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## SYSTEMATIC REVIEW

# Pre-operative Aortic Neck Characteristics and Post-operative Sealing Zone as Predictors of Type 1a Endoleak and Migration After Endovascular Aneurysm Repair: A Systematic Review and Meta-Analysis

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## WHAT THIS PAPER ADDS

Patients with hostile infrarenal neck anatomy are believed to have an increased risk of developing type 1a endoleak and migration after endovascular aneurysm repair (EVAR). However, previous reviews have only addressed single pre-operative aortic neck characteristics. This systematic review provides an overview of all pre-operative aortic neck characteristics and the post-operative real achieved sealing zone and their respective risk of type 1a endoleak and migration. Pre-operative aortic neck diameter, angulation, and length were found to be associated with the development of type 1a endoleak or migration after EVAR. The post-operative real achieved sealing zone might be an important addition during follow up.

**Objective:** Establishing the predictive value of neck characteristics and real achieved sealing zone is essential to foster risk stratified procedure selection and imaging surveillance. This systematic review provides an overview of pre-operative aortic neck characteristics and post-operative real achieved sealing zone and their respective risk of type 1a endoleak and migration after endovascular aneurysm repair (EVAR).

**Methods:** In agreement with PRISMA guidelines, MEDLINE, Embase, and Cochrane CENTRAL were searched. Data on neck characteristics, sealing zone, and EVAR outcome were extracted. Meta-analyses were performed to investigate the effect of neck diameter, angulation, and shape on type 1a endoleak (total, early  $\leq 90$  days, and late  $> 90$  days) and migration in patients who underwent EVAR. A qualitative summary was also provided.

**Results:** Thirty-three studies were included. Patients with a larger neck diameter had an increased risk of total type 1a endoleak (nine studies: OR 3.32, 95% CI 2.38 – 4.63), early type 1a endoleak (six studies: OR 2.64, 95% CI 1.27 – 5.48), late type 1a endoleak (six studies: OR 3.26, 95% CI 2.12 – 5.03), and migration (seven studies: OR 2.88, 95% CI 1.32 – 6.26). An angulated neck increased the risk of total type 1a endoleak (seven studies: OR 4.27, 95% CI 1.55 – 11.78) and late type 1a endoleak (seven studies: OR 5.56, 95% CI 2.19 – 14.13). Neck shape was not associated with type 1a endoleak. Neck length and real achieved sealing zone on post-EVAR computed tomography were identified as risk factors for type 1a endoleak and migration through qualitative summary.

**Conclusion:** There seems to be some consistent evidence that aortic neck diameter, angulation, and length are associated with the development of type 1a endoleak or migration. Real achieved sealing zone might be an important addition during follow up. However, a small number of studies, with serious limitations, could be included, and there was considerable variability in reporting patients and outcomes. A proposal for standardisation of aortic and EVAR data in future studies is provided.

**Keywords:** Abdominal aortic aneurysm, Aortic neck, Endovascular aneurysm repair, EVAR, Neck characteristics, Sealing zone

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## INTRODUCTION

Endovascular aneurysm repair (EVAR) is broadly implemented in the treatment of infrarenal abdominal aortic aneurysms (AAAs) because of good short term mortality and morbidity outcomes.<sup>1</sup> An important disadvantage of EVAR is the risk of type 1a endoleak and migration. These complications may result in re-pressurisation of the aneurysm and subsequent aneurysm rupture; therefore, lifelong imaging surveillance is required.<sup>2</sup> Patients with hostile infrarenal neck anatomy are at an especially increased risk of these type 1a endoleaks.<sup>3</sup> However, evidence based cutoff values to define aortic neck characteristics that preclude standard EVAR are still debated. These cutoff values are essential for optimal pre-operative sizing and planning to select the right treatment option for AAA patients (i.e., open repair or standard or complex EVAR).

A recent Delphi consensus established five parameters to classify hostile neck, with corresponding cutoff values: neck length (< 10 mm), infrarenal neck angulation ( $\beta \geq 60^\circ$ ), neck diameter (> 28 mm), > 50% circumferential calcification, and presence of a conical neck shape.<sup>4</sup> This paper expressed an expert opinion, and these specific parameters and cutoff values were not directly associated with clinical outcomes. Previous systematic reviews have focused on a single pre-operative neck characteristic and therefore could not address the risk of EVAR failure when a combination of hostile neck characteristics was present.<sup>5–9</sup> Although the literature suggests stratifying the risk of type 1a endoleak with the pre-operative anatomy and also with the post-operative real achieved sealing zone, evidence seems limited and a systematic review on clinical outcome is lacking.<sup>10,11</sup>

This systematic review aimed to provide an overview of pre-operative aortic neck characteristics and the post-operative real achieved sealing zone, and their respective risk of developing type 1a endoleak and migration after EVAR.

## METHODS

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 guidelines.<sup>12</sup> The review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (ID: CRD42021238094).

### Eligibility criteria

**Types of study.** Two types of study were eligible for inclusion in this systematic review: 1) observational studies, which divided the study groups based on pre-operative neck characteristics or post-operative real achieved sealing zone, comparing the incidence of type 1a endoleak and/or migration; and 2) case control studies comparing patients with and without type 1a endoleak and/or migration to identify pre-operative neck characteristics or the post-

operative real achieved sealing zone as risk factors. Both categories were analysed separately. Case reports, reviews, meta-analyses, commentaries, editorials, conference abstracts, animal and in vitro studies, and studies with < 10 patients or no control group were excluded. Studies written in non-European languages or studies without the availability of full text were also excluded.

**Types of patient.** Patients of any age treated electively for AAA with standard EVAR were included. Patients treated for symptomatic or ruptured AAA and those who underwent complex (fenestrated/branched/chimney) EVAR were excluded. Included articles had to address one or more pre-operative infrarenal neck characteristics (diameter, length, angulation, shape, thrombus, and calcification) and/or the post-operative real achieved sealing zone. The real achieved sealing zone can be defined as the length starting at the proximal end of the endograft fabric and over which the endograft material is in proper apposition to the aortic wall.<sup>11</sup> The pre-operative neck characteristics and proximal real achieved sealing zone had to be measured on a computed tomography angiography (CTA) scan.

### Search strategy and selection process

Three electronic databases were searched: MEDLINE, Embase, and Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy consisted of three major components (EVAR, neck anatomy/sealing zone, and outcome), which were combined with Boolean “AND”. A filter was used to exclude animal studies and studies published before 2010. The entire search strategy is provided in [Appendix 1](#). The search was finished on 13 October 2021 and complemented by cross referencing the included articles.

Two independent reviewers (R.Z. and C.R.) used titles and abstracts to assess all studies for eligibility and screened the remaining full texts. When consensus could not be reached, the two authors discussed the disagreement, and if disagreement persisted, a third person (J.V.) made the final decision.

### Data collection and risk of bias assessment

The initial data extraction and risk of bias assessment were performed by two authors (R.Z. and C.R.), both of whom cross checked the extracted data. Retrieved data were entered into a data extraction form. Authors of the included studies were contacted to request missing or incomplete data.

Risk of bias was separately assessed for the cohort studies and case control studies using the Newcastle—Ottawa Scale (NOS) for assessing the quality of non-randomised studies.<sup>13</sup> Observational studies were scored on selection, comparability, and outcome. Case control studies were scored on selection, comparability, and exposure. The comparability of the cohorts was assessed for anatomical characteristics and any additional factor (e.g.,

**Table 1. Characteristics of included studies reporting aortic neck characteristics, and/or sealing zone, and type 1a endoleak or migration after endovascular aneurysm repair**

Author year	Study design	Patients – n	Exposure	Control	EVAR period	Follow up – months	Type of endograft	Work station
<i>Diameter</i>								
AbuRahma <sup>19</sup> 2018	Single centre retrospective	688 (33/655)	>31 mm	≤31 mm	2003–2015	25.5 [1–140]	Excluder (60%), Zenith (17%), AneuRx (11%), Other (12%)	NR
Howard <sup>20</sup> 2018	Multicentre prospective	3 166 (1 189/1 977)	≥25 mm	<25 mm	2011–2017	Up to 60	Excluder (100%)	Planning software
Jim <sup>21</sup> 2010	Multicentre prospective	156 (53/103)	≥28 mm	<28 mm	2002–2003	Up to 60	Talent (100%)	Core Laboratory
Kaladji <sup>22</sup> 2015	Multicentre retrospective	908 (170/738)	≥32 mm stent	<32 mm stent	1998–2011	38±28.2	Zenith (45%), Talent (41%), Other (14%)	NR
Kouvelos <sup>23</sup> 2019	Multicentre retrospective	128 (64/64)	29–32 mm	26–28.9 mm	2009–2016	24 (12–84)	Endurant (100%)	OsiriX or 3Mensio
McFarland <sup>24</sup> 2019	Single centre retrospective	500 (108/392)	34–36 mm stent	≤32 mm stent	2000–2016	34.1	Excluder (28%), Talent (27%), Zenith (23%), Other (22%)	TeraRecon
Oliveira <sup>25</sup> 2017	Multicentre retrospective	427 (74/353)	≥30 mm	<30 mm	2008–2012	47 (28, 65)	Endurant (100%)	3Mensio
Oliveira <sup>26</sup> 2019	Multicentre prospective	1 257 (97/1,160)	≥30 mm	<30 mm	2009–2011	48.5 (32.8, 56.3)	Endurant (100%)	NR
Oliveira-Pinto <sup>27</sup> 2020	Single centre retrospective	502 (90/412)	34–36 mm stent	≤32 mm stent	2000–2016	52.8 (25.2, 87.6)	Endurant (54%), Excluder (41%), Talent (3%), Zenith (2%)	3Mensio
<i>Length</i>								
Forbes <sup>28</sup> 2010	Single centre retrospective	318 (68/250)	4–15 mm	>15 mm	2003–2008	52 [18–84]	Zenith (100%)	TeraRecon
Jim <sup>29</sup> 2010	Multicentre prospective	137 (35/102)	10–15 mm	>15 mm	2002–2003	Up to 60	Talent (100%)	Core Laboratory
<i>Angulation</i>								
Mathlouthi <sup>30</sup> 2020	Single centre retrospective	452 (45/407)	$\alpha >60^\circ$	$\alpha \leq 60^\circ$	2005–2017	34 (14, 56)	Zenith (58%), Endurant (21%), Excluder (14%), Other (7%)	Vital Images
AbuRahma <sup>31</sup> 2010	Single centre retrospective	234 (42/192)	$\beta \geq 60^\circ$	$\beta < 60^\circ$	2000–2008	25 [1–87]	Excluder, (44%), Ancure (21%), AneuRx (20%), Zenith (16%)	NR
Bastos Goncalves <sup>32</sup> 2010	Multicentre retrospective	110 (45/65)	Outside Endurant IFU*	Inside Endurant IFU*	2008–2009	Up to 1	Endurant (100%)	3Mensio
Chinsakchai <sup>33</sup> 2020	Single centre retrospective	198 (54/144)	$\beta >60^\circ$	$\beta \leq 60^\circ$	2010–2013	54.9 [1–82.9]	Zenith (51%), Endurant (47%), Excluder (2%)	OsiriX or 3Mensio
Freyrie <sup>34</sup> 2014	Multicentre prospective	802 (65/737)	$\beta \geq 60^\circ$	$\beta < 45^\circ$	2005–2012	Up to 36	Anaconda (100%)	NR
Malas <sup>35</sup> 2015	Multicentre prospective	218 (151/67)	$\beta \geq 60^\circ$	$\beta < 60^\circ$	2006–2011	Up to 24	Aorfix (100%)	M2S
Malas <sup>36</sup> 2017	Multicentre prospective	218 (151/67)	$\beta \geq 60^\circ$	$\beta < 60^\circ$	2006–2011	Up to 60	Aorfix (100%)	M2S
Oliveira <sup>37</sup> 2015	Multicentre retrospective	110 (45/65)	Outside Endurant IFU*	Inside Endurant IFU*	2008–2009	49.5 (30.5–58.4)	Endurant (100%)	3Mensio
Oliveira <sup>38</sup> 2018	Multicentre retrospective	110 (45/65)	Outside Endurant IFU*	Inside Endurant IFU*	2008–2009	89 (58, 102)	Endurant (100%)	3Mensio
Seike <sup>39</sup> 2020	Single centre retrospective	159 (89/70)	$\beta \geq 47^\circ$	$\beta < 47^\circ$	2007–2013	48±20	Excluder (43%), Zenith (28%), Endurant (18%), Other (11%)	Ziostation2
<i>Shape</i>								
Mwipatayi <sup>40</sup> 2013	Multicentre retrospective	66 (22/44)	Reverse taper	Standard	2008–2011	20 [14–46]	Endurant (100%)	TeraRecon
Pitoulas <sup>41</sup> 2017	Multicentre retrospective	156 (46/110)	Reverse taper	Cylindrical	2007–2015	31.4±19	Endurant (100%)	3D CTA software

Continued

**Table 1-continued**

Author year	Study design	Patients – n	Exposure	Control	EVAR period	Follow up – months	Type of endograft	Work station
Shutze <sup>42</sup> 2018	Multicentre prospective	3 077 (1 312/1 765)	Non-cylindrical	Cylindrical	2010–2016	19.8±16.9	Excluder (100%)	NR
<i>Thrombus</i>								
Bastos Goncalves <sup>43</sup> 2012	Multicentre retrospective	401 (43/346)	>25%	≤25%	2004–2008	Up to 60	Excluder (40%), Talent (40%), Endurant (17%), Zenith (3%)	3Mensio
<i>Risk stratification</i>								
Bastos Goncalves <sup>44</sup> 2015	Multicentre prospective	1 263 (18/1 245)	Type 1a endoleak	No type 1a endoleak	2009–2011	Up to 36	Endurant (100%)	NR
Grisafi <sup>45</sup> 2011	Single centre retrospective	100 (9/91)	Type 1a endoleak	No type 1a endoleak	2006–2007	19.3 [0–32.5]	Zenith (47%), AneuRx (44%), Excluder (7%), Powerlink (2%)	TeraRecon
Karathanos <sup>46</sup> 2016	Multicentre prospective	383 (11/372)	Type 1a endoleak	No type 1a endoleak	2011–2014	Up to 12	Excluder (56%), Endurant (21%), Zenith (9%), Other (14%)	OsiriX or 3Mensio
Schuermann <sup>47</sup> 2017	Multicentre retrospective	116 (36/80)	Type 1a endoleak or migration	No type 1a endoleak or migration	2005–2016	37 (25, 53) 18 (9, 33)	Endurant (41%), Zenith (27%), Talent (17%), Other (15%)	3Mensio
Schuermann <sup>48</sup> 2018	Multicentre retrospective	73 (36/37)	Type 1a endoleak	No type 1a endoleak	NR	15.1 (2.6, 47.1) 19.1 (13.9, 37.6)	Endurant (49%), Talent (21%), Zenith (16%), Other (14%)	3Mensio
Schuermann <sup>49</sup> 2021	Multicentre retrospective	88 (35/53)	Type 1a endoleak or migration	No type 1a endoleak or migration	NR	13 (3, 25) 19 (13, 31)	Endurant (51%), Talent (20%), Zenith (16%), Other (12%)	3Mensio
Tokunaga <sup>50</sup> 2017	Single centre retrospective	80 (9/71)	Migration	No migration	2007–2010	Up to 24	Zenith (58%), Excluder (42%)	TeraRecon
Wang <sup>51</sup> 2018	Multicentre prospective	205 (36/169)	Type 1a endoleak or migration or sac expansion	No endograft complications	2006–2011	48	Aorfix (100%)	M2S

Data are presented as mean, mean ± standard deviation, mean [range], median (range), or median (Q1, Q3), unless otherwise stated.

EVAR = endovascular aneurysm repair; 3D = three dimensional; NL = neck length;  $\alpha$  = suprarenal angulation;  $\beta$  = infrarenal angulation; NR = not reported; CTA = computed tomography angiography.

\* Endurant IFU = NL >15 mm and  $\beta$  ≤75° or  $\alpha$  ≤60° or NL >10 mm and  $\beta$  ≤60° or  $\alpha$  ≤45°.

sex, comorbidities, etc.). Any discrepancies were resolved through discussion. Risk of bias assessment was performed in Review Manager (RevMan) 5.2 software (The Cochrane Collaboration, Copenhagen, Denmark).

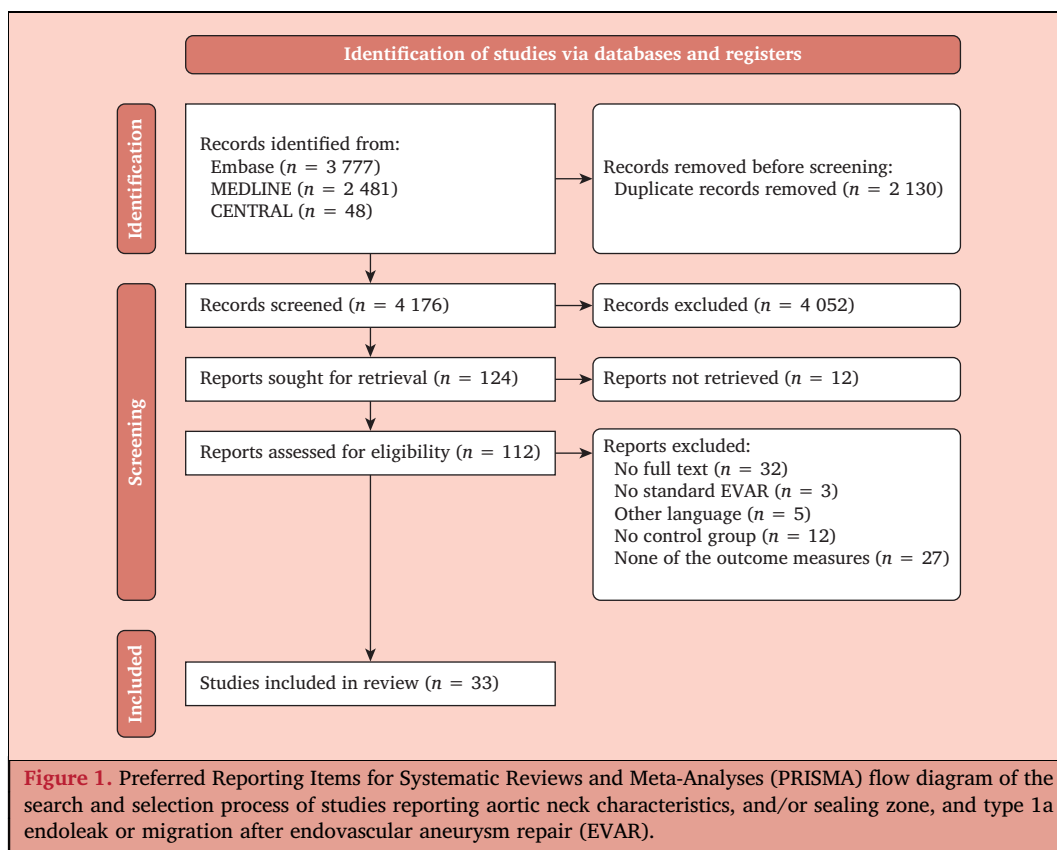
### Outcome measures and synthesis methods

Outcome measures were type 1a endoleak and/or migration on a post-operative CTA scan. Type 1a endoleak was analysed for three subgroups: total, early (on the first post-operative CTA scan ≤ 90 days), and late (> 90 days). Meta-analyses were performed when three or more studies could be included. Pooled estimates of dichotomous outcome data were calculated by the odds ratio (OR) and 95% confidence interval (CI) and presented as forest plots. The random effects model was used for each meta-analysis, since assuming a common (i.e., fixed) effect size was implausible and not expected. If multiple studies reported on the same cohort, only the study with the longest follow up was incorporated in the meta-analyses and qualitative summary. Statistical heterogeneity was assessed with the

Cochrane Q ( $\chi^2$ ) test, and the proportion of total variability in the effect estimates that was real rather than sampling error was assessed by calculating the  $I^2$  (0 – 40%, 30 – 60%, 50 – 90%, and 75 – 100% corresponded to small, moderate, substantial, and considerable amounts of heterogeneity, respectively).<sup>14,15</sup> It was planned to study sources of heterogeneity using subgroup analyses, only when at least 10 studies could be included. A  $\chi^2$  test with a  $p$  value < .10 indicated statistical significance. The meta-analyses were performed in the R environment (version 4.1.2; Foundation for statistical computing, Vienna, Austria; <https://www.R-project.org>) using the metaphor and meta packages.<sup>16,17</sup>

### Reporting bias and certainty assessment

Reporting biases were not assessed when a single meta-analysis included < 10 studies. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) scale was used to assess the degree of certainty in the body of evidence for each outcome.<sup>18</sup>



## RESULTS

### Literature search

The search yielded 6 306 studies, of which 4 176 remained after duplicates were removed. No additional studies were identified through cross referencing. The flow diagram of the search and selection process is presented in [Figure 1](#). After title and abstract screening, 124 studies remained for full text screening. Finally, 33 studies comparing EVAR outcomes in patients with different pre-operative neck characteristics or real achieved sealing zone were included.<sup>19–51</sup> The authors of three included studies provided additional data regarding the distribution between early and late type 1a endoleaks.

### Description of studies

The study design was retrospective for 22 studies and prospective for 11 studies, including 10 endograft device registries. The study characteristics, such as number of patients, definition of exposure and control group, EVAR period, and duration of follow up, are summarised in [Table 1](#). The overall study population varied between 66 and 3 166 patients, and the median follow up ranged between one and 89 months. Fifteen studies reported a single type of endograft, whereas the other 18 studies reported multiple types of endograft. Different vascular workstations were used. An overview of pre-operative anatomical characteristics for each study is provided in [Supplementary Table S1](#).

Nine studies compared proximal neck diameter,<sup>19–27</sup> two studies compared neck length,<sup>28,29</sup> 10 studies compared

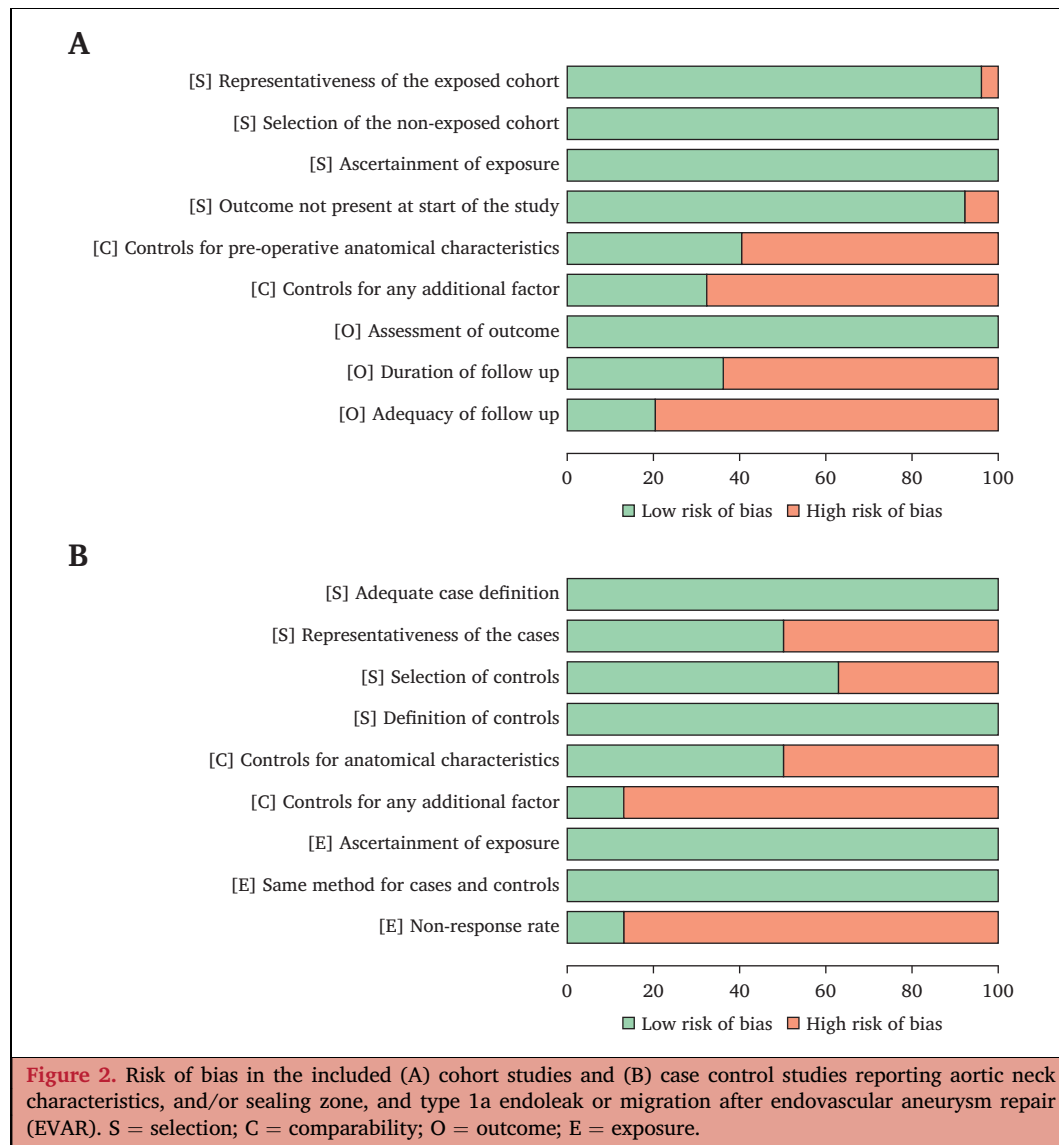
suprarenal and/or infrarenal angulation,<sup>30–39</sup> three studies compared neck shape,<sup>40–42</sup> and one study elaborated on the presence of thrombus.<sup>43</sup> No studies reported on calcification as a pre-operative aortic neck characteristic relative to type 1a endoleak or migration. Eight case control studies were identified that investigated pre-operative neck characteristics or the post-operative real achieved sealing zone as risk factors for type 1a endoleak and/or migration.<sup>44–51</sup>

### Assessment of quality

The risk of bias graph and summary are presented in [Figure 2](#) and in [Supplementary Figure S1](#), respectively. In general, all individual studies had a relatively high risk of bias. The cohort studies showed a low risk of bias for the selection of the exposed and non-exposed cohort. However, there was a high risk of bias for the comparability and outcome category, except for the assessment of the outcome. The case control studies showed a low risk of bias for case and control definition, ascertainment of exposure, and the same method of ascertainment for cases and controls. There was, however, a high risk of the representativeness of the cases, selection of controls, the comparability for anatomical characteristics and additional factors, and the non-response rate.

### Meta-analysis of neck diameter

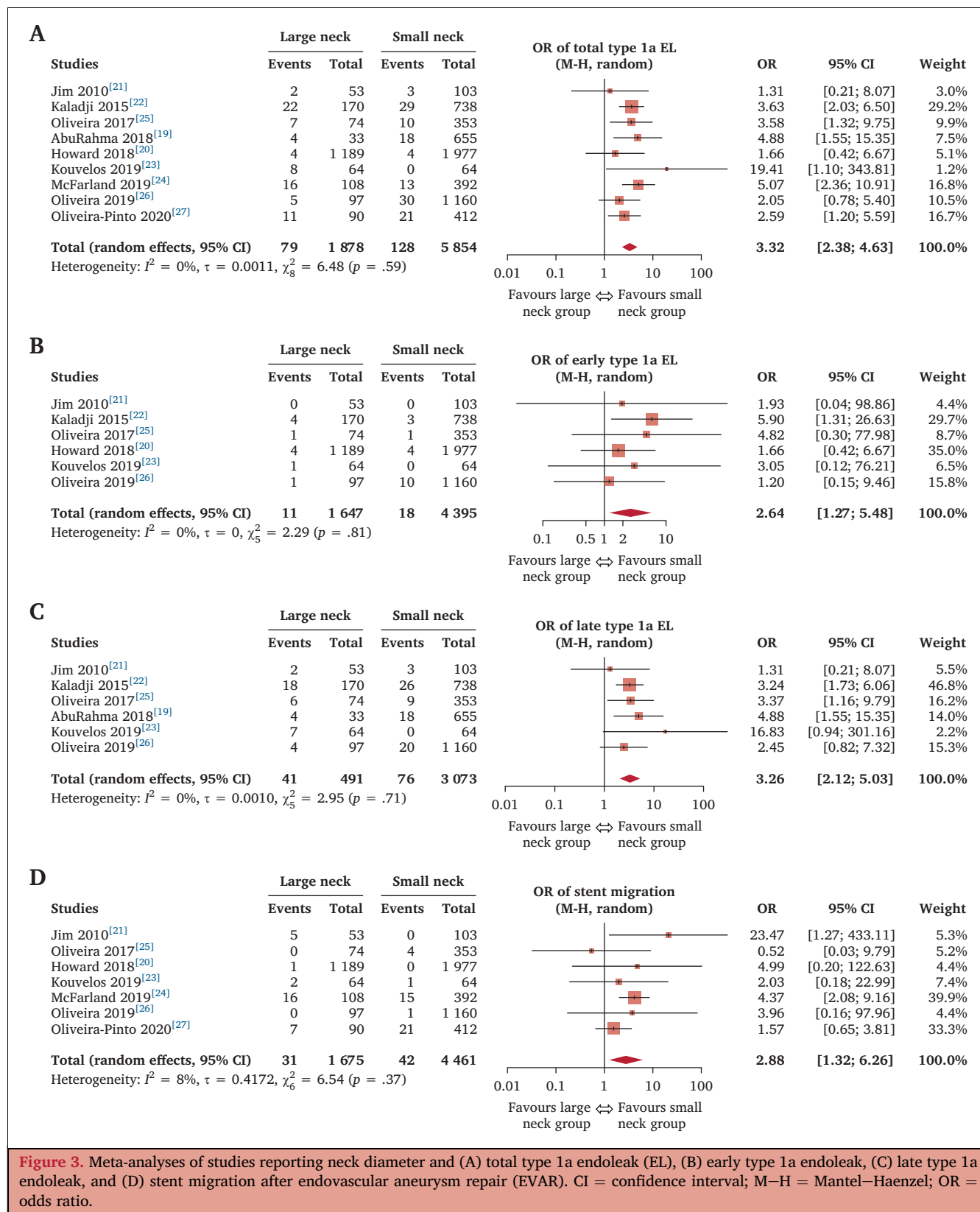
Nine studies included data on the total number of type 1a endoleaks, and six studies distinguished between early ( $\leq 90$  days) and late ( $> 90$  days) type 1a endoleak ([Figures 3A – C](#)). However, two studies reported on type 1 endoleak



without distinguishing between type 1a and 1b.<sup>19,21</sup> Furthermore, seven studies reported on migration (Figure 3D); most studies defined migration as > 10 mm, one study defined it as > 5 mm,<sup>27</sup> and two studies did not provide a definition.<sup>20,22</sup> The cutoff values for large neck diameter were > 30 mm,<sup>25,26</sup> > 31 mm,<sup>19</sup> 29 – 32 mm,<sup>23</sup> ≥ 28 mm,<sup>21</sup> and ≥ 25 mm.<sup>20</sup> Three studies used large endograft diameter instead of neck diameter, which was defined as endograft diameter ≥ 32 mm<sup>22</sup> or 34 – 36 mm.<sup>24,27</sup> Patients with a larger neck diameter had an increased risk of total type 1a endoleak (nine studies: OR 3.32, 95% CI 2.38 – 4.63), early type 1a endoleak (six studies: OR 2.64, 95% CI 1.27 – 5.48), late type 1a endoleak (six studies: OR 3.26, 95% CI 2.12 – 5.03), and migration (seven studies: OR 2.88, 95% CI 1.32 – 6.26). Heterogeneity was small ( $\chi^2$  test  $p > .10$ ;  $I^2 = 0 - 8\%$ ) across the studies in all outcomes. According to the GRADE scale, the quality of evidence was very low for all outcomes (Supplementary Table S2).

### Meta-analysis of angulation

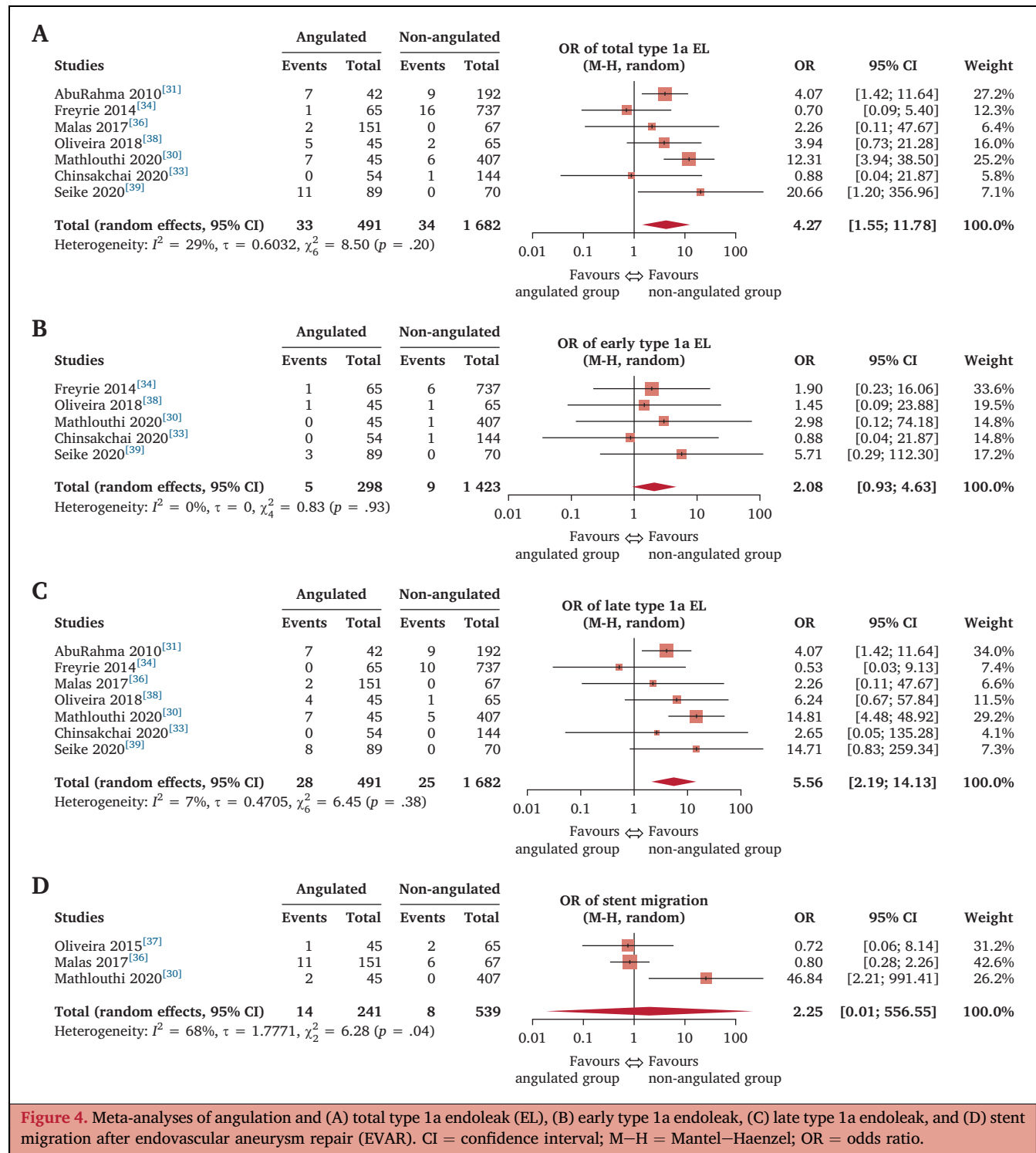
A comparison between angulated and non-angulated necks was performed in 10 studies. Six studies reported on infrarenal angulation ( $\beta$ ), one study reported on suprarenal angulation ( $\alpha$ ), and three studies reported a composite of infrarenal and suprarenal angulation and neck length. Three studies reported on the same cohort of Endurant patients,<sup>32,37,38</sup> and two studies reported on the same cohort of Aorfix patients.<sup>35,36</sup> This left seven unique studies that reported on type 1a endoleak (Figure 4A), of which five reported early type 1a endoleak (Figure 4B), seven late type 1a endoleak (Figure 4C), and three migration (Figure 4D). One study reported a composite of type 1 and type 3 endoleaks,<sup>36</sup> and one study reported type 1 endoleak without a distinction between type 1a and 1b.<sup>31</sup> The cutoff values for angulated necks were  $\beta \geq 60^\circ$ ,<sup>31,33,34,36</sup>  $\beta \geq 47^\circ$ ,<sup>39</sup> Endurant instructions for use (neck length > 15 mm and  $\beta > 75^\circ$  or  $\alpha > 60^\circ$  or neck length > 10 mm and  $\beta > 60^\circ$  or  $\alpha > 45^\circ$ ),<sup>38</sup> and  $\alpha > 60^\circ$ .<sup>30</sup> Patients with an angulated neck had an increased risk of total type 1a endoleak (seven studies: OR 4.27, 95% CI 1.55 – 11.78) and late type 1a



endoleak (seven studies: OR 5.56, 95% CI 2.19 – 14.13). There was no significant difference for early type 1a endoleak (five studies: OR 2.08, 95% CI 0.93 – 4.63) and migration (three studies: OR 2.25, 95% CI 0.01 – 556.55). Heterogeneity was considered small for total type 1a endoleak ( $\chi^2 p = .20$ ;  $I^2 =$

29%), early ( $\chi^2 p = .93$ ;  $I^2 = 0\%$ ) and late type 1a endoleak ( $\chi^2 p = .38$ ;  $I^2 = 7\%$ ). However, substantial inconsistency across studies was identified for migration ( $\chi^2 p = .043$ ;  $I^2 = 68\%$ ). The source of this statistical heterogeneity could not be explored due to the small number of included studies. According to the



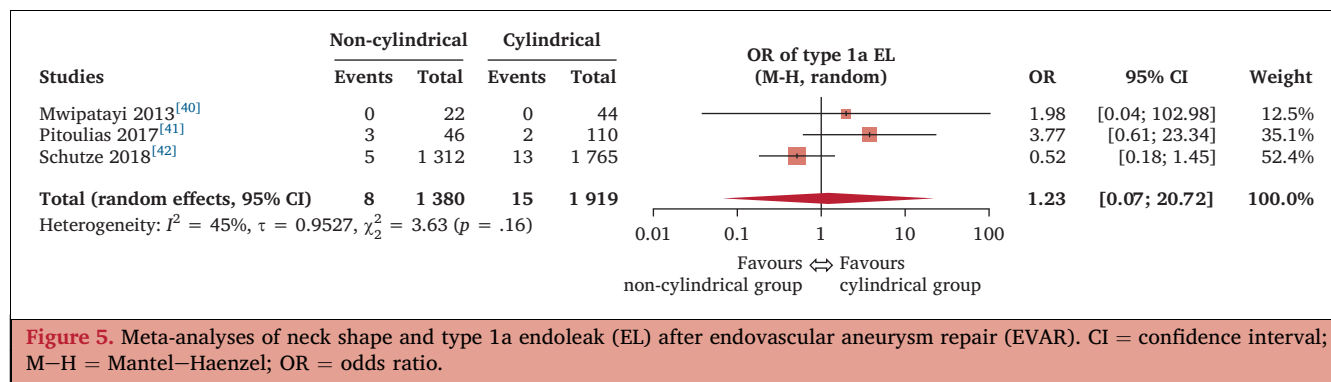


GRADE scale, the quality of evidence was very low for all outcomes (Supplementary Table S2).

**Meta-analysis of neck shape**

Three studies reported total type 1a endoleak and neck shape (Figure 5). One study compared reverse tapered necks with standard necks,<sup>40</sup> one study compared reverse tapered necks with cylindrical necks,<sup>41</sup> and another study compared non-cylindrical necks with cylindrical necks.<sup>42</sup> No

significant difference was reported between the cylindrical or standard and non-cylindrical or reversed tapered groups (three studies: OR 1.23, 95% CI .07 – 20.72), with moderate heterogeneity ( $\chi^2 p = .16$ ;  $I^2 = 45\%$ ). The source of this statistical heterogeneity could not be explored due to the small number of included studies. According to the GRADE scale, the quality of evidence was very low (Supplementary Table S2).



**Figure 5.** Meta-analyses of neck shape and type 1a endoleak (EL) after endovascular aneurysm repair (EVAR). CI = confidence interval; M-H = Mantel-Haenszel; OR = odds ratio.

### Additional outcomes

**Neck length and thrombus.** For neck length  $\leq 15$  mm vs.  $> 15$  mm, one study reported type 1 (a composite of 1a and 1b) endoleak and migration as outcome measures, whereas another study reported type 1a endoleak only.<sup>28,29</sup> There was no significant difference in outcome measures in either study. One study investigated the influence of neck thrombus ( $> 2$  mm in thickness along at least  $> 25\%$  of the circumference) on type 1a endoleak and migration.<sup>43</sup> No type 1a endoleak occurred in either group during follow up. Migration was more frequent in the thrombus group (OR 4.33, 95% CI 1.25 – 15.05;  $p = .023$ ).

### Risk stratification

The risk stratification category included eight case control studies.<sup>44–51</sup> Patients with type 1a endoleak and or migration were compared with uncomplicated controls to identify the prognostic value of pre-operative aortic neck characteristics and post-operative real achieved sealing zone. Three studies reported on the same study population<sup>47–49</sup> and, for that reason, only the study with the longest follow up time was incorporated in the qualitative summary.

**Neck diameter.** Of five studies that reported neck diameter, two found an association between neck diameter and type 1a endoleak or migration. A neck diameter  $> 30$  mm was associated with type 1a endoleak (OR 4.77, 95% CI 1.13 – 20.11;  $p = .032$ ),<sup>46</sup> and multivariable analysis showed that the larger proximal neck group ( $24.8 \pm 2.1$  mm) had a two fold risk of migration, sac expansion, or type 1a endoleak (OR 2.22, 95% CI 1.02 – 4.85;  $p < .05$ ) compared with the smaller neck group ( $20.1 \pm 1.6$  mm).<sup>51</sup> The other three studies found no statistically significant results: neck diameter was not significantly different ( $p = .34$ ) between the type 1a endoleak group ( $21.9 \pm 2.4$  mm) and control group ( $23.2 \pm 4.0$  mm),<sup>45</sup> large diameter neck (requiring 32 mm or 36 mm endograft) was not associated with type 1a endoleak or migration ( $p = .40$ ),<sup>44</sup> and neck diameter divided by endograft diameter was not significantly different between the migration group (migration  $\geq 3$  mm) and control group ( $0.866 \pm 0.054$  vs.  $0.885 \pm 0.051$ , respectively;  $p = .311$ ).<sup>50</sup>

**Neck length.** Among four studies that reported neck length, three identified an association between neck length and

type 1a endoleak or migration, and one study showed no significant difference. Neck length was significantly different between the migration group (migration  $\geq 3$  mm) and controls ( $21.3 \pm 6.8$  mm vs.  $28.3 \pm 12.4$  mm, respectively;  $p = .020$ ),<sup>50</sup> and between patients with migration and or type 1a endoleak (diagnosed  $> 1$  year after the initial EVAR procedure) and controls ( $14.0$  mm, interquartile range [IQR] 7.0 – 28.3 mm vs.  $24.1$  mm, IQR 5.1 – 33.0 mm, respectively;  $p = .013$ ).<sup>47</sup> In addition, neck length  $< 10$  mm (hazard ratio [HR] 8.9, 95% CI 2.5 – 31.2) was a significant risk factor for type 1a endoleak according to Bastos Gonçalves *et al.*<sup>44</sup> Grisafi *et al.*<sup>45</sup> reported no significant difference ( $p = .18$ ) in neck length between patients with and without type 1a endoleak ( $13.3 \pm 6.4$  mm and  $16.0 \pm 6.5$  mm, respectively).

**Neck angulation.** All six studies found no statistically significant association between suprarenal and/or infrarenal angulation and type 1a endoleak and/or migration, except one study. One study found that suprarenal angulation  $> 45^\circ$  was not significantly different between the type 1a endoleak group and the controls (0% vs. 2.3%, respectively;  $p = 1.0$ ).<sup>45</sup> Another study reported that the number of angulated necks ( $\geq 40^\circ$  infrarenal angulation) was not significantly different between the migration group and the controls (OR 0.98, 95% CI 0.16 – 5.2;  $p = .98$ ).<sup>50</sup> Bastos Gonçalves *et al.*<sup>44</sup> found that neck angulations  $> 60^\circ$  suprarenal or  $75^\circ$  infrarenal were not independent risk factors for type 1a endoleak and migration. Moreover, suprarenal and infrarenal angulation were not significantly different between the type 1a endoleak and migration group (diagnosed  $> 1$  year after the initial EVAR procedure) and controls ( $p = .74$  and  $p = .54$ , respectively).<sup>47</sup> Furthermore, an infrarenal neck angle between  $60^\circ$  and  $90^\circ$  was not associated with complication free survival (HR 1.00, 95% CI 0.99 – 1.02;  $p = .66$ ).<sup>51</sup> Conversely, Grisafi *et al.*<sup>45</sup> found that infrarenal angulation  $> 45^\circ$  was significantly more frequent ( $p = .006$ ) in the type 1a endoleak group compared with controls (67% vs. 25%, respectively).

**Neck shape, thrombus, and calcification.** Two studies reported on neck shape, and both studies found no statistically significant association between a tapered neck shape and type 1a endoleak or migration.<sup>44,45</sup> Three studies reported on thrombus and calcification, of which two found no

statistically significant association between the presence of thrombus and calcification and type 1a endoleak or migration,<sup>44,45</sup> and one study found that mural neck thrombus was associated with type 1a endoleak and migration.<sup>47</sup> Notably, the overall evidence for these neck characteristics was low, due to the small number of included studies.

**Post-operative real achieved sealing zone.** Two case control studies reported the post-operative real achieved sealing zone. Wang *et al.*<sup>51</sup> used the centre line length to define the proximal real achieved sealing zone. Centre line length was not associated with post-EVAR complications such as sac expansion, migration, and type 1a endoleak during follow up (HR 0.97, 95% CI 0.94 – 1.01;  $p = .16$ ). Schuurmann *et al.*<sup>48</sup> defined the real achieved sealing zone as the shortest length of circumferential apposition between the endograft and aortic wall. The median shortest apposition length on the first post-EVAR CTA scan was not significantly different between the type 1a endoleak group (14.7 mm, IQR 8.6 – 23.1 mm;  $p = .97$ ) and the migration group (10.4 mm, IQR 7.7 – 26.3 mm;  $p = .99$ ) compared with the control group (18.0 mm, IQR 6.4 – 21.4). The shortest apposition length on the last CTA before diagnosis of the complication was significantly shorter for the type 1a endoleak (9.2 mm, IQR 0.0 – 27.1 mm;  $p = .033$ ) and migration groups (10.2 mm, IQR 4.2 – 14.4;  $p = .040$ ) compared with the control group (18.6 mm, IQR 11.5 – 26.5 mm).

## DISCUSSION

This meta-analysis has demonstrated that AAA patients with a larger neck diameter are at higher risk of developing a type 1a endoleak (early, late, or total) and migration after EVAR. For patients with angulated necks, this higher risk was found for late and total type 1a endoleak. Due to the heterogeneity of the pooled data on neck diameter and angulation, caution must be exercised as cutoff values for EVAR suitability are lacking. The meta-analysis of neck shape was inconclusive, and an insufficient number of articles reported on neck length, calcium, and thrombus to perform a meta-analysis. The qualitative summary of the case control studies identified neck length as an important risk factor for type 1a endoleak and migration.

These findings are consistent with previous systematic reviews that focused on individual neck characteristics. The higher odds for developing type 1a endoleak in patients with a larger neck diameter were also reported in systematic reviews by Antoniou *et al.*<sup>6</sup> and Kouvelos *et al.*<sup>7</sup> The current results regarding neck angulation were also consistent with findings by Qayyum *et al.*<sup>9</sup> Although neck length is one of the most important neck characteristics for pre-operative planning,<sup>4,11</sup> this variable has not been described much in the literature. An explanation for this could be that patients with a short proximal neck length are almost exclusively treated with open surgical repair or complex (fenestrated, branched, or chimney) EVAR.<sup>52</sup>

The current meta-analyses included separate analyses for early and late type 1a endoleak. It makes sense that most type 1a endoleaks determined on the first post-EVAR CTA originate from the primary procedure. Too large diameter

necks treated by standard EVAR will result in undersizing of the endograft, which precludes proper circumferential apposition.<sup>53</sup> The diameter of the aortic neck may differ > 10% during the cardiac cycle, which is not always taken into consideration during pre-operative sizing and planning. Undersizing of an infrarenal endograft can only be treated with extension of the seal to the juxtarenal or suprarenal aorta. Angulation seems to not be an influence on early type 1a endoleak, provided the endograft is properly oversized and the neck diameter is not too large. Late type 1a endoleaks are most likely caused by progression of degenerative disease, proximal aortic neck dilatation, or migration of the endograft during follow up.<sup>54</sup> Large aortic neck diameter and severe angulation will negatively influence the real achieved post-EVAR sealing zone, which is underlined in this systematic review.

The heterogeneity of the included articles needs to be considered when interpreting the results. Most of the included studies lacked long term follow up. More specifically, 23 of the 33 included studies had a median follow up of < 3 years or no clear description of follow up. This may have led to an underestimation of the number of type 1a endoleak and occurrence of migration. Another important cause of heterogeneity is the difference in measurement and classification of the neck characteristics, especially for angulation and neck shape. The observational studies were divided based on one aortic neck characteristic. Authors used a multitude of cutoff values, which were not always based on the literature or device instructions for use. Moreover, other neck characteristics in some studies were significantly different as well; therefore, the meta-analyses for neck diameter, angulation, and shape should be interpreted with caution.

Aortic neck morphology is the combination of three dimensional (3D) neck characteristics instead of the sum of individual characteristics, which are often oversimplified. To approximate the true neck morphology, authors have proposed definitions of the hostile aortic neck,<sup>4,55</sup> although these still rely on two dimensional (2D) simplification. There is a need to move from estimating one or more 2D neck characteristics to a more realistic 3D approach. A statistical shape model of the aortic neck is a mathematical technique that breaks the complex 3D shape down into principal components that represent the actual 3D geometry of the aortic neck. This is a promising technique to overcome the limitations of the current simplified 2D measurements. Ultimately, it might be interesting to enhance such a model with fluid dynamic analysis to determine the risk of type 1a endoleak and migration in different aortic neck morphologies.<sup>56</sup> As an example, Consentino *et al.* associated the principal components from a statistical shape model of the ascending thoracic aortic aneurysm with clinical outcome data.<sup>57</sup>

Besides pre-operative planning, there is also much to gain regarding post-EVAR data extraction from CTA imaging. The real achieved sealing zone, measured as the shortest apposition length, might be an important indicator for lingering type 1a endoleak and migration. The current literature advocates that the post-operative real achieved sealing zone is a solid measurement to stratify patients into

either low risk or high risk categories for type 1a endoleak and migration.<sup>48,58,59</sup> A clinical decision algorithm was recently proposed by 11 European vascular surgeons to decide if and when adjunctive procedures and re-interventions are necessary, based on the real achieved sealing zone.<sup>11</sup> Implementing real achieved sealing zone measurements in clinical practice is a step toward detecting type 1a endoleak and migration at an early stage to decrease post-EVAR mortality.

### **Additional limitations**

A differentiation between early and late type 1a endoleak could not be made for all studies because this information was lacking in some reports. Furthermore, there was an overall high risk of bias, due to several reasons. First, most included studies were retrospective designs or prospective device registries. Second, not all authors reported the lost to follow up rate. Third, some articles used combined outcome measures (e.g., type 1a and 1b endoleak, or type 1 or 3 endoleak). More specifically, 23 studies used type 1a endoleak as outcome measure, four studies used type 1 endoleak, two studies type 1 or 3 endoleak, three studies type 1a endoleak or migration, and one study did not report endoleak (only migration). Migration was defined as > 3 mm in one study, > 5 mm in four studies, or > 10 mm in 12 studies. Fifteen studies did not report a definition or did not report migration at all. Fourth, most included studies did not have core laboratory analyses. Owing to this high risk of bias, the effect of some neck characteristics might be over-estimated or underestimated. Last, ruptured AAAs were not included, as hypovolaemia induced collapse of the juxtarenal and infrarenal aorta may influence optimal sizing in urgent cases, and may lead to relatively undersized endografts, which may influence post-EVAR sustainable seal.<sup>60</sup> Including ruptured AAAs would have further increased heterogeneity.

### **Proposal for standardisation of aortic and EVAR data in future studies**

The quality of reported EVAR data has improved since the publication of the Society for Vascular Surgery reporting standards for EVAR in 2002 and the STROBE guidelines in 2007.<sup>61–63</sup> These reporting standards need an update, and this systematic review has highlighted the lack of uniformity in scientific papers regarding EVAR. It identified several pre- and post-EVAR parameters that should be addressed to enhance uniformity. This concerns necessarily details of included endograft types, and duration of follow up, including the type of imaging surveillance and the lost to follow up rate (and the reason).

All CTA scans should be investigated using a dedicated vascular workstation with centreline reconstructions, and a uniform definition should be used for each pre- and post-EVAR parameter. The following pre-EVAR definitions and measurement methods are proposed based on literature and reporting standards:

- Aortic neck diameter: an average of two orthogonal diameters from adventitia to adventitia at the inferior border of the orifice of the lowest renal artery.<sup>19,23,25</sup>
- Aortic neck length: the centreline distance between the lowest renal artery baseline and the level where a 10% diameter increase relative to the neck diameter is observed.<sup>55</sup>
- Suprarenal angulation: the centreline angle between the longitudinal axis of the suprarenal aorta and the longitudinal axis of the AAA neck.<sup>63,64</sup>
- Infrarenal angulation: the centreline angle between the longitudinal axis of the AAA neck and the longitudinal axis of the AAA sac.<sup>63,64</sup>
- Aortic neck thrombus: > 2 mm thick and categorised as percentage of aortic neck circumference (< 25%, 25 – 50%, > 50%).<sup>63</sup>
- Aortic neck calcification: categorised as percentage of aortic neck circumference (< 25%, 25 – 50%, > 50%).<sup>63</sup>
- Conicity: the absolute percentage increase in aortic neck diameter between the lowest renal artery and 10 mm distal to the lowest renal artery baseline.<sup>55</sup>
- Intended oversizing (of the main body of the endograft regarding the pre-operative aortic neck diameter):

$$\left( \frac{\text{nominal endograft diameter}}{\text{post-EVAR neck diameter}} - 1 \right) \times 100\%^{65}$$

For post-EVAR outcomes, it is absolutely undesirable to pool different types of endoleak. Types 1a, 1b, 2, and 3 endoleak have different origins with different consequences, and the re-intervention strategy is different. Furthermore, in order to distinguish between technical failure, endograft associated complications, and progression of disease, endoleaks should be reported as intra-operative, early (< 90 days), or late (> 90 days). In contrast, migration is more difficult since clinically relevant migration differs for each individual patient. For instance, 5 mm migration in a patient with a post-operative sealing zone of 20 mm may be less relevant than 5 mm migration in a patient with a post-operative sealing zone of 10 mm. In the literature, most studies use > 10 mm as the definition for migration. This could be replaced by scoring absolute values of migration and clinically relevant migration in a binary fashion, as defined below.

The following post-EVAR definitions and measurement methods for post-operative CTA scans based on existing literature and a Delphi consensus of 11 European vascular surgeons are proposed:<sup>11</sup>

- Real achieved sealing zone: length starting at the proximal end of the endograft fabric and ending where the endograft material is no longer circumferentially apposed to the aortic wall. Measured over the centreline or as the shortest apposition length (with post-processing software).<sup>11</sup>
- Maximum AAA diameter: average of two orthogonal diameters (maximum and perpendicular) from adventitia to adventitia at the level of the maximum

aneurysm size. Or AAA sac volume can be used as an alternative method.<sup>66,67</sup>

- Effective oversizing (of the main body of the endograft regarding the post-operative aortic neck diameter):

$$\left( \frac{\text{nominal endograft diameter}}{\text{post-EVAR neck diameter}} - 1 \right) \times 100\%^{65}$$

- Type of endoleak: documented as present or absent (including 1a, 1b, 2, 3).<sup>62</sup>
- Clinically relevant migration: migration resulting in a decrease in the real achieved sealing zone < 10 mm, documented as present or absent. In addition, absolute values of endograft migration in mm should be documented.

The maximum AAA diameter can be measured and the type of endoleak can be reported on post-operative duplex ultrasound. For AAA growth and or the detection of an endoleak, it is advised to perform a CTA scan.

## CONCLUSION

There seems to be some consistent evidence that aortic neck diameter, angulation, and length are associated with the development of type 1a endoleak (and or migration) after EVAR. The post-EVAR real achieved sealing zone might be an important addition during follow up. However, a small number of studies with serious limitations (i.e., risk of bias) were included, and there was considerable variability in reporting on patients and outcome measures.

## CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2022.08.017>.

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