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REVIEW

The Concept of Risk Assessment and Being Unfit for Surgery

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WHAT THIS PAPER ADDS

This was a commissioned topical review on the risk assessment of, and being unfit for surgery.

The concept of risk assessment and the identification of surgical unfitness for vascular intervention is a particularly controversial issue today as the minimally invasive surgical population has increased not only in volume but also in complexity (comorbidity profile) and age, requiring an improved pre-operative selection and definition of high risk. A practical step by step (three steps, two points for each) approach for surgical risk assessment is suggested in this review. As a general rule, the identification of a "high risk" patient for vascular surgery follows a step by step process where the risk is clearly defined, quantified (when too "high"?), and thereby stratified based on the procedure, the patient, and the hospital, with the aid of predictive risk scores. However, there is no standardized, updated, and objective definition for surgical unfitness today. The major gap in the current literature on the definition of high risk in vascular patients explains the lack of sound validated predictive systems and limited generalizability of risk scores in vascular surgery. In addition, the concept of fitness is an evolving tool and many traditional high risk criteria and definitions are no longer valid. Given the preventive purpose of most vascular procedures performed in elderly asymptomatic patients, the decision to pursue or withhold surgery requires realistic estimates not only regarding individual peri-operative mortality, but also life expectancy, healthcare priorities, and the patient's primary goals, such as prolongation of life versus maintenance of independence or symptom relief. The overall "frailty" and geriatric risk burden, such as cognitive, functional, social, and nutritional status, are variables that should be also included in the analyses for stratification of surgical risk in elderly vascular patients.

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CONCEPT OF RISK ASSESSMENT AND BEING "UNFIT" FOR SURGERY

The concept of risk assessment and the identification of surgical unfitness for vascular intervention is a particularly controversial, debated, and challenging issue. Complications after surgical procedures are associated with a significant increase in mortality, prolonged intensive care and hospital lengths of stay, and marked increases in overall hospital costs. In the current cost-constrained healthcare environment, where the value of operative interventions is determined by outcomes, accurate assessment of operative risk is an important goal to guide clinical decision making. Now more than ever, the potential benefits associated with vascular surgery need to be balanced with alternative, mostly less invasive, strategies with lower risk exposure.[1]

In recent decades, the implementation of these new less invasive endovascular alternatives has modified the risk profile of vascular interventions. In addition, improvements in anesthetic care and the availability of modern cardiopulmonary assistance tools, have allowed for a lower perioperative burden with a decreased need for prolonged inpatient hospitalization. Finally, the systematic use of newer classes of medications such as statins and antiplatelet drugs have enhanced the durability of patency after

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vascular procedures and decreased the peri-operative risk of mortality and major adverse ischemic events.

Nevertheless, major concerns over patient safety still remain. Indeed, the minimally invasive surgical population has increased not only in volume but also in comorbidity profile and age. Therefore, improved pre-operative selection and definition of high risk are warranted.[2] Particularly for vascular surgery the individualized surgical risk/benefit assessment is challenging. This is because most vascular procedures mainly target prevention (e.g. prevention of stroke from carotid stenosis, death from aneurysm rupture, amputation from lower limb disease, etc.) and do not primarily provide an effective causal treatment for the underlying pathology of atherosclerosis.

Proper patient selection for vascular interventions is based on consideration of the complex interaction of patient specific variables, and procedure and operator related covariates. These insights should aim to assess the individual patient's peri-operative outcome in the context of his current life expectancy.

Even though a number of general "risk factors" of poor peri-operative outcome are well known, the complexity of the interaction among different factors makes it difficult to determine the exact individual risk estimation. This is underscored by a large proportion of the adverse events occurring in only a small proportion of high risk patients who can be readily identified pre-operatively.[3,4] Therefore, grouping of patients into "surgically fit" and "unfit" categories also remains largely subjective[3–5] because constantly evolving new technologies and economic interests potentially influence the selection strategy.[1]

RISK DEFINITION AND ASSESSMENT

As a general rule, there are three main components in the identification of high risk surgery. The first relates to the type of surgery, the second to the characteristics determining the physiological fitness of the patient, and the third to the technical circumstances in which the surgery needs to be performed. For instance, a situation of "adverse anatomy" (carotid restenosis, abdominal re-intervention, consequences of radiation therapy, etc.) can significantly alter the risk of the surgical procedure, regardless of the physiological fitness. As an additional component, in the current endovascular era, the institutional caseload/experience can affect the level of surgical risk expected in a vascular patient.

A practical step by step (three steps, two points for each) approach for surgical risk assessment is proposed.

First step: qualitative and quantitative definitions of operative risk

Goal directed definitions of surgical risk. The definition of surgical risk is a complex and sometimes controversial issue because of the subjective nature of elements in the assessment. These include diversity in the persons who evaluate the risk, the outcome measurement on which the risk is measured (risk of mortality, morbidity, cardiovascular complications), and the specific settings (populations, hospitals, procedures) for which the risk is assumed.[6]

a) Persons evaluating peri-operative risk. An objective and standardized definition of high risk is challenging because of different risk perceptions depending on previous experiences and expectations. There has been much speculation on the interaction between surgery and "risk" depending on who is making the assessment. As observed by Boyd, the patient, the family, the anesthesiologist, the surgeon, and the intensive care specialist all assume different priorities in defining the risk.[6] For a patient, risk can be measured as the ability to return to work or the possibility of disability, while for the anesthesiologist and the surgeon the risk of a procedure most likely implies the likelihood of an uneventful operative procedure and the possibility of peri-operative complications.

b) Variables for outcome assessment. The comparison of risks among different studies reporting on high risk surgical patients is problematic because different outcome variables (e.g., peri-operative mortality, peri-operative morbidity, mid-term survival, etc.) are reported as measures of risk. Mortality and cardiac events (major adverse clinical event, as a combination or mortality and myocardial infarction) are the most common outcome measures used to stratify categories of peri-operative risk and tend to be applicable to wider groups of operative procedures. However, assessment of peri-operative risk also depends on the specific surgical exposure. For instance, for a carotid procedure, assessment of peri-operative risk will primarily look at the incidence of peri-operative stroke and only in the second instance at myocardial infarction and death. In this particular instance, the concept of high risk would relate in the first instance to the probability of an excess exposure to stroke. For abdominal aortic aneurysm (AAA) procedures on the other hand, the main risks are related to the cardiopulmonary impact and related mortality, and less to the post-operative incidence of stroke. For peripheral artery disease procedures the risk of limb loss is still another priority of different order in the risk assessment. Finally, it should be underlined that only a minority of the peri-operative mortality may be related to cardiac events. In a recent study in vascular surgery patients undergoing infrarenal aortic replacement, only 28% of the observed deaths were associated with post-operative myocardial infarction and only 2% of peri-operative deaths could be attributed solely to myocardial infarction.[7] These data strongly suggest that peri-operative risk assessment should not focus solely on cardiac risk assessment.

c) Settings. Risk definition is also estimated differently depending on the type of intervention, the type of population at risk and the expected result of surgery. Improvements in the level of care have resulted in a substantial decrease in accepted peri-operative risk, even in the context of older age and higher comorbidity of the treated population. Furthermore, the hospital/institutional caseload and experience can affect the level of surgical risk offered to a vascular patient today. The centralization of vascular services to provide the best care with the lowest risks has cost implications (availability, transportation, etc.) and provokes ethical concerns for the individual surgeon, remaining an issue under debate.

Surgical risk quantification. The cutoff between patients assessed as being at "high risk" and those at "lower risk" is not standardized and risk quantification is difficult to define and compare between studies. Acceptable thresholds for surgical risk can differ whether based on mortality or a single complication alone or on a combination of different outcome variables such as mortality and other outcome measures (e.g. myocardial infarction, stroke, any major complication, etc.). As a common rule, the broader the combined outcome measure, the higher the acceptable threshold of risk is set.

Easily understandable definitions suggested that high risk would imply an individual risk of mortality as either >5% or twice the risk of the random population undergoing the procedure. However, in today's practice, with improved peri-operative care and surgical techniques, the incidence of peri-operative mortality or major morbidity is not now expected to exceed 1%.[8–10]

Surgical patients for whom the probability of mortality is greater than 20% should be considered at extremely high risk. There is indeed little probability that any hemodynamic optimization or other adjunctive actions will substantially decrease the risk of peri-operative mortality impact in these patients.

Second step: assessment of risk related to the procedure and to the patient to treat

As "high risk" is the risk to an individual patient compared with the risk to the population or the risk of the procedure compared with the risk of other surgical procedures as a whole,[6] peri-operative risk of complications may vary depending on the magnitude, type, duration, or urgency of the surgical procedure, the condition of the patient before surgery, and the prevalence of comorbidities.

Procedure related risk. Stratification of the risk related to procedure differs in the current guidelines. The last American Heart Association (AHA) cardiovascular guidelines for non-cardiac surgery define only two categories of procedural risk: a low risk procedure with a combined risk of a major adverse cardiac event (MACE) of <1% (such as cataract or plastic surgery), while procedures with a risk of MACE of >1% were considered at elevated risk.[8] The European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA) guidelines use a three-arm stratification for surgical risk during non-cardiac surgery with an intermediate additional category and a 5% cutoff to differentiate procedures at intermediate from those at high surgical risk.[9,10]

Open aortic and infra-inguinal procedures are both regarded as high risk procedures, while carotid interventions, either surgical (carotid endarterectomy, CEA) or endovascular (carotid stenting, CAS), have been regarded as low or intermediate risk procedures depending on their application to patients with asymptomatic or symptomatic carotid stenosis.[9,10]

Of note, infrainguinal revascularization, although a less extensive intervention, entails a cardiac risk similar to, or even higher than that of aortic procedures. This can be explained by the higher incidence of diabetes, renal dysfunction, ischemic heart disease, and advanced age in this patient population. This also explains why the risk related to peripheral artery angioplasty, which is a minimally invasive procedure, is not negligible.

The extent of surgical trauma is proportionate to the extent and duration of the intervention but also to the urgency of surgery. There is general agreement that the risk is increased in non-elective surgical repairs even though accurate timing stratification has not always been consistently reported in studies on high risk evaluation. Individual institutions may use slightly different definitions. Guidelines stratify surgical risk as a function of the time-sensitivity of an intervention. An emergency procedure is one in which life or limb is threatened if not operated within 6 hours. An urgent procedure is defined as the need for surgical intervention between 6 and 24 hours. This allows some time for a limited additional assessment and optimization of the patient. A time-sensitive procedure is one which can be delayed for >1–6 weeks to allow for further evaluation and optimization to improve outcome. An elective procedure is one in which the procedure could be delayed for up to 1 year.[8–10]

Patient related risk. Patient specific factors are of critical importance in predicting the peri-operative risk of vascular surgical procedures. Most of the studies on high risk patients in recent decades have focused on risk stratification tools, incorporating multiple patient specific factors. A key component in the pre-operative assessment of any patient is the evaluation of the presence of active or unstable cardiac conditions, functional capacity of the patient, and the presence of cardiac risk factors. Determination of functional capacity, measured in metabolic equivalents (METs) is a simple way to provide an objective assessment of reserve cardiac capacity. Although poor functional capacity, defined as less than 4 METs (the inability to climb two flights of stairs or run a short distance) has been associated with increased probability of mortality especially after thoracic surgery, this was not consistently reported in studies after non-cardiac surgery. Poor functional capacity remains a general predictor of poorer prognosis, but may on its own be an insufficient argument to refuse or postpone surgery.

Third step: stratification of risk according to available evidence (predictive risk models)

Risk stratification tools are usually developed using multivariate analysis of multiple risk factors for a specific outcome and may be differently established as "risk prediction models" or "risk scores/indices".[11,12] Risk prediction models estimate an individual probability of risk by entering the patient's data into a multivariate risk prediction model and may be more accurate predictors of an individual patient's risk than risk scores. Nevertheless, prediction models are quite complex to use in the day to day clinical setting. Risk scores have the advantage that they are simple to use in the clinical setting allowing scoring of a patient on a scale. Risk scores assign a weight to factors identified as independent predictors of an outcome with the weight for each factor often determined by the value of the regression coefficient in the multivariate analysis. The sum of the weights in the risk score then reflects the degree of risk. This system helps in defining and differentiating the "high risk" from the "low risk" patient based on stratification scale. However, scores do not provide an estimate for an individual patient's outcome.

Since investigators have progressively identified novel pre-operative, intra-operative, or post-operative potential predictors of surgical outcome, a multitude of scoring systems are now available to determine medical fitness status for surgery. These include "general" or "specific" score models but it should be acknowledged that many of these systems have become increasingly complex.

Generic risk models. "Generalized" risk prediction models were developed to stratify surgical patients with respect to peri-operative risk regardless of the type of surgery. One of the most widely accepted scores is the American Society for Anesthesiology Physical Status (ASA-PS) Classification. This generalized scoring system stratifies patients into categories based on their comorbidities and the subsequent risk to their everyday life to establish how fit they are to undergo an operation.[12] However, despite the proven ability in identifying patients at much higher risk than those in the general population, poor inter-rater reliability leading to some subjective interpretation makes the ASA-PS derived score less robust to use when applied outside anesthesiologist settings. In addition, it does not include a specific surgery related risk assessment. More complex, specific scoring systems have greater prognostic accuracy, but often require computerized calculation, which makes them less applicable in daily clinical practice. Therefore, ASA-PS scoring, although only a rough estimation, still remains helpful in predicting global peri-operative risk based on the patient's physical status. The surgical risk score and American College of Surgeons Risk Calculator represent other more detailed efforts to estimate the risks of surgery for a wide range of surgical procedures across many different specialties.[5] The accuracy and discriminative ability remain under debate.

Besides general models, more "specific" risk assessment tools were created to predict post-operative mortality in specific patient populations, including those undergoing vascular surgery. Despite the variability of the models, most of the scores have tended to focus on prediction of mortality and/or adverse cardiac events, without specifically addressing the occurrence of major morbidity that is not related to cardiac disease. The most widely accepted tool used to predict cardiac risk remains the Revised Cardiac Risk Index even though there is no uniform consensus.[13,14] A recent document based on National Surgical Quality Improvement Program (NSQIP) data suggested that the cardiac risk calculator (including type of surgery, dependent functional status, abnormal serum creatinine, American Society of Anesthesiologists' class, and increasing age) provides a risk estimate of peri-operative myocardial infarction or cardiac arrest with better performance than the Revised Cardiac Index.[13]

A systematic review of multiple stratifications tools for non-cardiac surgery suggested that the most promising risk predictors were the Portsmouth-Physiology and Operative Severity Score for the enumeration of Mortality (P-POSSUM) and the Surgical Risk Scale.[11] Nevertheless, the overall evidence was not sufficiently sound to support generalized application of any of the models. Most such instruments have been developed and validated in single center studies, which unfortunately limits any assessment of their general usefulness and reliability.

Risk models specific for vascular patients.

a) Risk stratification in elective abdominal aortic aneurysm (AAA) repair

A number of risk prediction models have been considered to determine the fitness status in AAA patients. These include the Leiden Risk Model Score, the Glasgow Aneurysm Score, the Vascular Biochemistry and Haematology Outcome Model (VBHOM), the Physiological and Operative Severity Score for the enUmeration of Mortality (POSSUM), the Medicare system (Medicare), and the Vascular Governance North West model (VGNW). Some models were specifically developed to assess the peri-operative risk for AAA repair such as the Customized Probability Index (CPI), the British Aneurysm Repair (BAR), the Abdominal Aortic Aneurysm Statistically Corrected Operative Risk Evaluation (AAA SCORE), or the EVAR risk Assessment (ERA) model.[15–39]

The main predictors applied and validation studies are summarized in Table S1 (supplementary material).

Not surprisingly, there is considerable overlap in these models and a number of patient related factors have consistently been shown to provide poor outcome in vascular patients with AAA. However, no risk stratification tool will perfectly predict outcome for patients with AAA. Unlike cardiac surgery, where some risk prediction models have been widely validated before acceptance and routine application in clinical practice (e.g. EuroSCORE and more recently EuroSCORE II), in AAA repair the sensitivity and specificity of risk models remain ill-defined and their implementation in clinical practice is limited. Reasons for this include doubts about the accuracy and applicability of models to contemporary practice, the inability to easily perform model calculations, and uncertainty over how such models might influence clinical practice. Lack of use may also be because of poor awareness among clinicians of the available options, and concerns regarding their complexity and accuracy. A final explanation for the suboptimal value of the currently available AAA models is related to the high rate of missing data in the databases used for generating these models.

Perhaps the major drawback limiting the applicability of AAA surgery risk scores is the lack of vigorous model validation. Despite substantial literature on the use of score systems to predict mortality after AAA repair, none of the models have consistently been validated nor tested on large populations.

Data from the recent literature on accuracy of various predictive scores raised uncertainty and led to contradictory conclusions. The EVAR 2 trial randomized patients who were physically ineligible for open repair (assessed with the modified Customized Probability Index, m-CPI) to endovascular repair of abdominal aortic aneurysm (EVAR) or no repair. No differences were found in 4 year survival but the peri-operative mortality after EVAR was 7.8%.[40,41] More recently Lim et al. defined a “high risk” group of patients undergoing EVAR in the Veterans Administration Hospitals using the same CPI score system of the EVAR 2 trial.[31] Interestingly, this study observed no excess mortality in the high risk group (0% high risk vs. 1.2% not high risk; $p = 1.0$) and early complication rates were similar in patients defined at high risk and those not at high risk (4% high risk vs. 6% not high risk; $p = .8$). The 1, 2, and 4 year survival rates in the high risk patients (85%, 77%, 65%) were lower than those in low risk patients (97%, 97%, 93%; $p < .001$). Of note, these rates in the high risk group were more favorable compared with a 36% 4 year survival in the EVAR 2 trial. Instead of the overall CPI score system, Lim identified five more reliable prognostic indicators of post-EVAR death: age, chronic kidney disease stages 4 and 5, congestive heart failure, home oxygen use, and current cancer therapy.[31]

The Dutch Randomized Endovascular Aneurysm Management (DREAM) trial used the Glasgow Aneurysm Score (GAS) to predict 30 day and 2 year mortality.[16] The study showed that the optimal cutoff value that predicts peri-operative outcomes was lower for open repair (75.5) than for EVAR (86.5), suggesting that fitter patients may benefit more from having endovascular rather than open repair. However, 2 years post-operatively this benefit for EVAR was lost. The authors concluded that GAS was most valuable in identifying low risk patients and not very useful for identifying high risk patients.[16]

Additional data from the recent literature have also shown contradictory conclusions. Egorova et al. applied a new scoring system in 44,630 patients, assessing several baseline risk factors (such as renal failure with dialysis, renal failure without dialysis, clinically significant lower extremity ischemia, patient age, heart failure, chronic liver disease, female gender, neurological disorders, chronic pulmonary disease, surgeon’s experience in EVAR, and hospital annual EVAR volume).[42] The authors identified a group of high risk patients that should not be treated by EVAR because of prohibitively high mortality even with endovascular treatment. Similar results were suggested by Faizer et al., in a study from a different database of 862 patients in whom the Glasgow Aneurysm Score, the Modified Leiden Score, and the Modified Comorbidity Severity Score were related to peri-operative mortality in both open repair and endovascular reconstruction.[23] The study showed that for patients at low medical risk, mortality did not differ between open repair and EVAR, whereas high risk patients derived significant benefit from EVAR. In contrast, a study of 22,830 patients in the Medicare population using a multiple logistic regression model to evaluate the risk prediction score for peri-operative mortality, concluded that mortality after AAA repair was primarily predicted by comorbidities, gender, and age, and that these predictors had similar effects for both methods of AAA repair.[24]

A large population based registry in Sweden to determine the operative mortality and long-term survival of elective EVAR compared with open repair in high risk patients surprisingly found that elective open repair had a better outcome. These data suggested that in a high risk cohort, patients deemed fit and suitable for open repair might have a better long-term outcome compared with patients deemed fit and suitable for EVAR.[38]

b) Risk stratification in ruptured AAA (rAAA) repair

Data on risk stratification in ruptured AAA repair are scarce. In such emergencies, medical fitness is not the first priority for the choice of treatment but instead the anatomical feasibility for EVAR. Multiple scoring systems have been applied, especially in Canada and England, to specifically predict mortality in rAAA. These include the Glasgow Aneurysm Score (GAS), the Hardman Index, the Vancouver score, and the Edinburgh Ruptured Aneurysm Score (ERAS).[32] The most common predictors are summarized in Table S2 (supplementary material). None of these scoring systems has been shown to be generally applicable. One of the reasons for the inconsistency of predictive scores in rAAA is the poor applicability, because of the high likelihood of missing the data required for score calculation in the emergency situation.

Despite the increasing number of published studies, the reliability, accuracy, and discriminatory ability of any of these scores to identify higher risk patients to be refused for surgery when presenting with a ruptured aortic aneurysm, remain unclear. In a validation study by van Beek et al., the updated GAS seemed to most accurately predict death after intervention but it was not sufficiently accurate to discriminate high risk patients. It did not identify patients with a >95% predicted death rate to reliably support the decision to withhold intervention.[43] Recent data from the randomized Amsterdam Acute Aneurysm Trial suggest that there are two groups of rAAA patients that should be separately identified and managed, because of different risk. The first group consists of hemodynamically unstable patients in whom time is very limited (13% survival after 2 hours). If surgical intervention is considered in these patients, care and logistics should be optimal to prevent dying. The second group consists of hemodynamically stable patients in whom survival is much better (96% after 2 hours).[44]

c) Risk stratification in peripheral vascular diseases repair

Compared with the extensive literature on scoring tools in the AAA population, the development of stratification systems for patients with peripheral vascular intervention is still at its beginning. There is a larger variability in patient populations (peripheral disease, critical limb ischemia (CLI), claudication, undergoing amputations, etc.), outcome measures (mortality, complications, limb salvage), and time of assessment (peri-operative, 1 year, etc.). Importantly, in patients with peripheral disease a number of factors other than cardiac also define the risk profile of an interventional procedure. These additional risk factors for increased operative mortality are age >80 years, dependent functional status, and renal disease (on dialysis).[45–48] Biancari et al. were the first group to attempt risk stratification in patients with CLI, with the development of the National vascular registry in Finland (FINNVASC) score.[49] (Table S3, supplementary material). This score determined the risk of a patient undergoing a major amputation or dying <30 days after an open surgical revascularization. In an effort to more specifically assess risk in this population, members of the Vascular Study Group of New England (VSGNE) used multi-institutional surgical outcome data to develop a targeted risk assessment tool for cardiac risk in patients undergoing lower extremity revascularization.[19] Other efforts to predict outcome in this patient population include the PREVENT (PRoject of Ex vivo vein GRaft Engineering via Transfection) III Score, which aimed to predict the likelihood of mortality or amputation at 1 year.[50–53] A more comprehensive, targeted risk assessment tool to predict 30 day major morbidity and mortality after bypass surgery for CLI was The Comprehensive Risk Assessment for Bypass based on the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP).[54]

Similar risk factors have been identified for the fitness of patients undergoing major amputation mainly provided by studies based on ACS-NSQIP or Veterans Administration (VA) databases.[55–59] A recent study based on ACS NSQIP data, developed a practical index system, including 11 components, with a range from 0 to 13 to predict mortality in patients undergoing major amputation. A score >5 was found to be associated with a high mortality risk: the 30 day mortality increasing from 1% at a score of 1, to 10% at a score of 5, and 38% at a score of 10.[45] Different stratification tools recently developed for patients with peripheral disease are summarized in Table S3 (supplementary material). Nevertheless, only a few accurate and generalizable data are available overall. There is inconsistent evidence to define a high risk category of patients allowing for widespread application of a predictive score to all peripheral procedures including endovascular interventions.

d) Risk stratification in thoracic aortic repair

Although the risk assessment in thoracic aortic surgery is a topic of major interest, it is not easy to develop reliable risk -stratification algorithms for predicting mortality in these patients. This is because the groups of patients scheduled for this type of surgery include a variety of aortic diseases, surgical techniques, and corresponding lesions of the aorta. The mortality rate after open thoracic surgery has decreased substantially during the last decades because of improvements in techniques, and with the introduction of hybrid or total endovascular approaches. The most common score systems to stratify the risk in thoracic aortic surgery rely on scores developed for open chest and cardiac surgery, such the European System for Cardiac Operative Risk Evaluation (EuroSCORE) and the updated Society of Thoracic Surgery (STS) risk calculator.[60,61]

e) Risk stratification in carotid stenosis interventions

Defining the term "high operative risk" has proven to be highly elusive for carotid surgery because multiple studies used "conventional" risk criteria.[62–64] Conventional criteria of high risk CEA were developed from large historical randomized carotid trials such as the North American Symptomatic Carotid Endarterectomy Trial (NASCET), Asymptomatic Carotid Atherosclerosis Study (ACAS), or the European Carotid Surgery Trial (ECST). Multiple changes and improvements have been achieved in carotid treatment over the years and "historical" risks appear outdated today. Most of the studies on risk scores for the development of post-CEA and post-CAS stroke or death carry important limitations.[65–72] The most relevant is the failure to reliably adjust for current disease and procedure specific variables. At present, there are no existing validated prediction models or objective risk scores that can be used to quantify the risk of adverse events in patients undergoing CAS or CEA. No specific risk factors, neither physiological nor anatomical, have yet been identified that can provide a clear cut definition of any absolute contraindications for CEA or CAS in modern times.

A number of reasons make it particularly challenging to define the concept of high risk in CEA or CAS populations.

a) Carotid interventions are categorized by guidelines within procedures at low or intermediate risk. The overall risk exposure is low and limited when compared with that for peripheral or aortic surgical procedures ("high risk procedures").
b) Unlike the assessment of risk in aortic or peripheral diseases, where the peri-operative risk is mainly affected by mortality and adverse cardiac outcomes,

the risk of a carotid procedure is mainly the risk of stroke. Patient and procedure related factors increasing the risk of stroke have a major impact in defining the concept of poor fitness for carotid intervention.

c) Also, procedures to treat carotid stenosis are among the interventions that have benefitted most from developments in technology and medical therapy. Indeed, the widespread use of statin, antiplatelets, and intensive lifestyle modification allowed for a substantial decrease in the stroke risk for patients with carotid disease.[8,9] After the introduction of CAS, any objective assessment of “risk” for a carotid procedure is challenged by the specific effect of operator experience.[64] There is large variability in the stroke risk of an endovascular carotid procedure by center and operators, which precludes generalization of the fitness for CAS.

In summary, the concept of risk exposure in carotid vascular procedures, including the best selection between CEA and CAS, remains unclear and must integrate operator experience and patient characteristics.

ADDITIONAL REMARKS IN RISK ASSESSMENT FOR VASCULAR PATIENTS: TREATMENT DENIAL AND FRAILTY

Implications of “fitness” for treatment refusal

One of the major implications of the lack of a standard definition of “medically unfit” for a vascular patient is the decision on whether to refuse invasive treatment, especially for patients with large aortic aneurysms. Given the higher frequency of rupture in larger aneurysms, a more aggressive surgical approach is often taken. However, in patients with important comorbidities, operative intervention may be delayed until aneurysm size has increased sufficiently to warrant the operative risk. Still, the debate about the use of EVAR in medically unfit patients continues because, to date it is not possible to assess for individual patients, whether the risk of future rupture outweighs the risk of the surgical intervention.[73–75] This is illustrated by the results of the EVAR-2 trial in which no difference in survival was found.[40,41] The decision to turn down corrective treatment may be even more challenging for the repair of a ruptured abdominal aortic aneurysm (rAAA). Paradoxically, a refusal of elective repair does not necessarily preclude a patient from successful emergency repair despite the reasons for turning down treatment being valid at the time of rupture.

However, there remains large variability among departments, hospitals, and countries. A recent comparative analysis of 11,799 patients with rAAA in England and 23,838 patients with rAAA in the USA showed that non-corrective treatment (no open or endovascular procedure performed) for rAAA was significantly more common in England than in the USA. Patients in the USA were more than three times as likely to be offered intervention for rAAA (OR 3.19; $p < .0001$).[73] In the same patients, the overall in hospital mortality was significantly greater in England than in the USA: 65.90% vs. 53.05%; OR 1.5, 95% CI 1.38–1.58 ($p < .0001$). This difference was mainly because US hospitals were less likely to manage rAAA by non-corrective treatment and offered aneurysm repair to a significantly greater proportion of patients. Based on these data, a more aggressive approach in selecting less fit patients may be justified, especially in teaching hospitals as data suggest that the lowest mortality for rAAA is seen in hospital settings with larger bed capacities and performing a greater proportion of cases endovascularly.[73]

Nevertheless, the overall life expectancy, the healthcare priorities, and primary patient goals, such as prolongation of life versus maintenance of independence or symptom relief are relevant priorities in assessing the benefit/risk for vascular procedures (mostly performed in asymptomatic patients for preventive purpose). Geriatric risk factors, such as cognitive, functional, social, and nutritional status, are variables that should be included in the analyses for stratification of surgical risk in these elderly patients. If surgery is unlikely to satisfy patient goals and major expectations, regardless of risk exposure and fitness, pursuit of a non-operative treatment may be better.

Frailty

A final step in the risk assessment relates to the current changes in demographics leading to ageing populations. Most of the pre-operative risk stratification tools for aortic aneurysms and other vascular procedures focus on cardiac risk but do not take into account the “physiology reserve” of elderly vascular patients. Age per se, seems to be responsible for only a small increase in the risk of complications, while cardiovascular, pulmonary, and renal disease are the most common risk factors contributing to greater peri-operative risk. In recent years an increasing number of studies have shown that decrement in physiologic reserve (frailty) may be associated with a reduced ability to recover from the insults of major stresses such as surgery.

The concept of frailty reflects the loss of physical and mental function and cumulative decline across multiple systems leading to increased vulnerability. Frailty has been found to be a strong predictor of morbidity and mortality beyond traditional risk factors such as age per se, ASA class, and other comorbidities.[76–78] Various indices and measurement tools, such as the Edmonton frailty score have been applied to encompass the overall geriatric risk. There is common agreement that high frailty, independent of other risk factors, is associated with higher mortality and morbidity of inpatients undergoing elective EVAR, open repair of AAA,[79] or peripheral vascular procedures.[80,81] Pre-operative assessment of frailty may be a useful adjunct in the pre-operative stratification of risk exposure and fitness.

CONCLUSION

Although in recent decades substantial decreases in peri-operative morbidity and mortality have occurred for most vascular procedures, some vascular patients still remain at high risk because of their physical status. Today, there is no standardized and objective definition of unfitness for vascular surgery. The major gap in the current literature on the definition of high risk in vascular patients explains the lack of sound validated predictive systems and limited generalizability of risk scores in vascular surgery. In addition, the concept of fitness is an evolving tool. A practical step by step (three steps, two points for each) approach for surgical risk assessment, as suggested, may be useful to address these challenges.

An individualized assessment of whether potential benefits of an intervention may outweigh the risks allows targeted optimization of treatment. Given the preventive role of most vascular procedures in asymptomatic elderly patients, the decision to pursue or withhold surgery requires realistic estimates not only of individual peri-operative mortality, but also of overall life expectancy, healthcare priorities, and primary patient goals, such as prolongation of life versus maintenance of independence or symptom relief. The assessment of risk exposure and fitness should allow surgery to satisfy patients' goals and major expectations; otherwise pursuit of a non-operative treatment may be better.

CONFLICT OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ejvs.2016.02.004.

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