

E.3 Complex AAAs

Full citation	de Guerre LE, Varkevisser RR, Swerdlow NJ, Liang P, Li C, Dansey K, van Herwaarden JA, Schermerhorn ML. Sex differences in perioperative outcomes after complex abdominal aortic aneurysm repair. Journal of vascular surgery. 2019 Jul 4.
Study details	<p>Study design: retrospective cohort</p> <p>Location(s): USA</p> <p>Study period: 2011 to 2017</p> <p>Aim of the study: to evaluate the association of female sex and perioperative outcomes after endovascular and open complex AAA repair in a nationwide registry</p>
Participants	<p>Sample size: EVAR group, n=1,260; OSR group, n= 1,010</p> <p>Inclusion criteria: patients undergoing endovascular or open repair of complex AAAs (defined as a proximal extent listed as juxtarenal, pararenal, or suprarenal or open procedures coded as repair of an AAA involving visceral vessels or EVAR using Cook Zenith Fenestrated Endovascular Graft)</p> <p>Exclusion criteria: open repair with an infrarenal proximal clamp position, emergency repair, patients with prior AAA repair, ruptured AAAs and thoracoabdominal aneurysms.</p> <p>Baseline characteristics:</p> <p>Median age (IQR): Women 75 (69–80), men 73 (67–79)</p> <p>Gender: EVAR group, 78.6% male; OSR group, 69.3% male</p> <p>Median aneurysm diameter: EVAR: women 5.5 (5.1–6), men 5.6 (5.1–6.2); OSR: women 5.7 (5.2–6.4), men 6 (5.5–6.75)</p> <p>Diabetes (insulin dependent): women 2.4%, men 2.5%</p> <p>Hypertension: women 80.2%; men 82.1 %</p> <p>COPD: women 22.2%; men 19.7%</p> <p>Congestive heart failure: women 1.7%; men 2.3%</p>
Methods	<p>Data collection: data were extracted from a detailed national surgical registry (the National Surgical Quality Improvement Program; NSQIP).</p> <p>Analysis: Authors examined independent associations between endovascular and open repair with the outcomes for female and male patients separately. Propensity scores calculated using logistic regression models and used to create inverse probability weights. No adjustment for anatomic complexity (to allow ‘the inherent anatomic differences between female and male patients to persist’).</p>
Intervention	Complex EVAR

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Comparator	Complex OSR
Outcomes	Perioperative mortality
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk – recruitment over ≥5 yrs, unclear that year of operation was controlled for in analysis</p> <p>1.2. Were cohorts from the same place? Low risk – cohorts were derived from the same national surgical registry.</p> <p>1.3. Is the definition of AAA the same across cohorts? Moderate risk – OSR excluded all infrarenal clamps (which is likely to include some cases that would be classified as juxtarenal if addressed with EVAR).</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk – separate analyses for men and women, each controlling for demographics.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk – good range of individual comorbidities.</p> <p>2.3. Does study control appropriately for AAA characteristics? Moderate risk – just diameter.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk - no post-intervention variables which could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – participants identified a detailed surgical registry with procedure codes specified.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – data obtained from a detailed surgical registry with procedure codes specified.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks appear to have been conducted on model specification/fit.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? Low risk – authors highlight that the NSQIP database required hospitals to provide complete 30-day follow-up on at least 95% of patients.</p> <p>4.3. Have different methods been compared within the study? High risk - different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? N/A</p> <p>5.3. Has balancing of the covariates been demonstrated? N/A</p> <p>Analysis – simple multivariable models</p>

Full citation	de Guerre LE, Varkevisser RR, Swerdlow NJ, Liang P, Li C, Dansey K, van Herwaarden JA, Schermerhorn ML. Sex differences in perioperative outcomes after complex abdominal aortic aneurysm repair. Journal of vascular surgery. 2019 Jul 4.
	<p>6.1 Is sample size adequate relative to number of covariates considered? High risk – 103 events; unknown number of covariates; probably >10</p> <p>6.2 Were interactions between treatment and other covariates considered? High risk – no interactions considered.</p> <p>Overall risk of bias: Moderate risk</p> <p>Directness: directly applicable</p>
Full citation	Fiorucci B, Speziale F, Kölbl T, Tsilimparis N, Sirignano P, Capoccia L, Simonte G, Verzini F. Short-and Midterm Outcomes of Open Repair and Fenestrated Endografting of Pararenal Aortic Aneurysms in a Concurrent Propensity-Adjusted Comparison. Journal of Endovascular Therapy. 2019 Feb;26(1):105-12.
Study details	<p>Study design: retrospective cohort</p> <p>Location(s): Germany and Italy</p> <p>Study period: 1998 to 2016 (OSR) / 2006 to 2015 (fEVAR)</p> <p>Aim of the study: to compare short- and midterm outcomes of patients treated with fEVAR and OSR for pararenal aortic aneurysms in patients from a group of high-volume centres in which both techniques were sufficiently well established to allow an up-to-date comparison of results</p>
Participants	<p>Sample size: EVAR group, n=41; OSR group, n= 102</p> <p>Inclusion criteria: unclear ('pararenal aortic aneurysms... consecutive patients electively treated with OSR or fEVAR')</p> <p>Exclusion criteria: urgent or emergent treatment for symptomatic or ruptured aneurysms</p> <p>Baseline characteristics:</p> <p>Mean age: fEVAR 73, OSR 71</p> <p>Gender: fEVAR group, 95.1% male; OSR group, 94.1% male</p> <p>Aneurysm diameter: NR</p> <p>Diabetes: fEVAR 4.9%, OSR 15.7%</p> <p>Hypertension: fEVAR 78.0%, OSR 89.2%</p> <p>COPD: fEVAR 36.6%, OSR 52.9%</p> <p>Renal failure: fEVAR 12.2%, OSR 28.4%</p> <p>Coronary artery disease: fEVAR 43.9%, OSR 32.4%</p>
Methods	<p>Data collection: Vascular databases containing prospectively collected data at 3 tertiary institutions were merged.</p> <p>Analysis: A propensity score according to type of treatment was constructed from a binary logistic regression using age, gender, CAD, and renal failure with a matching method that selected more than one participant from the OSR group for every patient in the fEVAR group.</p>

Full citation	Fiorucci B, Speziale F, Kölbl T, Tsilimparis N, Sirignano P, Capoccia L, Simonte G, Verzini F. Short-and Midterm Outcomes of Open Repair and Fenestrated Endografting of Pararenal Aortic Aneurysms in a Concurrent Propensity-Adjusted Comparison. Journal of Endovascular Therapy. 2019 Feb;26(1):105-12.
Intervention	Fenestrated EVAR
Comparator	Complex OSR
Outcomes	Perioperative mortality, perioperative complications (all, cardiovascular, respiratory, renal)
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? High risk – cohorts drawn from different periods in time</p> <p>1.2. Were cohorts from the same place? Low risk – cohorts were derived from the same centres.</p> <p>1.3. Is the definition of AAA the same across cohorts? Moderate risk – no details of inclusion criteria.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk – age and sex controlled for.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Moderate risk – only 2 individual comorbidities (coronary artery disease and renal failure).</p> <p>2.3. Does study control appropriately for AAA characteristics? High risk – none.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk - no post-intervention variables which could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – institution-specific datasets used but methods unclear.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – institution-specific datasets.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? High risk – medical records (although 'missing data for those with an overdue follow-up >18 months were obtained when feasible through telephone interviews with patients, family, or general practitioners')</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks appear to have been conducted on model specification/fit.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – possible differential missingness – especially given asymmetrical recruitment periods – with no valid adjustment considered.</p> <p>4.3. Have different methods been compared within the study? High risk - different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? High risk – method not reported</p> <p>5.2. Was overlap / common support appropriately assessed? High risk – no assessment reported</p>

Full citation	Fiorucci B, Speziale F, Kölbl T, Tsilimparis N, Sirignano P, Capoccia L, Simonte G, Verzini F. Short-and Midterm Outcomes of Open Repair and Fenestrated Endografting of Pararenal Aortic Aneurysms in a Concurrent Propensity-Adjusted Comparison. Journal of Endovascular Therapy. 2019 Feb;26(1):105-12.
	<p>5.3. Has balancing of the covariates been demonstrated? High risk – not reported</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? High risk – not reported how many covariates were considered.</p> <p>6.2 Were interactions between treatment and other covariates considered? High risk – no interactions considered.</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>
Full citation	Gupta PK, Brahmhatt R, Kempe K, et al. (2017) Thirty-day outcomes after fenestrated endovascular repair are superior to open repair of abdominal aortic aneurysms involving visceral vessels. J Vasc Surg. 66(6):1653-1658.
Study details	<p>Study design: retrospective cohort</p> <p>Location(s): USA</p> <p>Study period: 2008 to 2013</p> <p>Aim of the study: to compare 30-day outcomes after FEVAR and OSR of AAAs involving visceral vessels.</p>
Participants	<p>Sample size: FEVAR group, n=535; OSR group, n= 1,207</p> <p>Inclusion criteria: people who underwent EVAR or OSR of AAAs involving visceral vessels were included.</p> <p>Exclusion criteria: people who underwent thoracoabdominal aneurysm repair (CPT 33877 and ICD-9-CM 441.7) were excluded.</p> <p>Baseline characteristics:</p> <p>Mean age (range): FEVAR group, 75 (69-82) years; OSR group, 72 (66-77) years</p> <p>Gender: FEVAR group, 81.9% male; OSR group, 71.7% male</p> <p>Mean aneurysm diameter: not reported</p> <p>Diabetes: FEVAR group, 15.5%; OSR group, 10.8%</p> <p>Hypertension: FEVAR group, 79.4%; OSR group, 82.4%</p> <p>COPD: FEVAR group, 23.7%; OSR group, 20.6%</p> <p>Previous myocardial infarction, cardiac surgery or percutaneous cardiac intervention: FEVAR group, 26.4%; OSR group, 23.8%</p>
Methods	<p>Data collection: data were extracted from a detailed national surgical registry (the National Surgical Quality Improvement Program; NSQIP). The NSQIP database requires hospitals to provide complete 30-day follow-up on at least 95% of patients.</p> <p>Analysis: Forward stepwise multivariate logistic regression was performed. The inclusion criterion for multivariate analysis was a p value <0.1 on univariate analysis.</p>

Full citation	Gupta PK, Brahmhatt R, Kempe K, et al. (2017) Thirty-day outcomes after fenestrated endovascular repair are superior to open repair of abdominal aortic aneurysms involving visceral vessels. J Vasc Surg. 66(6):1653-1658.
Intervention	FEVAR
Comparator	OSR
Outcomes	30-day mortality, cardiac arrest, renal failure, and respiratory failure
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.4. Were cohorts from the same time period? Moderate risk – recruitment over ≥5 yrs, unclear that year of operation was controlled for in analysis</p> <p>1.5. Were cohorts from the same place? Low risk – cohorts were derived from the same national surgical registry.</p> <p>1.6. Is the definition of AAA the same across cohorts? Low risk – all participants had had complex aneurysms involving visceral vessels.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Moderate risk – model for primary outcome measure (30-day mortality) only controlled for age.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Moderate risk – model for primary outcome measure (30-day mortality) only controlled for history of COPD.</p> <p>2.3. Does study control appropriately for AAA characteristics? High risk – there is no indication that AAA characteristics were controlled for.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk - no post-intervention variables which could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – participants identified a detailed surgical registry with procedure codes specified.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – data obtained from a detailed surgical registry with procedure codes specified.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks appear to have been conducted on model specification/fit.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? Low risk – authors highlight that the NSQIP database required hospitals to provide complete 30-day follow-up on at least 95% of patients.</p> <p>4.3. Have different methods been compared within the study? High risk - different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? N/A</p>

Full citation	Gupta PK, Brahmhatt R, Kempe K, et al. (2017) Thirty-day outcomes after fenestrated endovascular repair are superior to open repair of abdominal aortic aneurysms involving visceral vessels. J Vasc Surg. 66(6):1653-1658.
	<p>5.3. Has balancing of the covariates been demonstrated? N/A</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? High risk – not reported how many covariates were considered.</p> <p>6.2 Were interactions between treatment and other covariates considered? High risk – no interactions considered.</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>
Full citation	Locham S, Faateh M, Dakour-Aridi H et al. (2018) Octogenarians Undergoing Open Repair Have Higher Mortality Compared with Fenestrated Endovascular Repair of Intact Abdominal Aortic Aneurysms Involving the Visceral Vessels. Ann Vasc Surg. 51:192-199.
Study details	<p>Study design: retrospective cohort study</p> <p>Location(s): USA</p> <p>Study period: 2006 to 2015</p> <p>Aim of the study: to compare 30-day outcomes of FEVAR versus OSR in octogenarians undergoing repair of AAA involving the visceral vessels</p>
Participants	<p>Sample size: FEVAR group, n=242; OSR group, n=306</p> <p>Inclusion criteria: people 80 ≥ years who underwent FEVAR or OSR for unruptured complex AAA involving visceral vessels were included.</p> <p>Exclusion criteria: concomitant open repairs, emergent cases, and patients <80 years or >90 years were excluded.</p> <p>Baseline characteristics:</p> <p>Median age (IQR): FEVAR group, 83 (82-86) years; OSR group, 82 (81-85) years</p> <p>Gender: FEVAR group, 81.7% male; OSR group, 64.1% male</p> <p>Mean aneurysm diameter: not reported</p> <p>Diabetes: FEVAR group, 12.8%; OSR group, 5.6%</p> <p>COPD: FEVAR group, 18.2%; OSR group, 15.4%</p> <p>Congestive heart failure: FEVAR group, 1.2%; OSR group, 0.7%</p> <p>Hypertension: FEVAR group, 82.2%; OSR group, 83.3%</p> <p>Disseminated cancer: FEVAR group, 0.8%; OSR group, 0.7%</p> <p>Bleeding disorders: FEVAR group, 9.1%; OSR group, 10.1%</p>

Full citation	Locham S, Faateh M, Dakour-Aridi H et al. (2018) Octogenarians Undergoing Open Repair Have Higher Mortality Compared with Fenestrated Endovascular Repair of Intact Abdominal Aortic Aneurysms Involving the Visceral Vessels. Ann Vasc Surg. 51:192-199.
Methods	Data collection: investigators identified participants and obtained data on their outcomes by querying the American College of Surgeons version of the National Surgical Quality Improvement Program (ACS-NSQIP) database using procedure codes. Authors highlighted that the ACS-NSQIP database routinely collects information based on patient's medical charts rather than billing data. Analysis: Multivariate logistic regression was performed. Covariates were chosen on the basis of clinical and statistical significance in univariate analysis (significance level not specified). All models were tested using variation inflation factor, Hosmer-Lemeshow goodness of fit test, and area under the receiver operating characteristic curve (C-statistic).
Intervention	FEVAR
Comparator	OSR
Outcomes	30-day mortality
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk – ≥5-yr recruitment with no adjustment for year of operation. 1.2. Were cohorts from the same place? Low risk – all participants were selected from the same national surgical registry. 1.3. Is the definition of AAA the same across cohorts? Low risk – the definition of AAA was similar across cohorts.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk – demographics, including age and gender, were controlled for. 2.2. Does study control appropriately for comorbidity and/or fitness? Low risk – a broad range of comorbidities were controlled for. 2.3. Does study control appropriately for AAA characteristics? High risk – the study did not control for AAA characteristics. 2.4. Could any adjustment variables have been affected by the intervention? Low risk - no post-intervention variables which could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – a detailed surgical registry was used to identify participants. 3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – outcomes were assessed using a detailed surgical registry was used with procedure and diagnosis codes specified. 3.3. Is method of data collection likely to record long-term outcomes accurately? N/A– no long-term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? Low risk – checks were performed using the Hosmer–Lemeshow test and the C-statistic 4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – there is no indication that the impact of missing data was considered. 4.3. Have different methods been compared within the study? High risk – different methods were not compared.</p>

Full citation	Locham S, Faateh M, Dakour-Aridi H et al. (2018) Octogenarians Undergoing Open Repair Have Higher Mortality Compared with Fenestrated Endovascular Repair of Intact Abdominal Aortic Aneurysms Involving the Visceral Vessels. Ann Vasc Surg. 51:192-199.
	<p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? N/A</p> <p>5.3. Has balancing of the covariates been demonstrated? N/A</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? High risk - number of events is <10 times greater than number of variables considered.</p> <p>6.2 Were interactions between treatment and other covariates considered? High risk – no interactions were considered.</p> <p>Overall risk of bias: High risk</p> <p>Directness: partially applicable</p>

Full citation	Locham S, Dakour-Aridi H, Bhela J, Nejim B, Bhavana Challa A, Malas M. Thirty-Day Outcomes of Fenestrated and Chimney Endovascular Repair and Open Repair of Juxtarenal, Pararenal, and Suprarenal Abdominal Aortic Aneurysms Using National Surgical Quality Initiative Program Database (2012-2016). Vascular and endovascular surgery. 2019 Apr;53(3):189-98.
Study details	<p>Study design: retrospective cohort study</p> <p>Location(s): USA</p> <p>Study period: 2012 to 2016</p> <p>Aim of the study: to compare short-term outcomes between endovascular (FEVAR and ChEVAR) and open repair of patients with suprarenal, juxtarenal, and pararenal AAAs using a large national surgical database</p>
Participants	<p>Sample size: fEVAR group, n=162; ChEVAR group, n=164, OSR group, n=865</p> <p>Inclusion criteria: All patients undergoing endovascular (fEVAR or ChEVAR) and open repair of juxtarenal, pararenal, and suprarenal AAA.</p> <p>Exclusion criteria: emergent, outpatient, ruptured, TAA type IV, acute conversion to open repair, and not documented/infrarenal aneurysms.</p> <p>Baseline characteristics:</p> <p>Median age (IQR): fEVAR 74 (69–80) years; ChEVAR 75 (69–81); OSR 72 (66–77) years</p> <p>Gender: fEVAR 82.7% male; ChEVAR 70.7% male; OSR 71.3% male</p> <p>Median aneurysm diameter: fEVAR 5.8; ChEVAR 5.8; OSR 5.9</p> <p>Diabetes: fEVAR 17.9%; ChEVAR 11.0%; OSR 11.9%</p> <p>COPD: fEVAR 29.0%; ChEVAR 23.8%; OSR 24.6%</p> <p>Congestive heart failure: fEVAR 3.7%; ChEVAR 3.7%; OSR 2.2%</p>

Full citation	Locham S, Dakour-Aridi H, Bhela J, Nejim B, Bhavana Challa A, Malas M. Thirty-Day Outcomes of Fenestrated and Chimney Endovascular Repair and Open Repair of Juxtarenal, Pararenal, and Suprarenal Abdominal Aortic Aneurysms Using National Surgical Quality Initiative Program Database (2012-2016). Vascular and endovascular surgery. 2019 Apr;53(3):189-98.
	Hypertension: fEVAR 84.6%; ChEVAR 87.2%; OSR 83.0% Chronic renal failure: fEVAR 44.7%; ChEVAR 45.0%; OSR 40.0% Prior AAA surgery: fEVAR 29.0%; ChEVAR 34.9%; OSR 31.7%
Methods	Data collection: investigators identified participants and obtained data on their outcomes by querying the American College of Surgeons version of the National Surgical Quality Improvement Program (ACS-NSQIP) database using procedure codes. Analysis: Multivariate logistic regression was performed. Statistically significant and clinically relevant covariates based on univariate analysis and prior literature were included. All models were tested using Hosmer–Lemeshow goodness-of-fit test and area under receiver operative curve.
Intervention	fEVAR / ChEVAR
Comparator	OSR
Outcomes	30-day mortality; 30-day renal failure; 30-day cardiopulmonary failure
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk – ≥5-yr recruitment with no adjustment for year of operation. 1.2. Were cohorts from the same place? Low risk – all participants were selected from the same national surgical registry. 1.3. Is the definition of AAA the same across cohorts? Low risk – the definition of AAA was similar across cohorts.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk – demographics, including age and gender, were controlled for. 2.2. Does study control appropriately for comorbidity and/or fitness? Low risk – a broad range of comorbidities were controlled for. 2.3. Does study control appropriately for AAA characteristics? Low risk – diameter and distal extent. 2.4. Could any adjustment variables have been affected by the intervention? High risk – controls for transfusion (appears to be perioperative).</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – a detailed surgical registry was used to identify participants. 3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – outcomes were assessed using a detailed surgical registry was used with procedure and diagnosis codes specified. 3.3. Is method of data collection likely to record long-term outcomes accurately? N/A– no long-term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? Low risk – checks were performed using the Hosmer–Lemeshow test and the C-statistic</p>

Full citation	Locham S, Dakour-Aridi H, Bhela J, Nejim B, Bhavana Challa A, Malas M. Thirty-Day Outcomes of Fenestrated and Chimney Endovascular Repair and Open Repair of Juxtarenal, Pararenal, and Suprarenal Abdominal Aortic Aneurysms Using National Surgical Quality Initiative Program Database (2012-2016). <i>Vascular and endovascular surgery</i>. 2019 Apr;53(3):189-98.
	<p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – there is no indication that the impact of missing data was considered.</p> <p>4.3. Have different methods been compared within the study? High risk – different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? N/A</p> <p>5.3. Has balancing of the covariates been demonstrated? N/A</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? High risk - number of events is <10 times greater than number of variables considered.</p> <p>6.2 Were interactions between treatment and other covariates considered? High risk – no interactions were considered.</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>
Full citation	Michel M, Becquemin J-P, Clément M-C, et al. (2015) Editor's choice – thirty day outcomes and costs of fenestrated and branched stent grafts versus open repair for complex aortic aneurysms. <i>Eur J Vasc Endovasc Surg</i>. 50:189-196
Study details	<p>Study design: retrospective cohort study</p> <p>Location(s): France</p> <p>Study period: 2010 - 2012</p> <p>Aim of the study: to compare 30 day outcomes and costs of fenestrated and branched stent grafts (f/b EVAR) and open surgery (OSR) for the treatment of complex abdominal aortic aneurysms (AAA) and thoraco-abdominal aortic aneurysms (TAAA).</p>
Participants	<p>Sample size: EVAR group, n=268; OSR group, n=1,678</p> <p>Inclusion criteria: high risk for open surgery; had an AAA >50 mm in men (45 mm in women), with or without thoracic aortic aneurysm >55 mm (50 mm in women), and with an infrarenal neck <10 mm in length or aneurysm extending to the suprarenal aorta</p> <p>Exclusion criteria: emergent and ruptured aneurysms as well as aortic dissections</p> <p>Baseline characteristics:</p> <p>Mean age (SD): EVAR group, 71.6 (8.5) years; OSR group, 69.2 (8.9) years</p> <p>Gender: EVAR group, 93.3% male; OSR group, 91.7% male</p>

Full citation	Michel M, Becquemin J-P, Clément M-C, et al. (2015) Editor's choice – thirty day outcomes and costs of fenestrated and branched stent grafts versus open repair for complex aortic aneurysms. Eur J Vasc Endovasc Surg. 50:189-196
	<p>Mean aneurysm diameter: not reported</p> <p>Para/juxtarenal AAA: EVAR group, 68.6%; OSR group, 82.4%</p> <p>Infradiaphragmatic TAAA: EVAR group, 15.7%; OSR group, 13.4%</p> <p>Supradiaphragmatic AAA: EVAR group, 15.7%; OSR group, 4.2%</p> <p>Hypertension: EVAR group, 61.5%; OSR group, 51.1%</p> <p>Hyperlipidemia: EVAR group, 42.4%; OSR group, 34.5%</p> <p>Diabetes: EVAR group, 14.5%; OSR group, 12.5%</p> <p>Coronary artery occlusive disease: EVAR group, 9.2%; OSR group, 8.2%</p> <p>Peripheral arterial disease: EVAR group, 8.0%; OSR group, 14.5%</p> <p>Cardiac insufficiency: EVAR group, 7.3%; OSR group, 3.2%</p> <p>Chronic pulmonary disease: EVAR group, 23.3%; OSR group, 14.4%</p> <p>Chronic renal disease: EVAR group, 8.8%; OSR group, 6.2%</p>
Methods	<p>Data collection: data for EVAR was collected using a multicentre prospective registry. Data for OSR was collected from the national hospital discharge database</p> <p>Analysis: multivariate analyses were performed on 30 day mortality using a Cox model</p>
Intervention	EVAR
Comparator	OSR
Outcomes	30-day mortality
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Low risk</p> <p>1.2. Were cohorts from the same place? Low risk – same country</p> <p>1.3. Is the definition of AAA the same across cohorts? High risk – EVAR cohort includes a greater proportion of thoracoabdominal AAAs</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk</p> <p>2.3. Does study control appropriately for AAA characteristics? Moderate risk – just extent</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk</p> <p>Data collection</p>

Full citation	Michel M, Becquemin J-P, Clément M-C, et al. (2015) Editor's choice – thirty day outcomes and costs of fenestrated and branched stent grafts versus open repair for complex aortic aneurysms. Eur J Vasc Endovasc Surg. 50:189-196
	<p>3.1. Is method of data collection likely to have identified suitable participants accurately? High risk – different databases were used for each arm</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? High risk – detailed surgical registries but different ones for each arm</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long-term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks reported</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? Low risk</p> <p>4.3. Have different methods been compared within the study? Moderate risk – different methods were compared, but all rely on assumption of selection on observables</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? High risk – not reported</p> <p>5.2. Was overlap / common support appropriately assessed? High risk – not reported</p> <p>5.3. Has balancing of the covariates been demonstrated? High risk – not reported</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? N/A</p> <p>6.2 Were interactions between treatment and other covariates considered? N/A</p> <p>Overall risk of bias: High risk</p> <p>Directness: Partially applicable (includes some TAAAs that are likely to be out of scope)</p>

Full citation	Orr NT, Davenport DL, Minion DJ et al. (2017) Comparison of perioperative outcomes in endovascular versus open repair for juxtarenal and pararenal aortic aneurysms: A propensity-matched analysis. Vascular. 25(4):339-345.
Study details	<p>Study design: retrospective cohort study</p> <p>Location(s): USA</p> <p>Study period: 2012 to 2015</p> <p>Aim of the study: to compare 30-day outcomes of EVAR versus OSR of juxtarenal and pararenal aortic aneurysms</p>
Participants	<p>Sample size of unmatched cohort: complex EVAR group, n=395; OSR group, n=610</p> <p>Sample size of matched cohort: complex EVAR group, n=263; OSR group, n=263</p>

Full citation	Orr NT, Davenport DL, Minion DJ et al. (2017) Comparison of perioperative outcomes in endovascular versus open repair for juxtarenal and pararenal aortic aneurysms: A propensity-matched analysis. <i>Vascular</i>. 25(4):339-345.
	<p>Inclusion criteria: all patients with juxtarenal or pararenal AAAs treated by EVAR or OSR between 2012 and 2015 were included</p> <p>Exclusion criteria: failed prior repairs, ruptured aneurysms or dissected aneurysms were excluded</p> <p>Baseline characteristics (of matched cohort):</p> <p>% <65 years: complex EVAR group, 15%; OSR group, 16%</p> <p>% >80 years: complex EVAR group, 21%; OSR group, 21%</p> <p>Gender: complex EVAR group, 74% male; OSR group, 76% male</p> <p>Mean aneurysm diameter: not reported</p> <p>Diabetes: complex EVAR group, 14%; OSR group, 10%</p> <p>Severe COPD: complex EVAR group, 21%; OSR group, 26%</p> <p>Coronary heart failure: complex EVAR group, 3.0%; OSR group, 3.4%</p> <p>Hypertension receiving treatment: complex EVAR group, 84%; OSR group, 83%</p> <p>Bleeding disorder: complex EVAR group, 12%; OSR group, 10%</p>
Methods	<p>Data collection: Data collection: investigators identified participants and obtained data on their outcomes by querying the American College of Surgeons version of the National Surgical Quality Improvement Program (ACS-NSQIP) database which contained information such as the proximal and distal extents of the aneurysm, specific operative characteristics, and 30-day postoperative vascular outcomes in both inpatient and outpatient settings.</p> <p>Analysis: Propensity score matching was performed to clinically match OSR and EVAR groups on preoperative risk and select perioperative factors that differed significantly in the unmatched groups (greedy nearest neighbour matching, caliper <0.15 standard deviations). Authors do not explicitly list what these factors were but examination of tables within the manuscript highlight that the following factors were significantly different between groups: mean age, ASA class, % with acute renal failure, % smokers, % with bleeding disorders, % who had same day elective surgery, mean duration of operation, % juxtarenal/pararenal, distal extent of the aneurysm, and renal stent placement. For the purpose of this review it is assumed that all these factors were controlled for when deriving propensity scores. Group comparisons were then performed between the matched groups.</p>
Intervention	Complex EVAR
Comparator	OSR
Outcomes	30-day mortality, length of stay, length of stay in ICU, discharge to home, reintervention (labelled return to OR), and adverse events (including Cardiac or respiratory failure, surgical site infection or dehiscence, renal insufficiency or failure, pneumonia, sepsis, DVT and pulmonary embolism)
Study Appraisal using NICE's	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Low risk – cohorts were drawn from the same time period.</p> <p>1.2. Were cohorts from the same place? Low risk – all participants were selected from the same national surgical registry.</p>

Full citation	Orr NT, Davenport DL, Minion DJ et al. (2017) Comparison of perioperative outcomes in endovascular versus open repair for juxtarenal and pararenal aortic aneurysms: A propensity-matched analysis. <i>Vascular</i> . 25(4):339-345.
bespoke risk of bias assessment tool	<p>1.3. Is the definition of AAA the same across cohorts? Low risk – there was a significantly higher proportion of juxtarenal AAA in the OSR group in the unmatched cohort. Following propensity score matching this difference became non-significant.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Moderate risk – as mentioned above (analysis), it is likely that only age was controlled for.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk – although it was not explicitly stated, it is likely that a good range of comorbidities were controlled for.</p> <p>2.3. Does study control appropriately for AAA characteristics? Low risk – although it was not explicitly stated, it is likely that AAA characteristics were controlled for.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? High risk – authors highlight that perioperative factors were controlled for. Some of which may have mediated the treatment effect.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – a detailed surgical registry was used to identify relevant participants.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – outcomes were assessed using a detailed surgical registry.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long-term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks were reported.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – authors do not report how or if missing data was accounted for in their analyses.</p> <p>4.3. Have different methods been compared within the study? High risk – different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? Low risk - greedy nearest neighbour matching was performed; caliper <0.15 standard deviations</p> <p>5.2. Was overlap / common support appropriately assessed? High risk – no assessment was reported.</p> <p>5.3. Has balancing of the covariates been demonstrated? Moderate - conventional hypothesis tests were performed, with no evidence of significant differences.</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? N/A</p> <p>6.2 Were interactions between treatment and other covariates considered? N/A</p>

Full citation	Orr NT, Davenport DL, Minion DJ et al. (2017) Comparison of perioperative outcomes in endovascular versus open repair for juxtarenal and pararenal aortic aneurysms: A propensity-matched analysis. <i>Vascular</i>. 25(4):339-345.
	Overall risk of bias: High risk Directness: directly applicable
Full citation	Raux M, Patel VI, Cochennec F, et al. (2014) A propensity-matched comparison of outcomes for fenestrated endovascular aneurysm repair and open surgical repair of complex abdominal aortic aneurysms. <i>J Vasc Surg</i>.60(4):858-63
Study details	Study design: retrospective cohort study Location(s): USA Study period: July 2001 to August 2012 Aim of the study: compare 30-day outcomes of FEVAR and OSR at 2 high-volume centres where FEVAR was undertaken for high-risk patients
Participants	Sample size on matched cohort: FEVAR group, n=42; OSR group, n=147 Inclusion criteria: people with complex aneurysms who underwent elective FEVAR or OSR were included. Only patients who would have required an actual or anticipated completely suprarenal or more proximal clamp position were included in the study. Exclusion criteria: people with type I-IV thoracoabdominal aneurysms, ruptured or symptomatic aneurysms, patients with a redo aortic surgery or a history of aortic intervention, and patients with actual or anticipated infrarenal clamp position were excluded. Baseline characteristics (of matched cohort): Mean age (SD): FEVAR group, 73 (10) years; OSR group, 73 (7.8) years Gender: FEVAR group, 88% male; OSR group, 82% male Mean aneurysm diameter: not reported Hypertension: FEVAR group, 74%; OSR group, 80% Myocardial infarction: FEVAR group, 26%; OSR group, 36% Chronic heart failure: FEVAR group, 14%; OSR group, 12% Coronary artery disease: FEVAR group, 43%; OSR group, 34% COPD: FEVAR group, 36%; OSR group, 25% Cerebrovascular accident: FEVAR group, 7.1%; OSR group, 7.5% Diabetes: FEVAR group, 19%; OSR group, 14%
Methods	Data collection: participants were identified by retrospective review of medical records from 2 high-volume medical centres: one centre only performed OSR and the other only performed FEVAR. Patients who received FEVAR were considered high-risk for OSR (High-risk criteria did not consider aneurysm morphology).

Full citation	Raux M, Patel VI, Cochennec F, et al. (2014) A propensity-matched comparison of outcomes for fenestrated endovascular aneurysm repair and open surgical repair of complex abdominal aortic aneurysms. J Vasc Surg.60(4):858-63
	Analysis: Propensity score matching was performed. Initially, multivariate regression was used to generate propensity scores by controlling for all variables that were found to be significantly associated (p values<0.05) with the odds of performing FEVAR in univariate analyses. These included demographic variables, multiple relevant comorbidities, as well as actual/ anticipated clamp location. Propensity score matching was then performed using the caliper method, matching each case (FEVAR) with four controls (OSR) ≤ 0.2 standard deviations of the propensity score. The propensity matched groups were then compared using univariate methods as well as multivariate analyses (using multivariate logistic regression).
Intervention	FEVAR
Comparator	OSR
Outcomes	30-day mortality, and adverse events (including procedural and graft complications, cardiac, renal, and respiratory complications) within 30 days of treatment
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk – ≥ 5-yr recruitment with no adjustment for year of operation</p> <p>1.2. Were cohorts from the same place? High risk – patients who underwent FEVAR and those who underwent OSR were treated at different hospitals.</p> <p>1.3. Is the definition of AAA the same across cohorts? Low risk – the definition of AAA is the same across cohorts.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk – the study controls for age and gender.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk – a good range of relevant comorbidities were controlled for.</p> <p>2.3. Does study control appropriately for AAA characteristics? Low risk – the study controlled for clamp location which is a proxy for aneurysm type/location.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk - no post-intervention variables which could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Low risk – participants were identified by reviewing medical records.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – outcomes were assessed using medical records</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long term data were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks were reported.</p>

Full citation	Raux M, Patel VI, Cochennec F, et al. (2014) A propensity-matched comparison of outcomes for fenestrated endovascular aneurysm repair and open surgical repair of complex abdominal aortic aneurysms. J Vasc Surg.60(4):858-63
	<p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? Low risk – due to the nature in which data were collected (direct review of medical records for short-term outcomes) it is unlikely that there would be a high amount of missing data.</p> <p>4.3. Have different methods been compared within the study? Moderate risk – different methods were compared but all relied on the same assumption about selection.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? Low risk – matching was performed using the caliper method, matching each case with four controls ≤ 0.2 standard deviations of the propensity score.</p> <p>5.2. Was overlap / common support appropriately assessed? High risk – no assessment was reported</p> <p>5.3. Has balancing of the covariates been demonstrated? Moderate risk – conventional hypothesis tests were performed, with no evidence of significant differences.</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? N/A</p> <p>6.2 Were interactions between treatment and other covariates considered? N/A</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>
Full citation	Tinelli G, Crea MA, de Waure C, et al. (2018) A propensity matched comparison of fenestrated endovascular aneurysm repair and open surgical repair of pararenal and paravisceral aortic aneurysms. J Vasc Surg. March:1-10
Study details	<p>Study design: retrospective propensity-matched cohort study</p> <p>Location(s): Italy</p> <p>Study period: January 2010 to June 2016</p> <p>Aim of the study: This study investigated the outcomes of a current series of patients treated with fenestrated and branched endovascular aneurysm repair (FEVAR) or open surgical repair (OSR) for pararenal abdominal aortic aneurysms (pr-AAAs), including juxtarenal, suprarenal, and type IV thoracoabdominal aneurysms. This study compares the outcomes of these procedures from two high-volume centers without the bias induced by a learning curve.</p>
Participants	<p>Sample size: FEVAR group, n=102; OSR group, n=102</p> <p>Inclusion criteria: all patients with a pr-AAA requiring suprarenal or supravisceral proximal clamping were included in the study</p>

Full citation	Tinelli G, Crea MA, de Waure C, et al. (2018) A propensity matched comparison of fenestrated endovascular aneurysm repair and open surgical repair of pararenal and paravisceral aortic aneurysms. J Vasc Surg. March:1-10
	<p>Exclusion criteria: all F-BEVAR patients were deemed unsuitable for OSR after multidisciplinary evaluation because of high-risk comorbidities. The study excluded patients treated for extent I to III thoracoabdominal aneurysms, ruptured or symptomatic aneurysms, and dissections or connective tissue disorder aneurysms.</p> <p>Baseline characteristics:</p> <p>Mean age (SD): FEVAR group, 71.8 (8.0) years; OSR group, 71.7 (7.0) years</p> <p>Gender: FEVAR group, 95.1% male; OSR group, 92.2% male</p> <p>Mean aneurysm diameter(SD): FEVAR group, 59.8 (8.8) cm; OSR group, 60.6 (9.3) cm</p> <p>Coronary artery disease: FEVAR group, 42.2%; OSR group, 38.2%</p> <p>COPD: FEVAR group, 40.2%; OSR group, 38.2%</p> <p>Chronic kidney disease: FEVAR group, 24.5%; OSR group, 27.5%</p> <p>Diabetes: FEVAR group, 12.7%; OSR group, 11.8%</p>
Methods	<p>Data collection: This retrospective cohort study compared the outcomes of FEVAR and OSR for pr-AAA by analysing prospectively collected data from two centres: the Aortic Center (ACL; Lille, France) and the Vascular Unit of Fondazione Policlinico Universitario Gemelli (FPUG; Rome, Italy)</p> <p>Analysis: Propensity matching</p>
Intervention	FEVAR
Comparator	OSR
Outcomes	30-day mortality, in-hospital mortality, end of study survival at a median follow-up of 38.9 months, theatre time, fluoroscopy time, adverse events, reintervention
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk - >5 years of recruitment without adjustment for year of operation</p> <p>1.2. Were cohorts from the same place? High risk – 2 different centres</p> <p>1.3. Is the definition of AAA the same across cohorts? Low risk</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk</p> <p>2.3. Does study control appropriately for AAA characteristics? Low risk –diameter and (anticipated) clamp level (as a proxy of proximal extent)</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Low risk – medical records</p>

Full citation	Tinelli G, Crea MA, de Waure C, et al. (2018) A propensity matched comparison of fenestrated endovascular aneurysm repair and open surgical repair of pararenal and paravisceral aortic aneurysms. J Vasc Surg. March:1-10
	<p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – medical records</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? High risk – no details given; reliance on medical records alone would be high risk</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks were reported.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – no details provided</p> <p>4.3. Have different methods been compared within the study? High risk – different methods were not compared</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? Moderate risk – caliper method – stated that threshold was 2 standard deviations of the propensity score (this is unusually high; it is possible the authors mean 0.2 SDs, which is common)</p> <p>5.2. Was overlap / common support appropriately assessed? Low risk – balance assessment was made using various tests and checking quantile-quantile plots</p> <p>5.3. Has balancing of the covariates been demonstrated? Moderate risk – conventional hypothesis tests were performed, with no evidence of significant differences.</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? N/A</p> <p>6.2 Were interactions between treatment and other covariates considered? N/A</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>

Full citation	Tsilimparis N, Perez S, Dayama A, et al. (2013) Endovascular repair with fenestrated-branched stent grafts improves 30-day outcomes for complex aortic aneurysms compared with open repair. <i>Ann Vasc Surg.</i> 27(3): 267-73.
Study details	<p>Study design: retrospective cohort study</p> <p>Location(s): USA</p> <p>Study period: 2005 to 2010</p> <p>Aim of the study: to compare the real-world operative and perioperative outcomes of FEVAR and OSR for complex AAA,</p>
Participants	<p>Sample size: FEVAR group, n=264 group, n=1,091</p> <p>Inclusion criteria: patients who underwent FEVAR or OSR for unruptured complex AAAs (juxtarenal and pararenal aneurysms and type IV thoracoabdominal aortic aneurysms) were included.</p> <p>Exclusion criteria: not reported.</p> <p>Baseline characteristics:</p> <p>Mean age (SD): FEVAR group, 74 (9) years; OSR group, 71 (9) years</p> <p>Gender: FEVAR group, 82.2% male; OSR group, 71.5% male</p> <p>Mean aneurysm diameter: not reported</p> <p>Diabetes: FEVAR group, 16%; OSR group, 11%</p> <p>Severe COPD: FEVAR group, 21.6%; OSR group, 20.5%</p> <p>Previous PCI: FEVAR group, 19.3%; OSR group, 19.4%</p> <p>Previous cardiac surgery: FEVAR group, 19.7%; OSR group, 23.5%</p> <p>Previous cardiac surgery: FEVAR group, 75%; OSR group, 85.2%</p> <p>Cardiovascular accident/stroke with neurologic deficit: FEVAR group, 2.3%; OSR group, 4.6%</p> <p>Previous operation within 30 days: FEVAR group, 1.9%; OSR group, 1.6%</p>
Methods	<p>Data collection: data were extracted from a detailed national surgical registry (the National Surgical Quality Improvement Program; NSQIP). Patients who underwent repair procedures for complex AAAs were identified using diagnostic codes and procedure codes.</p> <p>Analysis: Multivariable logistic regression was performed. Authors state that confounders were identified through running regression models with type of repair and one additional preoperative risk factor or demographic variable at a time as predictors and observing how the results differed from running a logistic model using age alone. A change of more than 10% between the crude and adjusted odds ratio of age was used as evidence that the covariate was a possible confounder. A final logistic regression model was run using type of repair and all confounders found in this way.</p>
Intervention	FEVAR
Comparator	OSR
Outcomes	30-day mortality

Full citation	Tsilimparis N, Perez S, Dayama A, et al. (2013) Endovascular repair with fenestrated-branched stent grafts improves 30-day outcomes for complex aortic aneurysms compared with open repair. <i>Ann Vasc Surg.</i> 27(3): 267-73.
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk – ≥5-yr recruitment with no adjustment for year of operation.</p> <p>1.2. Were cohorts from the same place? Low risk – cohorts were drawn from the same national surgical database.</p> <p>1.3. Is the definition of AAA the same across cohorts? High risk – no details of extent of complexity, which is likely to differ between OSR and EVAR, especially over 6-year period during which complex EVAR evolved</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Moderate risk – study only controls for age.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Moderate – a limited number of individual comorbidities were controlled for.</p> <p>2.3. Does study control appropriately for AAA characteristics? High risk – AAA characteristics were not controlled for.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk – no post-intervention variables that could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – data were collected from a detailed surgical registry.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – data were collected from a detailed surgical registry.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no details about checks for model specification/fit were reported.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – there is no indication that missing data were accounted for in the analyses.</p> <p>4.3. Have different methods been compared within the study? High risk – different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? N/A</p> <p>5.3. Has balancing of the covariates been demonstrated? N/A</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? High risk - number of variables considered is not reported, and is likely to be ≥1/10 number of events.</p>

Full citation	Tsilimparis N, Perez S, Dayama A, et al. (2013) Endovascular repair with fenestrated-branched stent grafts improves 30-day outcomes for complex aortic aneurysms compared with open repair. <i>Ann Vasc Surg.</i> 27(3): 267-73.
	6.2 Were interactions between treatment and other covariates considered? High risk – no interactions were considered. Overall risk of bias: High risk Directness: directly applicable
Full citation	Ultee KHJ, Zettervall SL, Soden PA, et al. (2017) Perioperative outcome of endovascular repair for complex abdominal aortic aneurysms. <i>J Vasc Surg.</i> 65(6):1567-1575.
Study details	Study design: retrospective cohort study Location(s): USA Study period: 2011 to 2013 Aim of the study: to examine perioperative outcomes of patients undergoing complex EVAR, focusing on differences with complex OSR and standard infrarenal EVAR. Note: data on complex EVAR is not considered in this review
Participants	Sample size: complex EVAR group, n= 411; OSR group, n=395 Inclusion criteria: people who underwent EVAR or OSR for unruptured juxtarenal, pararenal suprarenal (proximal extent) AAAs were included. All aneurysms treated with fenestrated endografts were also included. Exclusion criteria: people with thoracoabdominal aneurysms and ruptured AAA were excluded. People who underwent OSR with infrarenal aortic clamping were also excluded. Baseline characteristics: Mean age (SD): complex EVAR group, 74.9 (8.1) years; OSR group, 72.2 (8.3) years Gender: complex EVAR group, 77.6% male; OSR group, 66.8% male Mean aneurysm diameter: not reported Hypertension: complex EVAR group, 83.5%; OSR group, 85.1% Diabetes: complex EVAR group, 15.3%; OSR group, 11.1% COPD: complex EVAR group, 19.5%; OSR group, 23.5% Heart failure: complex EVAR group, 4.1%; OSR group, 2.0% Renal insufficiency: complex EVAR group, 19.7%; OSR group, 15.1%
Methods	Data collection: data were extracted from a detailed national surgical registry (the National Surgical Quality Improvement Program; NSQIP). Patients who underwent repair procedures for complex AAAs were identified using diagnostic codes and procedure codes. Analysis: Multivariate logistic regression was performed to assess independent risks associated with treatment approaches. Baseline characteristics were univariately tested, and predictors with a p value < 0.01 were added to the regression model.

Full citation	Ultee KHJ, Zettervall SL, Soden PA, et al. (2017) Perioperative outcome of endovascular repair for complex abdominal aortic aneurysms. J Vasc Surg. 65(6):1567-1575.
Intervention	Complex EVARsc
Comparator	OSR
Outcomes	30-day mortality and adverse events
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Low risk – cohorts were drawn from the same time period.</p> <p>1.2. Were cohorts from the same place? Low risk – all participants were identified using the same national registry.</p> <p>1.3. Is the definition of AAA the same across cohorts? Low risk – the definition of AAA was consistent across treatment arms.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk – study controlled for age and gender.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk – multiple comorbidities were controlled for. These varied according to outcome measure assessed.</p> <p>2.3. Does study control appropriately for AAA characteristics? High risk – AAA characteristics were not controlled for.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk – no post-intervention variables that could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – data were collected from a detailed surgical registry.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – data were collected from a detailed surgical registry.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no details about checks for model specification/fit were reported.</p> <p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? High risk – there is no indication that missing data were accounted for in the analyses.</p> <p>4.3. Have different methods been compared within the study? High risk – different methods were not compared.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? N/A</p> <p>5.3. Has balancing of the covariates been demonstrated? N/A</p>

Full citation	Ultee KHJ, Zettervall SL, Soden PA, et al. (2017) Perioperative outcome of endovascular repair for complex abdominal aortic aneurysms. J Vasc Surg. 65(6):1567-1575.
	<p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? High risk - number of variables considered is not clearly reported, but is very likely to be <1/10 of the number of events.</p> <p>6.2 Were interactions between treatment and other covariates considered? High risk – no interactions were considered.</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>
Full citation	Varkevisser RR, O'Donnell TF, Swerdlow NJ, Liang P, Li C, Ultee KH, Pothof AB, De Guerre LE, Verhagen HJ, Schermerhorn ML. Fenestrated endovascular aneurysm repair is associated with lower perioperative morbidity and mortality compared with open repair for complex abdominal aortic aneurysms. Journal of vascular surgery. 2018 Dec 12.
Study details	<p>Study design: retrospective cohort</p> <p>Location(s): USA</p> <p>Study period: 2012 to 2016</p> <p>Aim of the study: to compare perioperative outcomes using FEVAR with open complex AAA repair and infrarenal EVAR in a nationwide multicenter registry.</p>
Participants	<p>Sample size: FEVAR group, n=220; OSR group, n=181</p> <p>Inclusion criteria: all patients undergoing EVAR or open complex AAA repairs within the targeted NSQIP registry, using Current Procedural Terminology (CPT) codes; FEVAR cases identified using a code for the Zenith fenestrated device</p> <p>Exclusion criteria: nonelective repairs, thoracoabdominal or thoracic aneurysms, EVAR devices for infrarenal repair that were used <100 times, infrarenal EVARs with a concurrent CPT code for visceral vessel repair or open repair were excluded.</p> <p>Baseline characteristics:</p> <p>Median age (IQR): FEVAR group, 75 (69.5-81) years; OSR group, 72 (67–77) years</p> <p>Gender: FEVAR group, 82.3% male; OSR group, 77.2% male</p> <p>Median aneurysm diameter (IQR): FEVAR group, 5.6cm (5.3–6.0cm); OSR group, 5.8cm (5.5–6.5cm)</p> <p>Hypertension: FEVAR group, 80%; OSR group, 80.1%</p> <p>Diabetes (insulin dependent): FEVAR group, 2.7%; OSR group, 2.2%</p> <p>COPD: FEVAR group, 22.3%; OSR group, 18.8%</p> <p>Heart failure: FEVAR group, 3.2%; OSR group, 0.6%</p>

Full citation	Varkevisser RR, O'Donnell TF, Swerdlow NJ, Liang P, Li C, Ultee KH, Pothof AB, De Guerre LE, Verhagen HJ, Schermerhorn ML. Fenestrated endovascular aneurysm repair is associated with lower perioperative morbidity and mortality compared with open repair for complex abdominal aortic aneurysms. Journal of vascular surgery. 2018 Dec 12.
Methods	Data collection: data were extracted from a detailed national surgical registry (the National Surgical Quality Improvement Program; NSQIP). The NSQIP database requires hospitals to provide complete 30-day follow-up on at least 95% of patients. Analysis: inverse probability weighting using propensity scores based on logistic regression with a priori selection of variables (note >20 covariates in dataset with only around 200 events)
Intervention	FEVAR
Comparator	OSR
Outcomes	30-day mortality, cardiac arrest, renal failure, and respiratory failure
Study Appraisal using NICE's bespoke risk of bias assessment tool	<p>Selection</p> <p>1.1. Were cohorts from the same time period? Moderate risk – recruitment over ≥5 yrs, unclear that year of operation was controlled for in analysis</p> <p>1.2. Were cohorts from the same place? Low risk – cohorts were derived from the same national surgical registry.</p> <p>1.3. Is the definition of AAA the same across cohorts? High risk – FEVAR cases identified by device type; OSR cases identified using a code that includes all complex aneurysms (of which some would be unlikely to be amenable to FEVAR) – note that >30% of FEVAR group had AAAs classified as infrarenal, whereas OSR group had none, and FEVAR group was <20% suprarenal and OSR group >40%.</p> <p>Confounding</p> <p>2.1. Does study control appropriately for demographics? Low risk.</p> <p>2.2. Does study control appropriately for comorbidity and/or fitness? Low risk.</p> <p>2.3. Does study control appropriately for AAA characteristics? Moderate risk – AAA diameter controlled for but not extent.</p> <p>2.4. Could any adjustment variables have been affected by the intervention? Low risk - no post-intervention variables which could mediate the treatment effect were controlled for.</p> <p>Data collection</p> <p>3.1. Is method of data collection likely to have identified suitable participants accurately? Moderate risk – participants identified a detailed surgical registry with procedure codes specified.</p> <p>3.2. Is method of data collection likely to record perioperative outcomes accurately? Low risk – data obtained from a detailed surgical registry with procedure codes specified.</p> <p>3.3. Is method of data collection likely to record long-term outcomes accurately? N/A – no long-term outcomes were assessed.</p> <p>Analysis – general</p> <p>4.1. Were any checks conducted on model specification and/or fit? High risk – no checks appear to have been conducted on model specification/fit.</p>

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	<p>4.2. Are missing outcome data and covariates reported and, if necessary, adjusted for? Low risk – authors highlight that missing data were equally distributed between repair modalities.</p> <p>4.3. Have different methods been compared within the study? Moderate risk – different methods compared but all rely on the same assumption about selection.</p> <p>Analysis – matching</p> <p>5.1. Is the matching algorithm reported and reasonable? N/A</p> <p>5.2. Was overlap / common support appropriately assessed? Low risk – statement that the distribution of propensity scores in the treated and untreated groups were plotted. Trimming of extreme weights performed as a sensitivity analysis.</p> <p>5.3. Has balancing of the covariates been demonstrated? Low risk – stated that, after weighting, standardised differences were all $\leq 10\%$ (although no detail provided)</p> <p>Analysis – simple multivariable models</p> <p>6.1 Is sample size adequate relative to number of covariates considered? N/A</p> <p>6.2 Were interactions between treatment and other covariates considered? N/A</p> <p>Overall risk of bias: High risk</p> <p>Directness: directly applicable</p>