Association between sex and perioperative mortality following endovascular repair for ruptured abdominal aortic aneurysms

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Background: **Women are recognized to experience inferior outcomes following open surgery for elective or ruptured abdominal aortic aneurysm (rAAA) when compared with men. The objective of this review was to assess whether there is a sex difference on mortality in patients receiving endovascular aneurysm repair (EVAR) for rAAA.**

Methods: **A systematic literature review from 2005 to 2012 was performed to investigate early mortality risk of ruptured endovascular aneurysm repair (rEVAR) stratified by sex. Data were analyzed with random-effect meta-analysis; pooled odds ratios (ORs) were calculated for women compared with men.**

Results: **Thirteen studies provided the required information; in most (n = 9), data stratified by sex was identified through unpublished data from direct contact with authors. No study was randomized; there were four prospective and 10 retrospective series. Three were United States population studies. The number of women was limited in most articles. Data were available for 5580 patients treated with rEVAR; 1339 were women (23.9%). Perioperative mortality with rEVAR occurred in 473/1339 women (pooled rate 35.6%; 95% confidence interval [CI], 33.1-38.2) and in 1334/4241 men (pooled rate 31.7%; 95% CI, 30.3-33.1) without significant difference between sex categories (pooled odds ratio 1.22; 95% CI, 0.97-1.54; $P = .09$). There was no increased mortality risk in women vs men in ancillary analyses stratified by study size and after excluding unpublished data.**

Conclusions: **Women may benefit as much as men from EVAR for rAAA. Nevertheless, current evidence supporting EVAR for female patients with rAAA is weak and requires confirmation by further experiences with a larger female representation. (J Vasc Surg 2013;57:1684-92.)**

Women have higher mortality than risk-stratified men from abdominal aortic aneurysm (AAA) management and repair.[1,2] For untreated aneurysms, the risk of rupture is almost four times more likely in women than in men.[3] When undergoing aneurysm treatment, women are exposed to higher perioperative mortality risks with both elective open surgery and endovascular aneurysm repair (EVAR). In addition, mortality risk excess has been shown after emergent open repair for ruptured AAA (rAAA) in women.[1,2,4] Nevertheless, the natural history of women with AAA is largely unknown due to the modest representation of female patients in most studies analyzing AAA and the aortoiliac morphology that is usually less suitable for EVAR in women.[5,6] EVAR, compared with open repair, is reported to decrease early mortality risks associated with rAAA.[1,7-9] However, whether this less-invasive repair could be associated also with no risk-excess in women compared with men with rAAA, remains unclear. In this systematic review, early mortality rates of women vs men after endovascular repair of ruptured AAA (rEVAR) were analyzed.

METHODS

The review of literature was performed following current guidelines for comprehensive systematic reviews (Meta-analysis of Observational Studies in Epidemiology) and checklist. Literature search was performed using Medline and Cochrane Library databases to retrieve information on endovascular repair performed for rAAA in women. As current practice with rEVAR continues to evolve, the search was limited to the last 7 years (from January 2005 to June 2012) and to English language literature. Key words used were "ruptured aneurysms," "EVAR," "aortic stent graft," or "endovascular aneurysm repair." Since the information by sex in literature was scarce, additional terms such as "women," "females," "males," "sex," or "gender" were not used to restrict the initial search, but all available literature on rAAA was analyzed to retrieve data on rEVAR stratified by sex. Additional studies were identified by reviewing the reference lists of retrieved articles. Contact with authors was sought

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if articles were not available for logistic reasons or when no outcomes stratified by sex were presented in the published work. Inclusion was not limited to randomized controlled trials. Studies were included when fulfilling the following criteria: treatment was applied for rAAA; aneurysm repair was performed by endovascular route; 30-day or in-hospital mortality after AAA repair was reported. Reviews and case reports were excluded. Articles reporting on elective aneurysm repair, or stent graft repairs involving thoracic aorta and dissection, or open surgery for rAAA were excluded. If multiple reports were published from one group of authors or in case of multiple articles covering the same study populations, the most recent data were used.

Two authors (P.D.R., A.M.) independently reviewed and extracted data from each article using a dedicated data extraction table. The extracted data included study characteristics (study interval, study design, population settings), patients' demographics (number of males and females, age), comorbidities, and lesion characteristics (AAA diameter) when available and perioperative/in-hospital mortality.

Statistical analysis. Analyses of data stratified by sex and pooled comparisons were performed between women and men receiving treatment for rAAA. Since detailed information of mortality by sex was available in few published articles, authors of papers reporting on rEVAR were directly contacted to obtain additional information on their study population stratified by sex from unpublished data (ie, published and unpublished data).

In most studies, comorbidities, hemodynamics, and lesion and procedure characteristics were not stratified by sex, and it was not possible to assess differences between women and men undergoing rEVAR and to reliably adjust for potential baseline unbalances. Among the few articles with available data, there was no uniform definition of comorbidities (cardiac, pulmonary, renal disease, etc) and no comprehensive data reporting (eg, lack of data on hemodynamic status, blood loss, comprehensive mortality risk score, etc). Cardiac, renal, and pulmonary disease/comorbidity could not be clearly defined because the data were taken from multiple, potentially disparate reports, and the potential interaction of comorbidities was not analyzed in pooled analyses.

The primary outcome was perioperative mortality (30-day or in-hospital). Perioperative mortality was defined as mortality occurring within 30 days from repair or during hospital stay (for studies with in-hospital available data).

Since the identified articles varied largely for numbers and population settings, a random-effect meta-analysis was used to pool mortality rates across the studies. The random-effect analysis provided a weighted estimate of the effect of interest (mortality) according to the within-study and between-study variance, which implied that heterogeneity across the studies was reflected in the pooled results and confidence intervals (CIs).[10] The odds ratio (OR) of mortality among women compared with men receiving rEVAR was then calculated and correspondent 95% CIs were provided.

The inclusion of unpublished results could have introduced a bias, and therefore data were reanalyzed after exclusion of non-peer-reviewed results. Sensitivity analyses were conducted based on study size, publication of data, and outcome measure definition. Mortality in women vs men was separately analyzed (a) for studies including at least 10 women and those with smaller samples; (b) for articles with all published data and those with published and unpublished data; (c) after excluding the unpublished data of the personal contribution from principal investigator's center; (d) in studies reporting in-hospital mortality. We provided a power analysis by assuming an OR of 1.41 as a clinically relevant effect in men vs women, an incidence of 42.2% for mortality in men and 3:1 men:-women population ratio. Assumptions were based on data from large reviews on rAAA.[1] A minimum sample of 2052 patients was required at 90% power and 5% alpha level. Meta-analysis was conducted using a specific statistical package (Comprehensive meta-analysis package; Version 2 Biostat, Englewood, NJ; Review Manager [RevMan; computer program]; Version 5.1 Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011).

Search results. A total of 119 potentially relevant articles on rEVAR were identified. After abstract review, 35 studies not fulfilling inclusion criteria (eg, including thoracoabdominal aneurysms, aortic dissection, elective EVAR repairs, not reporting on outcome of interest after rEVAR, or case reports) and 18 review articles were excluded. Of the 66 articles retrieved as full text, detailed information stratified by sex was available in four published articles.[11-14] Authors of the other papers published on rEVAR were contacted by one researcher (P.D.R.) to provide additional information from unpublished data in women vs men. Only one author declined to provide personal data. From seven, it was clarified that no information on women was recorded in personal databases. There were 22 non-responders and eight authors with failing contact addresses. Ultimately, information on data stratified by sex was available from 13 studies,[11-23] while 15 were excluded as they were duplicated reports by the same institution or authors.[2-4,24-35] Personal contribution with 32 rAAA treated at the principal investigator's center (Perugia, Italy) were additionally pooled with those retrieved by the literature for a total of 14 articles providing information on EVAR for rAAA in women and men for the present review. Authors who provided unpublished data and contributed to this study are listed in the rEVAR in Women Collaborators Group (Appendix). See Fig 1 for literature search details.

Main characteristics of included studies are shown in Table I. None of the studies were randomized, but for one single-center study, a small number of patients enrolled in a randomized trial on rAAA were included with outside-trial patients.[21] There were 11 single-center case series (including authors' personal experience),[11,13,15-19,21-23]

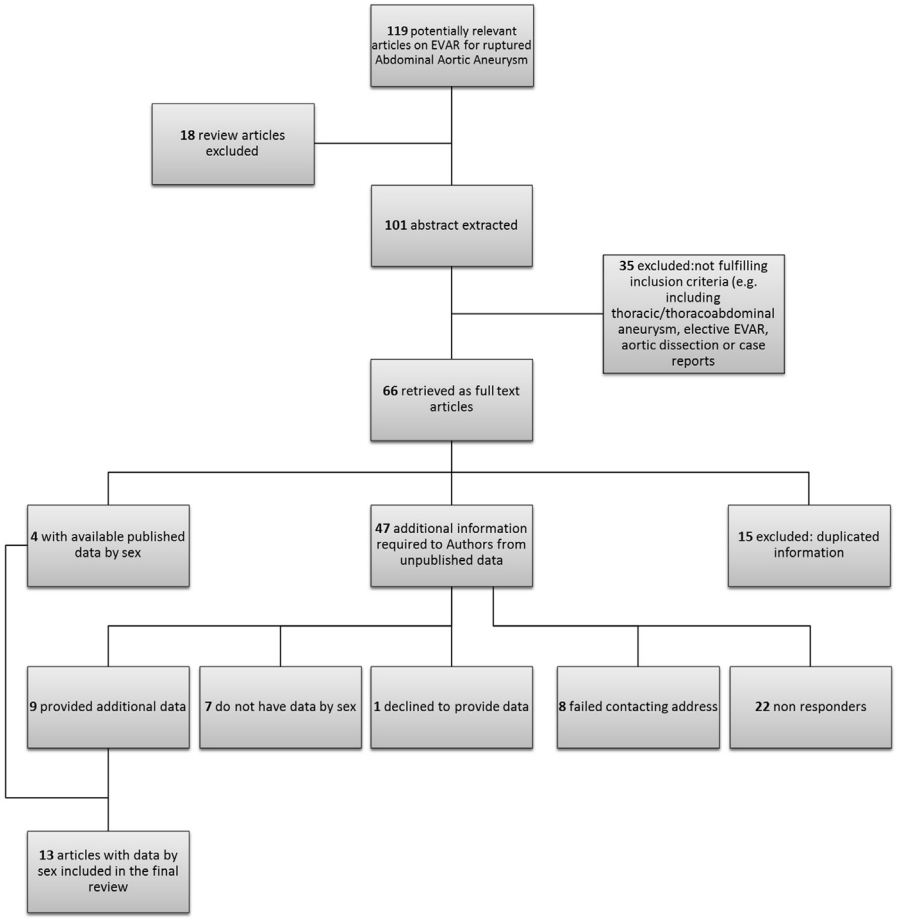

Fig 1. Literature search. *EVAR,* Endovascular repair for abdominal aortic aneurysm.

seven retrospective,[11,16-19,22,23] and four prospective studies[13,15,17,21] with variable range of patients and women percentages. Most included small numbers, with only four collecting 30 or more cases.[13,16,21,22] Three United States population studies with in-hospital data were included. The study by Leon et al was based on Illinois Hospital Association COMPdata database from 1995 to 2003[12]; the study by McPhee et al analyzed in-hospital events from the Nationwide Inpatients Sample from 2001 to 2006[20]; and the study by Egorova et al used the Medicare Beneficiary Database from 1995 to 2006.[14] We could not completely exclude that the same patients were included in the nationwide U.S. population-based studies, with partial overlapping of data, specifically those used in the Medicare Beneficiary Database from 1995 to 2006[14] that covered the period of the other two studies.[12,20] We tried to correct potential duplicated inclusions by repeating analysis of pooled data after the exclusion of the Medicare Beneficiary study.[14]

Two studies reported on in-hospital mortality.[12,20] Details of included studies are shown in Table I.

Personal experience results. This was a retrospective analysis of a prospectively maintained vascular database at a single center of Vascular Surgery (Perugia, Italy). Patients with evident AAA rupture on imaging were selected for this study. Between 2006 and 2012, 82 consecutive patients with plain rAAA were repaired in emergency: 32 underwent EVAR and 50 open surgery. All rEVAR were performed by operative teams available 24/7 using CE (European Conformity/Conformite Europeene)-approved or commercially available stent grafts, with surgical exposure or total percutaneous approach under general or local anesthesia.

Patient selection for EVAR or open surgical repair was dependent on the surgeon's discretion and was generally based on the morphologic inclusion criteria for a particular stent graft, according to contrast-enhanced computed tomography (CT) evaluation performed immediately in the Emergency Room after admission for rAAA and before treatment.

Prevalence of women was 15.9% (13/82). EVAR feasibility was similar in women (46.6%; n = 6/13) and men (37.7%; n = 26/69; $P = .78$). There was no difference in perioperative mortality rates between women and men after either open surgery (42.9% vs 41.9%; OR, 1.04; 95% CI, 0.2-5.23) or endovascular repair (16.7% vs

Table I. Main characteristics of included studies

Author year	*Study period*	*Mortality*	*Settings*	*Women*	*Men*	*Total*	*% women*
Single center							
Alsac 2005	2001-2004	Perioperative	Prospective study	2	15	17	11.8
Anain 2007	2001-2006	Perioperative	Retrospective study	6	24	30	20
Castelli 2005	2001-2004	Perioperative	Retrospective study	4	21	25	16
Guo 2009	1997-2007	Perioperative	Retrospective study	6	20	26	23
Guzzardi 2012	2005-2008	Perioperative	Retrospective study	2	26	28	7.1
Mehta 2012	2002-2009	Perioperative	Prospective study	33	73	106	31.1
Richards 2009	1994-2007	Perioperative	Prospective (including enrolled in randomized clinical trial)	12	68	80	15
Saqib 2010	2001-2010	Perioperative	Retrospective study	11	26	37	29.7
Ten Bosch 2010	2002-2008	Perioperative	Prospective study	3	22	25	12
Walker 2009	2004-2008	Perioperative	Retrospective study	2	22	24	8.3
Personal Perugia experience	2006-2012	Perioperative	Retrospective study	6	26	32	18.7
Multicenter							
Egorova 2011	1995-2006	Perioperative	U.S. (Medicare)	495	1421	1916	25.8
Leon 2005	1995-2003	In-hospital	U.S. (Illinois Hospital Association COMPdata)	14	41	55	25.4
McPhee 2009	2001-2006	In-hospital	U.S. (Nationwide Inpatient Sample)	743	2436	3179	23.4
Totals				1339	4241	5580	23.9

30.8%; OR, 0.4; 95% CI, 0.45-4.5; $P = .65$), even though there was a trend for lower mortality in women with EVAR. In adjusted analyses, age (OR, 1.14; $P = .0001$), shock on admission (OR, 3.72; $P = .02$), and open repair (OR, 5.46; $P = .008$) were independent predictors of perioperative mortality in rAAA.

Literature results. Data from included studies are summarized in Tables II and III. The total number of included patients was 5580: 1339 women and 4241 men. The proportion of women/men varied from 7.1% to 31.1% in single center studies and was higher in multicentric studies (23.4%-25.8%). There was little information on patients' characteristics by sex in published studies. Specifically, only five studies (including personal experience) provided data on comorbidities and aneurysm diameter before repair (Table III).[13,14,16,21] Cardiac, renal, and pulmonary disease/comorbidity could not be clearly defined because data were taken from multiple, potentially disparate reports. On average, women were older than men (Table II).

Perioperative (in-hospital/30-day) mortality occurred in 473/1339 women (pooled rate, 35.6%; 95% CI, 33.1-38.2) and in 1334/4241 men (pooled rate, 31.7%; 95% CI, 30.3-33.1). There was no increased risk in women vs men according to pooled data (OR, 1.22; 95% CI, 0.97-1.54; $P = .09$; Fig 2, *a*). Similar findings were obtained when the Medicare database study[14] was excluded from the analysis to avoid duplicated data[12,20] (pooled OR, 1.13; 95% CI, 0.83-1.54; $P = .43$; Fig 2, *b*).

Additional analyses were conducted according to study size, separating those including at least 10 women[12-14,20-22] (and mainly based on U.S. population databases[12,14,20]) from those with smaller female population.[11,15-19,23] Mortality rates were comparable between sex categories in both study subgroups. For the subgroup of six studies with large female population (>10), there were 466/1308 perioperative mortality events (pooled rate, 35.8%) in women and 1297/4065 in men (pooled rate, 32.0%): pooled OR, 1.23 (95% CI, 0.92-1.65; $P = .16$). Pooled analyses in the large female population subgroup of studies were repeated after the exclusion of the Medicare database[14] report: the pooled OR in women vs men was 1.19 (95% CI, 0.68-2.09; $P = .54$). In the subgroup of studies with a population of less than 10 women (including personal experience),[11,15-19,23] perioperative mortality occurred in 7/31 women (pooled rate, 24.3%) and 37/176 men (pooled rate, 22.8%) without a significant increase in mortality risk for women (pooled OR, 1.19; 95% CI, 0.46-3.09).

Mortality in women and men was reanalyzed after exclusion of the personal contribution of authors that was based on non-peer reviewed data (pooled OR, 1.25; 95% CI, 0.97-1.61; $P = .09$). Similarly, no statistically significant differences among sex categories were found in subgroup analyses by publication of data (ie, analyzing only studies with all published data[11-14] [pooled OR, 1.13; 95% CI, 0.59-2.16; $P = .70$] and those where additional unpublished results were retrieved by authors [pooled OR, 1.09; 95% CI, 0.92-1.29; $P = .34$; Fig 3).[15-23]

Mortality in women was lower in studies reporting in-hospital mortality,[12,20] but the rates between women and men were not statistically relevant (pooled OR, 0.59; 95% CI, 0.13-2.67; $P = .49$; Fig 4).

DISCUSSION

The evidence to support an EVAR first approach for women with rAAA is weak and largely based on population-based studies from the U.S. However, this review seems to corroborate this position by demonstrating that there is no mortality discrepancy between women and men receiving EVAR for rAAA. Pooled perioperative mortality rates in women were comparable to those in men (35.6% vs 31.7%), and no statistically significant differences were found (OR, 1.22; 95% CI,

Table II. Characteristics and perioperative (30-day/in-hospital) mortality of females and males treated by rEVAR

	No. of patients		*Age, years*		*30 day mortality*	
	Women	*Men*	*Women*	*Men*	*Women, No. (%)*	*Men, No. (%)*
Alsac 2005	2	15	–	–	2 (100)	2 (13.3)
Anain 2007	6	24	81.2	75	1 (16.7)	4 (16.7)
Castelli 2005	4	21	–	–	1 (25)	4 (19)
Egorova 2011	495	1421	78.8	77.5	203 (41)	475 (33.4)
Guo 2009	6	20	–	–	1 (16.7)	6 (30)
Guzzardi 2012	2	26	–	–	1 (50)	7 (26.9)
Leon 2005	14	41	–	–	2 (14.3)	18 (43.9)
McPhee 2009	743	2436	–	–	242 (32.5)	763 (31.3)
Mehta 2012	33	73	74.4	72.5	9 (27.2)	14 (19.2)
Richards 2009	12	68	77.9	74.2	6 (50.0)	23 (33.8)
Saqib 2010	11	26	–	–	4 (36.4)	4 (15.4)
Ten Bosch 2010	3	22	–	–	0	5 (22.7)
Walker 2009	2	22	–	–	0	1 (4.5)
Personal experience, Perugia, Italy	6	26	85.4	81.3	1 (16.7)	8 (30.8)
Total	1339	4241			473	1334

rEVAR, Endovascular repair for ruptured abdominal aortic aneurysm.

Table III. Characteristics of females and males undergoing rEVAR

	Aneurysm diameter		*Cardiac, %*		*Renal, %*		*Pulmonary, %*	
	Women	*Men*	*Women*	*Men*	*Women*	*Men*	*Women*	*Men*
Alsac 2005	–	–	–	–	–	–	–	–
Anain 2007	6.1	6.8	67	67	33	29	50	46
Castelli 2005	–	–	–	–	–	–	–	–
Egorova 2011	–	–	30.6	37.6	11.8	11.8	38	39.4
Guo 2009	–	–	–	–	–	–	–	–
Guzzardi 2012	–	–	–	–	–	–	–	–
Leon 2005	–	–	–	–	–	–	–	–
McPhee 2009	–	–	–	–	–	–	–	–
Mehta 2012	6.36	6.4	57.6	86.7	9.1	13.7	15.2	23.3
Richards 2009	8.0	7.9	33.3	48.2	–	45.4[a]	50	42.3
Saqib 2010	–	–	–	–	–	–	–	–
Ten Bosch 2010	–	–	–	–	–	–	–	–
Walker 2009	–	–	–	–	–	–	–	–
Personal experience, Perugia, Italy	7.85	7.17	50	26.9	16.7	15.4	–	30.8

rEVAR, Endovascular repair for ruptured abdominal aortic aneurysm.
[a]Creatinine >200 μmol/L.

0.97-1.54). Women/men mortality risk ratio was independent from volume of studies and inclusion of unpublished data. However, results should be interpreted cautiously because the overall numbers of women receiving rEVAR was limited, representing less than one-fourth of the male population, and pooled analysis of data could be underpowered to detect a difference. Post-hoc statistical power of our study was calculated. The sample of 5580 patients (that we retrieved in our systematic review) would allow to detect with 90% power an OR of 1.23 as the smallest effect size (ie, female vs male mortality). To detect with the same power an OR of 1.22 in female vs male mortality, which was the figure found in our pooled results, at least 5840 included cases would have been needed.

Furthermore, these mortality results can be considered applicable only for patients with anatomy suitable for EVAR. The overall low prevalence of women in studies reporting on rEVAR may be influenced by the more challenging anatomy resulting in lower suitability rates for EVAR in female patients as suggested by previous studies.[5,6] Sweet et al found that only 12% of women receiving EVAR met the neck criteria (length, diameter, angulation) recommended for using endovascular repair.[6] Slater et al found that 95% of patients with ruptured AAA and anatomical feasibility for EVAR were men.[5] The aorta and access arteries are often smaller in women, making EVAR more difficult to perform and more likely to fail (higher conversion rate).[1] It may be hypothesized that in the acute setting, women are very selectively assigned to EVAR, and only in

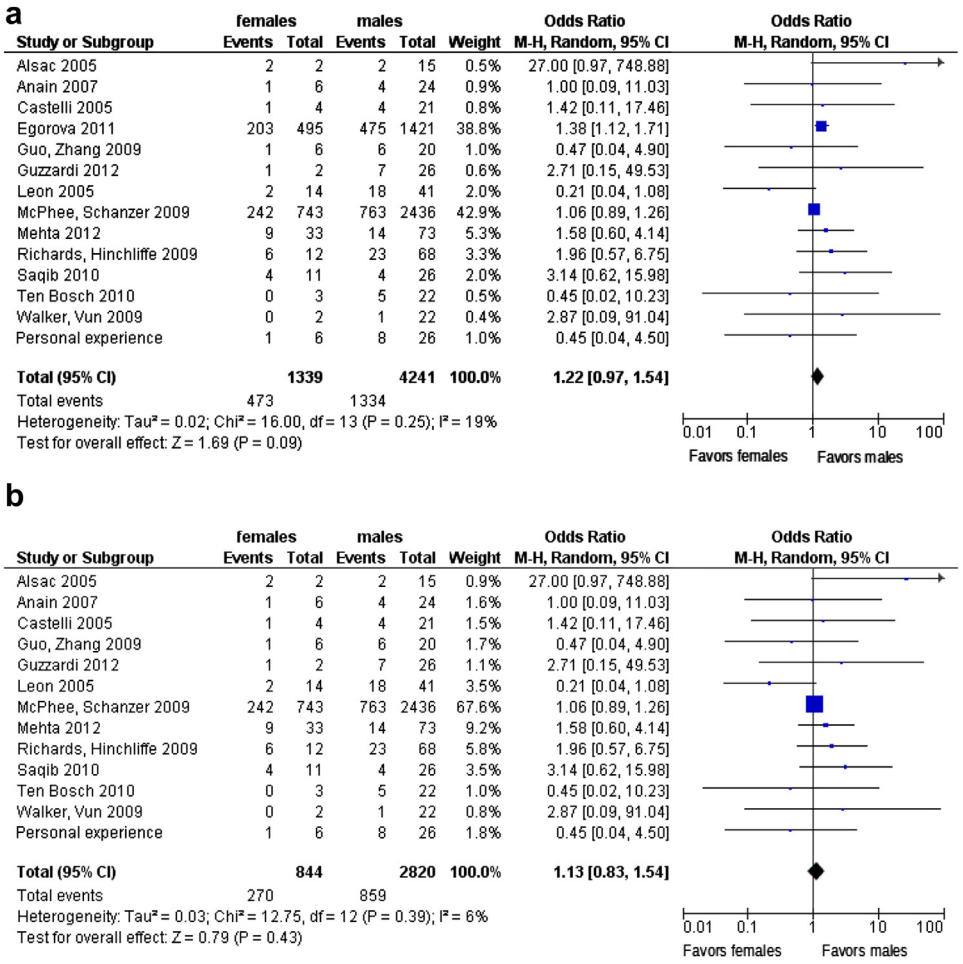

Fig 2. Perioperative (30-day/in-hospital) mortality in females and males undergoing endovascular repair for ruptured abdominal aortic aneurysm (rEVAR). **a,** All cases. **b**, Excluding Medicare duplicated. *CI*, Confidence interval.

the presence of a favorable aneurysm anatomy that might allow for lower perioperative risks. However, this assumption can only be supported as more imaging data on women with rAAA become available.

The early mortality rate found in this review in women undergoing rEVAR (35.6%) was not inconsistent but compared well with published results for open surgery that were not analyzed in this study as it had already been examined in multiple recent reviews and meta-analyses.[1,2,14] There is a general agreement that women are at increased mortality risk for open rAAA repair with pooled rates higher than those in the present review by rEVAR: 48.28% in the Medicare database[14] and 61.8% in the review of Grootenboer et al.[1]

The comparability of outcomes between men and women with rEVAR was somewhat unexpected, given the poor outcome shown in women after elective EVAR.[1,13,14] Mehta et al recently found that women were 3.4 times more likely to die following elective EVAR than men.[13] Grootenboer et al similarly showed more than two-fold increase in the risk of mortality in women vs men after elective EVAR in a systematic review: 2.9% vs 1.5% (OR, 2.4).[1] The most likely explanation of the elective EVAR-related risk excess in women might be due to the more challenging anatomy (smaller and more tortuous arteries) along with a delay in diagnosis and treatment. Women are less likely to undergo imaging (to detect early an aortic aneurysm) as well as other primary and secondary preventive measures including cardiovascular medications and lifestyle adjustment.[1,36] The higher comorbidity profile at advanced ages (women undergoing AAA repair are, on average, older than men) and especially the higher cardiovascular morbidity, often under-recognized in women at the time of repair, are likely to increase the operative elective risk.[1,13,14] On the contrary, it could be hypothesized that factors, other than comorbidities, potentially more equally distributed by sex (such as shock and hemodynamic instability) at time of aneurysm rupture, might affect outcome of repair and explain why the mortality risk excess in females compared with males in elective EVAR is not confirmed in emergent EVAR. However, a major limitation of ours as well as of other

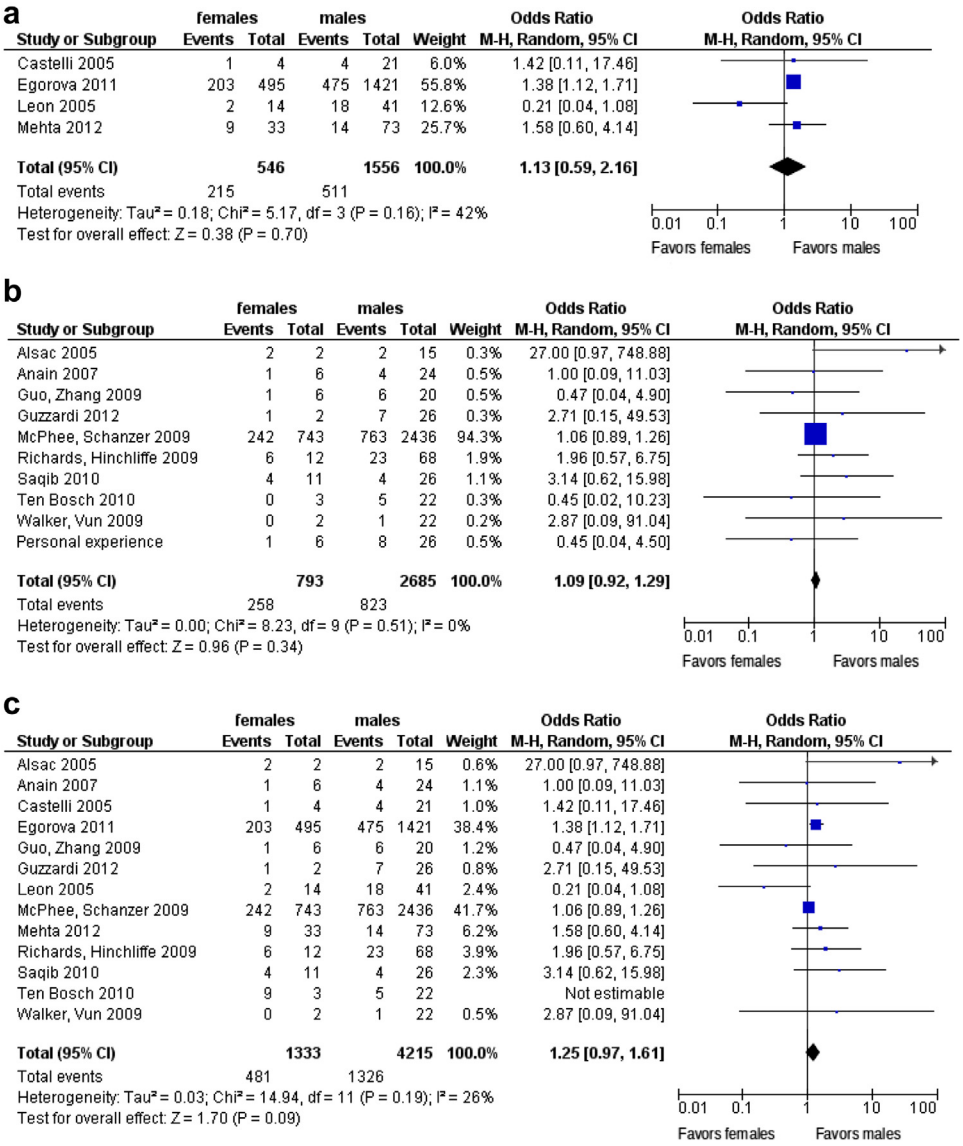

Fig 3. Perioperative (30-day/in-hospital) mortality in females and males undergoing endovascular repair for ruptured abdominal aortic aneurysm (rEVAR) in published vs unpublished data for female populations. **a,** Published cases. **b,** Studies with unpublished/published data. **c,** Excluding unpublished contribution of authors. *CI,* Confidence interval.

studies comparing mortality between men and women was the inability to adjust for confounding factors. We found that in studies performed for emergent AAA repair, comorbidities and hemodynamics were reported poorly, and only a few studies stratified data for men and women but without details regarding shock severity and type of aneurysm rupture. Cardiac, renal, and pulmonary disease/comorbidity could not be clearly defined because the data were taken from multiple, potentially disparate reports. Furthermore, we could have missed some data in unpublished series from non-responder authors, with the risk of "reporting bias" affecting results of our systematic review. Nevertheless, we could not know if these authors (without data stratified by sex in published work) detected any information in women. Any potentially obtainable data would be related to unpublished information. Other limitations of this review are the level and quality of the original reports (observational studies subject to selection bias) and the small numbers with very scarce female representation in most studies. Thereby, the results may be affected by the lack of standardization and comparability of populations, and there might be a lack of statistical power in order to detect a difference between sex categories. Another limitation is the inclusion of population-based databases with larger numbers but subject to limited accuracy in reporting and potential overlapping or duplicated data. We could not totally exclude that the same patients were included in the Medicare Beneficiary Database[14] that covered the period of

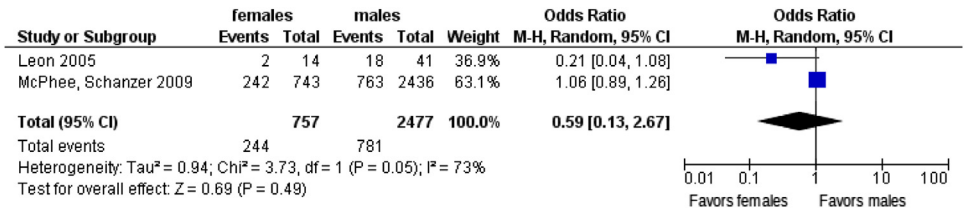

Fig 4. Mortality in females and males undergoing endovascular repair for ruptured abdominal aortic aneurysm (rEVAR) in studies reporting in-hospital outcome. *CI,* Confidence interval.

two other nationwide U.S. studies.[12,20] We attempted to correct potential duplicated inclusion by repeating analysis of pooled data after the exclusion of the Medicare Beneficiary study.[14] Finally, the review focused on early outcome, and the inclusion of in-hospital together with perioperative (30 days) data might be debatable. Nevertheless, we performed additional analyses to separate data from papers reporting only in-hospital outcome. A similar increase in mortality rates up to 30 days in females and males with maintained risk ration might be expected, but this could not be directly addressed with our data.

CONCLUSIONS

Women may benefit as much as men from EVAR for ruptured abdominal aneurysms. Early mortality risk in women may be comparable or not significantly increased with respect to men undergoing emergency EVAR. Nevertheless, current evidence to support an EVAR first approach for women with rAAA is weak and mainly based on population-based studies. This requires confirmation by further experiences with a larger female representation and data stratified by sex.

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AUTHOR CONTRIBUTIONS

Conception and design: PDR, PC, AM
Analysis and interpretation: PDR, ML, EC, GS, TR
Data collection: PDR, GS, TR, AM
Writing the article: PDR, AM
Critical revision of the article: PDR, ML, EC, PC, TR
Final approval of the article: PDR, ML, EC, GS, PC, TR, AM
Statistical analysis: PDR, EC, AM
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APPENDIX

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