Eur J Vasc Endovasc Surg (2019) 57, 796—807

SYSTEMATIC REVIEW

Reporting of Complications and Mortality in Relation to Risk Communication in Patients with an Abdominal Aortic Aneurysm: A Systematic Review

Sylvana M.L. de Mik [†], **Reza Indrakusuma** [†], **Dink A. Legemate, Ron Balm, Dirk T. Ubbink** [*]

Amsterdam UMC, University of Amsterdam, Department of Surgery, Amsterdam Cardiovascular Sciences, Amsterdam, the Netherlands

WHAT THIS PAPER ADDS

This review discusses the current reporting of complications and mortality in publications on abdominal aortic aneurysm surgery. Based on these outcomes, recommendations are provided to assist authors of vascular surgical literature in improving the reporting of complications, so that data can more easily be used for evidence based risk communication with patients.

Objectives: High-quality reporting of surgical risks is necessary for evidence-based risk communication in clinical practice. Risk communication is defined as the process of discussing benefits and harms of treatment options with patients. This review addressed the current quality of reporting of complications and mortality in publications on abdominal aortic aneurysm treatment, with a focus on items relevant to risk communication.
Design: A systematic review.
Materials: Randomised clinical trials, comparative observational studies and registries from 2010 onwards were eligible if they reported complications and/or mortality in patients with an asymptomatic abdominal aortic aneurysms who received primary treatment.
Methods: Quality of reporting was assessed by scoring items relevant to risk communication from the reporting standards of the Society for Vascular Surgery (SVS) and the Consolidated Standards of Reporting Trials (CONSORT) statement. Screening, quality assessment and data extraction were independently undertaken by two authors.
Results: Forty-seven publications were included. Nine of 47 publications (19%) provided no definition of complications. In 14 of 47 publications (30%), it was unclear whether the number of adverse events or the number of patients with adverse events were presented. Absolute risk differences were provided in 1 of 32 publications (3.1%) that compared complications between two treatment options. Forty-six of 47 publications reported mortality, of which 42 reported overall mortality rates (91%). Absolute risk differences were given in 2 of the 31 publications (6.5%) that compared mortality between two treatment options.
Conclusions: The quality of reporting of complications and mortality following primary abdominal aortic aneurysm treatment varied considerably. Better adherence to the SVS reporting standards and the CONSORT statement, as well as stating absolute risk differences may improve the quality of reporting and facilitate evidence-based risk communication.

Keywords: (Postoperative) Complications, Mortality, Aortic aneurysm, Abdominal, Evidence-based practice, Health communication
Article history: Received 4 July 2018, Accepted 17 January 2019, Available online 23 May 2019

INTRODUCTION

In order to communicate the evidence based risks of surgical procedures to patients in a uniform manner that is easily understood, surgeons must be able to extract these risks from the surgical literature. By extracting the latest evidence, surgeons can help patients understand the risks of surgical procedures through a process of discussing and explaining benefits and harms. This process is also known as risk communication.[1] Understanding treatment risks is crucial for patients in two ways. Firstly, it is required for a patient to give informed consent. Secondly, this understanding also allows patients to weigh effectively the benefits and harms of different treatment options, which

[†] S.M.L.d.M. and R.I. contributed equally to this work.
* Corresponding author. Amsterdam UMC, University of Amsterdam, Department of Surgery, Amsterdam Cardiovascular Sciences, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands.
E-mail address: d.ubbink@amc.nl (Dirk T. Ubbink).
1078-5884/
https://doi.org/10.1016/j.ejvs.2019.01.016

Table 1. Data extraction form for studies reporting complications and/or mortality in adult patients who underwent a primary treatment for an asymptomatic AAA

Data item	Scoring details
Is a definition of any specific adverse event given? (CONSORT extension for harms)	Zero = not reported Partial score = at least one adverse event is defined/references or supplementary materials are given that provide a definition for at least one adverse event Full score = all adverse events are defined/references or supplementary materials are given that provides definitions for all adverse events.
Are complications reported in terms of disease related or procedure related complications? (Reporting Standards of the SVS)	Zero = not reported Partial score = only disease related or procedure related complications are reported Full score = both disease related and procedure related complications are reported
Are complications reported according to time of occurrence relative to the operative procedure? (SVS)	Zero = not reported Partial score = some complications are reported according to time of occurrence relative to the operative procedure Full score = all complications are reported according to time of occurrence relative to the operative procedure
Are numbers of adverse events reported per treatment arm? (CONSORT)	Zero = not reported Partial score = numbers of some adverse events are reported per treatment arm Full score = numbers of all adverse events are reported per treatment arm
Is the overall number of patients with adverse events reported? (CONSORT)	Zero = not reported Partial score = the number of patients with adverse events are reported (e.g., seven of the 100 patients experienced one or more complications)
Is the overall number of patients without adverse events reported? (SVS)	Zero = not reported Partial score = the number of patients without adverse events are reported (e.g., 93 of the 100 patients did not experience any complications)
Is it clear if presented numbers are events or patients? (CONSORT)	Zero = unclear Partial score = number of events Full score = number of patients
Are numbers of patients reported per adverse event? (CONSORT)	Zero = not reported Partial score = numbers of patients with adverse events are reported for some adverse events (e.g., three patients had a myocardial infarction) Full score = numbers of patients with adverse events are reported for all adverse events
Are numbers of adverse events reported per patient? (CONSORT)	Zero = not reported Partial score = numbers of adverse events are reported per patient (e.g., 15 patients had one complication, eight patients had two complications) Full score = numbers and type of adverse events are reported per patient (e.g., of the patients with more than one complication, one patient had a urinary tract infection and delirium, one patient had a pneumonia and a wound infection)
Is separate information provided on the severity grade of any adverse events? (CONSORT and SVS)	Zero = not reported Partial score = information is provided on severity grading of some adverse events Full score = information is provided on severity grading of all adverse events
On what information is severity grading based? (SVS)	Zero = not reported Partial score = severity grading is based on authors' own definitions Full score = severity grading is based on previously published definitions
Is 2 x 2 table for complications available?	Zero = table cannot be made Partial score = table can be made Full score = table is provided Not applicable (NA) = single arm study
Are numbers as effect measures for complications reported?	Zero = not reported Full score = reported
Are percentages as effect measures for complications reported?	Zero = not reported Full score = reported
Is odds ratio as effect measure for complications reported?	Zero = not reported Full score = reported
Is hazard ratio as effect measure for complications reported?	Zero = not reported Full score = reported
Is relative risk as effect measure for complications reported?	Zero = not reported Full score = reported

Continued

Table 1-*continued*

Data item	Scoring details
Is absolute risk reduction as effect measure for complications reported?	Zero = not reported Full score = reported
Is number needed to harm as effect measure for complications reported?	Zero = not reported Full score = reported
How are deaths reported? In hospital, 30 day, peri-operative mortality	Zero = none of the definitions was used Partial score = one of the definitions was used Full score = all three definitions were used
Are deaths reported in terms of disease related or procedure related deaths?	Zero = not reported Partial score = only disease related or procedure related deaths are reported Full score = both disease related and procedure related deaths are reported
Are deaths reported according to time of occurrence relative to the operative procedure? (SVS)	Zero = not reported Partial score = some deaths are reported according to their time of occurrence relative to the operative procedure Full score = all deaths are reported according to their time of occurrence relative to the operative procedure
Is 30 day mortality reported? (SVS)	Zero = not reported Full score = reported
Is in hospital mortality reported?	Zero = not reported Full score = reported
Is overall mortality reported? (SVS)	Zero = not reported Full score = reported
Aneurysm related mortality (SVS)	Zero = not reported Full score = reported
Is a definition for aneurysm related mortality given? (SVS)	Zero = no definition given Full score = definition given NA = no aneurysm related mortality reported
Is 2 x 2 table for mortality available?	Zero = table cannot be made Partial score = table can be made Full score = table is provided NA = single arm study
Are numbers as effect measures for mortality reported?	Zero = not reported Full score = reported
Are percentages as effect measures for mortality reported?	Zero = not reported Full score = reported
Is odds ratio as effect measure for mortality reported?	Zero = not reported Full score = reported
Is hazard ratio as effect measure for mortality reported?	Zero = not reported Full score = reported
Is relative risk as effect measure for mortality reported?	Zero = not reported Full score = reported
Is absolute risk reduction as effect measure for mortality reported? (CONSORT)	Zero = not reported Full score = reported
Is number needed to harm as effect measure for mortality reported?	Zero = not reported Full score = reported

CONSORT = Consolidated Standards of Reporting Trials; SVS = Society for Vascular Surgery; NA = not applicable; AAA = abdominal aortic aneurysm.

enables them to participate in the decision making process.[2]

A clear understanding of treatment risks is particularly relevant in patients with asymptomatic abdominal aortic aneurysms (AAAs) who may undergo preventive surgery with potentially severe complications. This is also acknowledged in the 2019 European Society for Vascular Surgery (ESVS) AAA Guidelines, which, for the first time, involved the patient's perspective by organising a focus group meeting.[3] A recurring desire was that patients required contextualisation when confronted with possible risks of treatments.

Furthermore, previous publications on risk communication show that differences in complications and mortality between treatment options are best understood by patients when clear definitions and absolute risk differences (ARDs), and not relative risks, are used.[1,4,5] Despite the available literature on what information is required for risk communication, few studies have looked at whether this information can be extracted effortlessly from the available literature. Therefore, the authors systematically reviewed the current quality of reporting of complications and mortality relevant to risk communication in publications on primary treatment for asymptomatic AAAs, including whether ARDs were reported or had to be calculated by the readers themselves.

METHODS

This systematic review was conducted in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.[6]

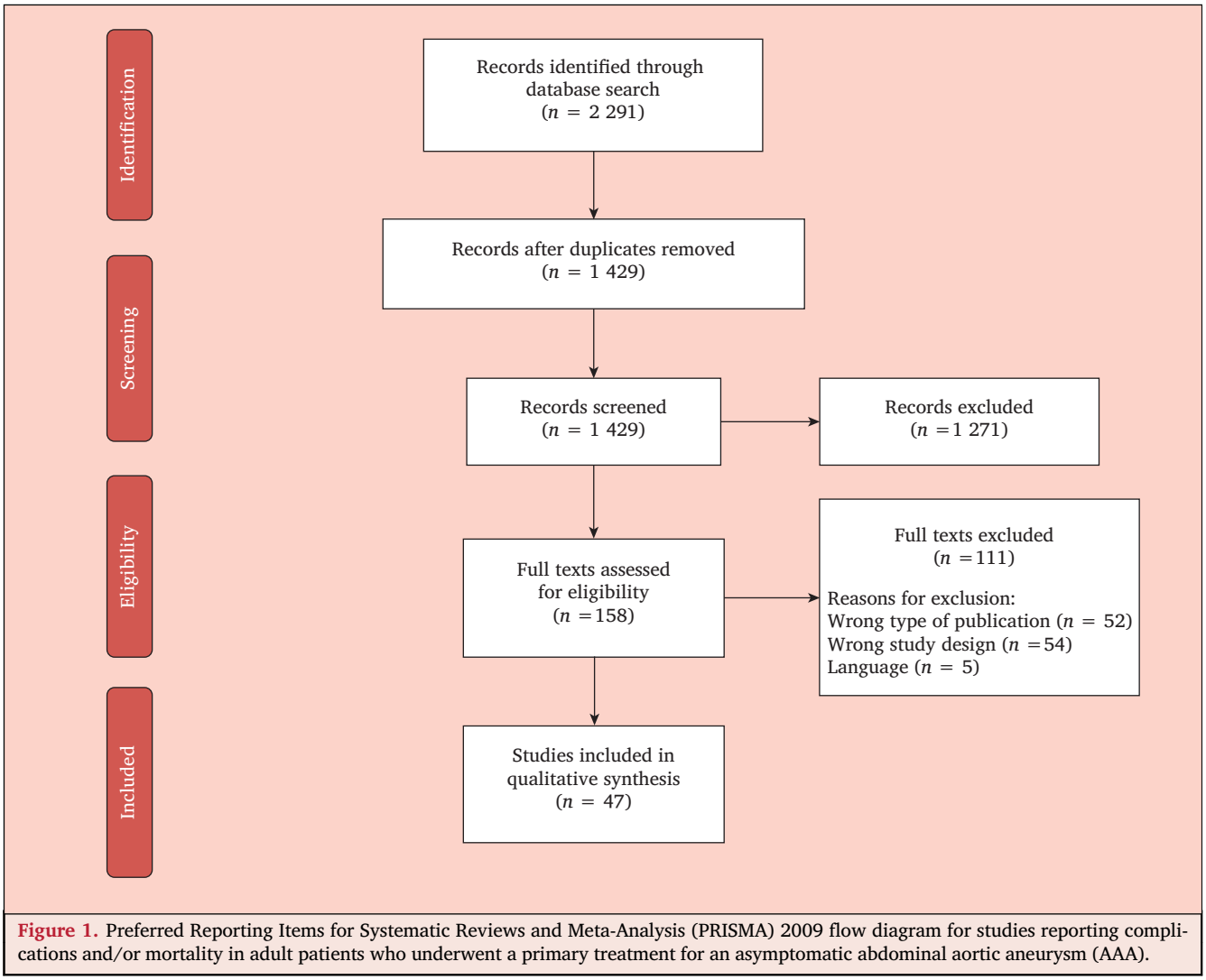

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) 2009 flow diagram for studies reporting complications and/or mortality in adult patients who underwent a primary treatment for an asymptomatic abdominal aortic aneurysm (AAA).

Protocol and registration

A review protocol in accordance with the PRISMA Protocols statement was registered in the PROSPERO database (registration number CRD42016039748), which is an international prospective register of systematic reviews.[7,8] The review protocol was amended during data collection in order to assess a homogenous study population. While the original review protocol included patients treated for an aneurysm located between the aortic arch and the iliac arteries, the eligibility criteria were narrowed to patients undergoing primary treatment for asymptomatic AAAs.

Eligibility criteria

Publications were eligible if authors reported complications and/or mortality in adult patients who underwent a primary treatment for an asymptomatic AAA. Primary treatment was defined as either elective open repair (OR) or endovascular AAA repair (EVAR) or active surveillance. Complex EVARs, such as fenestrated EVAR or the additional use of branches and chimneys were excluded, as was endovascular aneurysm sealing.

Randomised clinical trials (RCTs), retrospective studies (cohort or case control) comparing primary treatments, and registries were included. Registries were defined as multicentre prospective databases. Comparative studies were only included if they compared any of the primary interventions. Studies that compared one of the primary treatments with an excluded type of treatment, such as fenestrated EVAR, were excluded. Publications that did not compare primary treatment but subgroups, for example hostile neck vs. non-hostile neck of the aneurysm, were also excluded. Publications from 2010 onwards were eligible for inclusion as these were considered to reflect the current quality of reporting and because the CONSORT extension for harms[9] was formally included in the 2010 CONSORT statement.[10] Finally, any language other than English, German, or Dutch was excluded.

Information sources

The electronic databases of MEDLINE, Embase, and CENTRAL were searched from the year 2010 to the last search date of 8 May 2017.

Table 2. Characteristics of included studies reporting complications and/or mortality in adult patients who underwent a primary treatment for an asymptomatic AAA

Study	Publication year	Study design	Sample size	Intervention
Bockler *et al.*[22]	2010	Registry	180	Endovascular aneurysm repair (EVAR)
Brown *et al.*[23]	2010	Randomised controlled trial (RCT)	972	EVAR Open repair (OR)
Brown *et al.*[24]	2010	RCT	404	EVAR Conservative management
Carpenter *et al.*[25]	2010	Registry	157	EVAR
Cochennec *et al.*[15]	2010	Retrospective comparative study	131	EVAR OR
de Bruin *et al.*[26]	2010	RCT	351	EVAR OR
Greenhalgh *et al.*[27]	2010	RCT	404	EVAR Conservative management
Greenhalgh *et al.*[28]	2010	RCT	1252	EVAR OR
Jetty *et al.*[20]	2010	Retrospective comparative study	6461	EVAR OR
Ouriel *et al.*[29]	2010	RCT	728	EVAR Surveillance
Turnbull *et al.*[16]	2010	Registry	409	EVAR OR
Brown *et al.*[30]	2011	RCT	1252	EVAR OR
Cao *et al.*[31]	2011	RCT	360	EVAR Conservative management
Freyrie *et al.*[32]	2011	Registry	787	EVAR
Makaroun *et al.*[33]	2011	Registry	150	EVAR
Quinney *et al.*[34]	2011	Registry	1908	EVAR OR
Weale *et al.*[35]	2011	Registry	30	EVAR
Gupta *et al.*[36]	2012	Registry	651	EVAR OR
Kvinlaug *et al.*[37]	2012	Registry	111	EVAR
Lederle *et al.*[38]	2012	RCT	881	EVAR OR
Majumder *et al.*[39]	2012	Registry	106	EVAR
Stokmans *et al.*[40]	2012	Registry	1059	EVAR
de Bruin *et al.*[41]	2013	RCT	189	EVAR OR
de la Motte *et al.*[42]	2013	Registry	1701	EVAR OR
Scheinert *et al.*[43]	2013	Registry	60	EVAR
Tang *et al.*[44]	2013	Registry	1172	EVAR
Trenner *et al.*[45]	2013	Registry	36 594	EVAR OR
Coppi *et al.*[46]	2014	Registry	60	EVAR
Debus *et al.*[47]	2014	Registry	2041	EVAR OR
Mehta *et al.*[48]	2014	Registry	155	EVAR
Piffaretti *et al.*[49]	2014	Prospective comparative study	276	EVAR OR
Pratesi *et al.*[50]	2014	Registry	872	EVAR
Siracuse *et al.*[51]	2014	Registry	5915	EVAR OR
Waits *et al.*[52]	2014	Registry	3215	EVAR OR
Bastos Goncalves *et al.*[53]	2015	Registry	1263	EVAR
Grundmann *et al.*[54]	2015	Registry	3039	EVAR OR
Huang *et al.*[55]	2015	Retrospective comparative study	1534	EVAR OR

Table 2-*continued*

Study	Publication year	Study design	Sample size	Intervention
Schermerhorn *et al.*[56]	2015	Retrospective comparative study	79 932	EVAR OR
de Donato *et al.*[57]	2016	Registry	161	EVAR
Ersryd *et al.*[58]	2016	Registry	5271	EVAR OR
Khashram *et al.*[59]	2016	Registry	1340	EVAR OR
Maudet *et al.*[60]	2016	Registry	334	EVAR
Patel *et al.*[61]	2016	RCT	1252	EVAR OR
Singh *et al.*[62]	2016	Registry	150	EVAR
Siracuse *et al.*[63]	2016	Registry	1546	EVAR OR
Kato *et al.*[64]	2017	Retrospective comparative study	55	EVAR OR
Schmitz-Rixen *et al.*[65]	2017	Registry	4768	EVAR OR

EVAR = endovascular aneurysm repair; RCT = randomised controlled trial; OR = open repair; AAA = abdominal aortic aneurysm.

Search

The search was constructed according to the Population, Intervention, Comparison and Outcome (PICO) framework, with the assistance of a clinical librarian. The full search is available in Appendix S1 (Supplementary Material).

Study selection

Two authors independently screened titles and abstracts of the publications identified using the search strategy. Subsequently, they independently verified the eligibility of all full text papers. Disagreements were resolved by discussion, and, if necessary, by asking a third co-author to act as an arbitrator.

Data collection process

The two review authors, both independently and in duplicate, extracted data using a predefined data extraction form. This form was piloted using the first 15 publications and final adjustments were then made. The reviewers resolved discrepancies by discussion and, if necessary, by asking the arbitrator.

Data items

The following general study characteristics were extracted: author, publication date, study design, number of patients, and type of treatment.

There are several generic and disease specific guidelines that recommend what authors should report in their publications. The goal of such guidelines is to encourage clear and uniform reporting, so that readers can critically appraise publications more easily. Clear and uniform reporting not only enhances the readers' ability to compare study results from different publications, but also to understand the reported information and communicate it clearly to others, including patients.

Firstly, there is the updated and extended Consolidated Standards of Reporting Trials (CONSORT) statement, which is relevant for all RCTs and includes reporting of harms.[9,10] The CONSORT extension for harms is especially relevant to the purpose of the present study. This extension recommends authors report definitions of complications, the overall number of patients with and without complications, and the absolute risk of each complication.

Secondly, there are the Reporting Standards of the Society for Vascular Surgery (SVS), which are specific to studies on patients with an AAA.[11] The SVS reporting standards prescribe definitions for complications and mortality relevant to patients with AAA, such as for aneurysm related mortality. This definition includes "all deaths due to aneurysm rupture, primary or secondary procedure or surgical conversion". As the current assessment focused on the reporting of complications and mortality specifically for risk communication, a selection of items necessary for risk communication was made from these guidelines. The full data extraction form is shown in Table 1. The source of each data item is also given, either from the SVS reporting standards or the CONSORT statement. In addition, the reporting of a 2 × 2 table, ARDs, or other effect measures was registered.[4,5]

Risk of bias

The methodological quality of included studies was evaluated independently by two authors, using checklists issued by the Dutch Cochrane collaboration.[12] The corresponding checklists for RCTs and for cohort and case control studies were used.

Summary of measures

Primary outcome measures were the percentages of publications that received a zero, partial, or full score for each data item.

Synthesis of results

Data items on complications and mortality were awarded a zero (not reported) or a full score (completely reported),

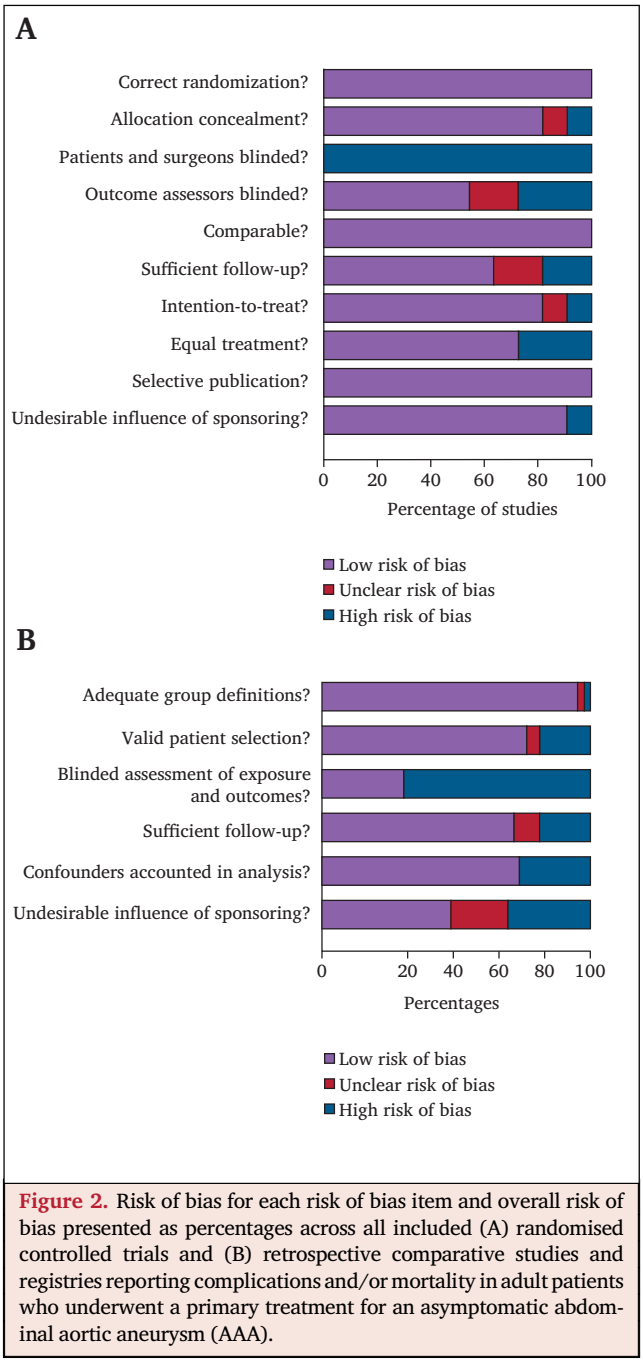

Figure 2. Risk of bias for each risk of bias item and overall risk of bias presented as percentages across all included (A) randomised controlled trials and (B) retrospective comparative studies and registries reporting complications and/or mortality in adult patients who underwent a primary treatment for an asymptomatic abdominal aortic aneurysm (AAA).

whereas other data items were given a zero, partial, or full score, depending on the type of data item (Table 1).

A meta-analysis was not conducted, as the present interests did not lie in a pooled estimate of the actual complication rate. Hence, a publication bias analysis using funnel plots was also not undertaken.

RESULTS

Study selection

A total of 2291 records were identified. After removing duplicate records, two review authors screened 1429 titles and abstracts, of which 158 publications underwent full text screening. After reading the full texts, the authors excluded 111 publications. These exclusions were based on type of publication (e.g., conference abstract or invited commentary), study design (e.g., ruptured AAA or comparisons between time cohorts or sex) or language (three publications in Chinese, two in Hungarian). Forty-seven publications were included for critical appraisal and data extraction (Fig. 1).

Study characteristics

Eleven RCTs, six retrospective comparative studies, and 30 registries were included. Thirty-two of 47 publications were comparative studies. The median sample size was 787 patients (interquartile range 161—1546). Endovascular repair was studied in 47 publications, open repair in 26, and active surveillance in four (Table 2).

Risk of bias within studies

Overall, the risk of bias in RCTs was low (Fig. 2A). In three of 11 (27%) RCTs comparing EVAR with OR the follow up strategies in the study arms differed.

Of the six retrospective comparative studies and the 30 registries, a high risk of bias was found with regard to the role of the sponsor in 13 publications (36%), whereas in another nine publications the role of sponsoring was unclear (Fig. 2B).

Results of individual studies

All 47 publications reported complications. Fig. 3 provides an overview of the quality of reporting of complications. Definitions were given for all complications in 10 of the 47 (21%) publications. In 14 of 47 publications (30%) it was unclear whether the authors were reporting the number of patients per complication or the number of events per complication. Information on the severity of complications was provided in 22 of 47 publications (47%). Although only one of the 32 (3%) comparative studies reported the ARD, sufficient information to calculate the ARD (e.g., a 2 × 2 table) was provided in 27 of 32 publications (84%).

Forty-six of 47 publications reported any type of mortality. Overall mortality was reported in 42 of these 46 (91%) publications. Twenty of 46 (43%) publications reported aneurysm related mortality, of which nine (45%) publications reported a definition of aneurysm related mortality. ARDs were reported in only two of 31 (6%) comparative studies, yet in 26 of these 31 (84%) studies sufficient information was provided to calculate the ARD. Fig. 4 provides an overview of the overall quality of reporting of mortality.

DISCUSSION

This systematic review of 47 papers published since 2010 on primary AAA treatment showed that the reporting of complications and mortality varied substantially between publications.

Quality of reporting of complications

Only a minority of publications provided definitions of the complications on which they reported, and a few graded

the severity. Both findings are consistent with previous literature. For instance, Meghelli *et al*.[13] determined that only 49 of 179 (27%) surgical RCTs in patients with oesophagogastric or gynaecological cancer gave a definition of adverse events. Whereas Rosenthal *et al*.[14] found that only 23 of 46 (50%) surgical RCTs published in high level surgical journals (*Annals of Surgery*, *JAMA Surgery*, or the *British Journal of Surgery*) reported definitions of post-operative complications. Furthermore, they also observed that only 21 of 46 (46%) of the included studies graded the severity of complications. Thus, not reporting definitions of complications appears to be a systematic flaw in the surgical literature. This holds particularly true for RCTs, as the CONSORT extension for harms has been available since 2004, and explicitly recommends providing definitions for all reported complications.[9]

Another observed shortcoming was the ambiguity of the reported numbers of complications, as it was often unclear what the numbers represented. Without clarification any complication rate can either be the event rate of a specific complication or the rate of patients with this specific complication. Authors must therefore specify which of these numbers they provide. This distinction is relevant when explaining this to patients, as they may not always realise that they run the risk of multiple or repeated complications. Sharing both numbers may clarify this and may be further elaborated on by communicating how many patients developed one, two, or more complications.

The publication of Cochennec *et al*.[15] is an example of how to report complications correctly. They report clear definitions of some of the complications, while also providing an accurate reference for the definition of all other complications. In addition, they report the severity of complications, clearly state that the numbers provided are the number of patients, and provide a 2 × 2 table, although no ARDs are given.

Quality of reporting of mortality

Almost half of the publications reported aneurysm related mortality, which is defined in the SVS reporting standards.[11] However, in most publications reporting aneurysm related mortality, it was unclear whether the authors used the SVS definition or any definition at all. More importantly, whether or not death is aneurysm related may not be as crucial to patients as it seems to the surgeon. Patients are likely to be more concerned about the risk of dying, irrespective of its cause. Even though the large majority of studies reported overall mortality, it is still not reported by all studies.

An example of how to report mortality correctly is the publication of Turnbull *et al*.[16] They clearly reported overall mortality using ARDs. Furthermore, there is a trend towards reporting 90 day mortality instead of 30 day mortality for

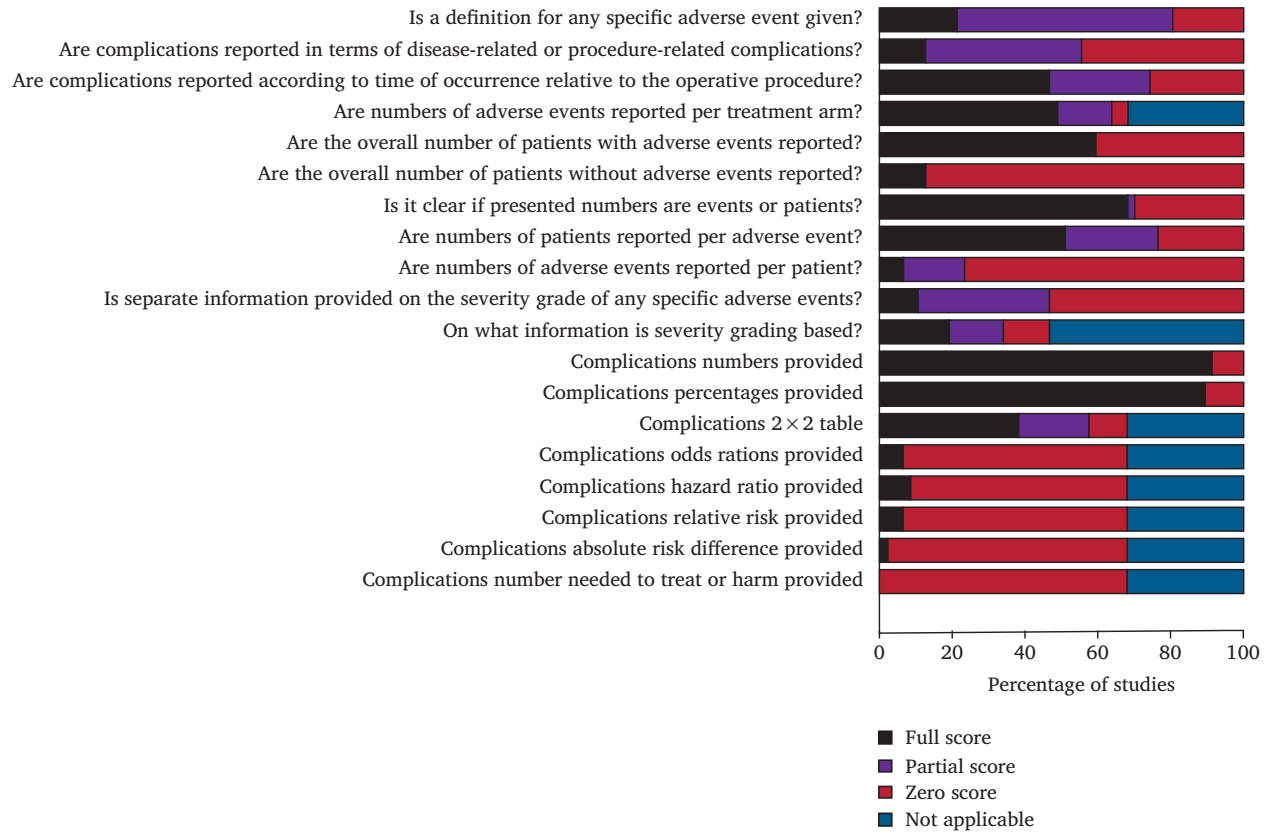

Figure 3. Quality of included studies reporting complications in adult patients who underwent a primary treatment for an asymptomatic abdominal aortic aneurysm (AAA). The definitions of scores are given in Table 1.

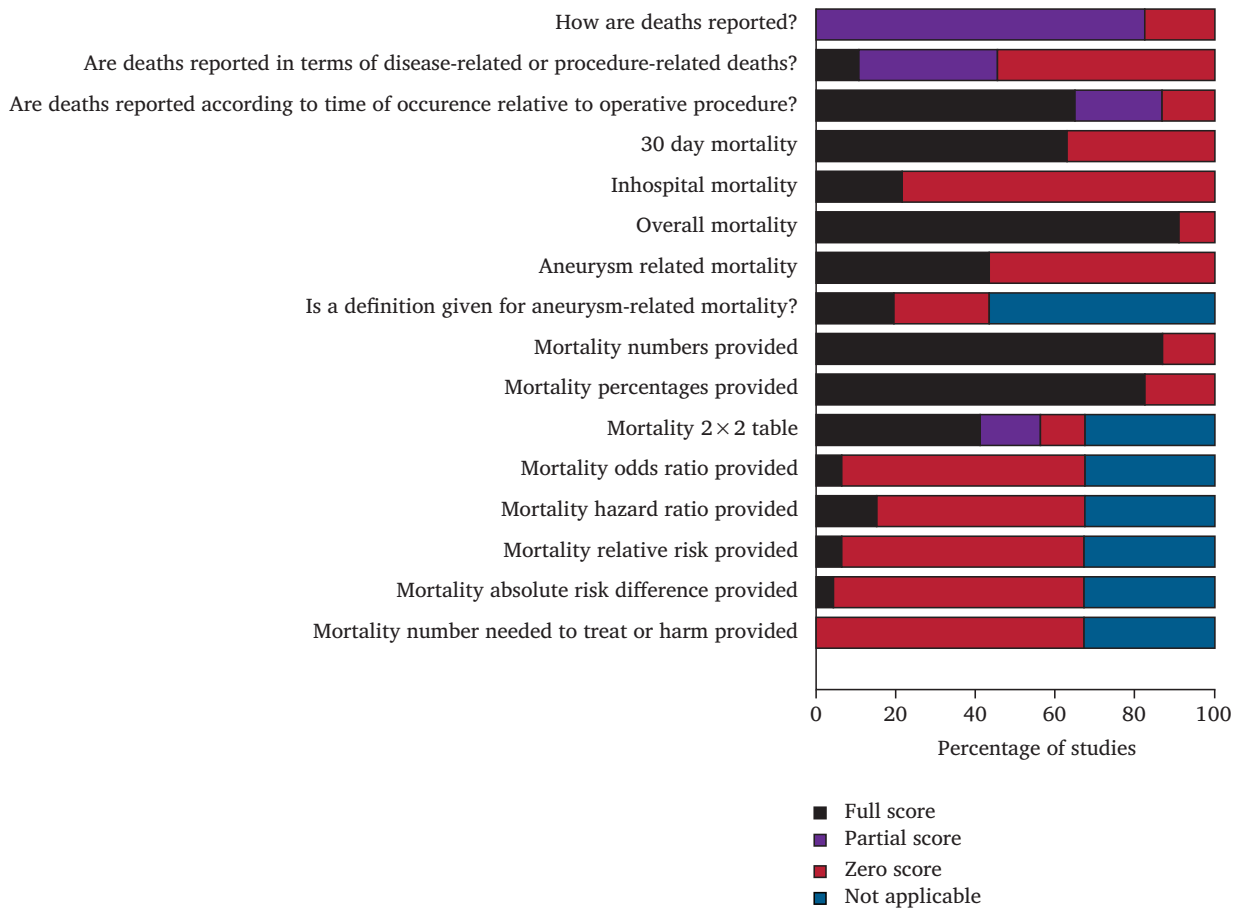

Figure 4. Quality of included studies reporting mortality in adult patients who underwent a primary treatment for an asymptomatic abdominal aortic aneurysm (AAA). The definitions of scores are given in Table 1.

surgical patients, because an important number of surgery related deaths occur beyond 30 days.[17] Unfortunately, none of the studies reported 90 day mortality, nor is this outcome included in either the CONSORT statement or SVS reporting standards.

Implications for clinical practice

This systematic review shows that it is a challenge for readers to extract all necessary information regarding risks from the included publications. This process of retrieving information from the literature may be enhanced if the quality of reporting is improved. Several recommendations are presented in Table 3, to help surgeons transfer factually correct information to their patients. For example, authors should report the overall number of surviving patients with one or more complications, so that surgeons can use this information to explain risks in natural frequencies as opposed to percentages: for example, for every 100 patients undergoing a treatment, five of 100 patients die of complications following treatment, of the surviving patients

Table 3. Recommendations for reporting surgical risks in patients with abdominal aortic aneurysms

• Report complications and mortality in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement and Society for Vascular Surgery (SVS) reporting standards.[9–11]
• Report the number of patients per complication.[9,a]
• Report the number of events per complication.[9,a]
• Report the number of patients who suffered from either one, two, three, or more complications.[9]
• Report the overall number of patients with complications in a 2 × 2 table and calculate risk differences between different treatment options, including confidence intervals.[4,5]
• Report the overall number of surviving patients with one or more complications.[1,18]
• Report the number of surviving patients without any complication.[1,18]
• Report the number of deceased patients.[1,18]
• Report the 90 day mortality.[17]

[a] If authors choose to report only one of these numbers, this must be clearly specified.

Table 4. Suggested template for reporting complications and mortality related to endovascular and open repair of abdominal aortic aneurysms (AAA)

Endovascular aneurysm repair (EVAR)			Open repair				
Number of surviving patients with one or more complications ($n =$)	Number of surviving patients without a complication ($n =$)	Number of deceased patients ($n =$)	Number of surviving patients with one or more complications ($n =$)	Number of surviving patients without a complication ($n =$)	Number of deceased patients ($n =$)	Absolute risk difference in complications 95% confidence interval	Absolute risk difference in mortality 95% confidence interval

10 develop one or more complications, and 85 of 100 patients are free of complications (see Table 4 for a template). As shown in previous studies, presenting risks as natural frequencies increases understanding.[18] Yet, if the overall number of patients with one or more complications is reported for all patients, deceased patients with one or more complications are counted as both "with one or more complications" and as "deceased", thus, exceeding the total of 100 patients used in this example. Finally, reporting absolute risk differences is preferred in risk communication, as this is best understood by patients and avoids the risk of overestimation if relative risks are used.[19] An example can be found in the publication by Jetty *et al*.[20] In this study, 3.4% of patients died within 30 days of OR vs. 1.8% of patients following EVAR. This can be presented either as an impressive reduction in relative risk of 53% (= 1.8%/3.4%) or an ARD of merely 1.6% (= 3.4−1.8%). Unfortunately, few of the included publications provided ARDs. Although 2 × 2 tables allow readers to calculate ARDs themselves, stating the actual ARDs is much more convenient for readers.

Limitations

The current review has some limitations. Firstly, the eligibility criteria of the original review protocol were amended during the study. Consequently, studies that were initially included were retrospectively excluded on the basis of the new eligibility criteria, yet the search strategy was not amended. This is reflected in the high number of studies found in the search, and the relatively small number of publications ultimately included. As the original search included publications about asymptomatic AAAs, it is unlikely relevant publications were missed.

Secondly, the items scored were selected from the CONSORT statement and SVS reporting standards based on their relevance to reporting mortality and complications. Items relevant to other types of comparisons of treatment options, such as economic evaluations, were not addressed.

Thirdly, another important aspect of risk communication is whether the published data can be generalised to individual patients. In order to determine generalisability, other factors should be reported for readers to take into consideration. At the very least these factors should entail the inclusion and exclusion criteria of the study population and patient characteristics, such as age, relevant comorbidities, and pre-operative anatomy, including aortic diameters. While the reporting quality of these factors is undeniably important, it was beyond the scope of the present review.

Fourthly, it is important to differentiate between *how* risks such as complications and mortality are presented vs. *which* risks are finally discussed with patients. In fact, the patient's perspective on which complications should be discussed requires further study, as complications reported in publications may not always be relevant to patients. Further insight can be improved by involving patients in selecting relevant outcomes in new trials, which can subsequently be reported in publications. Additionally, patients can participate in the writing of new guidelines, as was done for the ESVS AAA guidelines.[3,21]

CONCLUSIONS

This systematic review demonstrates that the current quality of reporting of complications and mortality concerning patients with an asymptomatic AAA varies considerably. These recommendations may assist future authors of surgical studies to improve the reporting of complications and mortality, so that their data can more easily be used for evidence based risk communication with patients.

ACKNOWLEDGMENTS

The authors would like to thank F.S. van Etten-Jamaludin, clinical librarian and medical information specialist, for her assistance in preparing the literature search.

CONFLICTS OF INTEREST

None.

FUNDING

This study was funded by the AMC Foundation, which was not involved in the study design, data analysis, or interpretation of results.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2019.01.016.

REFERENCES

1 Ahmed H, Naik G, Willoughby H, Edwards AG. Communicating risk. *BMJ* 2012;**344**:3996.

2 Stiggelbout AM, Van der Weijden T, De Wit MP, Frosch D, Legare F, Montori VM, et al. Shared decision making: really putting patients at the centre of healthcare. *BMJ* 2012;**344**:256.
3 Wanhainen A, Verzini F, Van Herzeele I, Allaire E, Bown M, Cohnert T, et al. European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg* 2019;**57**:8–93.
4 Paling J. Strategies to help patients understand risks. *BMJ* 2003;**327**:745–8.
5 Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. *BMJ* 2003;**327**:741–4.
6 Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *J Clin Epidemiol* 2009;**62**:1006–12.
7 Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;**4**:1.
8 University of York. *PROSPERO: International Prospective Register of Systematic Reviews*. Available at: https://www.crd.york.ac.uk/prospero/. [Accessed 17 December 2018].
9 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004;**141**:781–8.
10 Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010;**63**:1–37.
11 Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg* 2002;**35**:1048–60.
12 Scholten RJPM, Offringa M, Assendelft WJJ. *Inleiding in Evidence-Based Medicine: Bohn, Stafleu*. Van Loghum; 2013.
13 Meghelli L, Narducci F, Mariette C, Piessen G, Vanseymortier M, Leblanc E, et al. Reporting adverse events in cancer surgery randomized trials: a systematic review of published trials in oesophago-gastric and gynecological cancer patients. *Crit Rev Oncol Hematol* 2016;**104**:108–14.
14 Rosenthal R, Hoffmann H, Dwan K, Clavien PA, Bucher HC. Reporting of adverse events in surgical trials: critical appraisal of current practice. *World J Surg* 2015;**39**:80–7.
15 Cochennec F, Marzelle J, Allaire E, Desgranges P, Becquemin JP. Open vs endovascular repair of abdominal aortic aneurysm involving the iliac bifurcation. *J Vasc Surg* 2010;**51**:1360–6.
16 Turnbull IC, Criado FJ, Sanchez L, Sadek M, Malik R, Ellozy SH, et al. Five-year results for the Talent enhanced Low Profile System abdominal stent graft pivotal trial including early and long-term safety and efficacy. *J Vasc Surg* 2010;**51**:537–44.
17 Mani K, Bjorck M, Lundkvist J, Wanhainen A. Improved long-term survival after abdominal aortic aneurysm repair. *Circulation* 2009;**120**:201–11.
18 Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping patients decide: ten steps to better risk communication. *J Natl Cancer Inst* 2011;**103**:1436–43.
19 Ranganathan P, Pramesh CS, Aggarwal R. Common pitfalls in statistical analysis: absolute risk reduction, relative risk reduction, and number needed to treat. *Perspect Clin Res* 2016;**7**:51–3.
20 Jetty P, Hebert P, van Walraven C. Long-term outcomes and resource utilization of endovascular versus open repair of abdominal aortic aneurysms in Ontario. *J Vasc Surg* 2010;**51**:577–83.
21 Powell JT, Ambler GK, Svensjo S, Wanhainen A, Bown MJ. Beyond the AAA guidelines: core outcome sets to make life better for patients. *Eur J Vasc Endovasc Surg* 2019;**57**:6–7.
22 Bockler D, Fitridge R, Wolf Y, Hayes P, Silveira PG, Numan F, et al. Rationale and design of the endurant stent graft natural selection global postmarket registry (ENGAGE): interim analysis at 30 days of the first 180 patients enrolled. *J Cardiovasc Surg* 2010;**51**:481–91.
23 Brown LC, Brown EA, Greenhalgh RM, Powell JT, Thompson SG, UK EVAR Trial Participants. Renal function and abdominal aortic aneurysm (AAA): the impact of different management strategies on long-term renal function in the UK EndoVascular Aneurysm Repair (EVAR) Trials. *Ann Surg* 2010;**251**:966–75.
24 Brown LC, Greenhalgh RM, Thompson SG, Powell JT, UK EVAR Trial Participants. Does EVAR alter the rate of cardiovascular events in patients with abdominal aortic aneurysm considered unfit for open repair? Results from the randomised EVAR Trial 2. *Eur J Vasc Endovasc Surg* 2010;**39**:396–402.
25 Carpenter JP, Garcia MJ, Harlin SA, Jordan WD, Jung MT, Krajcer Z, et al. Contemporary results of endovascular repair of abdominal aortic aneurysms: effect of anatomical fixation on outcomes. *J Endovasc Ther* 2010;**17**:153–62.
26 De Bruin JL, Baas AF, Buth J, Prinssen M, Verhoeven EL, Cuypers PW, et al. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. *N Eng J Med* 2010;**362**:1881–9.
27 United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, Powell JT, Thompson SG, Epstein D. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. *N Eng J Med* 2010;**362**:1872–80.
28 United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, Powell JT, Thompson SG, Epstein D, Sculpher MJ. Endovascular versus open repair of abdominal aortic aneurysm. *N Eng J Med* 2010;**362**:1863–71.
29 Ouriel K, Clair DG, Kent KC, Zarins CK. PIVOTAL Investigators. Endovascular repair compared with surveillance for patients with small abdominal aortic aneurysms. *J Vasc Surg* 2010;**51**:1081–7.
30 Brown LC, Thompson SG, Greenhalgh RM, Powell JT, UK EVAR Trial Participants. Incidence of cardiovascular events and death after open or endovascular repair of abdominal aortic aneurysm in the randomized EVAR Trial 1. *Br J Surg* 2011;**98**:935–42.
31 Cao P, De Rango P, Verzini F, Parlani G, Romano L, Cieri E, et al. Comparison of surveillance versus aortic endografting for small aneurysm repair (CAESAR): results from a randomised trial. *Eur J Vasc Endovasc Surg* 2011;**41**:13–25.
32 Freyrie A, Gargiulo M, Fargion A, Gallitto E, Pratesi C, Stella A, et al. Anaconda™: the Italian Registry. Study protocol and preliminary perioperative results. *J Cardiovasc Surg* 2011;**52**:629–35.
33 Makaroun MS. One-year outcomes of the US regulatory trial of the endurant stent graft system. *J Vasc Surg* 2011;**54**:601–8.
34 Quinney BE, Parmar GM, Nagre SB, Patterson M, Passman MA, Taylor S, et al. Long-term single institution comparison of endovascular aneurysm repair and open aortic aneurysm repair. *J Vasc Surg* 2011;**54**:1592–7.
35 Weale AR, Balasubramaniam K, MacIerewicz J, Hardman J, Horrocks M. Outcome and safety of Aorfix™ stent graft in highly angulated necks—a prospective observational study. *Eur J Vasc Endovasc Surg* 2011;**41**:337–43.
36 Gupta PK, Ramanan B, Lynch TG, Gupta H, Fang X, Balters M, et al. Endovascular repair of abdominal aortic aneurysm does not improve early survival versus open repair in patients younger than 60 years. *Eur J Vasc Endovasc Surg* 2012;**43**:506–12.
37 Kvinlaug KE, Lawlor DK, Forbes TL, Willoughby R, MacKenzie KS, DeRose G, et al. Early results from a Canadian multicenter prospective registry of the Endurant stent graft for endovascular treatment of abdominal aortic aneurysms. *J Endovasc Ther* 2012;**19**:58–66.
38 Lederle FA, Freischlag JA, Kyriakides TC, Matsumura JS, Padberg Jr FT, Kohler TR, et al. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. *N Engl J Med* 2012;**367**:1988–97.
39 Majumder B, Urquhart G, Edwards R, Irshad K, Velu R, Reid DB. Early clinical experience with the Anaconda re-deployable endograft in 106 patients with abdominal aortic aneurism: the west of Scotland Anaconda registry. *Scott Med J* 2012;**57**:61–5.

40 Stokmans RA, Teijink JA, Forbes TL, Bockler D, Peeters PJ, Riambau V, et al. Early results from the ENGAGE registry: real-world performance of the Endurant Stent Graft for endovascular AAA repair in 1262 patients. *Eur J Vasc Endovasc Surg* 2012;**44**:369–75.

41 de Bruin JL, Vervloet MG, Buimer MG, Baas AF, Prinssen M, Blankensteijn JD, et al. Renal function 5 years after open and endovascular aortic aneurysm repair from a randomized trial. *Br J Surg* 2013;**100**:1465–70.

42 de la Motte L, Jensen LP, Vogt K, Kehlet H, Schroeder TV, Lonn L. Outcomes after elective aortic aneurysm repair: a nationwide Danish cohort study 2007–2010. *Eur J Vasc Endovasc Surg* 2013;**46**:57–64.

43 Scheinert D, Pratesi C, Chiesa R, Coppi G, Brunkwall JS, Klarenbeek G, et al. First-in-human study of the INCRAFT endograft in patients with infrarenal abdominal aortic aneurysms in the INNOVATION trial. *J Vasc Surg* 2013;**57**:906–14.

44 Tang T, Sadat U, Walsh S, Hayes PD, ENGAGE Investigators. Comparison of the endurant bifurcated endograft vs. aortouniiliac stent-grafting in patients with abdominal aortic aneurysms: experience from the ENGAGE registry. *J Endovasc Ther* 2013;**20**:172–81.

45 Trenner M, Haller B, Sollner H, Storck M, Umscheid T, Niedermeier H, et al. Twelve years of the quality assurance registry abdominal aortic aneurysm of the German Vascular Society: Part 1: trends in therapy and outcome of non-ruptured abdominal aortic aneurysms in Germany between 1999 and 2010. *Gefasschirurgie* 2013;**18**:206–13.

46 Coppi G, Njila M, Coppi G, Saitta G, Silingardi R, Pratesi C, et al. INCRAFT stent-graft system: one-year outcome of the INNOVATION trial. *J Cardiovasc Surg* 2014;**55**:51–9.

47 Debus ES, Nullen H, Torsello G, Lang W, Flessenkamper I, Hupp T, et al. Treatment of abdominal aortic aneurysms in Germany. Quality assurance data 2013. *Gefasschirurgie* 2014;**19**:412–21.

48 Mehta M, Henretta J, Glickman M, Deaton D, Naslund TC, Gray B, et al. Outcome of the pivotal study of the Aptus endovascular abdominal aortic aneurysms repair system. *J Vasc Surg* 2014;**60**:275–85.

49 Piffaretti G, Mariscalco G, Riva F, Fontana F, Carrafiello G, Castelli P. Abdominal aortic aneurysm repair: long-term follow-up of endovascular versus open repair. *Arch Med Sci* 2014;**10**:273–82.

50 Pratesi C, Piffaretti G, Pratesi G, Castelli P, ITER Investigators. Italian Excluder Registry and results of Gore Excluder endograft for the treatment of elective infrarenal abdominal aortic aneurysms. *J Vasc Surg* 2014;**59**:52–7.

51 Siracuse JJ, Gill HL, Graham AR, Schneider DB, Connolly PH, Sedrakyan A, et al. Comparative safety of endovascular and open surgical repair of abdominal aortic aneurysms in low-risk male patients. *J Vasc Surg* 2014;**60**:1154–8.

52 Waits SA, Sheetz KH, Campbell DA, Ghaferi AA, Englesbe MJ, Eliason JL, et al. Failure to rescue and mortality following repair of abdominal aortic aneurysm. *J Vasc Surg* 2014;**59**:909–14.

53 Bastos Goncalves F, Hoeks SE, Teijink JA, Moll FL, Castro JA, Stolker RJ, et al. Risk factors for proximal neck complications after endovascular aneurysm repair using the endurant stentgraft. *Eur J Vasc Endovasc Surg* 2015;**49**:156–62.

54 Grundmann RT. Treatment of abdominal aortic aneurysms (AAA) 2014: registry report from the German Institute of vascular healthcare Research (DIGG) of the German Society for Vascular Surgery and Vascular Medicine. *Gefasschirurgie* 2015;**20**:376–84.

55 Huang Y, Gloviczki P, Oderich GS, Duncan AA, Kalra M, Fleming MD, et al. Outcome after open and endovascular repairs of abdominal aortic aneurysms in matched cohorts using propensity score modeling. *J Vasc Surg* 2015;**62**:304–11.

56 Schermerhorn ML, Buck DB, O'Malley AJ, Curran T, McCallum JC, Darling J, et al. Long-term outcomes of abdominal aortic aneurysm in the Medicare population. *N Engl J Med* 2015;**373**:328–38.

57 de Donato G, Setacci F, Bresadola L, Castelli P, Chiesa R, Mangialardi N, et al. Aortic neck evolution after endovascular repair with TriVascular Ovation stent graft. *J Vasc Surg* 2016;**63**:8–15.

58 Ersryd S, Djavani-Gidlund K, Wanhainen A, Bjorck M. Abdominal Compartment syndrome after surgery for abdominal aortic aneurysm: a nationwide population based study. *Eur J Vasc Endovasc Surg* 2016;**52**:158–65.

59 Khashram M, Jenkins JS, Jenkins J, Kruger AJ, Boyne NS, Foster WJ, et al. Long-term outcomes and factors influencing late survival following elective abdominal aortic aneurysm repair: a 24-year experience. *Vascular* 2016;**24**:115–25.

60 Maudet A, Daoudal A, Cardon A, Clochard E, Lucas A, Verhoye JP, et al. Endovascular treatment of infrarenal aneurysms: comparison of the results of second- and third-generation stent grafts. *Ann Vasc Surg* 2016;**34**:95–105.

61 Patel R, Sweeting MJ, Powell JT, Greenhalgh RM, UK EVAR Trial Investigators. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. *Lancet* 2016;**388**:2366–74.

62 Singh MJ, Fairman R, Anain P, Jordan WD, Maldonado T, Samson R, et al. Final results of the endurant stent graft system in the United States regulatory trial. *J Vasc Surg* 2016;**64**:55–62.

63 Siracuse JJ, Schermerhorn ML, Meltzer AJ, Eslami MH, Kalish JA, Rybin D, et al. Comparison of outcomes after endovascular and open repair of abdominal aortic aneurysms in low-risk patients. *Br J Surg* 2016;**103**:989–94.

64 Kato T, Tamaki M, Tsunekawa T, Motoji Y, Hirakawa A, Okawa Y, et al. Health-related quality of life prospectively evaluated by the 8-item short form after endovascular repair versus open surgery for abdominal aortic aneurysms. *Heart Vessels* 2017;**32**:960–8.

65 Schmitz-Rixen T, Steffen M, Grundmann R. Treatment of abdominal aortic aneurysms (AAA) 2015: registry report from the German Institute of vascular healthcare Research (DIGG) of the German society for vascular surgery and vascular medicisne. *Gefässchirurgie* 2017;**22**:180–8.