Meta-Analysis of the Sources of Bleeding after Adult Cardiac Surgery

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Prof. J.A. Kaplan
Editor-in-Chief,
Journal of Cardiothoracic and Vascular Anesthesia

Oulu October 23, 2017

Dear Editor,

we would grateful if you would consider the attached article entitled: "**Meta-analysis of the Sources of Bleeding after Adult Cardiac Surgery**" for possible publication in *The Journal of Cardiothoracic and Vascular Anesthesia.*

The article is original and data unpublished. The authors state that they do not have any conflicts of interest related with this study.

Best regards

Prof. Fausto Biancari, on behalf of the other co-authors.

*Title Page (complete with Author details)

Meta-analysis of the Sources of Bleeding after Adult Cardiac Surgery

Short title: Surgical bleeding after cardiac surgery

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Abstract

Objective: This study was planned to pool existing data on the proportion and prognostic impact of sources of bleeding on early outcome in patients requiring re-exploration after adult cardiac surgery.

Design: Systematic review of the literature and meta-analysis.

Setting: Multistitutional study.

Measurements and main results: A literature review was performed to identify any study being published since 1990 evaluating the outcome of patients who underwent re-exploration for excessive bleeding or tamponade after adult cardiac surgery.

Eighteen studies including 2455 patients fulfilled the selection criteria; their pooled incidence of re-exploration was 4.6% (95%CI 3.9-5.2%, I^2 92%). Pooled in-hospital/30-day mortality in patients who underwent re-exploration for bleeding was 11.6% (95%CI 7.9-15.4%, I^2 86%). Surgical sites of bleeding were observed in 65.1% of cases (95%CI 57.2-73.1%, I^2 95%); cardiac site bleeding was observed in 42.9% (95%CI 31.7-54.2%, I^2 91%) and mediastinal/sternum site bleeding in 28.5% (95%CI 17.9-39.2%, I^2 92%). The sternum was the site of bleeding in 18.0% of cases, anastomoses in 10.0%, the body of the grafts in 20.6%, the bed of the internal mammary artery in 13.0% and cannulation sites in 4.1%. Meta-regression showed that re-exploration for bleeding was associated with lower in-hospital/30-day mortality compared to diffuse bleeding (p=0.003). A modified surgical hemostasis checklist to reduce re-exploration for bleeding is proposed.

Conclusions: Surgical site bleeding is observed in two-thirds of patients undergoing re-exploration after adult cardiac surgery. Meticulous surgical technique and systematic intraoperative checking of potential surgical sites of bleeding is expected to reduce the risk of such a severe complication.

Abstract word count: 250 words

Keywords: Coronary artery bypass; cardiac surgery; bleeding; resternotomy, re-exploration, surgical source.

Introduction

Excessive bleeding requiring re-exploration is associated with poor outcome,[1] and significant incremental costs.[2] In general, re-exploration is part of the spectrum of severe and massive perioperative blood loss requiring large amount of blood transfusion.[3] A significant variability of severe blood loss and re-exploration for bleeding has been observed at institutional[4] and individual surgeon's level.[5,6] These observations suggest that perioperative bleeding may be related to differences in surgical skills and in the management of perioperative bleeding. Since a number of reoperations are secondary to technical factors,[7] there is a need to estimate the proportion and types of surgical sites of bleeding as a means to reduce such a severe complication. Furthermore, knowledge of the nature of perioperative bleeding may be of importance in studies evaluating the efficacy and harms of antithrombotic drugs. The aim of the present meta-analysis is to investigate the sources of bleeding after adult cardiac surgery and their impact on early outcome.

Methods

The present systematic review and meta-analysis is registered in the International prospective register of systematic reviews PROSPERO with the reference code [redacted].

Search Strategy

A literature review was performed through PubMed, Scopus, ScienceDirect and Google Scholar on August 2017, to identify any study being published since 1990 evaluating the outcome of patients who underwent re-exploration for excessive bleeding or tamponade after adult cardiac surgery. The retrieval terms were "re-exploration", "resternotomy", "reoperation", "bleeding" combined with "cardiac surgery" OR "coronary artery bypass". Once the abstracts of potentially relevant studies were scrutinized, each study was independently evaluated by three investigators ([redacted]) for inclusion or exclusion from this analysis. Reference lists of retrieved articles were searched as well. The guidelines for Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) were applied.[8]

Treatment Definition and Inclusion/Exclusion Criteria

For the purpose of this analysis, eligible studies were those reporting on the sources of bleeding in patients who underwent re-exploration for excessive bleeding or tamponade after adult cardiac surgery. Studies that met the Population, Interventions, Comparison and Outcomes (PICO) criteria (Tab. 1) were included in the present meta-analysis.

To enter this analysis, studies had to fulfil all these inclusion criteria: (1) provide data on patients who underwent re-exploration for excessive bleeding or tamponade after any adult cardiac surgery procedure; (2) include patients aged 18 years or older; (3) report data on the type of bleeding, i.e. diffuse or surgical bleeding; (4) be a prospective or retrospective observational investigation; (5) be published in English language as a full article; (6) include at least 10 patients who underwent reoperation; and (7) be published since 1990.

Articles were ineligible for study inclusion if they (1) reported ambiguous or inaccurate data (discrepancies between data reported in the text and tables); (2) did not provide any information on the type of bleeding; (3) data was reported only in abstracts; (4) reported data on other than cardiac surgery interventions; (5) and/or included pediatric patients (6).

Data Extraction

Data was independently retrieved by three investigators ([redacted]). Disagreement on collected data was settled by consensus between these investigators. No attempt was made to obtain specific or missing data from the authors. The following data were extracted and collected on a dedicated datasheet: first author, year of publication, study period, overall number of adult cardiac surgery procedures performed during the study period, number of re-explorations for bleeding and tamponade type of intervention, patients' age, gender, major comorbidities, sources of bleeding, in-hospital/30-day mortality and stroke. Types of bleeding were classified as surgical sources of bleeding or diffuse bleeding/undetermined origin. Surgical sources of bleeding were further classified as cardiac sources when bleeding was from cardiac structures and/or bypass grafts.

Sources of bleeding were defined as mediastinal when bleeding originated from vessels of the pericardium or external to pericardium, i.e. vessels of the sternum, neck and diaphragm. The quality of the included studies was assessed by two investigators ([redacted]) using the National Heart, Lung, and Blood Institute (NHLBI) criteria for study quality assessment of case-control series (https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/case_series; accessed on January 17, 2017).

Outcomes

The primary outcome of this study was the nature of bleeding, i.e. diffuse bleeding or any bleeding originating from one or more surgical sites. Patients having concomitant surgical site bleeding and diffuse bleeding, were categorized as having surgical bleeding. The secondary outcome was in-hospital/30-day postoperative mortality.

Statistical Analysis

Statistical analysis was performed using the Open Meta-Analyst software (Brown University, Providence, RI, USA; *http://www.cebm.brown.edu/openmeta/*). To control for the anticipated heterogeneity among observational studies, absolute values and means were pooled using random effects models. Heterogeneity across studies was evaluated using the I^2 test. The results are expressed as untransformed proportions and means with their 95% confidence intervals (CI). Leave-one-out sensitivity analysis was performed to confirm consistency of the overall analysis. The impact of risk factors on in-hospital/30-day mortality was evaluated by meta-regression analysis. A $p<0.05$ was considered statistically significant.

Results

Eighteen studies including 2455 patients [5,9-25] fulfilled the pre-specified selection criteria and were included in this analysis (Fig. 1). Characteristics and main data reported in these studies are summarized in Table 2. Three studies [5,10,21] were considered of good quality according to the NHBLI criteria and reported in details all surgical sites of bleeding.

The pooled incidence of re-exploration was 4.6% (95%CI 3.9-5.2%, I^2 92%, 17 studies, 51497 patients) (Fig. 2). Pooled in-hospital/30-day mortality in patients who underwent re-exploration for bleeding was 11.6% (95%CI 7.9-15.4%, I^2 86%, 15 studies, 1763 patients).

Surgical sites of bleeding were observed in 65.1% of cases (95%CI 57.2-73.1%, I^2 95%, 18 studies, 2455 patients) (Fig. 3). Cardiac site bleeding was observed in 42.9% of cases (95%CI 31.7-54.2%, I^2 91%, 9 studies, 788 patients) and mediastinal/sternum site bleeding in 28.5% of cases (95%CI 17.9-39.2%, I^2 92%, 9 studies, 882 patients). In particular, the sternum was the site of bleeding in 18.0% of cases (95%CI 12.6-23.5%, I^2 86%, 9 studies, 1509 patients), anastomosis site in 10.0% of cases (95%CI 5.3-14.6%, I^2 91%, 10 studies, 1603 patients), the body of the grafts in 20.6% of cases (95%CI 12.9-28.2%, I^2 79%, 8 studies, 976 patients), the bed of the internal mammary artery in 13.0% of cases (95%CI 8.1-17.9%, I^2 74%, 6 studies, 887 patients) and cannulation site in 4.1% of cases (95%CI 1.8-6.4%, I^2 79%, 10 studies, 1130 patients).

Meta-regression showed that the rate of re-exploration for bleeding was not associated with increased early mortality (p=0.146). Higher prevalence of isolated coronary artery bypass grafting was associated with lower risk of in-hospital/30-day death (p=0.007). Furthermore, meta-regression showed that re-exploration for surgical site bleeding was associated with lower in-hospital/30-day mortality (p=0.003) (Fig. 4). This finding was confirmed also when two outliers with early mortality >20% were excluded from the analysis (p=0.003).

Discussion

There is a burden of evidence on the negative prognostic impact of re-exploration for excessive bleeding on the outcome after adult cardiac surgery,[1,9] but less clear are the factors underlying this severe complication. Preoperative antithrombotic drugs and certain patient characteristics are thought to be the major determinants of severe postoperative bleeding.[26] Identification of patients with bleeding diathesis is a cornerstone of point-of-care management of perioperative bleeding, but there is a lack of evidence of its efficacy in reducing the risk of re-exploration for excessive bleeding.[27] Indeed, preoperative thromboelastometry may fail to predict severe bleeding due to surgical site bleeding.[25] The results of this pooled analysis suggest that severe bleeding indicating reoperation for surgical hemostasis is related to surgical site bleeding in two-thirds of patients undergoing adult cardiac surgery. Several studies included in this analysis indicated that these bleeding sites are more frequently from cardiac structures/vascular grafts than mediastinal/sternal vessels. Sites of insertion of temporary pace-maker wires and of chest tubes may account for less frequent causes of excessive bleeding.[5,10,28] These findings suggest that most of severe bleeding events can be prevented by a meticulous surgical technique and systematic checking of potential sites of bleeding. After having observed that severe bleeding originated mostly from surgical sites,[16] Loor et al.[7] introduced a checklist for a systematic intraoperative evaluation of potential surgical sources of bleeding. These authors demonstrated that the use of this hemostasis checklist, which guides surgeons through a systematic checking of potential bleeding sites (cannulation sites, anastomoses, aortotomies, atriotomies, ventriculotomies, thymus, pericardium, mammary artery bed and sternum), significantly reduced the risk of re-exploration for bleeding. These authors did not assess whether this approach might have reduced also the chest drain output and the amount of blood transfusion. However, re-exploration for excessive bleeding is part of a spectrum of severe and massive bleeding occurring immediately after surgery or later on as a manifestation of retained blood syndrome.[29] Indeed, the individual surgeon's impact on the risk of re-exploration seems to correlate with the amount of postoperative blood loss.[5] Therefore, we may expect that meticulous surgical hemostasis may contribute also to an overall reduction of perioperative blood loss.

These observations indicate that a surgical hemostasis checklist as proposed originally by Loor and colleagues[7] may be a valid means to reduce severe postoperative bleeding. Since available studies on this topic brought knowledge on further potential sites of bleeding, we modified Loor and colleagues' checklist by adding body of vascular grafts, epicardial pace-maker insertion sites, drainage insertion sites and neck vessels as surgical sites requiring systematic checking (Tab. 3).

The lack of individual patient data does not allow an accurate analysis of factors associated with increased risk of operative mortality in patients undergoing re-exploration for bleeding. However, meta-regression analysis of this aggregate data suggests that increased prevalence of isolated coronary artery bypass grafting was associated with lower risk of in-hospital/30-day mortality (p=0.007). This finding can be explained by the more complex nature of procedures other than isolated coronary surgery. Meta-regression showed also that re-exploration for surgical site bleeding was associated with lower in-hospital/30-day mortality compared to diffuse or indeterminate bleeding (p=0.003). This observation suggests that identification of a surgical source of bleeding is associated with prompt surgical hemostasis and a more favorable outcome. On the contrary, surgical and pharmacological treatment for diffuse bleeding is far more complex and may be associated with residual blood loss and large amount of blood transfusion. Furthermore, coagulopathy resulting in diffuse bleeding is often related to the use of potent antithrombotic drugs in acute coronary syndrome and this may account for the higher mortality risk of these patients.[30]

This pooled analysis has a number of limitations. First, most of the retrieved studies were of retrospective nature and surgical site bleeding was not the primary outcome of these analyses. Second, surgical site bleeding might occur in presence of diffuse bleeding, but these cases were not clearly reported in the original studies. For the sake of simplicity and because of limited specific data, these patients were categorized as having surgical bleeding. However, it is unclear whether surgical site bleeding associated with diffuse bleeding carries an even worse prognosis than diffuse bleeding alone. Third, the available data does not clarify whether a number of surgical sites of bleeding were due to perioperative coagulopathy, to failure of surgical technique or a combination of both of these factors. The latter may significantly bias the real nature of perioperative bleeding. Finally, the available studies did not evaluate the prognostic impact of surgical site bleeding versus diffuse bleeding on early postoperative outcome. Therefore, the present finding of lower operative mortality in patients with surgical site bleeding compared to those with diffuse bleeding should be viewed within the limits of any regression analysis of aggregate data.

Conclusions

Surgical site bleeding is observed in two-thirds of patients undergoing re-exploration after adult cardiac surgery. Meticulous surgical technique and systematic intraoperative checking of potential surgical sites of bleeding is expected to reduce the risk of such a severe complication.

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Legends to figures

Figure 1. Literature search flowchart.

Figure 2. Forest plot of re-exploration for excessive bleeding after adult cardiac surgery.

Figure 3. Forest plot of surgical site of bleeding after adult cardiac surgery.

Figure 4. Meta-regression plot on the impact of rate of surgical site of bleeding and early mortality.

Table 1. Participants, intervention, comparison and outcomes (PICO) of the present meta-analysis.

PICO	Description
Population	Patients who underwent adult cardiac surgery
Intervention	Re-exploration for excessive bleeding or tamponade after adult cardiac surgery
Comparison	None
Outcomes	Sources of bleeding, in-hospital/30-day mortality, stroke

Table 2

Table 2. Characteristics and data of the included studies.

Author	Year of publication	Type of study	NHLBI quality rating	No. of patients	Re-exploration rate (%)	Isolated CABG (%)	Urgent / emergency procedure (%)	Surgical site bleeding (%)	In-hospital / 30-day mortality (%)
Sethi	1990	P	Fair	36	4.7	100	0.0	38.9	-
Unsworth-White	1995	R	Fair	85	3.8	42.4	-	70.6	22.4
Sellman	1997	R	Fair	378	4.4	73.8	-	85.7	5.8
Hall	2001	R	Good	82	3.6	-	-	67.1	9.8
Karthik	2004	R	Fair	89	3.1	100	29.2	82.0	4.5
Chu	2004	P	Fair	11	3.5	100	100	0.0	-
Choong	2007	P	Fair	191	5.9	55.0	36.1	78.0	11.0
Gwozdziewicz	2008	R	Fair	98	2.3	63.3	15.3	54.1	11.2
Okonta	2011	R	Fair	342	3.4	74.3	-	61.1	-
Vivacqua	2011	R	Fair	285	-	-	80.7	79.6	-
Biancari	2012	R	Good	113	5.6	100	60.2	73.5	6.2
Čanádyová	2012	R	Fair	152	3.4	38.8	42.8	55.3	37.5
Kristensen	2012	R	Fair	101	7.0	24.8	14.9	56.4	15.8
Ozolina	2012	P	Fair	11	12.5	-	-	81.8	0.0
Ghavidel	2015	P	Fair	42	10.5	100	4.8	76.2	4.8
Fröjd	2016	R	Fair	320	5.9	36.9	23.4	67.2	7.5
Kim	2016	R	Fair	101	3.7	32.7	29.7	67.3	16.8
Lopes	2016	P	Good	18	5.6	33.3	0.0	83.3	-

R: retrospective study; P: prospective study; CABG: coronary artery bypass grafting.

Table 3. Modified checklist to prevent surgical site bleeding.

Anatomical sites
Cardiac sites
□ Cannulation sites
□ Vascular anastomoses
□ Body of vascular grafts
□ Aortotomies, atriotomies, ventriculotomies
□ Epicardial pace-maker wires insertion site
Mediastinum
□ Thymus
□ Pericardium
□ Neck
□ Drain insertion sites
Chest wall
□ Internal mammary artery bed
□ Sternum

Figure 1
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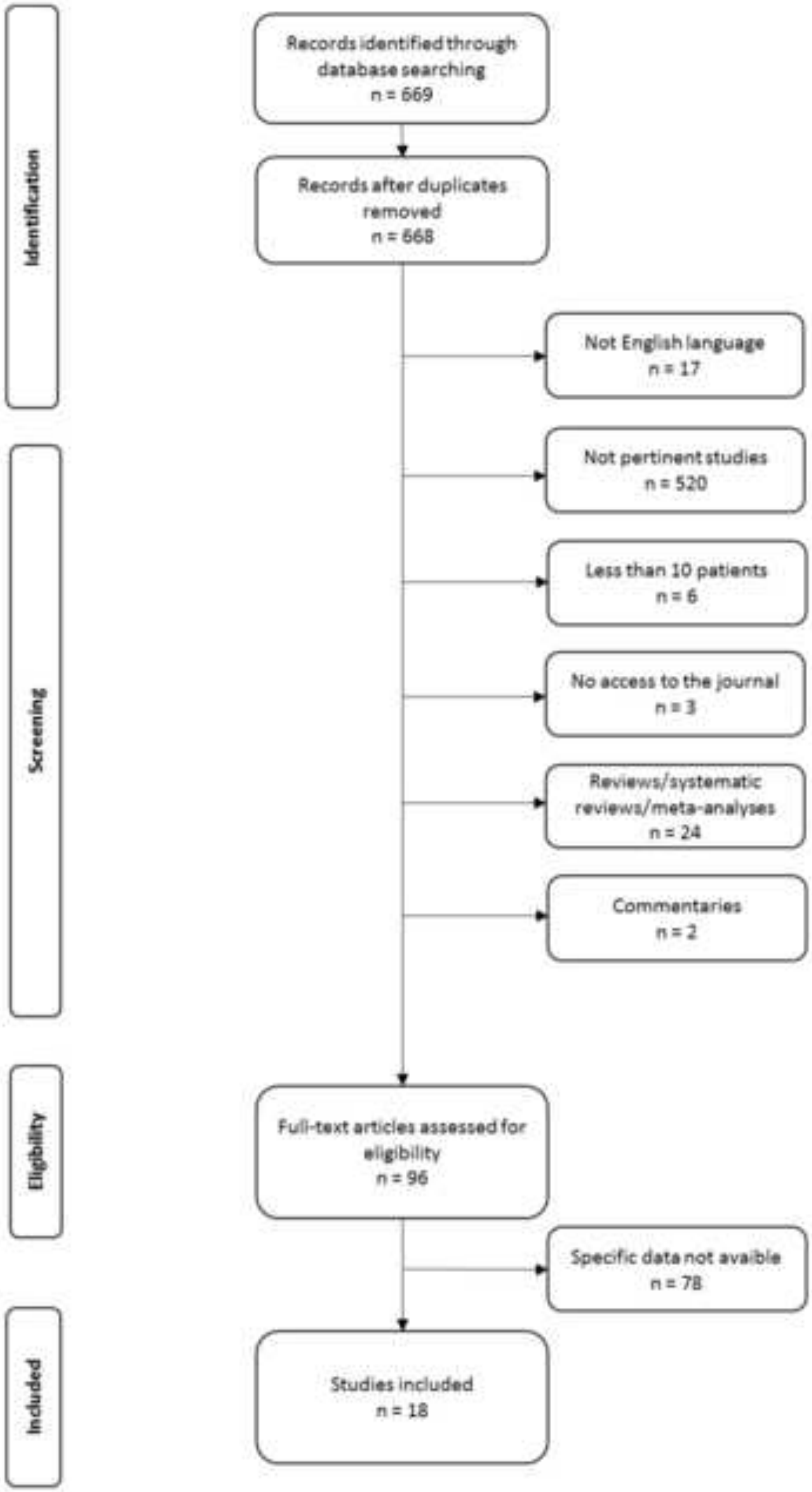

Figure 2

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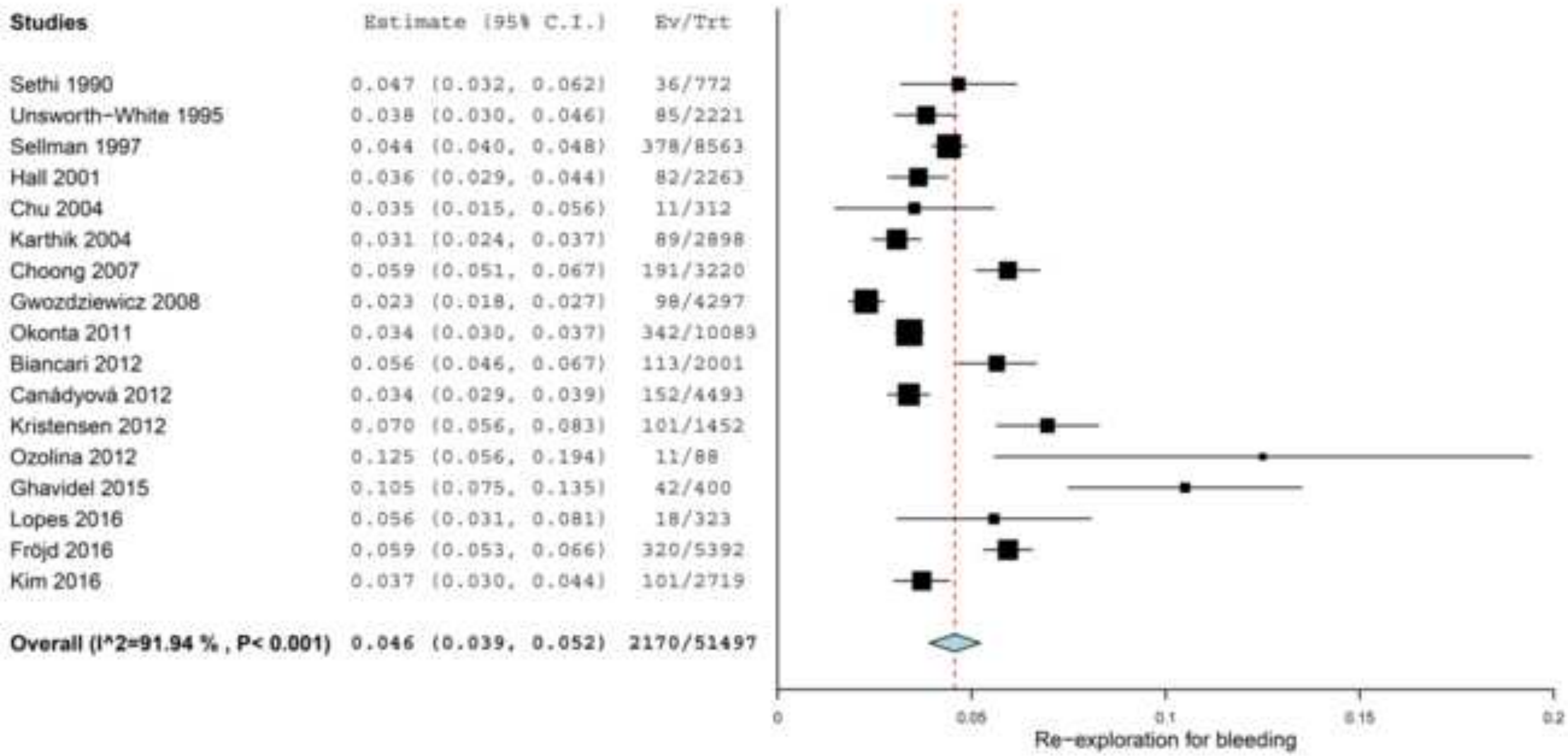

Figure 3

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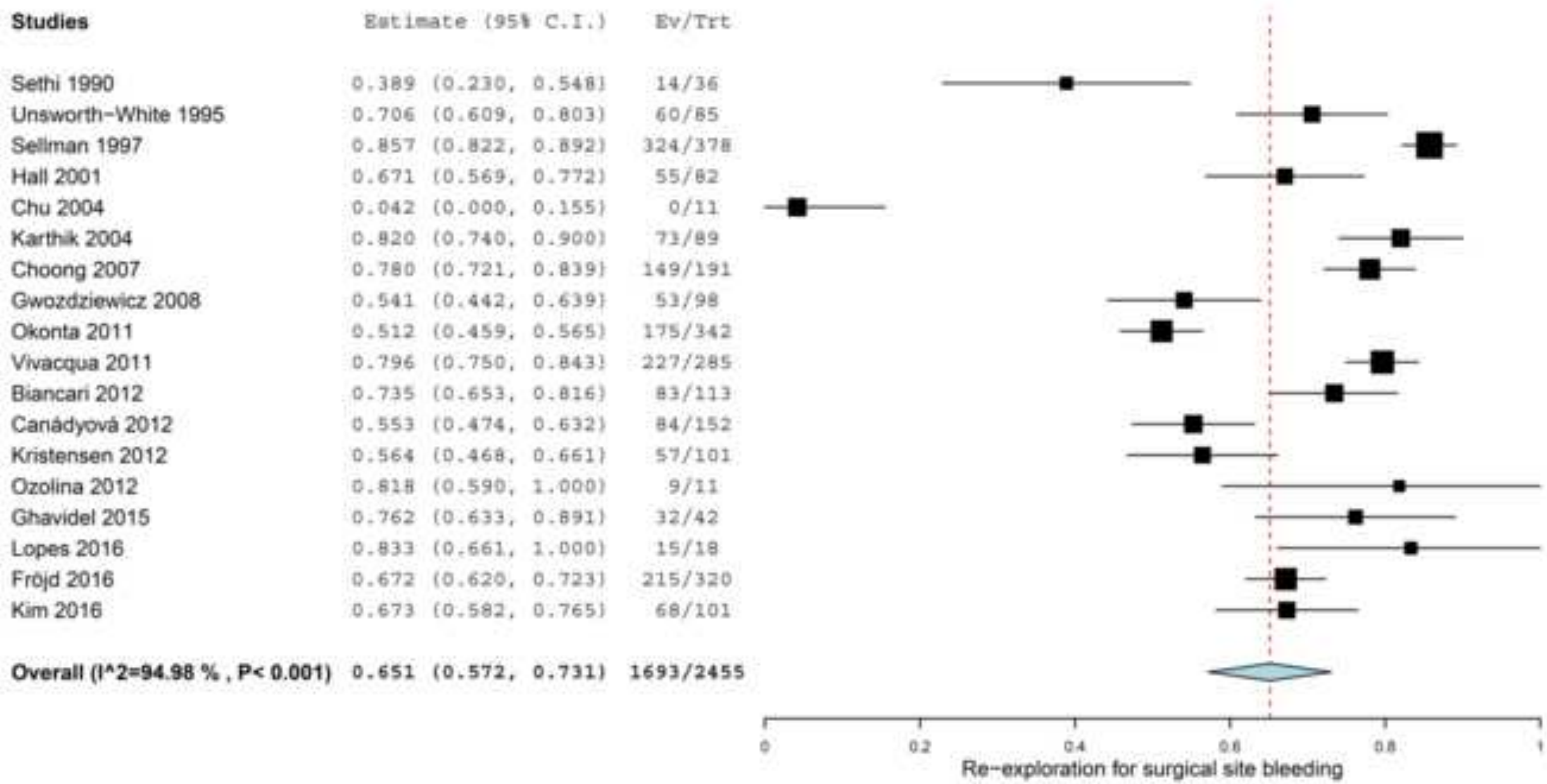
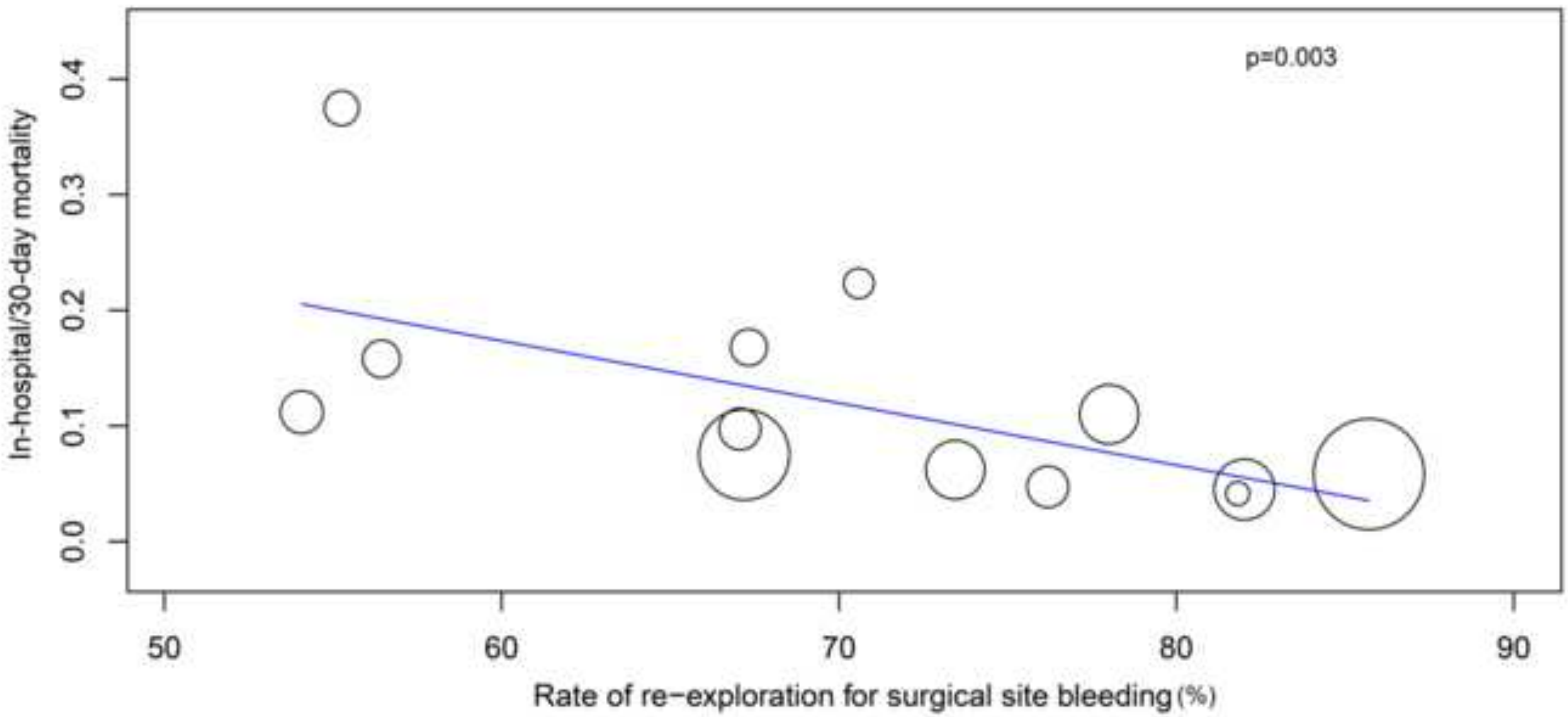


Figure 4


p=0.003
In-hospital/30-day mortality
0.0
0.1
0.2
0.3
0.4
50
60
70
80
90
Rate of re−exploration for surgical site bleeding (%)