

# Routine open abdomen treatment compared with on-demand open abdomen or direct closure following open repair of ruptured abdominal aortic aneurysms: A propensity score–matched study

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## Abstract

**Objective:** To investigate whether a strategy of treatment with a primarily open abdomen improves outcome in terms of mortality and major complications in patients treated with open repair for a ruptured abdominal aortic aneurysm compared to a strategy of primary closure of the abdomen.

**Design:** Retrospective cohort study.

**Methods:** Patients treated with a primarily open abdomen at a centre where this strategy was routine in most ruptured abdominal aortic aneurysm patients were compared to a propensity score–matched control group of patients who had the abdomen closed at the end of the primary operation in a majority of the cases.

**Results:** In total, 79 patients treated with a primarily open abdomen after open repair for ruptured abdominal aortic aneurysm at Sahlgrenska University Hospital were compared to a propensity score–matched control group of 148 patients. The abdomen was closed at the end of the procedure in 108 (73%) of the control patients. There was no difference in 30-day mortality between patients treated with a primarily open abdomen at Sahlgrenska University Hospital and the controls, 21 (26.6%) versus 49 (33.1%),  $p=0.37$ . The adjusted odds ratio for mortality at 30 days was 0.66 (95% confidence interval: 0.35–1.25) in patients treated with a primarily open abdomen at Sahlgrenska University Hospital compared to the controls. No difference was observed between the groups regarding 90-day mortality, postoperative renal failure requiring renal replacement therapy, postoperative intestinal ischaemia necessitating bowel resection or postoperative bleeding requiring reoperation.

**Conclusions:** The study did not show any survival advantage or difference in major complications between patients treated with a primarily open abdomen after open repair for ruptured abdominal aortic aneurysm and propensity-matched controls where the abdomen was primarily closed in a majority of the cases.

## Keywords

Ruptured abdominal aortic aneurysm, abdominal aortic aneurysm, open repair, abdominal compartment syndrome, mortality, closure vacuum assisted

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## Introduction

Abdominal compartment syndrome (ACS) is a well-known complication in patients treated with open or endovascular repair for ruptured abdominal aortic aneurysms (rAAA), reported in 6.8%–29%.<sup>1–3</sup> This is not surprising given the risk factors of ACS: abdominal surgery, hemoperitoneum, acidosis, polytransfusion, hypothermia, shock or hypotension, coagulopathy and age, all common characteristics in patients with rAAA.<sup>4</sup>

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ACS is associated with a higher mortality and severe complications in patients treated for rAAA.<sup>5-7</sup> A strategy of leaving the abdomen primarily open in patients undergoing open repair or rAAA, instead of performing decompressive laparotomy on demand, eliminates the risk of ACS and may also alleviate the physiological burden induced by ACS development while undetected and between the time of detection until a decompressive laparotomy can be performed.

Previous reports from observational studies suggest that leaving the abdomen primarily open after rAAA repair may improve survival by eliminating the risk of ACS.<sup>8-11</sup> However, the literature on the subject is scarce and it remains unclear if a strategy of routinely leaving the abdomen open with delayed closure in patients treated for rAAA with open repair can improve outcome. Current guidelines recommend laparotomy if ACS develops after rAAA surgery.<sup>12</sup> Since open abdomen treatment requires resources for repeated redressings in the operating room and could also possibly carry an increased risk of infection and abdominal wall hernia, it is of importance that the possible benefits of primary open abdomen treatment are scientifically evaluated. The aim of this propensity-matched retrospective cohort study was to investigate whether leaving the abdomen open with delayed closure can improve outcome in terms of mortality and major complications in patients treated for rAAA with open repair, compared to closing the abdomen at the end of the primary operation. The study was made possible since the Department of Vascular Surgery at Sahlgrenska University Hospital (SUH) has adopted a strategy of routinely leaving the abdomen open after open repair for rAAA, in contrast to other Swedish hospitals, thus accumulating cases that can be compared to controls.

## Methods

### Study design

The study was designed as a retrospective cohort study comparing patients treated with open abdomen following open repair for rAAA at SUH and propensity score-matched controls treated at other Swedish vascular centres. The primary endpoint was 30-day mortality, while secondary endpoints were 90-day mortality, bowel ischaemia, need of postoperative renal replacement therapy, postoperative bleeding and requiring surgery.

### Setting and participants

Patients treated for rAAA at SUH from May 2008 to December 2014 were identified in the Swedish National Registry for Vascular Surgery (Swedvasc). Patients treated with endovascular aortic repair (EVAR) were excluded. Medical charts for the identified patients treated with open repair for rAAA were reviewed. Intraoperative deaths and

patients with mycotic, inflammatory or other non-standard abdominal aortic aneurysms were excluded, as were non-Swedish citizens lacking a Swedish personal identification number (due to lack of reliable registry-based mortality data). A total of 31 patients who had the abdomen primarily closed after open repair for rAAA at SUH in the time period were also excluded.

A control group with patients registered in the Swedvasc as treated with open repair for rAAA at other vascular centres in Sweden was constructed using propensity score matching. The propensity score matching was based on nearest neighbour with two controls per patient. The controls were matched with respect to age, gender, perioperative blood loss, preoperative unconsciousness, serum creatinine level and the preoperative comorbidities cardiac disease, hypertension, diabetes, respiratory disease and history of cerebrovascular event.

Comorbidities reported in Swedvasc were defined as follows – diabetes: diabetes with medical treatment; cardiac disease: history of coronary artery disease or congestive heart failure; hypertension: hypertension with medical treatment; pulmonary disease: chronic obstructive pulmonary disease or emphysema or other chronic pulmonary disease with symptoms and previous transitory ischemic attack (TIA)/stroke: previous transient ischaemic attack, ischaemic or haemorrhagic stroke. Preoperative renal failure was defined as a serum creatinine level above 150  $\mu\text{mol/L}$  in accordance with previous Swedvasc studies.<sup>13,14</sup>

Ethical approval was obtained from the regional ethical review boards at the University of Gothenburg (reference no. 553-14). Individual patient informed consent is not required for registry studies in Sweden.

### Surgical technique

Patients treated with a primarily open abdomen at SUH had a vacuum-assisted closure system (Abdominal dressing V.A.C.<sup>®</sup> Therapy<sup>™</sup>, KCI, San Antonio, TX, USA) applied and activated at 125 mmHg continuous negative pressure at the end of the primary procedure. The vacuum system and dressings were then changed in the operating theatre along with inspection of the abdominal viscera every second to third day. When the abdomen could not be closed without tension at one of the early redressings, a polypropylene mesh was sutured to the fascial edges and gradually tightened until the fascia and skin could be closed without tension. This technique using mesh-mediated fascial traction, described by Petersson et al.,<sup>15</sup> was used in 20 (25.3%) of the patients treated with a primarily open abdomen at SUH. In order not to prolong the primary operation, the mesh was not sutured to the fascial edges at the end of the first procedure, but at one of the early redressings. In the remaining patients treated with a primarily open abdomen, and surviving to have the abdomen closed, delayed fascial closure was possible without using mesh-mediated fascial traction.

## The Swedvasc registry

The Swedvasc has nationwide coverage since 1994. The registry is web-based and prospectively collects data on risk factors and details about the vascular procedure and individual patient outcomes including pre- and postoperative complications at 30 days. Data are filled in by the surgeon or appointed staff. The Swedvasc is interconnected with the Swedish Population registry, allowing for highly accurate data regarding mortality in all registered patients with a Swedish personal identification number. The validity for AAA procedures in the Swedvasc has been reported to be 93.1%–98.8% (external validity) and 96.2% (internal validity).<sup>16,17</sup>

## Statistical method

A pre-specified analysis plan was followed that defined the outcomes, known confounders and the strategy for the binary multivariable logistic regression model. Normally distributed continuous data were described with mean and standard deviation (SD), while categorical variables were described in absolute and relative frequencies. Student's t-test was used for two-group comparison of means. All tests were two-sided and the significance level was set at 0.05. Fischer's exact tests were used for comparison of categorical data. Binary logistic regression was used for analysis of potential confounders influencing the outcomes. A univariate analysis was performed followed by multivariable adjusted analyses. Age, sex and open abdomen were 'a priori' introduced in the multivariable logistic regression model, as were risk factors showing significant differences between groups in univariate analysis. Odds ratios were calculated with 95% confidence intervals (CIs). A power calculation was not performed since all patients treated with a primarily open abdomen after open repair for rAAA at SUH in the defined period were included in this retrospective study. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS 23.0; IBM Corp., Armonk, NY, USA).

## Results

In all, 227 patients treated for rAAA with open repair were included in the study. A flowchart of patient selection is shown in Figure 1. A total of 79 patients were treated with primarily open abdomen following open repair for rAAA at SUH; 10 patients in the propensity score-matched control group (n=158) had to be excluded because they were misclassified in the Swedvasc when reviewing the medical records (3 patients with non-ruptured AAA, 1 patient with an intramural aortic haematoma, 2 with isolated iliac aneurysms, 3 patients who did not survive the operation and 1 patient with aortoiliac occlusive disease). Of the 148 remaining controls and following review of the medical charts, 40 (27.0%) were found to have been treated with a primarily

open abdomen and 108 (73%) with a primarily closed abdomen. Control patients treated with a primarily open abdomen at other hospitals were treated surgically in a similar fashion as patients treated with primarily open abdomen at SUH, with a vacuum-assisted closure system and delayed fascial closure.

All 148 propensity score-matched control patients were included in the analyses. The control group thus included 108 patients (73%) with a primarily closed abdomen and 40 (27%) with a primarily open abdomen. Thus, in the analysis, patients treated with a primarily open abdomen at a centre where this strategy is routine in most rAAA patients are compared to a control group where this was not a clinical routine in a majority of the patients (73% of the patients had the abdomen primarily closed).

## Baseline data

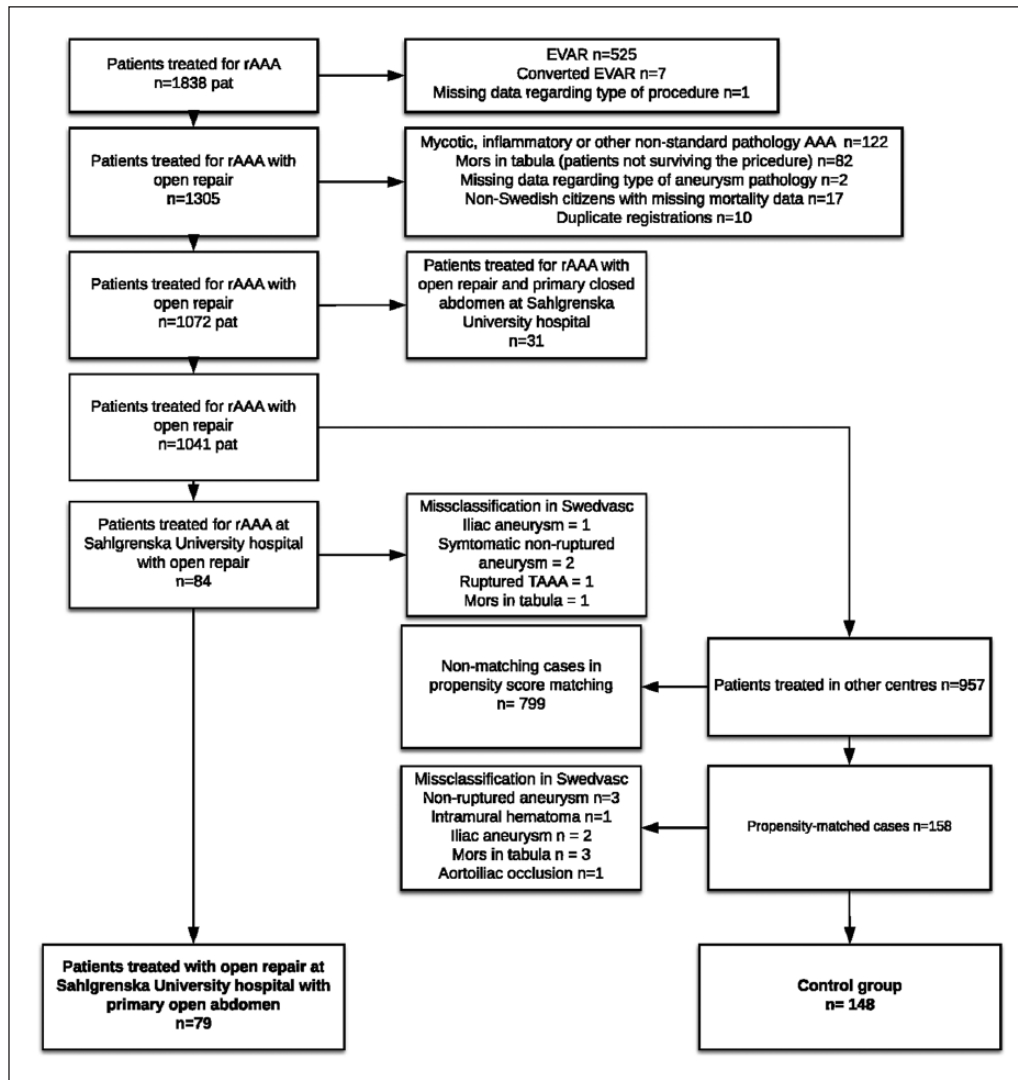
There were no significant differences at baseline regarding age, sex, comorbidities, aneurysm diameter, frequency of suprarenal clamping or perioperative bleeding between patients treated for rAAA with open repair and primarily open abdomen at SUH and the controls, suggesting that the propensity score match was successful. Data regarding some baseline data were missing: respiratory disease n=2, hypertension n=2, diabetes n=1, syncope n=4 and suprarenal clamping n=9. Baseline data are shown in Table 1.

## Mortality and complications

There was no difference in 30- or 90-day mortality between patients treated with open repair and primarily open abdomen for rAAA at SUH and the controls. The need of postoperative renal replacement therapy as well as the frequency of bowel ischaemia requiring bowel resection was similar in patients treated with open repair and primarily open abdomen for rAAA at SUH and the controls. No significant difference with regard to reintervention due to bleeding was observed between patients treated with open repair and primarily open abdomen for rAAA at SUH and controls. Mortality and major complications are shown in Table 2.

The crude odds ratio for mortality at 30 days was 0.73 (95% CI: 0.40–1.34) in patients treated with primarily open abdomen at SUH compared to the controls. When adjusted for confounders (age, sex, perioperative bleeding > 5000 mL and preoperative serum creatinine > 150 µmol/L), the odds ratio for mortality at 30 days was 0.66 (95% CI: 0.35–1.25, p=0.20) in patients treated for rAAA with open repair and primarily open abdomen at SUH compared to the controls. Results of the multivariable logistic regression analysis are displayed in Table 3.

Mortality in the subset of patients treated with open abdomen in the control group was 20/40 (50%). Patients in the control group treated with a primarily open abdomen had a perioperative bleeding >5000 mL in 36/40 (90%) compared



**Figure 1.** Flowchart of patient inclusion.

to 62/108 (57.4%) in patients with a primarily closed abdomen ( $p < 0.0001$ ).

The median duration of open abdomen treatment in patients surviving to have the abdomen closed was 4 days (range 1–28) in patients treated with a primarily open abdomen at SUH compared to 10 days (range 2–35) in the subset of control patients treated with a primarily open abdomen ( $p = 0.002$ ).

### *Aortic graft infection complications*

Four (5.1%) of the patients treated with a primarily open abdomen at SUH developed a graft infection, compared to three (2%) of the control patients (two with a primarily closed and 1 with a primarily open abdomen;  $p = 0.24$ ). Three of the four patients with graft infection following treatment with a primarily open abdomen at SUH died within 90 days. One was treated conservatively with antibiotics during 18 months

and then developed an aortoduodenal fistula and underwent a subacute resection of the graft and reconstruction of the aorta using a femoral vein as described by Nordanstig et al.,<sup>18</sup> after which the recovery was uneventful. Two of the three patients with graft infection in the control group died within 90 days and one was treated conservatively with chronic antibiotic therapy and died 32 months after the aortic repair for unknown reasons.

### *Overall rAAA treatment results at SUH*

For comparison, 226 patients were registered as treated for rAAA at SUH in the time period. When excluding non-standard rAAA and non-Swedish citizens with uncertain mortality data due to lack of a Swedish personal identity number, 203 patients were treated for a standard rAAA with EVAR or open repair at SUH during the study period. Of those, 119 (58.6%) were treated with open repair and 84 (41.4%) with EVAR.

**Table 1.** Clinical characteristics and risk factors in patients treated with a primarily open abdomen after open repair for a ruptured abdominal aortic aneurysm at Sahlgrenska University Hospital compared to propensity-matched controls treated with open repair for rAAA at other vascular centres where open abdomen treatment was not a clinical routine (the abdomen was closed in 73% of the control patients and primarily left open in 27%).

Clinical characteristics	Primary open abdomen at Sahlgrenska University Hospital, n (%)	Controls, n (%)	p
Female	19(24.1)	35(23.6)	1.00
Age <sup>a</sup>	73.1 ± 6.8	73.1 ± 8.3	0.99
Cardiac disease	32(40.5)	55(37.2)	0.67
Pulmonary disease	18(22.8)	29(19.9)	0.61
Previous TIA/stroke	14(17.7)	26(17.6)	1.00
Hypertension	54(69.2)	89(60.5)	0.24
Diabetes	10(12.7)	16(10.9)	0.67
Reported preoperative syncope	48(62.3)	85(58.2)	0.57
Perioperative bleeding >5000 mL	50(63.3)	98(66.2)	0.66
Preoperative creatinine >150 mmol/L	20(25.3)	25(16.9)	0.16
Aneurysm diameter (mm) <sup>b</sup>	78.6 ± 17.0	76.6 ± 15.3	0.39
Suprarenal clamping <sup>c</sup>	27(34.6)	34(24.3)	0.12

TIA: transitory ischemic attack.

Values in parenthesis are percentages.

<sup>a</sup>Mean age (years) ± SD.

<sup>b</sup>Mean aneurysm diameter (mm) ± SD.

<sup>c</sup>Aortic clamping above one or both renal arteries or suprarenal balloon occlusion.

**Table 2.** Mortality and major complications in patients treated with primary open abdomen at Sahlgrenska University Hospital compared to propensity-matched controls from other vascular centres in Sweden where open abdomen treatment was not a clinical routine (the abdomen was closed in 73% and primarily left open in 27% of the control patients).

	Patient treated for rAAA with primarily open abdomen at Sahlgrenska University Hospital (n = 79)	Controls (n = 148)	p
30-day Mortality	(26.6%) 21	(33.1%) 49	0.37
90-day Mortality	(34.2%) 27	(36.7%) 54	0.77
Postoperative renal failure with need of renal replacement therapy	(31.6%) 25	(26.4%) 39	0.44
Postoperative intestinal ischaemia requiring bowel resection	(8.9%) 7	(14.2%) 21	0.29
Reoperation due to bleeding	(6.3%) 5	(14.9%) 22	0.08

rAAA: ruptured abdominal aortic aneurysm.

Values are n (%).

Nine of the patients operated on with an intention of open repair did not survive the procedure, leaving 110 patients treated with open repair surviving the procedure.

The 30-day mortality in patients treated with EVAR was 20.2% (17/84) compared to 27.7% (33/119) in patients treated with open repair (including patients with primarily open abdomen, primarily closed abdomen and non-survivors of the surgical procedure). The 30-day mortality in patients treated with primarily open abdomen after open repair for rAAA at SUH was 26.6% (21/79) compared to 9.7% (3/31) in patients treated with a primarily closed abdomen after open repair (9 non-survivors of the surgical procedure excluded). The patients with a primarily closed abdomen represented a subset of stable patients with limited/contained haematomas and less perioperative bleeding.

## Discussion

The aim of this study was to investigate whether leaving the abdomen primarily open with vacuum-assisted delayed wound closure in patients treated with open repair for rAAA can improve outcome compared to patients where the abdomen is primarily closed. Patients treated with a primarily open abdomen at SUH were compared to propensity score-matched controls treated at other vascular centres, where we had expected that the abdomen had been closed primarily in most cases. However, after review of the medical charts, it was revealed that 27% of the propensity-matched controls had been treated with a primarily open abdomen and 73% with a primarily closed abdomen. The aim to compare treatment with a primarily open abdomen versus a primarily

**Table 3.** Multivariable logistic regression analysis of 30-day mortality in patients treated with primary open abdomen at Sahlgrenska University Hospital compared to propensity-matched controls from other vascular centres in Sweden where open abdomen treatment was not a clinical routine (the abdomen was closed in 73% and primarily left open in 27% of the control patients).

	OR crude	CI 95%	OR adjusted <sup>a</sup>	CI 95%
	Mortality at 30 days		Mortality at 30 days	
Primary open abdomen at Sahlgrenska University Hospital (missing=0)	0.73	0.40–1.34	<b>0.66</b>	<b>0.35–1.25</b>
Age(per year; missing=0)	1.04	1.00–1.08	1.04	1.00–1.25
Females (missing=0)	1.30	0.68–2.48	1.37	0.70–2.71
Perioperative bleeding >5000 mL (missing=0)	2.04	1.08–3.83	2.39	1.22–4.68
Creatinine >150 µmol/L (missing=0)	2.67	1.37–5.22	3.28	1.62–6.66
Respiratory disease (missing=2)	1.50	0.77–2.94		
Previous heart condition (missing=0)	1.32	0.74–2.34		
Previous TIA/stroke (missing=0)	0.95	0.45–2.01		
Hypertension (missing=2)	1.26	0.69–2.28		
Diabetes (missing=1)	0.80	0.32–2.00		
Syncope (missing=4)	0.95	0.53–1.70		
Treated at centre where >30% of rAAA patients were treated with EVAR during the time period (missing=0)	1.09	0.62–1.91		
Suprarenal aortic clamping <sup>b</sup> (missing=9)	0.95	0.50–1.82		

OR: odds ratio; CI: confidence interval; EVAR: endovascular aortic repair; TIA: transient ischaemic attack.

<sup>a</sup>Multivariable logistic regression analysis adjusted for primarily open abdomen treatment at Sahlgrenska University Hospital, age, sex, perioperative bleeding and preoperative serum creatinine >150 µmol/L.

<sup>b</sup>Clamping above one or both renal arteries or suprarenal balloon occlusion. Bold values signifies the main result in the study.

closed abdomen after open repair for rAAA could thus not be completely fulfilled. Thus, the comparison in this study was actually performed between patients treated with a primarily open abdomen at a centre where this strategy was a clinical routine in most rAAA patients treated with open repair and a propensity-matched control group where this strategy was not a clinical routine (73% of the patients were treated with a primarily closed abdomen). In this setting, the study could neither demonstrate any survival advantage nor any difference in the major postoperative complication rate (renal failure, intestinal ischaemia or postoperative bleeding) among patients treated with primarily open abdomen at the SUH, compared to propensity score-matched controls treated at other vascular centres in Sweden, where the abdomen was primarily closed in a majority of the cases.

An observation in the study was a difference in the rate of aortic graft infection with 5.1% graft infections in patients treated with a primarily open abdomen at SUH compared to 2% in the controls. No conclusions can be made from this non-significant ( $p=0.24$ ) finding, but it cannot be ruled out that the lack of significance is a result of a type II error and thus might be an area of future study. The incidence of abdominal wall hernia after open abdomen treatment was not investigated in this study and requires further study.

EVAR for rAAA was available at SUH in the time period and was used in a majority of patients with suitable anatomy. Thus, the patients treated with open repair in this study were a subset of patients with short or no proximal neck and/or

inadequate distal landing zones and/or access vessels. Stable patients with contained haematomas who underwent open repair had the abdomen primarily closed and were not included in the study. Thus, the studied patients at the SUH treated with open repair and primarily open abdomen is a selection of patients with unfavourable aneurysm anatomy, large perioperative blood loss and a marked circulatory instability. Propensity score matching was used to create a control group resembling this selection. Further robustness in the analysis was added with an extensive multivariable logistic regression model allowing for adjustment for known confounders. Despite our efforts to create comparable groups and account for known confounders, we did not observe any survival benefit at 30 days in patients treated with a primarily open abdomen after open repair for rAAA compared to patients with a primarily closed abdomen, after adjustment for confounders in the multivariable logistic regression model.

Scientific data comparing primarily open abdomen with delayed closure and primarily closed abdomen after open repair for rAAA are scarce. In a recent report from Acosta et al.,<sup>11</sup> a lower mortality as well as a lower incidence of intestinal ischaemia was observed in a cohort of patients treated with open, hybrid or endovascular technique and a primarily open abdomen for a variety of aortic diseases (ruptured and non-ruptured AAA's, thoraco-abdominal aneurysms and aortic dissection) compared to patients who had the abdomen opened at a secondary operation (mainly but

not exclusively for ACS). An earlier report suggesting a mortality benefit with a primarily open abdomen assessed a subset of rAAA patients where it was difficult to close the abdomen at the time for the primary operation and compared this subset of patients with patients in need of a second operation with delayed abdominal closure due to intraabdominal hypertension.<sup>8</sup> In a limited sample reported by Oelschlager et al.,<sup>9</sup> no significant difference in mortality was observed between patients with a primarily open versus closed abdomen following open repair for rAAA. Given the limited existing data on the subject and the absence of evidence supporting prophylactic treatment with open abdomen, this is not recommended in the current guidelines by the World Society of the Abdominal Compartment Syndrome (WSACS) or in a relatively recent review published by Björck and colleagues.<sup>4,19</sup>

This study focused on patients where treatment with a primarily open abdomen after open repair for rAAA was an integral part of the clinical routine in most patients and compared them with a propensity-matched control group. Differences both in patient characteristics and study designs between this study and previous reports make any comparisons difficult.

A strength of this study is the fairly large cohort of patients treated with a primarily open abdomen after open repair for rAAA from a centre where this regimen was routinely applied in most patients. The sample size allows for adjustment for multiple confounding factors in a multivariable logistic regression model in a cohort of rAAA patients, which previous studies have been unable to do, due to sample sizes not allowing for multivariable analysis. Another strength is that the control group was created with propensity scoring, resulting in a more comparable control group.

An important limitation is the fact that as many as 27% of the control patients were treated with a primarily open abdomen, that is, the same treatment the study aimed at evaluating. This was unforeseen when the propensity scored control group was created and was observed after review of the medical charts from the other vascular centres. We had expected that the clinical routine of leaving the abdomen open would be substantially less common. If treatment with a primarily open abdomen after open repair for rAAA would be associated with a lower mortality and less complications, the fact that 27% of the control patients were treated in this way may result in a type 2 (beta) error. A further limitation of this study is the observational design with an inherent risk of bias. There is a possibility of misclassification due to coding errors, but if present, it is probably non-differential. Finally, there might also be residual confounding, unaccounted for in the propensity score matching and uncontrolled for in the multivariable logistic regression model.

Ideally, the question of whether leaving the abdomen open with delayed closure can improve outcome in rAAA patients treated with open repair should be answered with a randomized controlled trial. However, such a study would be

very difficult to perform, for several different reasons. In an era with an increasing use of EVAR in rAAA patients, it would be demanding to include a large enough sample of rAAA patients treated with open repair to have sufficient power. Furthermore, surgeons may be reluctant to randomize patients with large haematomas and swelling, where abdominal closure cannot be made without tension. In the context of these challenges associated with a randomized controlled study, we believe that this propensity-matched retrospective study is a valuable contribution on the subject.

In conclusion, routine open abdomen treatment with delayed closure after open rAAA repair was neither associated with a lower short-term mortality nor less major postoperative complications compared to a propensity score-matched control group where a majority of the patients had the abdomen closed at the end of the primary operation. Therefore, this study does not lend support to routine use of open abdomen treatment after surgical rAAA repair.

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### Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Ethical approval

Ethical approval for this study was obtained from the Regional Ethical Review Board of Gothenburg (Approval No. 553-14).

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### Informed consent

Informed consent was not sought for this study because individual patient informed consent is not required for registry studies in Sweden.

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