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Controversial results of the Revised Cardiac Risk Index in elective open repair of abdominal aortic aneurysms: Retrospective analysis on a continuous series of 899 cases

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ABSTRACT

Background: Low reliability of Revised Cardiac Risk Index (RCRI) in predicting major cardiac events (MACE) among Vascular Surgery patients emerged in recent literature, suggesting procedure-specific risk evaluation - particularly in major surgery.
Methods-results: Comorbidities, perioperative variables, RCRI and MACE were retrospectively analyzed in a consecutive series of 899 elective open abdominal aortic aneurysm (AAA) repairs performed at our Institution. Possible MACE predictors were studied through univariate/multivariable analysis (logistic regression, MVRE) and stepwise-backward elimination/odds ratio (MVR-SBE/OR). Patients were divided by clampsite in 2 subgroups: 1. infrarenal (690 cases); 2. pararenal (209 cases). RCRI resulted predictive for MACE in the whole dataset but its performance resulted lower for pararenal aneurysms ($p = 0.11$) than for infrarenal ones ($p \le 0.00$). Among RCRI covariates of the whole cohort, dilated cardiomyopathy ($p \le 0.001$), ischemic cardiopathy ($p \le 0.01$) and cerebrovascular disease ($p \le 0.02$) resulted predictive. Peripheral arteriopathy also related to MACE ($p \le 0.03$). At MVR-SBE/OR analysis, the following resulted to be MACE predictors: dilated cardiomyopathy ($p \le 0.001$), cerebrovascular disease ($p \le 0.02$), and surgical access ($p = 0.04$) in subgroup 1; previous myocardial infarction ($p \le 0.01$), congestive failure ($p \le 0.03$) and chronic pneumopathy ($p = 0.04$) in subgroup 2.
Conclusions: Predictability of RCRI in elective AAA surgery is influenced by clampsite and resulted to be lower in aneurysms requiring suprarenal clamping. Variables included in the RCRI show to have different weights when patients are stratified by clampsite. Some variables not included in the RCRI model significantly affect the onset of MACE. RCRI should be revised to elaborate a specific score for AAAs including further MACE predictors, to improve risk assessment and to support proper surgical strategy.

1. Introduction

Morbidity and mortality in patients undergoing vascular surgery are significantly affected by coronary artery disease and perioperative cardiac events. It is estimated that among patients undergoing a vascular procedure up to 50% have some degree of coronary disease, and up to 10% of asymptomatic patients have severe disease revealed by coronarography [1]. The incidence of perioperative myocardial ischemia in vascular patients may be as high as 18–35% in the highest-risk patients [2]. Therefore, the assessment of risk of major adverse cardiac event (MACE) is paramount to the preoperative discussion for any procedure: adequate preoperative arrangement of medical therapies can be prescripted and – when feasible – less invasive endovascular procedures can be alternatively proposed to patients recognized at high risk for MACE. Several risk-scoring systems have been derived for patients undergoing non-cardiac surgery, among these the most popular is the Cardiac Risk Index (CRI) proposed by Goldman et al. in 1977 [3] and its revised version (RCRI) published by Lee et al. in 1999 [4]. The RCRI was derived from a dataset of 4315 patients undergoing non-cardiac surgery; six independent predictors of cardiac complications were identified (high-risk surgical procedure, history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, insulin-dependent diabetes, preoperative serum creatinine > 2 mg/dl) and risk was calculated assigning 1 point to each predictor found. A lower predictive performance of RCRI in patients undergoing open surgery for abdominal aortic aneurysm (AAA) was already highlighted in the original article published by Lee et al. [2] and it was related to the very small subset of AAAs included in the derivation cohort. Despite this cautionary note by its authors themselves, RCRI is still considered by many clinicians to be the "gold standard" for preoperative clinical risk stratification also in vascular patients [2,5–7]. However, the

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predictive value of RCRI in vascular surgery patients has been questioned by numerous authors [8–11] and a significantly poorer performance of RCRI when applied to specific intervention groups has been observed, suggesting the need of a procedure-specific index for risk stratification [6]. Moreover, there is evidence from literature that some variables not included in the RCRI algorithm (*i.e.* age, chronic obstructive pulmonary disease - COPD, coronary artery disease, chronic renal failure) should be added in a new score system specific for vascular surgery patients. With particular reference to open repair of abdominal aortic aneurysms (AAAs), RCRI underestimated risk of cardiac complications up to three times the observed values [12] and proximal clampsite significantly affect the risk of MACE [6,7,13,14]. The aim of our study was to verify the adequacy of RCRI, to investigate further independent factors, currently not included in the RCRI model, and to evaluate the possible effects of proximal aneurysm extension on RCRI in a substantial series of consecutive patients who have undergone conventional repair of AAA at a tertiary care center.

2. Methods

The study reviewed the records of all patients undergoing elective open AAA repair between 1990 and 2012 at "A. Gemelli" University Hospital in Rome. Emergency interventions, infective aneurysms, anastomotic pseudoaneurysms, and endovascular procedures were all excluded from the study. The aneurysm extent was assigned based on preoperative imaging or intraoperative findings and each case was classified as infrarenal or pararenal according to the SVS recommended reporting standard [15] and assigned to a subgroup based on clampsite. The rationale for subgroups creation was to verify the possible role of clampsite on predictive value of RCRI and its individual covariates. At enrollment, the patients signed an informed consent form regarding the use of their personal data. The study was conducted in accordance with the Declaration of Helsinki.

2.1. Preoperative comorbidities

Ischemic cardiopathy (history of angina, or positive stress test result, or NSTEMI), past acute myocardial infarction (AMI) (history of AMI, positive ECG), past coronary interventions (CABG or PTCA), congestive failure or dilated cardiomyopathy (clinical history, echocardiography, cardiologist's evaluation), hypertension (clinical history, patients medications), insulin-dependent diabetes mellitus, smoke (active or past), cerebrovascular disease (TIA, minor or major stroke), past carotid procedures (CEA, CAS) COPD (staged according to the GOLD guidelines [16]), renal function (normal function if CCl > 70 ml/min, renal failure if CCl < 70 ml/min), preoperative dialysis (end-stage chronic renal failure), peripheral artery disease (PAD) (Lériche-Fontaine stage II or higher) Ankle-Brachial Index (ABI) considered either as a continuous or binary variable (*i.e.* normal = 1, abnormal < 1).

2.2. Operative variables

Surgical approach (midline laparotomy, extraperitoneal access, toracophrenolaparotomy), proximal clampsite (infrarenal *vs.* suprarenal, or inter-renal, or supramesenteric, or supraceliac), operative time, proximal clamp time, overall clamp time, estimated blood loss, transfused blood (homologous and from cell saver), i.v. crystalloids.

2.3. Perioperative complications

MACE (acute myocardial infarction or dysrhythmia or acute pulmonary edema diagnosed by ECG, positive troponin and CK-MB, and echocardiography report when found), postoperative renal failure (increased value of serum creatinine at least double than preoperative), postoperative dialysis (temporary or permanent), pulmonary complications (mechanical ventilation > 72 h, pneumonia at chest X-ray, or need for tracheostomy) neurologic complications, gastro-intestinal complications.

All interventions were performed by trained vascular surgery staff under direct supervision or with the participation of the chief of Vascular Surgery Unit (FS). MACE was considered as the primary end-point.

2.4. Statistical methods

As part of this analysis, in order to evaluate the weight of all covariates studied on the whole study group and on the subgroups 1 and 2, the tests of equality across strata were performed. This was done in order to explore whether or not to include the predictor covariate in the final model. Intergroup differences in complications were determined by logistic regression analysis and multivariable stepwise backward elimination. Odds ratio (OR) estimates and 95% CIs were obtained for risk variables in the model. The predictor covariates were included in the final model if the test had a p-value of ≤0.25 at the univariate correlation analysis with MACE, not only for the single components of the RCRI but also for the other variables that in literature were found to be significant (*e.g.* COPD, PAD, age) [17,18]. Descriptive data were summarized using frequencies and percentages and continuous variables were analyzed using means and standard deviations (mean ± standard deviation). The differences in continuous variables were evaluated through Student *t*-test or Mann-Whitney *U* Test, after assessing the normal distribution of the variables through Shapiro-Wilk test. Using the median and relative receiver operating characteristic (ROC) analysis as a cutoff value some covariates were considered as continuous or binary variables. Intergroup differences are considered statistically significant at the $p \leq 0.05$ level. Statistical analysis was performed using Stata IC 14 for Mac (Intercooled Stata 14 for MacIntosh, Stata Corporation College Station, TX, USA, 2015).

3. Results

3.1. Whole dataset

Complete records were obtained for 899 elective repairs of atherosclerotic AAA. Descriptive statistics on the incidence of comorbidities-risk factors, operative variables and postoperative complications are detailed in Tables I–III. The study population was composed of 846 men and 53 women, all white Caucasians with a mean age of 69.86 yrs. (SD ± 7.2; range 45–87). Male subjects were prevalent (16:1) and older than the female population. Coronary artery disease (ischemic cardiopathy or past AMI), hypertension, smoking and COPD were found at considerable rates. MACE occurred in 86 patients (9.57%). A significant correlation of MACE with RCRI ($p \leq 0.01$, *df* 1–897, F 11.73) resulted at univariate analysis. The multivariable stepwise-backward elimination (MVR-SBE) showed a significant correlation with MACE only for some factors that are already included in RCRI. These factors are: dilated cardiomyopathy ($p \leq 0.001$, 95% CI 1.67–4.50, OR 2.74), ischemic cardiopathy ($p \leq 0.01$, 95% CI 1.17–2.96, OR 1.87), and cerebrovascular disease ($p \leq 0.02$, 95% CI 1.13–3.61, OR 2.02). On the other hand, PAD - which is presently not included in RCRI - showed to be significantly related to MACE ($p \leq 0.03$, 95% CI 1.08–3.10, OR 1.83).

3.2. Subgroup 1 (infrarenal clamp, 690 cases)

In this subset, 61 patients (8.8%) presented with perioperative MACE. At univariate analysis, RCRI showed a good performance ($p \leq 0.01$, *df* 1–688, F 8.59). The univariate analysis of possible predictors of MACE in the subgroups can be seen in Table IV. MVR-SBE demonstrated a significant correlation of MACE with dilated cardiomyopathy ($p \leq 0.001$, 95% CI 1.65–5.24, OR 2.94), cerebrovascular disease ($p \leq 0.02$, 95% CI 1.52–5.68, OR 2.94) and surgical access ($p \leq 0.04$, 95% CI 0.31–0.96, OR 0.55).

Table I
Preoperative comorbidities.

Variable	Study group (899 pts.)	Subgroup 1 (690 pts.)	Subgroup 2 (209 pts.)
	Cases, n (%)	Cases, n (%)	Cases, n (%)
Ischemic cardiopathy	296 (32.9)	224 (32.5)	72 (34.4)
Past AMI	212 (23.6)	158 (23)	54 (25.8)
Congestive heart failure	14 (1.6)	10 (1.4)	4 (1.9)
Dilatative heart disease	168 (18.7)	133 (19.3)	35 (16.7)
Past CABG/PCI	104 (11.6)	74 (10.7)	30 (14.3)
Hypertensive cardiopathy	368 (41)	260 (37.7)	108 (51.7)
Hypertension	647 (72)	479 (69.4)	168 (80.4)
Cerebrovascular ischemia	111 (12.3)	80 (11.6)	31 (14.8)
Past CEA/CAS	33 (3.7)	21 (3)	12 (5.7)
COPD	719 (80)	543 (78.7)	176 (84.2)
Stage 0	180 (20)	147 (21.3)	33 (15.7)
Stage 1	510 (56.7)	391 (56.7)	119 (57)
Stage 2	158 (17.6)	115 (16.6)	43 (20.6)
Stage 3	51 (5.7)	37 (5.4)	14 (6.7)
Smoking	258 (28.7)	196 (28.4)	62 (29.7)
IDDM	8 (0.9)	5 (0.7)	3 (1.4)
PAD	151 (16.8)	109 (15.8)	42 (20.1)
Creatinine clearance < 70 ml/min	200 (22.2)	143 (20.7)	57 (27.3)
Chronic hemodialysis	5 (0.5)	2 (0.29)	3 (1.4)

AMI acute myocardial infarction; CABG coronary artery bypass graft; PCI percutaneous coronary procedure; CEA carotid endarterectomy; CAS carotid stenting; COPD chronic obstructive pulmonary disease; IDDM insulin-dependent diabetes mellitus; PAD peripheral arterial disease.

Table II
Operative details of patients undergoing open AAA repair.

	Study group (899 pts.)	Subgroup 1 (690 pts.)	Subgroup 2 (209 pts.)
	No. (%) or mean (SD), range	No. (%) or mean (SD), range	No. (%) or mean (SD), range
Surgical approach			
Transperitoneal	378 (42)	333 (48.3)	45 (21.5)
Extraperitoneal	518 (57.7)	357 (51.7)	161 (77)
Toracophrenolaparotomy	3 (0.3)	–	3 (1.4)
Proximal clampsite			
Infrarenal	690 (76,7)	690 (100)	–
Suprarenal	166 (18.4)	–	166 (79.4)
Supramesenteric	6 (0.7)	–	6 (2.9)
Supraceliac	37 (4.1)	–	37 (17.7)
Operative time (minutes)	296.9 (77), 115–675	286.7 (74), 115–550	331.6 (77), 200–675
Proximal clamp time (minutes)	–	–	36.7 (25), 13–268
Overall clamp time (minutes)	83.9 (35.9), 20–330	83.3 (34.3), 20–310	86.3 (41.4), 33–330
Intraoperative fluids			
Estimated blood loss (liters)	0.9 (0.71) 0.1–8	0.8 (0.68), 0.1–8	1.67 (0.8), 0.3–4
Cell saver blood (liters)	0.74 (0.64) 0.3–9.5	0.66 (0.46), 0.3–3.6	0.99 (0.98), 0.1–9.5
Blood transfusion (liters)	0.67 (0.49) 0.3–5.7	0.76 (0.33), 0.3–2.1	0.85 (0.75), 0.3–5.7
Crystalloids (liters)	5.9 (3.1) 0.5–18	5.9 (3.1), 0.5–18	5.7 (3.1), 1.1–17

SD = standard deviation.

3.3. Subgroup 2 (suprarenal clamp, 209 cases)

In this subset, perioperative MACE occurred in 25 patients (12%). The predictive performance of RCRI at univariate analysis was much poorer ($p = 0.11$, *df* 1–207, F 2.63). The univariate analysis of possible predictors of MACE in this subgroup is reported in Table IV. MVR-SBE demonstrated a significant correlation of MACE with previous AMI ($p \leq 0.01$, 95% CI 1.3–8, OR 3.23), congestive heart failure ($p \leq 0.03$, 95% CI 1.23–114.93, OR 11.89), and COPD ($p \leq 0.04$, 95% CI 0.79–51.13, OR 6.37).

4. Discussion

Our study is a retrospective investigation in 899 cases on the adequacy of RCRI in predicting MACE following elective open repair of AAAs and to verify the possible effect of proximal clampsite on RCRI performance. In a previous study [19], we observed a very poor correlation of RCRI with perioperative cardiac events in a selected group of pararenal AAAs. Therefore, based on the hypothesis that the clampsite might be an independent discriminant variable, we studied RCRI in a larger study group that included also infrarenal AAAs. The reliability of RCRI in vascular surgery patients has been questioned by several authors in the last few years [8–11] and most criticism was based on the small number of vascular patients included (21% of the subjects in the validation group [4]), and even less AAAs (110 cases [4]). A lower performance of RCRI has been observed for vascular interventions in general, suggesting the need of a dedicated risk stratification tool. Moreover, the cardiac risk in vascular patients resulted procedure-dependent and an up to threefold underscoring by RCRI after open repair of AAAs has been reported [12]. A specific risk index for vascular surgery patients should, therefore, consider the different invasiveness of the conventional open procedures [6,20] and should evaluate separately the endovascular interventions now available [2]. In recent literature some factors not included in the original RCRI algorithm, such as age [6,12,20–22] and previous coronary revascularization [7,22], resulted as relevant predictors of MACE in procedure-specific evaluation [6], however both resulted irrelevant in our analysis.

In our study, RCRI resulted to be a predictive tool only when applied to the whole dataset of AAAs (*i.e.* irrespective of the proximal clampsite) and to infrarenal aneurysms subgroup, but its correlation with MACE was poorer in pararenal aneurysms. This finding has already been reported [7] and also our results support the advisability of adding the clampsite to the model. The higher incidence of MACE in pararenal group can be explained by several reasons: while most of infrarenal AAAs, including patients at high risk for MACE, are now addressed to endovascular treatment, pararenal aneurysms still are mostly of surgical competence so this particular subset includes cases with higher risk for perioperative cardiac events. Moreover, preoperative cardiac risk assessment is often driven by patient's history but noninvasive tests for

Table III
Postoperative complications.

Variable	Study group (899 pts.)	Subgroup 1 (690 pts.)	Subgroup 2 (209 pts.)
	Cases, n (%)	Cases, n (%)	Cases, n (%)
MACE	86 (9.57)	61 (8.8)	25 (12)
Arrhythmia	50	37	12
AMI/NSTEMI	35	24	13
Pulmonary complication	81 (9)	52 (7.5)	29 (13.9)
pARF	52 (5.8)	26 (3.8)	26 (12.4)
Temporary dialysis	12 (1.3)	5 (0.7)	7 (3.3)
Permanent dialysis	1 (0.1)	–	1 (0.4)
Neurologic complications	9 (1)	6 (0.87)	3 (1.4)
GI complications	48 (5.3)	35 (5)	13 (6.2)

MACE major adverse cardiac event; AMI acute myocardial infarction; NSTEMI non-ST elevation myocardial infarction; pARF postoperative acute renal failure; GI gastrointestinal.

Table IV
Univariate analysis of comorbidities *vs.* MACE (dependent) in whole study group, subgroups 1 (infrarenal) and 2 (pararenal).

Variable	Study group (899 pts.)	Subgroup 1 (690 pts.)	Subgroup 2 (209 pts.)
	p	p	p
Access	0.31	0.02	0.13
CEA/CAS	0.64	0.01	0.72
Previous AMI	0.01	0.20	0.02
Previous CABG/PCI	0.51	0.13	0.34
Dilated cardiomyopathy	0.01	0.01	0.08
Ischemic cardiopathy	0.01	0.08	0.03
Congestive failure	0.01	0.21	0.01
Stroke/TIA	0.01	0.01	0.73
IDDM	0.66	0.50	0.09
COPD	0.08	0.31	0.10
COPD stage	0.06	0.28	0.12
PAD	0.01	0.05	0.09
ABI < 1	0.01	0.03	0.37

CEA carotid endarterectomy; CAS carotid stenting; AMI acute myocardial infarction; CABG coronary artery bypass graft; PCI percutaneous coronary procedure; TIA transient ischemic attack; IDDM insulin-dependent diabetes mellitus; COPD chronic obstructive pulmonary disease; PAD peripheral arterial disease; ABI Ankle-Brachial Index.

myocardial ischemia showed limited impact in high- or low-risk groups [4]. Finally, the hemodynamic consequences of suprarenal (and eventual visceral) clamping can be considered as the ultimate stress test [2] and unmask a silent coronary disease with dramatic consequences.

When single components of RCRI were evaluated in a multivariable model on the whole dataset, we found a statistical association with dilated cardiomyopathy, ischemic cardiopathy and cerebrovascular disease but not with diabetes nor chronic renal failure; furthermore, PAD – presently not included in the RCRI model – also resulted a relevant risk factor for MACE. These findings suggest, in AAA patients, a greater weight and different interaction of some variables compared with others, and the importance of PAD as risk covariate. The severity of concomitant PAD in vascular surgery patients increases independent prognostic information in the presence of RCRI risk factors [23], and in other studies the ABI predicted cardiac complications with accuracy similar to that of RCRI [24]. In a procedure-specific model [7], history of prior peripheral revascularization was associated with an increased risk of cardiac events after open AAA repair. In our study, the predictive value of ABI was not confirmed by multivariable analysis. A possible role of cerebrovascular disease in postoperative MACE could be due to the association between carotid disease and concomitant coronary disease [25]. The incidence of AAA in diabetic patients is low [26,27], and in our series only 8 patients were on insulin therapy; however, diabetes negatively affected postoperative mortality rates in several studies [28,29]. Although concomitant insulin-dependent diabetes is included in the RCRI, its correlation with MACE has been observed after some types of vascular interventions but not (also in our experience) after open aneurysm surgery [7]. Chronic renal failure (CRF) resulted irrelevant in our analysis, unlike other studies [7], however the criteria used by different authors to assess renal function are inhomogeneous and some reports included in the CRF group also end-stage/dialysis patients that – also in our opinion - should be considered separately [12,20,21,30–32].

The results of the multivariable stepwise backward elimination analysis of subgroups of patients based on clampsite are interesting because the predictors in subgroup 1 were totally different from those in subgroup 2, and of those for the whole dataset only two were found in the subgroups, both in subgroup 1. This could be due to different sizes of subgroup and consequent different incidence of single covariates, suggesting further studies such as a propensity score matching. In our opinion, however, the clampsite influences some variables to express differently and reciprocally interact. Multivariable analysis highlighted a primary importance of cardiopulmonary status (previous AMI, history of congestive failure, COPD) on postoperative MACE in pararenal AAAs. This would advise systematic and careful preoperative evaluation of coronary status and respiratory performance in this subset of patients. COPD resulted as a significant predictor of MACE in vascular surgery patients in various reports [6,7,12]. In our study, COPD was not significantly related to MACE at univariate analysis of the whole dataset ($p = 0.08$). However, COPD resulted a predictive factor at multivariable analysis in the pararenal aneurysms subgroup ($p \leq 0.04$) but not in the infrarenal AAA subgroup ($p \leq 0.60$). Smoking was found at similar rates between subgroups, and patients in subgroup 2 presented COPD at higher – although not significantly different – rates, so the effect of COPD on MACE occurrence in pararenal cases could be explained by the effects of proximal clamping, larger blood loss and higher rates of pulmonary complications.

The role of surgical access on postoperative complications after open AAA repair is unclear and current literature on this topic results to be incomplete and inconclusive [33] possibly due to the increasing shift towards endovascular treatments. Some authors found no evidence [34] about a possible correlation between access and postoperative MACE, while others [35] reported lower rates of MACE with extraperitoneal access. In present study, such relationship was found only in the infrarenal aneurysms subgroup. The prevalence of extraperitoneal access in our series repairs could only suggest a protective effect of this access against cardiac complications.

We recognize some limitations to our work: the study is retrospective, patients considered unfit-for-surgery due to unacceptable operative risk were not included, subgroups have different sizes, and more accurate preoperative cardiac evaluation (*i.e.* stress test or coronarography) was limited to cases with history of cardiac disease. Nevertheless, the analysis of our data suggests that in the specific evaluation of cardiac risk for open surgical repair, AAAs cannot be considered as a unique condition independently from proximal aneurysm extension because this involves different options for surgical strategy (*e.g.* open *vs.* endovascular), possible visceral ischemia and related effects, variations in the length of intervention, duration and position of proximal clamping and its consequences on cardiac performance, all of them possibly affecting the final outcome, included the risk for MACE.

5. Conclusions

In our study, the performance of RCRI in assessing the risk of MACE was good in patients undergoing open AAA repair in general and in infrarenal aneurysms, although some variables included in the score resulted more weighty than others, and PAD should be included in a possible revised model. Reliability of RCRI in predicting perioperative MACE resulted significantly lower for pararenal aneurysms. In this particular subset, MACE resulted mostly affected by preoperative cardiorespiratory status. Our results suggest that, in open AAA surgery, RCRI should be revised adding procedure-specific assessment that allows proper assignment of surgical strategy and perioperative care in the individual patient.

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Disclosures

None.

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