), even if all modifiable risk is eliminated. It is unfortunate, moreover, that most potential preoperative interventions have not been subject to rigorous evaluation and routine testing (*e.g.* electrocardiograms, chest x-ray, blood tests), and have consequently not been shown to reduce surgical risk. Perioperative beta-blockers are an example of the difficulties that may be masked by preoperative optimization. Beginning in the late 1990s, some small studies showed that beta-blockers reduced the perioperative risk of cardiac events for high-risk patients. Consequently, assessing eligibility for perioperative beta-blockers was considered rational. However, a large trial showed that despite the reduction in cardiac events, perioperative beta-blockers also increased the risks of stroke and mortality, and clinical guidelines have since been updated to reflect their limited perioperative role [2,13].

Conclusions

Outside of cancer staging and technical issues, inoperability criteria do not apply to modern perioperative medicine. Rather, physicians must be able to identify high-risk surgical patients and correctly stratify the perioperative risks in order that both the patient and the surgical team can discuss potential alternatives and take the appropriate clinical decision. Both clinicians and patients require information regarding surgical risks to determine the type of operation required, or indeed whether surgery should be performed at all. Predicting postoperative risks and identifying patients at higher risk of adverse events has traditionally been based on the experience of individual surgeons and published statistics, either from single institution studies or clinical trials. Unfortunately, these estimates are generally not specific to the risk facts associated with a particular patient.

While important progress has been made in the preoperative identification of high-risk surgical patients, substantial challenges remain. The NSQIP, although not perfect, appears to be the most appropriate and complete tool for this purpose. Finally, the increased ability to identify high-risk surgical patients will help expensive perioperative monitoring and intervention resources to the relatively small subgroup of surgical patients most likely to benefit from them.

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