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MESTRADO INTEGRADO EM MEDICINA

2020/2021

Gonçalo Miguel Santos e Araújo

Prevalence, risk factors and complications of post-implantation syndrome after endovascular abdominal aortic aneurysm exclusion: a systematic review

Prevalência, fatores de risco e complicações do síndrome pós-implantação após tratamento endovascular dos aneurismas da aorta abdominal: revisão sistemática

Março, 2021

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Mestrado Integrado em Medicina

Área: Angiologia e cirurgia vascular

Tipologia: Dissertação

Trabalho efetuado sob a Orientação de:

Professor Doutor Armando Mansilha

E sob a Coorientação de:

Dr. Joel Sousa

Trabalho organizado de acordo com as normas da revista:

Atca médica Portuguesa

Março, 2021

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UC Dissertação/Projeto (6º Ano) – DECLARAÇÃO DE REPRODUÇÃO

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Angiologia e Cirurgia Vascular

TÍTULO DISSERTAÇÃO/MONOGRAFIA (riscar o que não interessa)

Prevalence, risk factors and complications of post-implantation syndrome after endovascular abdominal aorta aneurysm exclusion: a systematic review

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Faculdade de Medicina da Universidade do Porto, 31/03/2021

Assinatura conforme cartão de identificação: Gonçalo Miguel Santos e Araújo

Prevalence, risk factors and complications of post-implantation syndrome after endovascular abdominal aortic aneurysm exclusion: a systematic review

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ABSTRACT

INTRODUCTION

Despite the proven benefits of endovascular aneurysm repair (EVAR), it has been demonstrated that such procedures can trigger a systemic inflammatory response, named post-implantation syndrome (PIS). The etiology and prognostic implications of this condition have been described in the literature, with conflicting results. Through this work, we aim to review the prevalence, risk factors and complications of post-implantation syndrome after EVAR.

EVIDENCE ACQUISITON

A literature search was performed on MedLine, Scopus and Web of Science databases, which returned 41 studies. Nineteen studies were included. Data were extracted using piloted forms, and, if necessary, authors were contacted to obtain further information.

EVIDENCE SYNTHESIS

In this systematic review, 19 studies reporting significant evidence about prevalence, risk factors and complications of PIS after EVAR were analyzed. PIS prevalence ranged from 11.4% to 44%, with four different definitions of PIS applied in sixteen different studies where they were reported. The only variable found to be systematically associated with the occurrence of PIS was polyester stentgraft fabric. Seven studies reported such findings, with PIS prevalence ranging from 14%-56.1% for patients treated with polyester grafts comparing to 0%-17.9% for those treated with ePTFE grafts. Regarding PIS-related complications, seven studies reported an association between PIS and worse outcomes after intervention. Out of these, three reported PIS to be associated with a significant

higher risk of post-operative cardiovascular complications during the first 30 days after surgery, while one also determined an higher risk of complications in the first year of follow up. Five studies demonstrated that PIS increases length of hospital stay while one reported lower quality of life for patients with this condition.

CONCLUSION

Prevalence of PIS varies greatly in literature due to the absence of standardized diagnostic criteria. Some studies report an association between PIS and short-term as well as long-term adverse events, including MACE. Nonetheless, current evidence is scarce and no conclusion can be strongly drawn.

Key words: Post-implantation syndrome; endovascular aneurysm repair; abdominal aortic aneurysm; major adverse cardiovascular events; inflammation

RESUMO

INTRODUÇÃO

Apesar dos benefícios comprovados do tratamento endovascular dos aneurismas da aorta (endovascular aneurysm repair - EVAR), tem sido demonstrado que esta técnica pode desencadear uma resposta inflamatória sistémica, denominada de Síndrome pós implantação [1]. A etiologia e as implicações no prognóstico deste síndrome têm sido descritas na literatura, com resultados discordantes. Através deste trabalho, pretendemos rever a prevalência, fatores de risco e complicações do SPI (síndrome pós-implantação) após EVAR.

MÉTODOS

Foi realizada pesquisa de literatura via MedLine Scopus e Web of Science, resultando num total de 41 estudos. Destes, 19 estudos foram incluídos. Os dados foram extraídos de acordo com as normas e, caso necessário, os autores foram contactados para obter informação adicional.

RESULTADOS

Nesta revisão sistemática, analisámos 19 estudos que reportavam evidência significativa acerca da prevalência, fatores de risco e complicações do SPI após EVAR. A prevalência variou entre 11.4% e 44%, demonstrando uma grande variabilidade entre os estudos. A única variável que foi sistematicamente reportada como estando em associação com a ocorrência de SPI foi a utilização de stents de poliéster. Esta associação foi demonstrada

em sete estudos, sendo que a prevalência de SPI variou entre 14%-56.1% no grupo de pacientes nos quais se utilizou stents de poliéster enquanto que no grupo submetido a stents de ePTFE a prevalência variou entre 0%-17.9%. Relativamente às complicações associadas ao SPI, sete estudos reportaram uma associação entre a ocorrência de SPI e um pior prognóstico após a intervenção. Destes, três estudos demonstraram que o SPI se associava a um maior risco de complicações cardiovasculares nos primeiros 30 dias pós operatório, sendo que um destes estudos verificou, ainda, um maior risco de complicações durante o primeiro ano. Cinco estudos verificaram um aumento do tempo de hospitalização associado à ocorrência de SPI, enquanto que outro estudo reportou uma pior qualidade de vida associada a este síndrome.

CONCLUSÃO

A prevalência do SPI apresenta elevada discrepância na literatura, devido à ausência de critérios de diagnósticos uniformizados. Alguns estudos demonstram uma associação entre a ocorrência do SPI e a ocorrência de efeitos adversos a longo e a curto prazo, incluindo eventos cardiovasculares major. Contudo, a evidência atual é escassa, não sendo possível tirar conclusões significativas.

1. INTRODUCTION

Endovascular aneurysm repair (EVAR) has revolutionized abdominal aortic aneurysm treatment, broadening treatment indications for higher risk patients. A number of randomized trials and registries have compared this technique with open surgery and the majority of them agree in a significant decrease in 30-day operative mortality rate after EVAR.[2-7] Nonetheless, despite the proven benefits of EVAR, it has been demonstrated that endovascular stentgrafting may elicit an unexpected systemic inflammatory response, which has been named post-implantation syndrome (PIS). [8,9]

PIS is defined as fatigue and fever associated with a rise in inflammatory biomarkers. Which markers should be used and their cutoff values is a matter of debate and there are several proposed combinations of fever, leukocytosis and elevated C-reactive protein used as definition of PIS in the literature.[10] In fact, while some authors define PIS as the presence of fever in association with an elevated C reactive protein serum level, the majority adapt the systemic inflammatory response syndrome criteria (SIRS) and define PIS as the presence of fever in association with leukocytosis.[11,12] This lack of universally accepted definition has led to several conflicting publications and probably explains why the reported incidence of PIS varies so widely. [13,14]

Although PIS is an established medical condition, its etiology is not entirely clear. Several risk factors are known to contribute to it, and include graft material, thrombosis of the aneurysm sac, bacterial translocation due to transient sigmoid ischemia or even contrast-induced neutrophils degranulation.[15-20] Nonetheless, no consensus has been reached on this matter.

In the majority of cases, PIS presents as a transient, self-limited and a benign response that occurs early in the post-operative period.[21,22] However, recent publications report that

such inflammatory response might lead to post-operative adverse events, including cardiovascular ones.

Through this work, we aim to review the prevalence, risk factors and complications of post-implantation syndrome after EVAR.

2. MATERIALS AND METHODS:

The Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines were followed.[23] The aim of the study, eligibility criteria and outcomes were predefined in a protocol. Ethics approval was not required.

Information sources and search strategy

A literature search was performed on the MedLine, Scopus and Web of Science databases on July 23, 2020. The search strategy for MedLine can be found in: ""Post implantation syndrome" OR "Postimplantation syndrome" AND (EVAR or TEVAR)"".

The references of included studies and other important publications were hand searched for additional reports.

Study selection and eligibility criteria

All articles located in the initial search strategy had their abstracts and titles independently screened by two authors, with any discrepancies resolved by discussion.

All studies reporting post-implantation syndrome after endovascular aneurysm exclusion, both abdominal, thoracic and thoracoabdominal, were considered. In order to be eligible for inclusion, articles must report patients demographics and comorbidities, endovascular treatment provided and prevalence of PIS. Only articles written in English were considered.

Studies were excluded if they did not report on any of the defined outcomes. Reviews and invited commentaries were also excluded. No studies were excluded based on year of publication.

Data collection process and data items

Data was extracted using piloted forms, and, if necessary, the authors were contacted to obtain further information.

The following variables were extracted: study design, demographics, type of endovascular treatment provided, graft material, definition of PIS applied, prevalence of PIS and acute / midterm complications after PIS.

The risk of bias of each included study was assessed using the NHLBI study quality assessment tool for observational cohort and cross-sectional studies.

3. RESULTS:

3.1. Study selection

The search strategy yielded 41 studies, out of which 13 were excluded based on title and abstract screening, once duplicates were removed. The remaining 28 studies were selected for consideration of full text, out of which 19 met the defined eligibility criteria. The study selection process is summarized in Figure 1.

3.2. Study characteristics

All studies were observational (12 retrospective and 7 prospective). 2733 patients were included, out of which 2589 underwent endovascular aneurysm repair, 52 thoracic endovascular aneurysm repair (TEVAR) and 58 endovascular aneurysm sealing (EVAS). All procedures were elective (Table I).

Median age ranged between 71,0[24] and 75,7[21] years-old and the female to male patient ratio ranged between from 0,74[21] to 0,97[25]. The most frequently reported patient comorbidities were hypertension (55%[26] – 93.9%[25]), coronary artery disease (17%[21] – 56.6%[11]), congestive heart failure (8%[17] – 19%[25]), chronic lung disease (8%[27] – 50%[25]), smoking (31%[17] – 64%[25]), diabetes mellitus (12%[24] – 49%[28]) and dyslipidemia (28%[26] – 82%[25]). Aneurysm diameter, duration of intervention and contrast volume used were also assessed. (Table II)

Study characteristics are summarised on Table I.

3.3 Risk of Bias

The risk of bias of each included study was assessed using the NHLBI study quality assessment tool for observational cohort and cross-sectional studies.

Eight studies were judged to have high risk of bias[11,16,21,25,27,29-31]. The following domains were found to be associated with the highest risk of bias: 1)- Exposure assessed more than once over time; 2)- Different levels of exposure; 3)- Repeated exposure assessment; 4)- Outcome assessors blinded to the exposure status of participants; 5)- Key potential confounding variables measured and adjusted statistically.

The risk of bias assessment of these studies is present in table III and figure 2.

3.4. Quality assessment

The present review has limitations, mainly due to the small sample size and observational nature of the included studies. Moreover, the study populations were not similar and only three studies included over 200 participants. Seven studies[15,17,25,30,32-34] were conducted prospectively, whereas the rest were retrospective, which further hindered their quality.

3.5. Definition and prevalence of PIS

Out of the nineteen included studies, sixteen provided the applied definition of PIS. Such definition differed significantly among studies, so that:

- 11 studies defined PIS as persisting body temperature of >38°C lasting for >1 day and a white blood cell (WBC) count of >12,000/mm^3 despite antibiotic therapy;
- 1 study defined PIS as continuous temperature of >38°C lasting for >1 day and a WBC count of >11,000/mm^3 despite antibiotic therapy and negative culture results;

- 1 study defined PIS as continuous temperature of >38°C lasting for >1 day and a hs-CRP>10 mg/L;
- 1 study defined PIS as the presence of at least 2 of the following criteria: persisting body temperature >38ºC lasting for >1 day, leukocyte count >12,000/mL, and hs-CPR >10 mg/L;

Table IV provides detailed information regarding the different definitions of PIS applied in the literature.

Regarding PIS prevalence, it was reported in 15 studies, and ranged between 11,4% to 44,0% (table IV).

3.6. Etiology and risk factors of PIS

Sixteen studies reported pre-operative and intra-operative predictors of PIS. The most commonly reported predictor was stentgraft material, although several others were described, including mural thrombus, contrast volume, duration of intervention and baseline comorbidities.

3.6.1. Stentgraft material

The impact of stentgraft material on PIS prevalence is described in nine studies. Published evidence is consensual on this matter, with seven studies reporting an increased prevalence of PIS in patients treated with polyester stentgrafts rather than ePTFE.

Moreover, as reported by Voute *et al*, stentgraft material appears to influence the duration of PIS, with longer duration of symptoms for patients treated with polyester stentgrafts, when comparing with ePTFE counterparts.[17]

Detailed prevalence of PIS per stentgraft material is described in table V.[10,17,25-27,29,32-34]

3.6.2 Mural thrombus

The impact of both chronic and new-onset mural thrombus volume was described in three studies, with rather conflicting evidence.

Kakisis *et al* reported that the volume of new-onset thrombus was significantly higher in patients with PIS, whereas no difference was found in the volume of chronic mural thrombus between patients with and without PIS. [26]

The impact of fresh sac thrombus on post-operative inflammatory response was further reinforced by Martineli *et al* who, in a single-center retrospective review, demonstrated that patients treated by endovascular aneurysm sealing had lower post-operative values of all major indices of inflammation when comparing to the EVAR cohort.[35]

Unlike the previous studies, Lee *et al* reported that the elevation of inflammatory markers was not influenced by the volume of fresh thrombus but was in fact proportional to the volume of chronic mural thrombus.[21]

3.6.3. Duration of surgery

The mean duration of intervention was reported in nine studies, and varied between 100[11]-120[36] minutes in PIS group and 82[28]-122[36] minutes in non-PIS group. No correlation was reported between the duration of surgery and the prevalence of PIS in any of these studies.

3.6.4. Volume of contrast medium

The volume of contrast medium was reported in nine studies, and varied between 120[11]-240[29] mL in the PIS group and 135[11]-260[15] mL in the non-PIS group. No correlation was reported between volume of contrast used and the prevalence of PIS in any of these studies.

3.6.5. Baseline demographic and clinical characteristics

Baseline clinical and demographic characteristics were described in 17 studies. All studies reported no significant differences between PIS and non-PIS groups regarding demographics, comorbidities and perioperative clinical outcomes.

Arnatouglou *et al* reported that heart failure was an independent predictor of PIS (p=0,03), with a threefold increase of such outcome in this subgroup of patients (95% CI: 1.1-8.5 times).[32] Sartipy *et al* reported that PIS was more frequent in patients with coexisting ischemic heart disease (40,0% vs 75%; p=0,03) and chronic obstructive pulmonary disease (5% vs 25%; p=0,04).

3.7 PIS-related complications

Seven studies reported PIS-related complications and its impact on post-operative outcomes.

a)- Major adverse cardiovascular outcomes (MACE)

Three studies reported the impact of PIS on post-operative cardiovascular outcomes. All studies assessed short-term complications (in the first 30 days after EVAR)[10,25,32] and one also reported mid-term complications (up to 12 months after EVAR)[25]. (table VI and VII)

Arnaoutoglou *et al* assessed the prevalence of adverse events at 30 days after EVAR in a series of 214 consecutive patients (137 in PIS group and 77 in non-PIS group).[32] These adverse events were defined as any major adverse cardiovascular event (MACE), acute renal failure, readmission, and death by any cause. In this series, during the first 30 days, adverse events after EVAR were significantly more frequent in the PIS group (25.9%; 20/77) when comparing with the non-PIS group (2.9%; 4/137) and MACE was reported in 16.8% of the patients in the PIS group (13/77) versus 2.2% of the patients in the non-PIS group (3/137).

In another paper published by the same group, both short and mid-term complications associated with PIS were assessed.[25] Adverse events were significantly more common in the PIS group at 30 days (26,2% vs 3,4%; $p<0.001$) and 12 months post-operatively (18,8% vs 5.1%; <0.001). When MACE was specifically assessed, the same tendency was observed, with significantly more events in the PIS group at 30 days (18,4% vs 2,6% ; $p<0.001$) and 12 months (17,2% vs 4,3%; $p<0.001$)

Sousa *et al* reported similar findings, with a 30-days MACE rate of 20% in the PIS group compared to 0% in the non-PIS group[10]. This study also assessed the prevalence of myocardial injury after non-cardiac surgery (MINS), with significant differences between groups (33,3% in the PIS group vs 14,4% in the non-PIS group).

b)- Hospital length of stay

Five studies reported the effect of PIS on hospital length of stay. Four studies reported increased hospital stay in patients with PIS, while the remaining reported no differences between groups. [11,25,32,35] (Table VIII).

d)- Patient's quality of life

One study assessed the impact of PIS in patient's quality of life (QoL). It was reported that patients with PIS felt significantly more limited in carrying out their daily physical activities and were more emotionally discouraged and depressed/anxious about their state of health. [28]

e)- Endoleak

One study assessed the relation between endoleak and PIS. Known *et al* observed that the incidence of type II endoleaks was significantly higher in non-PIS group, concluding that PIS can be beneficial in preventing type II endoleaks in the long term. [24]

4. DISCUSSION

Post-implantation syndrome is a common condition after endovascular aneurysm repair, with a reported prevalence varying between 11,4% and 44,0%. Such variability is mainly attributed to the absence of uniformized diagnostic criteria for this pathology, with several proposed combinations of fever, leukocytosis and elevated C-reactive protein used throughout the literature. In this systematic review, only 16 studies reported the definition of PIS that was applied, and 4 different definitions were used.

Regarding PIS etiology, there was a clear consensus on the role of endograft material on its development. Several studies have been conducted on this matter, with different publications reporting that fabric, stent structure or stent alloy can impact such condition. Nonetheless, despite all the proposed mechanisms, the only component that appears to systematically influence the prevalence of PIS is fabric, particularly polyester. Differences between the type of stentgraft used and the incidence of PIS suggest that different materials can interfere with the inflammatory response, with higher inflammatory reactions documented both *in vitro* and *in vivo* for polyester grafts.

The real prognostic significance of PIS is also a matter of debate. Although the pathophysiology of PIS is not well understood and the relation of this systemic inflammatory response with patient's outcome is not totally established, most studies report PIS as a self-limited, transient and a benign response that occurs early in the post-operative period. Nonetheless, some patients experience short and mid-term complications derived from this pathology, ranging from decreases in quality of life to major cardiovascular events. Such complications were reported in seven studies, and MACE, increased length of hospital stay and decreased quality of life were the most frequently acknowledged.

Out of these seven studies, three reported PIS to be associated with a significant higher risk of MACE during the first 30 days following surgical intervention. Additionally, one of them also evidenced a higher incidence of MACE during the first post-operative year.

Regarding the impact of this condition on patients quality of life, those with PIS experienced greater limitations in the execution of their daily physical activities, and were more emotionally discouraged and depressed about their health situation.

Finally, this condition can sometimes hinder post-operative recovery and increase the length of hospital stay. In fact, five studies reported a significant prolonged hospital stay in patients who develop PIS after intervention.

This results show how PIS can influence the outcome after an EVAR, mainly due to its implication on cardiovascular events, which demonstrated an important impact on morbidity and mortality in this patients. Thus, patients who developed PIS should be subject to a closer surveillance during the first year after EVAR.

Considering the effect of PIS on patient's outcome, the main question remains how to approach and treat patients with this inflammatory response after an EVAR. In fact, published evidence is limited and no therapeutic algorithm has been established.[37] However, it seems reasonable that in certain cases, post-operative administration of anti-inflammatory drugs may be beneficial in high-risk patients who present with severe PIS after EVAR, therefore limiting the inflammatory response and possible consequences.[11] Recently, Motte *et al* evaluated the effect of the pre-operative administration of methylprednisolone, compared to placebo, in patients who underwent EVAR. It was demonstrated that patients treated with steroids experienced lower post-operative inflammatory responses, although no differences between groups were reported at 30-

days follow-up.[13] Nonetheless, attention to the drugs is mandatory, given their association with cardiovascular morbidity and mortality.[38]

There is currently an ongoing randomized placebo-controlled clinical trial that aims to evaluate whether the perioperative administration of Naproxen, an anti-inflammatory drug with a beneficial cardiovascular safety profile, can have any impact on the inflammatory response and patient's outcome during the first year after EVAR.

This review has limitations mainly due to the small sample size and difference in the PIS definition through the included studies. Moreover, study design was not consistent in all studies and study populations were not similar.

5. CONCLUSION

Prevalence of PIS varies greatly in literature due to the absence of standardized diagnostic criteria. Some studies report an association between PIS and short-term as well as long-term adverse events, including MACE. Nonetheless, current evidence is scarce and no conclusion can be strongly drawn. Current trials assessing the role of anti-inflammatory drugs on PIS prevalence and related adverse events could bring further insights on such matter.

Table I - Characteristics of included study populations

Study	Study design	N° of patients	Median age (range), years	Male	Procedure (n)	Graft (n)	Material (n)
Martinelli, O *et al* [35]	Observational	169	72 (63-81)	86% (145/169)	111 EVAR 58 EVAS	Excluder® - n= 55 AFX® - n= 56	Polyester - 55 ePTFE - 56
Arnaoutoglou, E *et al*[29]	Observational	40	74.2 (53-87)	95% (38/40)	EVAR	Talent® - n=16 Excluder® - n=16 Anaconda® - n=5 Zenith®- n=2	Polyester - 17 ePTFE - 23
De, L La Motte *et al*[36]	Observational	66	74 (58-87)	89% (59/66)	EVAR	Zenith® - n= 66	Polyester - 66
Arnaoutoglou *et al*[32]	Observational	214	72.3 (64-80)	97% (206/214)	EVAR	Endurant®- n= 108 Anaconda® - n= 11 Zenith® - n= 7 Powerlink® - n= 1 Aorfix® - n= 1 Excluder® - n= 86	Polyester - 128 ePTFE - 86
Ito, E *et al*[27]	Observational	128	74 (57-90)	82% (105/128)	EVAR	Excluder® - n= 33 EPL/AFX® - n= 36 Aorfix® - n= 32 Endurant® - n= 26 Zenith® - n= 1	Polyester - 59 ePTFE - 69
Arnaoutolgou *et al*[11]	Observational	162	73 (53-91)	95% (155/162)	148 EVAR 14 TEVAR	----------	----------
Arnaoutolgou *et al*[25]	Observational	182	72.4 (64-80)	96% (175/182)	EVAR	----------	Polyester - 108 ePTFE - 74
Vôute, M.T. *et al*[17]	Observational	149	72.6 (65-80)	87.9% (130/149)	EVAR	----------	Polyester - 82 ePTFE - 67
Kakisis, J.D. *et al*[26]	Observational	87	72.6 (67-78)	93% (81/87)	EVAR	----------	Polyester - 57 ePTFE - 3
Nano, G *et al*[28]	Observational	740	73.4 (53,1-90.7)	----------	EVAR	Anaconda®- n= 118	Polyester - 118
Kwon, H *et al*[24]	Observational	204	71 (64-79)	90% (190/204)	EVAR	----------	Polyester - 163 ePTFE - 4141 ePTFE
Sartipy, F *et al*[34]	Observational	45	74 (62-86)	87% (39/45)	EVAR	----------	Polyester - 32 ePTFE - 1313 ePTFE
Chang, C. K, *et al* [16]	Observational	38	75.1 (57.8-86.5)	76% (29/38)	TEVAR	----------	----------
Sousa, J *et al*[10]	Observational	133	75.66 (68,5-83)	95.5% (127/133)	EVAR	----------	Polyester - 107 ePTFE - 26
Rita Ferreira, *et al*[33]	Observational	149	73 (66-80)	88% (131/149)	EVAR	----------	----------
Verladi, G.F. *et al*[31]	Observational	124	75 (67-83)	91.9% (114/124)	EVAR	----------	----------
Lee, J.H. *et al*[21]	Observational	34	75.7 (67-54)	74% 25/34)	EVAR	----------	Polyester - 34
Sartipy, F *et al*[30]	Observational	69	74 (62-93)	83% (57/69)	EVAR	----------	Polyester - 49 ePTFE - 20
Lee, J. *et al*[21]	Observational	34	75.7 (6.,2-84.2)	74% (25/34)	EVAR	----------	Polyester - 34

Table II- Population Demographics

		HT	CAD	CHF	CPD	Smoker	DM	Dyslipidemia	Procedure duration (min)	Contrast media [39]	Aneurysm diameter (cm)
Martinelli, O *et al*	Total	66.3%	--------	-------	--------	-------	15.4%	41.4%	EVAS: 120 ± 28,1 EVAR: Group A – 132 ± 21,2 Group B – 120 ± 55	EVAS: 180 ± 34 EVAR: Group A – 185 ± 30 Group b – 80 ± 55	--------
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
Arnaoutolgou, E *et al*	whole	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	105 (80-150)	260 (55-720)	5.5 (4.8-8.4)
	PIS	--------	--------	-------	--------	-------	-------	--------	102.5 (80-160)	240 (80-340)	5.35 (4.9-9.8)
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
De, L La Motte *et al*	whole	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	Non-PIS	73%	60%	-------	23%	31%	15%	--------	--------	--------	6 (5.6-6.9)
	PIS	75%	42%	-------	50%	55%	20%	--------	--------	--------	6.2 (5.7-7.2)
	p	1.00	0.13	-------	0.04	0.08	0.75	--------	--------	--------	0.22
Arnaoutolgou, E *et al* [32]	whole	87.3%	51.6%	14.95%	46.7%	60.3%	21%	78.5%	--------	--------	--------
	Non-PIS	86.1%	47.8%	12.4%	42.3%	59.9%	19.7%	77.4%	108 (59-157)	151.6 (62.7-240)	--------
	PIS	89.6%	58.4%	19.5%	54.5%	61%	23.4%	80.5%	112.9 (60-166)	149 (38-260)	--------
	p	0.462	0.149	0.164	0.086	0.865	0.527	0.591	0.521	0.853	--------
Lee, J. H *et al*	whole	73.7%	17.5%	-------	-------	-------	14.5%	--------	--------	--------	--------
	Non-PIS	77%	19%	-------	-------	-------	15%	--------	--------	--------	--------
	PIS	63%	13%	-------	-------	-------	13%	--------	--------	--------	--------
	p	0.65	1.00	-------	-------	-------	1.00	--------	--------	--------	--------
Ito, E *et al*	whole	62.5%	18.75%	-------	7.8%	-------	12.3%	28.1%	Polyester: 132 (80-276) Excluder®: 131 (81-306) APX®: 126 (63-264)	Polyester: 140 (37-320) Excluder®: 130 (82-395) APX®: 98 (46-239)	Polyester: 50 (34-67) Excluder®: 48.5 (33-100) AFX®: 43 (28-79)
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
Arnaoutologlou, E *et al* [31]	whole	83.4%	56.6%	-------	43.9%	55.4%	18.6%	68.6%	--------	--------	--------
	Non-PIS	82.3%	54.8%	-------	42.4%	56.6%	20.3%	69.9%	95 (60-310)	135 (30-720)	5.5 (4.8-12)
	PIS	87.7%	65.3%	-------	51%	57.1%	16.3%	71.4%	100 (60-280)	120 (45-400)	5.6 (4.9-11)
	p	0.39	0.22	-------	0.32	0.95	0.55	0.85	0.67	0.37	0.39
Arnaoutouglou, E *et al* [25]	whole	93.9%	52.7%	19.3%	50%	64.3%	21.4%	82.3%	--------	--------	--------
	Non-PIS	94.8%	48.7%	15.4%	44.4%	63.2%	20.5%	82.9%	111.2 (62-160)	166.3 (78-154)	5.8 (4.8-6.8)
	PIS	92.3%	60%	26.2%	60%	66.2%	23.1%	81.2%	115.3 (63-168)	159.4 (43-275)	5.9 (4.7-7.1)
	p	0.347	0.144	0.08	0.07	0.411	0.686	0,483	0.599	0.656	0.546
Vôute, M. T. *et al*	whole		44.4%	8.7%	16.1%	30.9%	16.1%	29.5%			
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	58.4 (57.4-69.4)
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	61.1 (59-73)
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	0.22
Kakisis, JD *et al*	whole	55%	32%		20%	38%	15%	28%	--------	--------	54.6 (47.8-61.4)
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
Sartipy, F *et al*	whole	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	Non-PIS	--------	43.8%	-------	10.5%	10.5%	15.7%	--------	--------	--------	--------
	PIS	--------	75%	-------	25%	25%	33.3%	--------	--------	--------	--------
	p	--------	0.03	-------	0.04	0.29	0.45	--------	--------	--------	--------
Nano, G *et al*	whole	86.4%	52.5%		24.6%		49.1%	38.1%			
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
Kwon, H *et al*	whole	71.2%	32.7%	-------	41.6%	63.9%	11.8%	--------	--------	--------	--------
	Non-PIS	71.7%	36.3%	-------	42.8%	67.4%	15.2%	--------	3.1 (2-4.2)	--------	56.9 (46.4-77.4)
	PIS	70.3%	25%	-------	39.1%	56.3%	10.9%	--------	2.9 (1.8-4)	--------	56.8 (46.7-66.6)
	p	0.868	0.147	-------	0.648	0.156	0.514	--------	0.369	--------	0.939
Sartipy, F *et al*	whole	--------	48.9%	-------	--------	11.1%	15.55%	22.2%	--------	--------	--------
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
Chang, C. K, *et al*	whole	89%	55%	-------	--------	-------	16%	--------	6.8 (4.9-8.7)		67 (57-77)
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
Sousa, J *et al*	whole	84.2%	39.1%	14.3%	24.8%	-------	21.8%	66.9%	--------	--------	--------
	Non-PIS	84.7%	39.8%	13.6%	22.9%	-------	21.2%	66.1%	--------	--------	--------
	PIS	80%	33.3%	20%	40%	-------	26.7%	73.3%	--------	--------	--------
	p	0.434	0.425	0.364	0.131	-------	0.421	0.542	--------	--------	--------
Lee, J. *et al* [21]	whole	74%	18%			-------	15%		--------	--------	57.2 (47.8-66.6)
	Non-PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	PIS	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------
	p	--------	--------	-------	--------	-------	-------	--------	--------	--------	--------

HT-hypertension; CAD – coronary heart disease; CHF-cardiac heart failure; CPD – chronic pulmonary disease

Table III risk of bias

	Research question or objective cleary stated	Study population clearly specified and defined	Participation rate of eligible persons at least 50%	All the subjects selected or recruited from the same or similar populations.	Inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants	Sample size justification, power description, or variance and effect estimates provided	Exposure(s) of interest measured prior to the outcome(s) being measured	Timeframe sufficient	Study examine different levels of the exposure as related to the outcome	Exposure measures clearly defined	Exposure assessed more than once over time	Outcome measures clearly defined	Outcome assessors blinded to the exposure status of participants	Loss to follow-up after baseline 20% or less	Key potential confounding variables measured and adjusted statistically
Martinelli, O et al 34	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Arnaoutoglou, E et al33	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No
De, L La Motte et al35	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Arnaoutoglou et al29	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No
Ito, E et al27	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No
Arnaoutolgou et al11	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No
Arnaoutolgou et al25	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No
Vôute, M.T. et al17	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes
Kakisis, J.D. et al26	Yes	Yes	Yes	Yes	yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Nano, G et al28	Yes	Yes	Yes	yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No
Kwon, H et al24	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Sartipy, F et al32	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Chang, C. K, et al 16	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No
Sousa, J et al10	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Rita Ferreira, et al30	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Verladi, G.F. et al38	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Lee, J.H. et al21	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Sartipy, F et al31	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

Table IV- Incidence and definition of PIS *per* study

Author	Year	Definition	Incidence % (n)
Martinelli, Di *et al*	2020	≥2: -PBT >38ºC -LC >12,000/mL -hs-CPR >10 mg/L	EVAS – 13,8% (8/58) EVAR – 38,7% (43/111)
Sousa, Joel *et al*	2020	PBT >38ºC + LC> 11,.00/mL	11.4% (15/133)
Ferreira, Rita *et al*	2019	----------	39% (58/149)
Veraldi, GF *et al* [31]	2018	PBT >38ºC + LC>12.000/mL	44% (55/124)
Lee, JH *et al* [21]	2018	PBT >38ºC + LC>12.000/mL	23.5 % (8/34)
Arnaoutoglou, E *et al* [25]	2016	PBT >38ºC + LC>12.000/mL	35.7% (65/182)
Kwon, H *et al*	2016	PBT >38ºC + LC>12.000/mL	31.4% (64/204)
Arnaoutoglou, E *et al* [32]	2015	PBT >38ºC + LC>12.000/mL	36 % (77/214)
Sartipy, F *et al*	2015	PBT >38ºC + LC>12.000/mL	22.2 % (10/45)
Nano, G *et al*	2014	PBT >38ºC + LC>12.000/mL	20.3 % (24/142)
Sartipy, F *et al* [30]	2014	PBT >38ºC + LC>12.000/mL	17.4% (12/69)
Kakisis, JD *et al* [26]	2014	PBT >38ºC + LC>12.000/mL	39%(34/149)
Vôte, MT *et al* [17]	2012	PBT >38ºC + hs-CRP>10 mg/L	38.9 % (58/149)
Anaoutolgou, E *et al* [15]	2011	PBT >38ºC + LC>12.000/mL	35 %(14/43)
Arnaoutoglou,E *et al* [11]	2010	PBT >38ºC + LC>12.000/mL	30.2% (49/162)

PBT - peak body temperature; LC - leukocyte count; hs-PCR – high-sensivity C-reactive protein

Table V- Incidence of PIS according to stentgraft fabric

Study	Fabric		Graft	p
	Polyester	ePTFE		
Arnaoutoglou, E *et al*[29]	41.4% (12/29)	11.7% (2/17)	Talent® – 37.5% (6/16) Zenith® - 50% (1/2) Anaconda®–100% (5/5) Excluder® – 11.7%(2/17)	0,002
Arnaoutoglou *et al* [32]	52.3% (67/128)	11.6% (10/86)	Endurant® – 51.8% (56/108) Anaconda® – 81.8% (9/11) Zenith® – 14.3% (1/7) Powerlink® – 0% (0/1) Aorfix ®– 100% (1/1)	<0.01
Arnaoutolgou *et al* [25]	52.7% (57/108)	10.8% (8/74)	----------	<0.001
Vôute, M.T. *et al* [17]	56.1% (46/82)	17.9% (12/67)	----------	<0.001
Kakisis, J.D. *et al* [26]	----------	13%	Excluder® – 13% Endurant® – 20% Zenith® – 35% Anaconda® – 71%	<0.001
Sartipy, F *et al* [34]	28.1% (9/32)	7.7% (1/13)	----------	0.24
Sousa, J *et al* [10]	14% (15/107)	0% (0/26))	----------	0.031

Table VI- Reported 30 days complication rates

Study	Adverse event			MACE		
	Non-PIS	PIS	p	Non-PIS	PIS	p
Arnaoutoglou, E *et al*[32]	2.9 % (4/137)	25.9% (20/77)	<0.001	2.2% (3/137)	16.8% (13/77)	<0.001
Arnaoutoglou, E, *et al* [25]	3.4% (4/117)	26.2% (17/65)	<0.001	2.6% (3/117)	18.4% (12/65)	<0.001
Sousa, J *et al* [10]	-	-	-	0 % (0/118)	20% (3/15)	<0.001

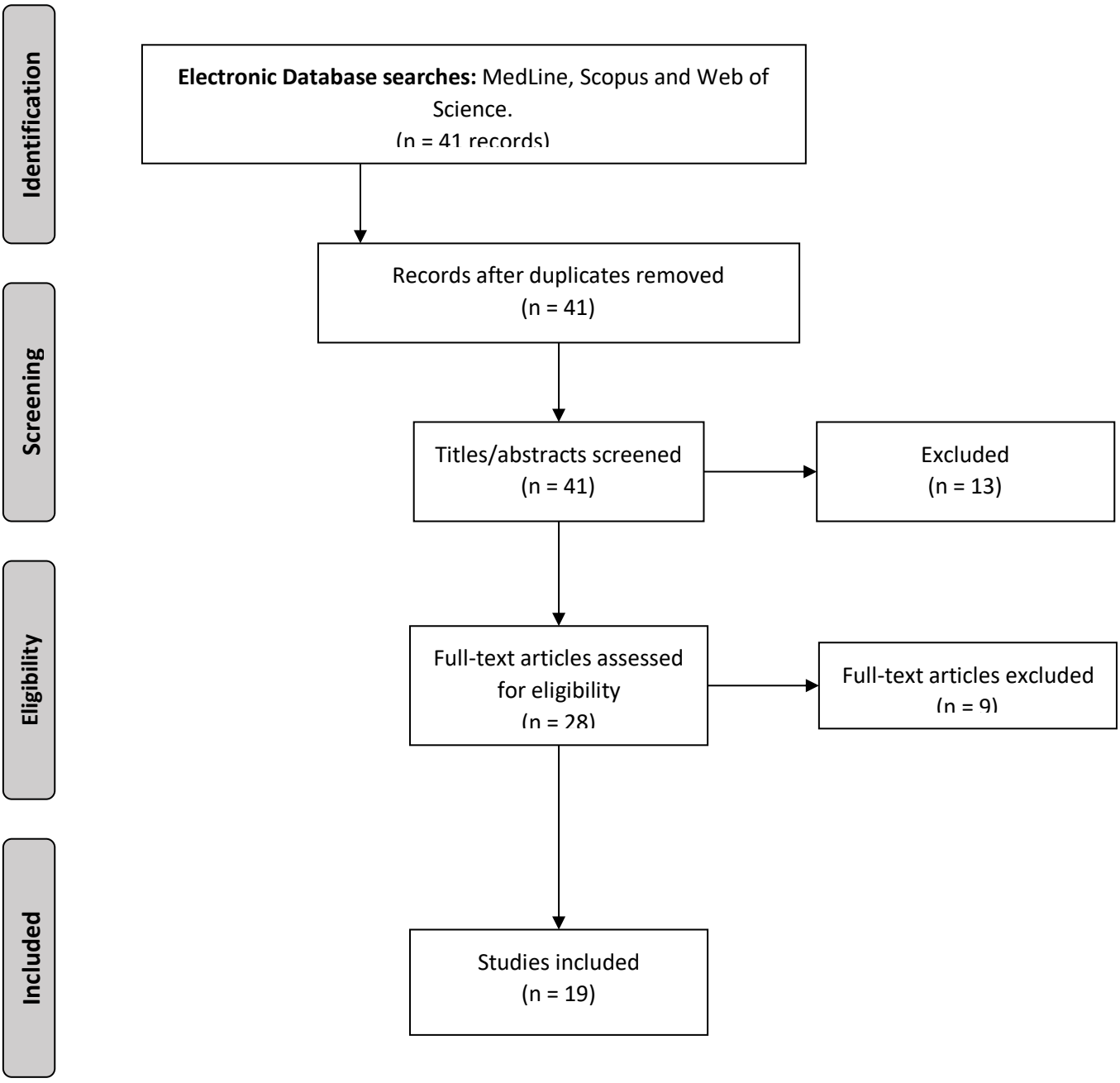
Table VII- Reported 12 months complication rates

Study	Adverse event			MACE		
	Non-PIS	PIS	p	Non-PIS	PIS	p
Arnaoutolgou, E *et al*[25]	5.1% (6/117)	18.8% (12/64)	<0.001	4.3% (5/117)	17.2% (11/64)	<0.001

Table VIII- Hospital stay

	Non-PIS *Days (range)*	PIS *Days (range)*	p
Arnaoutoglou E *et al*[11]	3 (2-7)	5.5 (2-9)	0.002
Arnaoutoglou E *et al* [32]	3 (2-29)	6 (3-26)	<0.001
Arnaoutoglou E *et al* [25]	3 (3-45)	6 (5-7)	<0.001
De, Vogt *et al*[36]	4 (3-6)	5 (4-7)	0.13
Martinelli *et al* [35]	4	7	-------

Figure 1 – Flowchart PRISMA



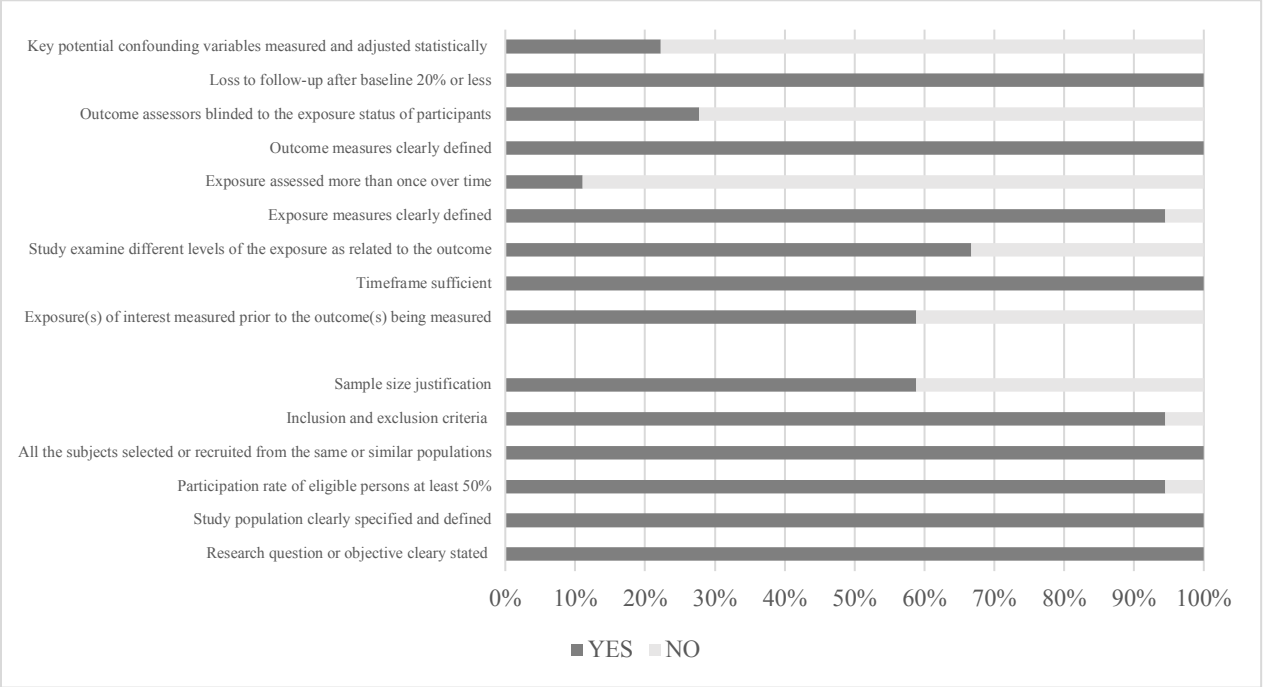


Figure 2 – Risk of bias of the included studies according to the NHLBI study quality assessment tool

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Annexes

Reporting guidelines –Annals of vascular surgery

Form of manuscript

Manuscripts should be succinct. Manuscripts must be double spaced and formatted to include continuous line numbers. Omit well-known and previously published material. Introductions may contain interesting and relevant historical background, but such material should be inserted judiciously. Discussions should focus on the work at hand, including only those references that directly relate to the subject.

Manuscripts must conform to standard usage and are subject to editorial changes according to the policies of the journal. Generic names of drugs should be used whenever possible. State all measurements in metric units.

Body of paper should be organized in the following manner: Abstract, Introduction, Material and Methods, Results, Discussion, and Conclusion (note organization may vary according to category of manuscript). Acknowledgments of persons who have contributed to the scientific development or production of the manuscript. References, typed double spaced, sequentially in the order they appear in the text. Tables, typed double spaced on separate pages, and identified by Roman numerals in the order they appear in the text, including a brief descriptive title. Legends to illustrations, typed double spaced in numerical order.

Abbreviations must be spelled out the first time they are used. Abbreviations in the abstract are discouraged and should be kept to a minimum in the body of the text. Standard international units (SI units) should be used.

Data Analysis. Appropriate statistical methodology should be used when applicable. Engage the assistance of a biostatistician in the preparation of your data if necessary.

Article structure

Subdivision - numbered sections Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods Provide sufficient details to allow the work to be reproduced by an independent researcher. Methods that are already published should be summarized, and indicated by a reference. If quoting directly from a previously published method, use quotation marks and also cite the source. Any modifications to existing methods should also be described.

Theory/calculation A Theory section should extend, not repeat, the background to the article already dealt with in the Introduction and lay the foundation for further work. In contrast, a Calculation section represents a practical development from a theoretical basis.

Results Results should be clear and concise.

Discussion This should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Appendices If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

• ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.

• ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script behind the English transliteration. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower- case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

• ***Corresponding author.*** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. This responsibility includes answering any future queries about Methodology and Materials. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

• ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Structured abstract A structured abstract, by means of appropriate headings, should provide the context or background for the research and should state its purpose, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations.

Abbreviations Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Tables

Tables should be numbered in the order in which they are mentioned in the text, and given a brief, descriptive title. Omit all horizontal or vertical rules from the body of the table. Glossy prints and reduced versions of typewritten tables are unacceptable. All acronyms, abbreviations, and unusual units of measurement used in the title, headings, or body of the table should be fully explained in a footnote. For footnotes, use these symbols in sequence: *, †, ‡, §, [], ||, ¶, #, **, ††, superscript lowercase letters. If a table or any data

therein have been previously published, a footnote to the table must give full credit to the original source.

References

Only references cited in the text should be included in the reference list; cite references in the text by superscript numbers. The reference list must be numbered according to the order of mention of references in the text. The list format should conform to that set forth in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (Vancouver style) (http://www.icmje.org), except the first three authors are cited followed by et al. Do not cite as a reference any work that has not been published or accepted for publication. Manuscripts in preparation or submitted (but not yet accepted for publication) are not acceptable as a reference nor are oral presentations. Manuscripts fully accepted for publication but not yet published should be cited as "in press." Note that journal abbreviations must follow the style used in the Cumulated Index Medicus. For periodical references, give the surnames of authors and their initials, title of article, publication name, year, volume, and inclusive page numbers. For books, give the surnames of authors and their initials, chapter title (if applicable), editors' surnames and initials, book title, volume number (if applicable), edition number (if applicable), city of publisher, full name of publisher, year of publication, and inclusive page numbers of citation.

Reporting Guidelines – PRISMA

1) Identify the report as a systematic review, meta-analysis, or both
   Page 3: "Prevalence, risk factors and complications of post-implantation syndrome after endovascular abdominal aortic aneurysm exclusion: a systematic review"

2) Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number
   Page 4

3) Describe the rationale for the review in the context of what is already known
   Page 7 : "Through this work, we aim to review the prevalence, risk factors and complications of post-implantation syndrome after EVAR"

4) Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).
   Page 7: "Through this work, we aim to review the prevalence, risk factors and complications of post-implantation syndrome after EVAR."

5) Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.
   Page 8: "In order to be eligible for inclusion, articles must report patients demographics and comorbidities, endovascular treatment provided and prevalence of PIS"

6) Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched
   Page 8: "A literature search was performed on the MedLine, Scopus and Web of Science databases"

7) Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated
   Page 8: “The search strategy for MedLine can be found in: ““Post implantation syndrome” OR “Postimplantation syndrome” AND (EVAR or TEVAR)””.”

8) State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).
   Page 8: “All studies reporting post-implantation syndrome after endovascular aneurysm exclusion, both abdominal, thoracic and thoracoabdominal, were considered”;

9) Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators
   Page 8: “Data was extracted using piloted forms, and, if necessary, the authors were contacted to obtain further information. “

10) List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made
    Page 8: “The following variables were extracted: study design, demographics, type of endovascular treatment provided, graft material, definition of PIS applied, prevalence of PIS and acute / midterm complications after PIS.”

11) Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis
    Page 9: “The present review has limitations, mainly due to the small sample size and observational nature of the included studies”

12) Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram
    Page 9: “The search strategy yielded 41 studies, out of which 13 were excluded based on title and abstract screening, once duplicates were removed. The

remaining 28 studies were selected for consideration of full text, out of which 19 met the defined eligibility criteria."
Page 21: Flowchart PRISMA

13) For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations
Page 17: table 1

14) Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).

Page 15: "The risk of bias of each included study was assessed using the NHLBI study quality assessment tool for observational cohort and cross-section studies. Eight studies were judged to had high risk of bias[11,16,21,25,27,29-31]"

15) Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).
Page 16 "This results show how PIS can influence the outcome after an EVAR, mainly due to its implication on cardiovascular events, which showed an important impact on morbidity and mortality in this patients. So, patients who developed PIS should be subject to a closer surveillance during the first year after EVAR. "

16) Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).
Page 16: "This review has limitations mainly due to the small sample size and difference in the PIS definition through the included studies. Moreover, study design was not consistent in all studies and study populations were not similar. "

17) Provide a general interpretation of the results in the context of other evidence, and implications for future research

Page 16: “Considering the effect of PIS on patient’s outcome, the main question remains how to approach and treat patients with this inflammatory response after an EVAR. In fact, published evidence is limited and no therapeutic algorithm has been established”

18) Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.