



REVIEW ARTICLE

# The long-term outcomes of open and endovascular repair for abdominal aortic aneurysm: A meta-analysis



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Received 1 December 2018; accepted 21 January 2019

Available online 23 March 2019

## KEYWORDS

Abdominal aortic aneurysm;  
Endovascular repair;  
Meta-analysis;  
Open surgery

**Summary** To provide a meta-analysis of studies evaluating long-term all-cause mortality, aneurysm-related mortality and re-intervention after open or endovascular repair for abdominal aortic aneurysm. Electronic bibliographic sources were interrogated using a combination of free text and controlled vocabulary searches to identify studies comparing the long-term outcomes of open and endovascular repair for abdominal aortic aneurysm. The review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement standards. Fixed effect or random effects models were used. We retrieved 4 randomized controlled trials (RCTs; 2,783 patients), 7 nonrandomized trials (86,035 patients). The primary outcome was all-cause mortality. Heterogeneity was high and publication bias could not be excluded. Despite these limitations, the analysis showed that open and endovascular abdominal aortic aneurysm repair had similar all-cause mortality (OR 1.16, 95% CI, 0.89–1.51) over 5 years follow up, which was maintained after at least 10 years of follow-up (OR 0.87, 95% CI, 0.73–1.03). There was no significant difference in aneurysm-related mortality by 5 years or longer follow-up. A significantly lower proportion of patients undergoing open repair required reintervention (OR 0.38, 95% CI 0.24–0.64), which was maintained over 5 years of follow-up. There is no long-term survival difference between the patients who underwent open or endovascular aneurysm repair. There is significantly higher risk of reinterventions after endovascular aneurysm repair.

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## 1. Introduction

In the 1990s, endovascular aneurysm repair (EVAR) was introduced and then become as the treatment of choice for abdominal aortic aneurysm (AAA).<sup>1,2</sup> During the time of 1999–2008, there were 4 multicentre randomized trial of EVAR versus open repair from Europe and USA.<sup>3–6</sup> These studies have shown that EVAR made a significant reduction in 30-day operative mortality and length of hospital stay, but the early survival benefit of EVAR may be lost over time. This phenomenon has also been noted in many other studies, including EUROSTAR<sup>7</sup> (EUROpean collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair) and the Medicare database,<sup>8</sup> but it was still no satisfactory explanation emerged. The outcomes over 10-year follow-up for these studies will be essential. In 2016, EVAR trial-1<sup>9</sup> show that EVAR has an inferior late survival compared with open repair with 15.8 years follow up and DREAM study show the cumulative overall survival difference between open repair and endovascular become larger in 12 years follow-up than 6 years.<sup>10</sup> If the time of follow-up extending, it was still a question whether the open repair would benefit more than EVAR. Therefore, the aim of this systematic review and meta-analysis was to investigate long-term outcomes, including all-cause mortality, aneurysm-related mortality and reintervention associated with EVAR and open aneurysm repair.

## 2. Methods

### 2.1. Information sources and search strategy

This systematic review was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. The search string was: ("open" OR "open repair" OR "conventional") AND (endovascular OR "endovascular repair" OR EVAR) AND ("abdominal aortic aneurysm" OR "abdominal aortic aneurysms" OR "abdominal aneurysm") AND (Filters for controlled trials). The literature search was applied to PubMed, Embase, ISI Web of Science, Cochrane Library from 1991 to November 2017 and restricted to articles published in English due to limited funding for translation.

According to the eligibility criteria, we searched all relevant clinical studies and the reference lists were manually searched for completeness. Firstly, we ruled out articles that were apparently unrelated to our study by title and abstract reviewed. Then we read articles thoroughly to determine whether they should be included or not. Studies with less than 100 patients were excluded.

### 2.2. The inclusion and exclusion criteria

The studies comparing long-term outcome of open and EVAR for AAA were retrieved for analysis. The long-term outcome was defined as the time of follow up over 5 years. Articles were restricted based on the study design. Therefore, randomized controlled trials (RCTs), prospective and retrospective studies were all included. Studies reporting ruptured AAA, urgent repair or new endovascular devices were excluded, such as the chimney technique and branched stent-graft.

The primary endpoint was defined as the all-cause mortality. The secondary endpoints included aneurysm-related mortality and re-intervention. In the cases of multiple reports from the same study, in order to avoid duplication of data that only the most detailed or the latest reports were included.

### 2.3. Data retrieval

Two authors (ZGC and SPT) independently collected data from including studies. When disagreement occurred, a third author (YJL) was resorted to resolve the controversy. Information extracted from each study included the following: basic information about the included studies, such as first author, publication year, patient recruitment period, number of patients and long-term follow-up results.

### 2.4. Statistical analysis

The software of Review Manager (RevMan) version 5.3 was used for Cochrane reviews. Funnel plot (in RevMan version 5.3), Begg's and Egger's test (in Stata version 12.1) were used to assess publication bias. Quality assessment was conducted for RCTs in RevMan, and not randomized controlled trials (nRCTs) were assessed by the Newcastle–Ottawa scale, whose scores  $\geq 6$  were considered to be of high quality.<sup>11</sup>

Heterogeneity of included researches were tested with Chi-square and heterogeneity index,  $I^2$ . Individual study odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. Summary estimates of ORs were determined under a random-effects model when there was heterogeneity among the studies ( $I^2 > 50\%$ ), or a fixed effects model was applied. A two-sided P value  $< 0.05$  was regarded as statistically significant for all analyses.

## 3. Results

### 3.1. Characteristics of included studies and quality assessment

The details of literature search strategy are provided in the supporting information (S1 Table 1). 2820 articles from

English databases were retrieved. After screening the titles and abstracts, 51 articles remained. When carefully examining the full texts, we excluded another 40 articles for reasons listed in the diagram. Finally, we included 11 studies including 63,183 patients for the meta-analysis (Fig. 1). The pooled clinical characteristics of patients was obtained (Table 1). Two authors independently assessed the methodological quality of the selected studies using the Newcastle–Ottawa scale for retrospective studies (Table 2) and Cochrane risk of bias tool for RCTs (Fig. 2). The RCTs were well designed and the thorough Newcastle–Ottawa scale score >6 (7 of 7 studies), all indicate high quality of including studies.

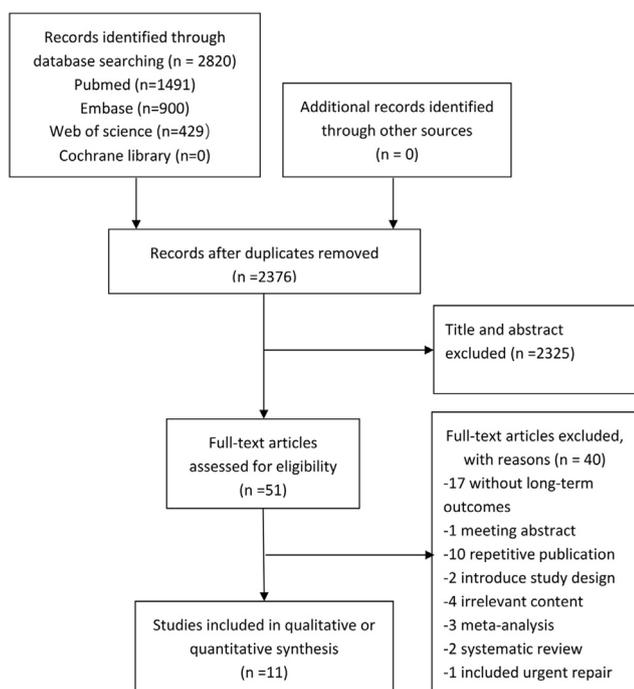


Figure 1 Flow diagram of study selection.

### 3.2. Publication bias assessment

We assessed the publication bias by visual inspection of funnel plot (with RevMan 5.3) as well as Begg’s and Egger’s tests (with Stata 12.1). With visual inspection, there seems to be symmetry in the funnel plot, indicating the low possibility of publication bias (Fig. 3). To further address this problem, we also performed Begg’s and Egger’s tests, and found no significant publication bias (all  $p > 0.05$  in Begg’s test or Egger’s test) (Fig. 4). Symmetry of funnel plots and Egger’s and Begg’s tests show that the risk of selective reporting bias is low.

#### 3.2.1. Meta-analysis of primary endpoints

There were 4 RCTs and 7 nRCTs included. A total of 63,183 patients were included in this part of study. Among them, 32,927 underwent EVAR and the remaining 30,256 received open repair. The heterogeneity test (Chi-square = 112.66,  $p < 0.00001$ ,  $I^2 = 91\%$ ) indicated a significant heterogeneity among these studies. Then subgroup and sensitivity analyses were carried out to find the source of heterogeneity (Table 3).  $p_1$  evaluates the heterogeneity among included studies.  $p_2$  evaluates the statistical significance level between the two interventions. If  $p_1$  is less than 0.05 in a fixed effect model, it means the heterogeneity among included studies is significant and the combined result ( $p_2$  value) is not solid and convincing. The year of study publication is the main source of the heterogeneity among studies, and if we omitted studies published before 2010, the heterogeneity decreases from 91% to 27% and the OR decrease from 1.02 to 0.99. Finally, a random effect model was employed to draw a more conservative and safer conclusion ( $\tau^2 = 0.00$ ; OR 1.16, 95%CI 0.89–1.51;  $Z = 1.10$ ,  $p = 0.57$ ) (Fig. 5). So according to the statistics in Table 3, it can be elicited that open and EVAR had no survival difference in the long-term follow-up.

### 3.3. Meta-analysis of aneurysm-related mortality

The 5 studies that reported the clinical results of aneurysm-related mortality. Four of these studies were RCTs and one

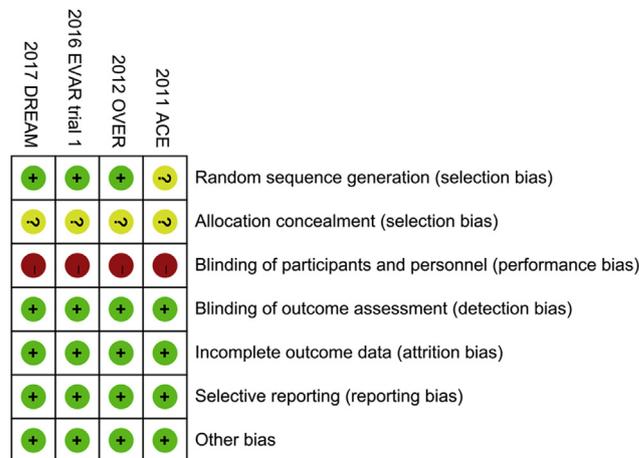
Table 1 Characteristics of included studies.

| Study/author year                   | Study location | Recruitment period (Year) | Study design        | Intervention |        | Patients Male/Female no. | Follow up |                | Mean age |
|-------------------------------------|----------------|---------------------------|---------------------|--------------|--------|--------------------------|-----------|----------------|----------|
|                                     |                |                           |                     | Open         | EVAR   |                          | Maximum   | Mean or Median |          |
| ACE 2011 <sup>5</sup>               | France         | 2003–2008                 | RCT                 | 149          | 150    | 296/3                    | 5         | 3              | 69.4     |
| OVER 2012 <sup>6</sup>              | USA            | 2002–2008                 | RCT                 | 437          | 444    | 876/5                    | 9         | 5.2            | 70       |
| EVAR trial 1 2016 <sup>9</sup>      | UK             | 1999–20004                | RCT                 | 626          | 626    | 1135/117                 | 15.8      | 12.7           | 74.1     |
| DREAM 2017 <sup>10</sup>            | Europe         | 2000–2003                 | RCT                 | 178          | 173    | 161/161                  | 12        | 12             | 70.1     |
| Yann Gouëffic 2005 <sup>12</sup>    | France         | 1995–2001                 | Retrospective study | 289          | 209    | 370/128                  | 7         | 2.6            | 69.8     |
| Santiago Chahwan 2007 <sup>13</sup> | USA            | 1996–2005                 | Retrospective study | 417          | 260    | 531/146                  | >5        | NR             | 72.4     |
| Kevin Mani 2009 <sup>14</sup>       | Sweden         | 1987–2005                 | Retrospective study | 2922         | 855    | 3221/555                 | 20.8      | 9.1            | 71.9     |
| Shiyan Ren 2012 <sup>15</sup>       | China          | 1998–2008                 | Retrospective study | 136          | 89     | 175/50                   | 10.8      | 3.75           | 68       |
| Hong-Gi Lee 2013 <sup>16</sup>      | Korea          | 1996–2004                 | Retrospective study | 273          | 501    | 548/226                  | 10        | 6.95           | 73.7     |
| MEDICARE 2015 <sup>8</sup>          | USA            | 2001–2008                 | Retrospective study | 39,966       | 39,966 | 62,059/17,873            | 8         | NR             | 75.6     |
| Koji Maeda 2017 <sup>17</sup>       | Japan          | 2006–2014                 | Retrospective study | 81           | 71     | 132/20                   | 7         | 2.72           | 74       |

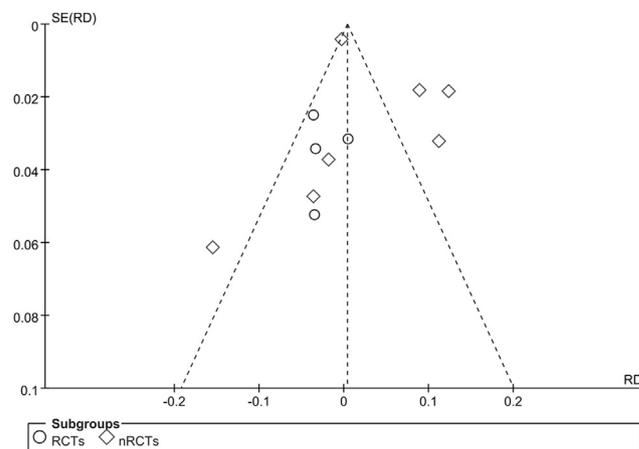
RCT randomized controlled study, EVAR endovascular aneurysm repair, NR not reported.

**Table 2** Quality assessment of cohort studies based on the Newcastle–Ottawa Scale (range, 1–9 stars).

| Study                          | Selection                            |                                 | Ascertainment                                   |                         | Comparability                  |            | Outcome                   |                       | Total  |
|--------------------------------|--------------------------------------|---------------------------------|---|-------------------------|--------------------------------|------------|---------------------------|-----------------------|--------|
|                                | Representativeness of exposed cohort | Selection of non-exposed cohort | Demonstration that outcome was not at the start | Control for main factor | Controls for additional factor | Assessment | Follow-up was long enough | Adequacy of follow-up |        |
| Yann Gouëffic <sup>12</sup>    | 1                                    | 1                               | 1   | 0                       | 0                              | 1          | 1                         | 0                     | 9 of 9 |
| Santiago Chahwan <sup>13</sup> | 1                                    | 1                               | 1   | 0                       | 0                              | 1          | 1                         | 0                     | 9 of 9 |
| Kevin Mani <sup>14</sup>       | 1                                    | 1                               | 1   | 1                       | 1                              | 1          | 1                         | 0                     | 9 of 9 |
| Shiyan Ren <sup>15</sup>       | 1                                    | 1                               | 1   | 0                       | 0                              | 1          | 1                         | 0                     | 9 of 9 |
| Hong-Gi Lee <sup>16</sup>      | 1                                    | 1                               | 1   | 1                       | 0                              | 1          | 1                         | 0                     | 9 of 9 |
| MEDICARE <sup>8</sup>          | 1                                    | 1                               | 1   | 1                       | 1                              | 1          | 1                         | 0                     | 9 of 9 |
| Koji Maeda <sup>17</sup>       | 1                                    | 1                               | 1   | 0                       | 0                              | 1          | 1                         | 0                     | 9 of 9 |



**Figure 2** Quality of RCTs according to the Cochrane Collaboration Manual. Red: High risk; Yellow: Unclear risk; Green: Low risk \*.



**Figure 3** Funnel plots of studies included.

retrospective study. The heterogeneity test in aneurysm-related mortality (Chi-square = 8.47, P = 0.08, I2 = 53%) indicated the existed heterogeneity among these studies. Subgroup and sensitivity analyses cannot identify any study as the main source of the significant heterogeneity. So random effect model was employed. Open repair was not associated with a higher aneurysm-related mortality (OR 1.13, 95%CI 0.58–2.20; Z = 0.35, p = 0.73; random effect model, Tau<sup>2</sup> = 0.27) (Fig. 6).

### 3.4. Meta-analysis of re-intervention

The 7 studies that reported the clinical results of re-intervention. Four of these studies were RCTs and three retrospective studies. The heterogeneity test in re-intervention (Chi-square = 73.63, P < 0.00001, I2 = 92%) indicated the high heterogeneity among these studies. Subgroup and sensitivity analyses cannot identify any study as the main source of the significant heterogeneity. So random effect model was employed. Open repair had low re-intervention rate than EVAR (OR 0.38, 95% CI 0.24–0.64;

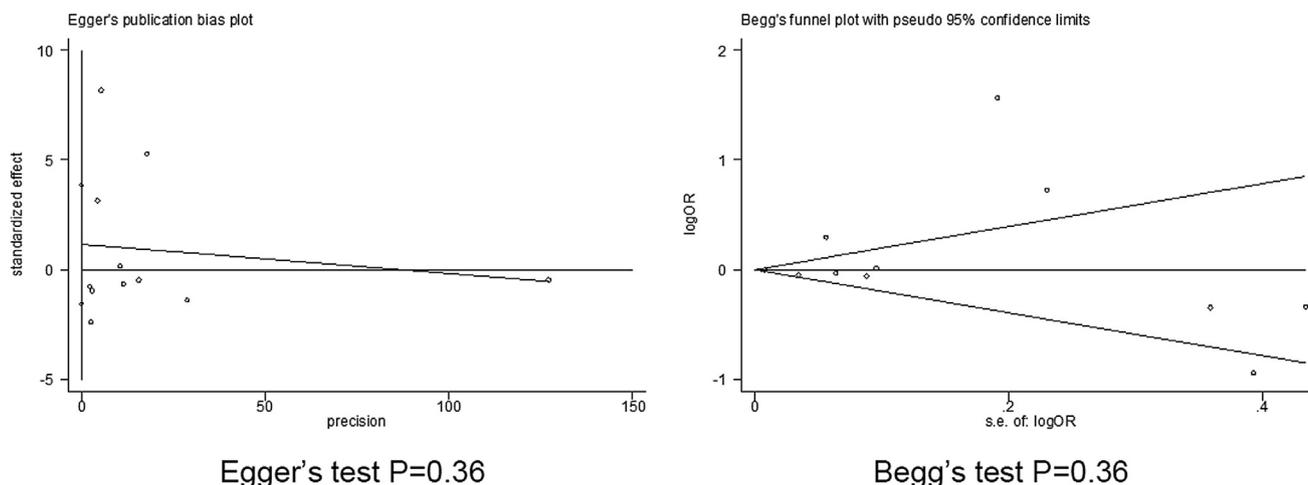


Figure 4 Egger's and Begg's tests for publication bias.

Table 3 Summary of subgroup and sensitivity analyses of primary endpoints.

|   | Number of studies | Heterogeneity                                    |                |          | OR (95% CI)       | Effect size | P2   |
|---|-------------------|--|----------------|----------|-------------------|-------------|------|
|   |                   | Chi-square (for FE) or Tau <sup>2</sup> (for RE) | I <sup>2</sup> | P1       |                   |             |      |
| Total studies (FE)                          | 11                | 112.66   | 91%            | <0.00001 | 1.02 [0.98, 1.05] | 0.97        | 0.33 |
| Total studies (RE)                          | 11                | 0.15   | *              | *        | 1.16 [0.89, 1.51] | 1.10        | 0.57 |
| RCTs (FE)                                   | 4                 | 1.63   | 0%             | 0.65     | 0.90 [0.76, 1.06] | 1.30        | 0.19 |
| nRCTs (FE)                                  | 7                 | 108.73   | 94%            | <0.00001 | 1.02 [0.99, 1.06] | 1.25        | 0.21 |
| nRCTs (RE)                                  | 7                 | 0.23   | *              | *        | 1.35 [0.90, 2.02] | 1.47        | 0.14 |
| Omitting studies published before 2010 (FE) | 8                 | 9.57   | 27%            | 0.21     | 0.99 [0.95, 1.02] | 0.89        | 0.38 |
| The studies follow-up over 7 years (FE)     | 7                 | 8.73   | 31%            | 0.19     | 0.99 [0.95, 1.02] | 0.85        | 0.40 |
| The studies follow-up over 10 years (FE)    | 4                 | 0.52   | 0%             | 0.91     | 0.87 [0.73, 1.03] | 1.63        | 0.10 |

FE fixed effect model, RE random effect model.

\*In a random effect model, Tau<sup>2</sup> should be employed to indicate the heterogeneity rather than I<sup>2</sup> and p1 value.

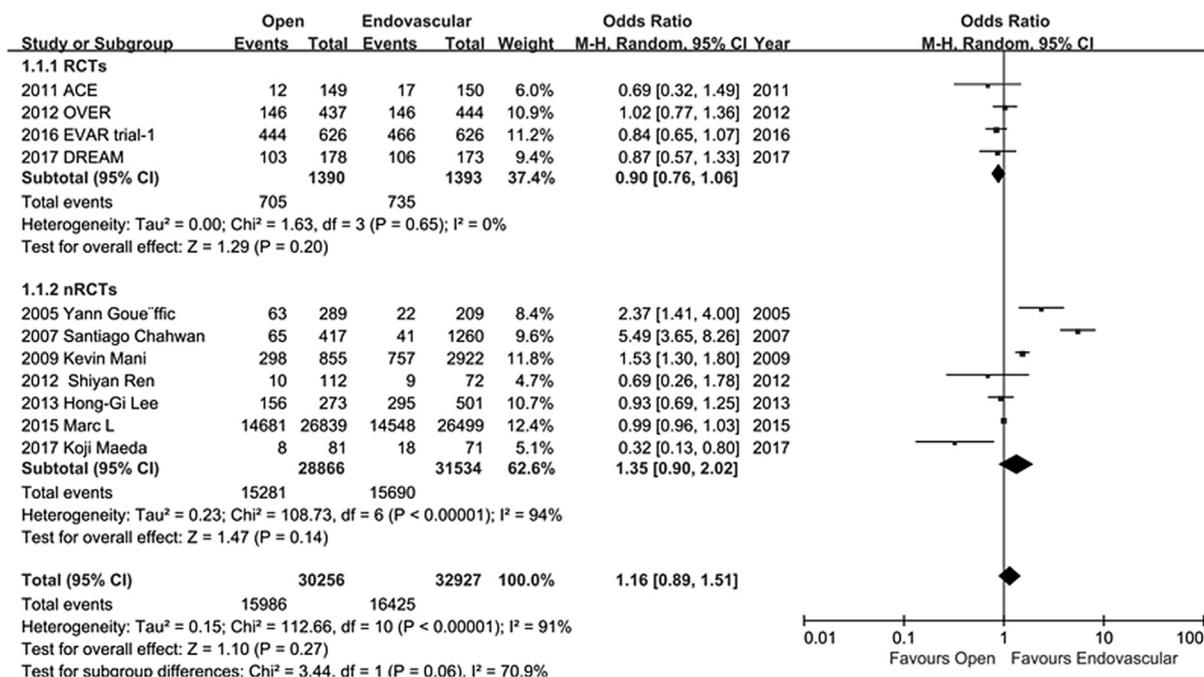


Figure 5 Forest plot for all-cause mortality.

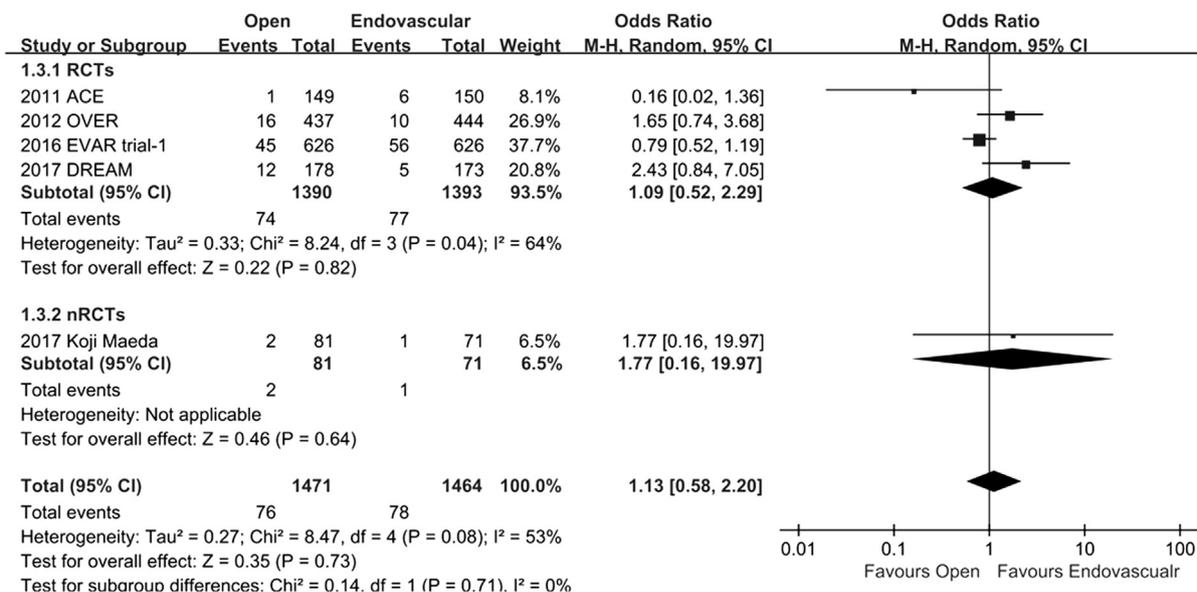


Figure 6 Forest plot for aneurysm-related mortality.

Z = 4.13, p < 0.0001; random effect model, Tau<sup>2</sup> = 0.31) (Fig. 7).

#### 4. Discussion

The EVAR has been regarded as an important treatment of choice for AAA, since it was introduced in 1990s. Many studies showed the short-term outcomes of operative mortality in favour of EVAR, but these benefits may disappear over the time.<sup>18,19</sup> In 2013, P. W. Stather et al carried out a meta-analysis show that there was no difference in all-cause mortality by 4-year follow-up.<sup>20</sup> In 2017, Powel et al s carried out meta-analysis of individual-patient data

from EVAR-1, DREAM, OVER and ACE trials show that patients of marginal fitness had no early survival advantage from EVAR compared with open repair over 5 years.<sup>21</sup> The limitation of above studies were that whose data from EVAR-1 and DREAM was published in 2010 instead of 2016. However, both newest result of the EVAR trial and DREAM study show that the cumulative overall survival difference between open repair and endovascular become larger over ten years follow-up.<sup>9,10</sup> Therefore, the longer outcomes over 5 years, such as a 10-year comparison, for these patients will be essential.

In order to address above issues, we carry out this study that not only extracted the latest data from EVAR trial-1, DREAM trial and US Medicare study results, but also

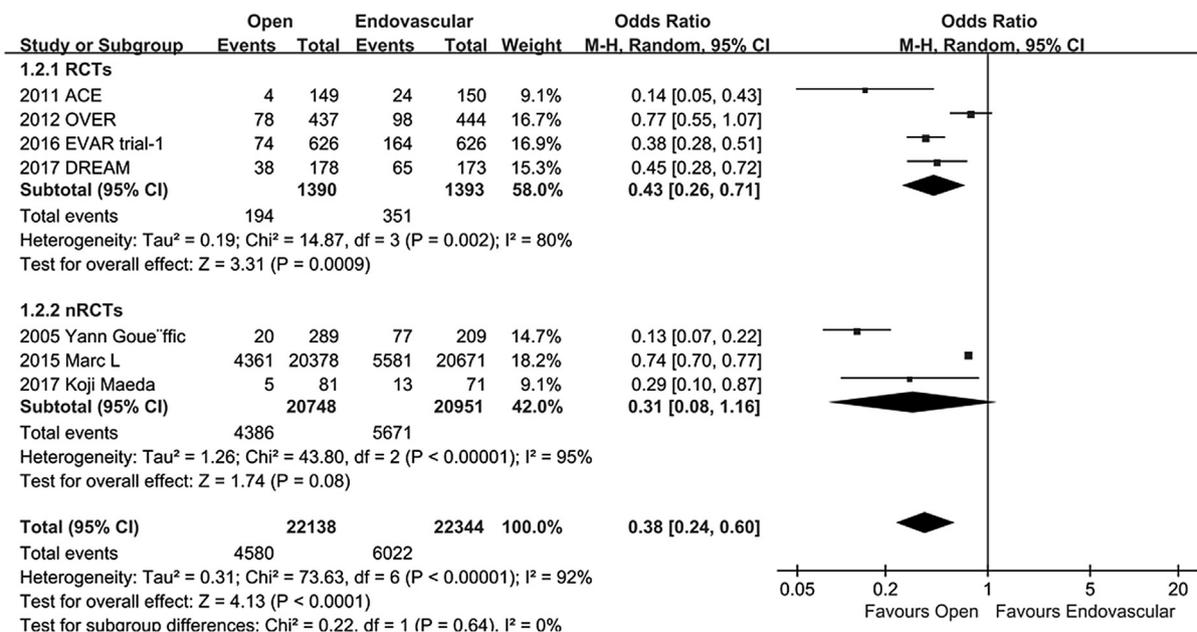


Figure 7 Forest plot for re-intervention.

included 7 non-randomized studies that would add further generalizability to the results. The combination of randomized and non-randomized studies in meta-analysis should be undertaken with cautions. Therefore, the characteristic of nRCTs were matched at the design stage and all studies achieved at least six of nine stars of the Newcastle–Ottawa Scale. Besides, a sensitivity analysis of both RCTs and nRCTs were independently performed (Fig. 5 and Table 3). To our knowledge, this is the most updated and comprehensive meta-analysis of this topic so far reported.

Though, the long-term survival was similar with open repair and EVAR, if we take the subgroup analysis into deeper consideration that the more benefit from open surgery may achieve with the longer follow-up. The odd ratio of EVAR to open repair significantly decrease from 1.16 (over 5 years) to 0.99 (over 7 years) and to 0.87 (over 10 years). This phenomenon has been confirmed from the early and long term (over 10 years) follow-up result of EVAR-1<sup>9,22,23</sup> and DREAM<sup>4,10,24</sup> studies. Especially in EVAR-1 study, beyond 8 years of follow-up, patients in open repair had a significantly lower mortality than EVAR ( $P = 0.048$ ). However, the ‘catch-up’ in mortality could be attenuated to minimize by using more recent EVAR devices and coupled with more rigorous surveillance. Therefore, it is still need more recent studies with longer term follow up to confirm which is better choice for AAA.

Open and EVAR repair were equivalent with respect to late aneurysm-related mortality by 5-year or greater follow-up. The result is similar to previous reported, which show no aneurysm-related mortality difference at both 2-year and 4-year.<sup>20</sup> However, the different result was demonstrated by Powell et al study by 3 years follow-up,<sup>21</sup> which showed aneurysm-related mortality was five times higher in the EVAR group (mainly due to secondary rupture or reinterventions). The vary outcomes added to the debate regarding this matter. Further investigations focused on whether the EVAR’s early survival advantage was either maintained or disappeared in subgroups of patients categorized by preoperative characteristics.

Another challenge to the durability of EVAR is that the study reports a significantly lower rate of reintervention for open repair (OR 0.38;  $P < 0.0001$ ), which is similar with previous report.<sup>24</sup> A criticism of earlier reports from EVAR1 and DREAM trial that not all incision-related reinterventions were recorded after open repair. These concerns have been addressed and the rate of incisional hernia repairs were reported in their newly long-term follow-up. We believe this is a more accurate analysis because these hernias were the result of the open AAA repairs. Besides, the reinterventions of type II endoleak, the commonest reported complication of EVAR, may contribute to the erosion of survival benefit over 30 days. However, from recent views that type II endoleak may pay no effect on survival and some patients could free from reinterventions. In addition, the more adequate surveillance in EVAR group and advanced endografts are being used, thus improving outcomes for patients undergoing endovascular intervention.<sup>25</sup>

Several limitations must be recognized in this study. First, the main limitation of our study was that the information was extracted from the published reports of each

trial, without accessing to the raw data. As a consequence, the analysis was confined to the time points specified in each study, which were not always directly comparable. Second, a number of concerns have arisen regarding the long-term durability of EVAR, but our study did not analyse the reasons for the catch-up mortality in the EVAR groups. Third, heterogeneity was high because both RCTs and nRCTs were included. Some recruitment into these trials was completed several years ago and endografts vary a lot. Challenges in the future to maintain the initially better results of being in the EVAR group include the need to halt the dilating disease process as well as devices that allow for this inevitable dilating process over the years.

## 5. Conclusion

There is no long-term survival difference between the patients who underwent open or endovascular aneurysm repair. There is significantly higher risk of reinterventions after endovascular aneurysm repair.

## Conflict of interest

None interest conflict.

## Funding

None.

## Acknowledgments

We would like to thank all the people who made contributions to this meta-analysis.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.asjsur.2019.01.014>.

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