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REVIEW ARTICLE

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Systematic review of groin wound surgical site infection incidence after arterial intervention

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Abstract

The objectives were to determine the surgical site infection incidence (including superficial/deep) fter arterial intervention through non-infected groin incisions and identify variables associated with incidence. MEDLINE, EMBASE and CENTRAL databases were searched for randomised controlled trials and observational studies of adults undergoing arterial intervention through a groin incision and reported surgical site infection. Infection incidence was examined in subgroups, variables were subjected to meta-regression. One hundred seventeen studies reporting 65 138 groin incisions in 42 347 patients were included. Overall surgical site infection incidence per incision was 8.1% (1730/21 431): 6.3% (804/12 786) were superficial and 1.9% (241/12 863) were deep. Superficial infection incidence was higher in randomised controlled trials (15.8% [278/1762]) compared with observational studies (4.8% [526/11 024]); deep infection incidence was similar (1.7% (30/1762) and 1.9% (211/11 101) respectively). Aneurysmal pathology ($\beta = -10.229$, $P < .001$) and retrospective observational design ($\beta = -1.118$, $P = .002$) were associated with lower infection incidence. Surgical site infection being a primary outcome was associated with a higher incidence of surgical site infections ($\beta = 3.429$, $P = .017$). The three-fold higher incidence of superficial surgical site infection reported in randomised controlled trials may be because of a more robust clinical review of patients. These results should be considered when benchmarking practice and could inform future trial design.

KEYWORDS

groin incisions, surgical site infection, vascular

Key Messages

- groin wound surgical site infection (SSI) incidence varies in the literature
- the overall groin wound SSI incidence in the literature on 65 138 incisions in 42 347 patients was 8.1% (per incision)

- this systematic review searched the MEDLINE, EMBASE and CENTRAL databases and aimed to investigate how the variability of study design, the pathology being treated and the primary outcome may influence the reported SSI incidence after arterial intervention
- although incidence pooled from observational studies may represent the SSIs most apparent to vascular surgeons, it is likely a gross underestimation of superficial SSIs, which are more robustly captured in randomised controlled trials
- these pooled incidences can aid benchmarking and inform future trial design

1 | INTRODUCTION

A groin incision is commonly used in vascular surgery to expose the femoral vessels and is used for many frequently performed procedures.[1,2] Given the groin's proximity to the external genitalia and anal canal, skin flora and predisposition to intertrigo (particularly in obese patients)[3]; it is unsurprising that groin wound surgical site infections (SSIs) are commonly experienced by vascular surgery patients—a population with a high prevalence of risk factors for nosocomial infection such as diabetes and smoking.[1,2]

SSIs are a significant source of patient morbidity and increased health care costs.[4] SSIs may lead to vascular graft infection, requiring re-operation or amputation and may result in mortality.[5-7] 'How can we reduce surgical-site infection in vascular surgery?' was recently identified as a research priority amongst health care professionals in vascular surgery in a modified Delphi exercise[8]; and identifying adjuncts that prevent groin wound SSIs has been the focus of several studies.[9] Despite this, vascular surgery specific guidelines currently lack recommendations on strategies to monitor and prevent SSIs.[10,11]

The incidence of groin wound SSI following arterial intervention via a non-infected surgical field reported in the literature varies considerably,[2,12-14] which poses a challenge for those who wish to benchmark their own outcomes against accepted standards, and for those planning to evaluate groin wound SSI preventing interventions in adequately powered trials. The true incidence of groin wound SSI after vascular intervention is unknown; and factors that may give rise to the varying reported incidences between studies are incompletely understood.

Therefore, the primary objective of this review was to determine the reported incidence of groin wound SSI after arterial intervention through a clean surgical field. Secondary objectives were to determine the incidence of superficial and deep/organ space groin wound SSIs after arterial intervention; to determine the incidence of groin wound SSI in different study types (ie, randomised controlled trial [RCT] versus observational study) and design (ie, SSI reported as a primary or secondary outcome); and to identify variables that are associated with a higher or lower reported incidence of groin wound SSI.

2 | METHODS

This study was conducted in accordance with guidance in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement,[15] and was prospectively registered with the International prospective register of systematic reviews (PROSPERO; CRD42020185170).

2.1 | Data sources, search terms and inclusion/exclusion criteria

The MEDLINE, EMBASE and CENTRAL databases were searched without date restriction using the following terms: ([SSI OR SSIs OR surgical site infection OR surgical wound infection OR wound infection] AND [vascular OR arterial] AND [groin OR femoral]). The search was undertaken on 3rd June 2021.

The inclusion criteria were:

- RCTs and observational cohort studies including patients undergoing arterial intervention through a groin incision (including re-do incisions).
- Patients aged 18 and above.
- Outcome of SSI.

The exclusion criteria were:

- Venous or cardiac procedures.
- Procedures for trauma.
- Pre-existing groin infection (eg, infected pseudoaneurysm).
- No groin wound SSI outcome reported.
- No English version of abstract available.
- Systematic reviews.

- Preliminary results/interim results articles/abstract publication from meeting presentation (if the subsequent full results were identified)

2.2 | Review methods

Duplicate article removal was performed before any screening. Each of the following steps were conducted separately by two reviewers, with discrepancies referred to a third reviewer: titles and abstract screen (B.L.G., D.T.L., E.K.M., E.M., G.A.), full text screen (B.L.G., D.T.L., E.K.M., E.M., G.A.), screening of the references and related articles of the included articles (B.L.G., E.M.), data extraction (B.L.G., D.T.L., E.K.M., E.M.) and study assessment (Cochrane's risk-of-bias tool for randomised trials for RCTs and the Newcastle-Ottawa Scale for observational studies: B.L.G., D.T.L., E.K.M.).[16,17]

The primary outcome was the overall reported incidence of SSIs. Secondary outcomes were:

- the reported incidence of superficial and deep/organ-space SSIs;
- the incidence SSI in subgroups of studies based on:
  - study design (RCT/observational, prospective/retrospective),
  - pathology (aneurysmal/occlusive/mixed),
  - reported definition of SSI (not reported/author defined or previously published definition: Szilagyi,[18] Centers for Disease Control and Prevention [CDC] definition,[19] Southampton Wound Scale[20] and ASEPSIS score),[21]
  - whether SSI was a primary outcome (including: single primary outcome, coprimary outcome or if part of a composite primary outcome) or not,
  - subgroups within studies (intervention and control arms of RCTs);
- the proportions of patients that were current smokers, had ischaemic heart disease, had diabetes, were obese (defined as body mass index >30 kg^2), had prosthetic bypass/patch;
- the results of meta-regression analysis to identify factors associated with a higher reported incidence of SSIs;
- the reported incidences of seroma, haematoma, lymphatic leak and re-intervention to manage SSI; and surgical/medical interventions which can impact risk of SSI (longitudinal/oblique incisions, antibiotic prophylaxis, solution used for skin preparation, pre-operative skin shaving, pre-operative bathing/showering and intra-operative normothermia/glycaemia control).

Groin incisions can be unilateral or bilateral. SSI incidences were calculated on a 'per incision' basis and are reported as such unless otherwise stated. Whenever possible, the number of SSIs and/or groin incisions were derived to avoid loss of data from studies that did not explicitly report an SSI incidence 'per incision'. Studies that exclusively reported SSIs on a 'per patient' basis (including patients undergoing both unilateral and bilateral groin incision) were included, but data from these studies were only used to compare reported SSI incidence 'per patient' with the incidence 'per incision', and not used for any further analyses.

2.3 | Statistical analyses

Pooling of demographic variables such as male to female ratio, mean age and follow-up duration utilised the weighted mean. Data collection was designed to allow for calculation of actual incidence of SSIs (overall and subgroups). Meta-regression was used to investigate what variables impact on SSI incidence and was performed using weighted least squares regression (weighted with the inverse-variance method). Only 'per incision' data were used for regression analyses. First, univariate analyses of patient-level and study-level variables determined to be relevant by the authorship team was performed. Variables reaching $P < .1$ were then entered into forward stepwise multivariate analysis. Regression results are presented with 95% confidence intervals (95% CI). Statistical significance was defined was $P < .05$. In cases of variables with missing data being considered for inclusion in regression analyses, missing data analyses were performed. Missing data analyses consisted of examining proportion of data missing and determining whether data were missing completely at random (MCAR) with Little's MCAR test ($P < .05$ indicating data were not MCAR). Variables with a high proportion of data missing not at random were considered unsuitable for case-wise deletion regression and multiple imputation. Analyses were performed using Excel (Microsoft) and SPSS version 26 (IBM).

3 | RESULTS

After duplicate removal, the initial search produced 1160 articles (Figure 1). Following title and abstract screen, 194 articles underwent full-text review. The reference lists and related articles screen identified a further 21 articles for review. After exclusions during the full-text screen, a total of 117 articles were included. The references for all included articles are listed in Supplementary material 1.

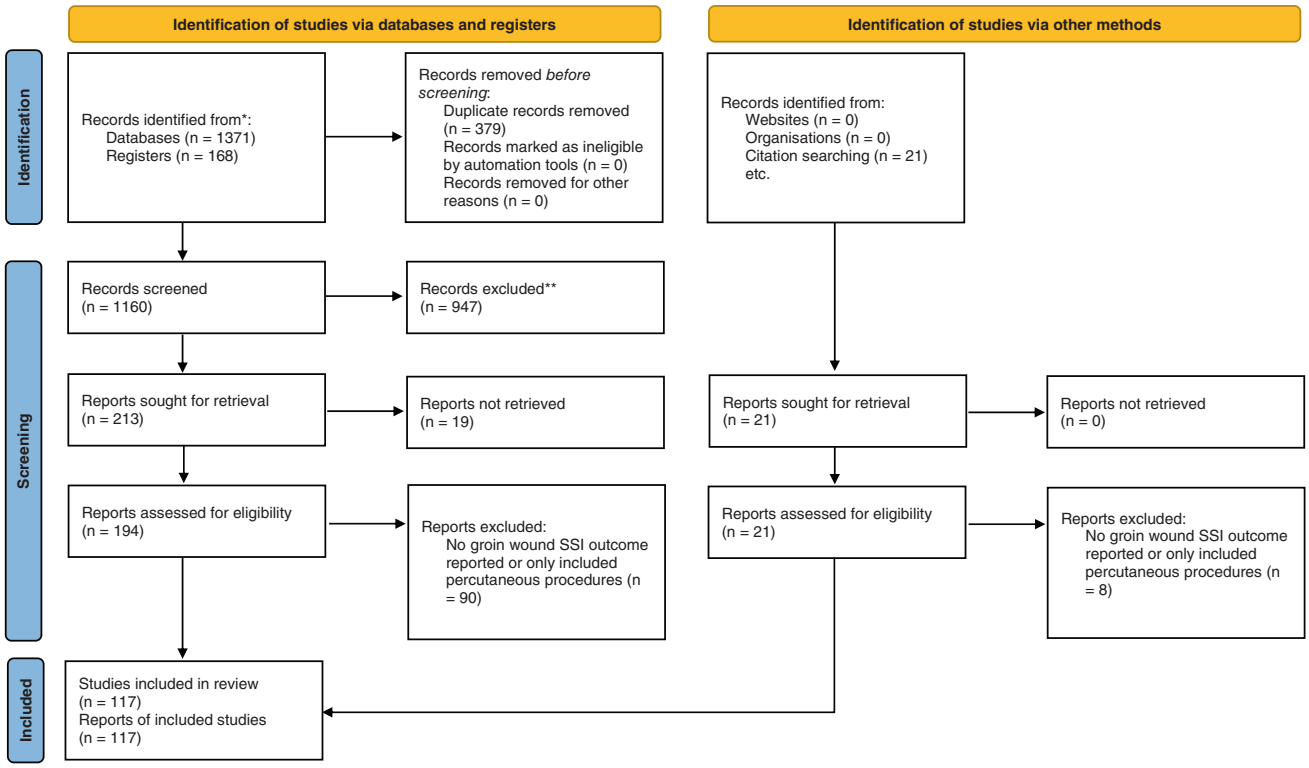

FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Adapted from Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71. doi:10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/)

3.1 | Demographic details

Most included studies were observational (N = 84), the remainder were RCTs (N = 33) (Table 1). Studies were published between 1978 and 2021. Overall, there were 65 138 groin incisions in 42 347 patients (60 283 incisions in 38 122 patients in observational studies; 4855 incisions in 4225 patients in RCTs). The weighted mean male to female ratio was 6.4 (6.8 in observational studies, 3.1 in RCTs), and weighted mean age was 71.4 years (71.7 for observational studies, 68.6 for RCTs). Studies were grouped according to the pathology being treated in their cohort: only occlusive disease (N = 58), only aneurysmal disease (N = 20), or aneurysmal and occlusive disease (N = 34). Five studies did not report details of their population in sufficient detail to determine which pathology category was most appropriate.

SSI was a primary, coprimary or composite primary outcome in 79 studies (28 RCTs and 51 observational). Eighty-six studies (21 431 incisions) reported SSIs using 'per incision' as a denominator, and 66 (37 565 patients) reported SSIs using 'per patient' as a denominator (35 studies reported data both 'per incision' and 'per patient'). Most studies (N = 65) did not report how SSI was defined or provided an author derived definition, 27 studies used the CDC definition,[19] 22 used the Szilagyi definition,[18] two used the Southampton wound score,[20] and one used the ASEPSIS score.[21] The definitions/criteria are described in Supplementary material 2.

Fewer than half of all studies report categorising SSIs into superficial and deep (n = 40); of these studies, 12 did not report how SSI was defined, 6 used an author definition, 11 used the CDC definition and 11 used Silagyi. Calculated percentages for subgroups (eg, superficial and deep SSIs) reported below did not, therefore, always summate to total SSI percentages.

Reviewers determined 48.5% of RCTs to have a high risk of bias, 45.5% to have some concern for bias, and 6.1% to have a low risk of bias (Supplementary material 3). The median Newcastle-Ottawa score for observational studies was 5 and range was 1 to 7 (Supplementary material 4).

3.2 | Overall SSI rates

There were 1730/21 431 SSIs, equating to an SSI incidence of 8.1% per incision (Table 2). There were more superficial SSIs (6.3%) compared with deep/organ-space SSIs (1.9%). Overall SSI incidence was lower in studies

TABLE 1 Study demographic data

1st Author	Year	Location	Study type[a]	Centres[b]	Pathology[c]	N patients total	N patients with groin incision	N groin incisions total	M:F ratio	Mean age	Follow up	SSI a primary outcome	SSI definition
Aaron	2015	Minneapolis, USA	3	1	1	484	411	822	NR	NR	30 days	No	NR
Adams	2017	Houston, USA	2	2	2	43	43	45	2.3	63.6	12 months	NR	NR
Akingboye	2017	London, UK	3	1	3	69	69	138	4.3	68.5	2.7 years	No	NR
Al-Khoury	2009	Pittsburgh, USA	3	1	2	95	95	105	1.2	68.3	12 months	No	NR
Ambur	2009	Cleaveland, USA	3	1	2	337	337	422	NR	NR	30 days	Yes	Szilagyi
Ameli	1990	Toronto, Canada	2	1	2	44	44	88	1.4	63.0	Mean 28.4 months	Yes	Author defined
Audu	2018	Lebanon, USA	3	1	3	256	256	NR	2.1	68.8	180 days	Yes	CDC
Avraham	2019	Jerusalem, Israel	3	1	1	195	195	325	11.7	73.0	NR	No	NR
Bakshi	2019	Atlanta, USA	3	1	2	136	136	144	2.4	60.0	90 days	Yes	NR
Bennett	2016	Durham, USA	3	1	2	284	284	284	1.6	64.0	NR	Yes	Author defined
Bertges	2021	Burlington, USA	1	2	2	242	242	234	2.35	67.0	30 days	Yes	CDC
Bosanquet	2013	Llantrisant, UK	3	1	2	170	38	38	1.8	65.8	NR	Yes	CDC
Buck	2015	Boston, USA	3	2	1	4112	3004	5648	4.6	74.1	NR	No	NR
Caiati	2000	New York, USA	2	1	1	100	100	176	7.3	75.3	NR	Yes	Szilagyi
Campbell	1994	Exeter, UK	2	1	2	496	496	563	NR	NR	2–62 months	Yes	Author defined
Caputo	2011	St Louis, USA	3	1	3	38	38	76	NR	75.6	Mean 28 months	No	NR
Cavallaro	2013	Rome, Italy	3	1	2	6	6	12	NR	NR	Mean 39 months	No	NR
Chaudery	2020	London, UK	3	2	2	322	322	322	3.0	72.0	Median 15 months	No	NR
Chester	1983	Southampton, UK	1	1	2	35	35	35	2.5	68.0	7 days	Yes	Author defined
Chester	1992	Epsom, UK	1	1	3	149	149	167	1.3	70.0	10 days	Yes	Author defined
Chin	2016	New Haven, USA	3	2	1	833	470	940	NR	69.0	30 days	No	CDC
Costa Almeida	2014	Coimbra, Portugal	2	1	2	60	60	60	5.0	67.9	30 days	Yes	Szilagyi
Criado	1998	Baltimore, USA	3	1	2	715	NR	125	NR	NR	NR	No	NR
Curry	2017	Portland, USA	3	1	2	699	568	568	2.1	68.0	30 days	Yes	CDC
Dagli	2018	Konya, Turkey	3	2	2	11	11	22	2.7	67.8	NR	No	NR
DeCarlo	2020	Boston, USA	3	1	2	281	281	553	1.0	67.6	90 days	No	Szilagyi
Derksen	2008	Nieuwgein, The Netherlands	3	1	2	140	140	140	3.8	66.0	30 days	Yes	CDC

(Continues)

TABLE 1 (Continued)

1st Author	Year	Location	Study type[a]	Centres[b]	Pathology[c]	N patients total	N patients with groin incision	N groin incisions total	M:F ratio	Mean age	Follow up	SSI a primary outcome	SSI definition
Dillavou	2019	Durham, USA	3	2	NR	370	370	370	NR	NR	NR	Yes	CDC
Dorigo	2016	Florence, Italy	3	2	2	210	82	164	4.0	64.5	mean 38.1 months (1–96)	No	NR
Dunlop	1990	Edinburgh, UK	1	1	NR	99	99	127	31.0	67.0	NR	Yes	NR
Eleissawy	2019	Tanta, Egypt	1	2	2	53	25	25	NR	72.0	12 months	No	NR
Engelhardt	2018	Ulm, Germany	1	1	3	132	132	132	3.9	71.0	42 days	Yes	Szilagyi
Etezadi	2011	Miami, USA	3	1	1	445	375	557	6.7	76.3	Mean 14 months	No	NR
Fischer	2012	Philadelphia, USA	3	1	3	231	231	263	1.7	63.4	NR	Yes	Author defined
Fleming	2018	Cork, Ireland	3	1	2	151	151	NR	NR	71.0	6 weeks	Yes	NR
Giovannacci	2002	Solothurn, Switzerland	1	1	3	213	213	266	1.5	68.3	5 days	No	NR
Gombert	2018	Aachen, Germany	1	2	2	188	188	217	0.7	66.5	30 days	Yes	Szilagyi
Goueffic	2017	Nantes, France	1	2	2	117	58	58	0.9	68.0	2 years	No	NR
Gwilym	2020	Newport, UK	2	2	3	1039	1039	1337	2.1	71.0	90 days	Yes	CDC
Hasselmann	2015	Malmo, Sweden	2	1	3	219	219	350	2.4	71.0	3 months	Yes	CDC
Hasselmann	2019	Malmo, Sweden	1	1	3	178	178	202	1.4	71.0	3 months	Yes	CDC
Healy	1989	Nashville, USA	1	2	2	50	50	100	NR	NR	Mean 10 months	Yes	NR
Hinchliffe	2003	Nottingham, UK	3	1	3	231	231	462	8.6	72.0	Mean 29 months	No	Author defined
Hines	2010	NY, USA	3	1	2	27	27	27	1.1	66.0	22.7 months	No	NR
Jackson Slappy	2003	Jacksonville, USA	3	1	1	77	77	150	14.4	75.0	2 weeks, 1 month, 6 months	Yes	NR
Jean-Baptiste	2008	Nice, France	3	1	1	40	21	42	1.0	75.0	30 days	No	NR
Josephs	1993	Boston, USA	2	1	3	69	69	89	1.6	65.5	NR	Yes	CDC
Kaiser	1978	Nashville, USA	1	1	3	565	358	358	NR	NR	NR	Yes	Szilagyi
Kang	2008	Boston, USA	3	1	2	58	58	65	2.3	71.4	27 months	No	NR
Karl	2012	Frankfurt, Germany	3	1	NR	14	14	14	NR	NR	NR	Yes	NR
Kauvar	2016	Fort Gordon, USA	3	2	1	3122	1589	3178	4.3	73.0	30 days	No	NR

TABLE 1 (Continued)

1st Author	Year	Location	Study type[a]	Centres[b]	Pathology[c]	N patients total	N patients with groin incision	N groin incisions total	M:F ratio	Mean age	Follow up	SSI a primary outcome	SSI definition
Kent	1996	Boston, USA	2	2	2	156	50	77	1.6	71.5	NR	Yes	Szilagyi
Kimmel	1994	Allentown, USA	3	1	3	1637	1637	NR	NR	NR	NR	Yes	NR
Koetje	2015	Zwolle, Netherlands	2	1	2	90	90	90	2.5	70.0	NR	Yes	Szilagyi
Kougias	2013	Texas, USA	2	1	2	604	604	NR	NR	NR	NR	Yes	NR
Kuy	2014	Milwaukee, USA	3	1	3	106	106	106	1.6	62.0	30 days	Yes	CDC
Kwon	2018	Philadelphia, USA	1	1	3	122	122	147	1.7	64.3	30 days	Yes	Szilagyi
Lagana	2006	Varese, Italy	2	1	1	30	30	33	9.0	76.0	Mean 15.2 months	No	NR
Langenberg	2018	Breda, Netherlands	3	1	2	229	229	233	1.6	70.7	3 months	Yes	CDC
Lawlor	2011	Ontario, Canada	1	1	3	51	51	81	NR	69.4	2 weeks/ healed	Yes	ASEPSIS score
Lawrence	2014	California, USA	3	2	1	182	141	177	15.7	72.0	30 days	No	NR
Lee	2017	Ontario, Canada	1	1	2	102	102	102	3.3	68.5	90 days	Yes	CDC
Maeda	2015	Tokyo, Japan	3	1	1	1604	1604	2799	4.0	75.2	Mean 36 months	Yes	CDC
Maitrias	2016	Amiens, France	3	1	2	108	108	127	3.2	63.0	Median 30 months	No	NR
Makaloski	2018	Hamburg, Germany	3	1	1	206	93	93	2.0	68.0	30 days	No	NR
Matatov	2013	Shreveport, USA	3	1	3	90	90	115	2.0	54.0	30 days	Yes	Szilagyi
May	1993	Scarborough, UK	1	1	2	64	64	64	3.6	63.4	NR	Yes	NR
Mohammed	2013	Houston, USA	3	1	2	454	454	454	112.5	65.0	30 days	Yes	NR
Moore	1996	California, USA	2	2	1	46	46	46	8.2	71.6	Mean 14 months	No	NR
Mousa	2018	Virginia, USA	1	1	NR	30	30	30	1.1	65.0	30 days	Yes	NR
Murphy	1995	Dublin, Ireland	1	1	2	114	114	173	1.7	67.0	14 days	Yes	NR
Nam	1999	Philadelphia, USA	3	2	3	250	247	247	1.6	67.8	NR	Yes	NR
Newington	1991	Bristol, UK	3	1	3	661	661	873	2.0	70.0	NR	Yes	NR
Nguyen	2017	Virginia, USA	3	1	2	89	89	97	NR	64.0	Mean 28 months	No	NR
Nikulainen	2019	Turku, Finland	3	1	3	256	256	330	2.9	77.0	30 days	Yes	Szilagyi
Oliviera	1993	California, USA	3	1	2	16	16	16	16.0	65.0	Mean 28 months	No	Author defined (within 30 days)

(Continues)

TABLE 1 (Continued)

1st Author	Year	Location	Study type[a]	Centres[b]	Pathology[c]	N patients total	N patients with groin incision	N groin incisions total	M:F ratio	Mean age	Follow up	SSI a primary outcome	SSI definition
Ott	2012	Hannover, Germany	3	1	3	756	310	310	3.4	66.0	NR	Yes	CDC
Ozaki	2014	Houston, USA	1	2	3	500	62	124	2.6	67.6	30 days	Yes	CDC
Parikh	2017	Miami, USA	3	1	2	150	150	156	1.3	65.0	Mean 219 days	Yes	Szilagyi
Parizh	2018	New York, USA	3	1	2	221	221	NR	NR	68.0	90 days	Yes	CDC
Patrick	2010	Charleston, USA	1	1	3	169	97	NR	2.1	65.0	90 days	Yes	NR
Pejkic	2014	Belgrade, Serbia	2	1	2	120	120	240	4.5	61.6	6 months	Yes	Author defined
Pesonen	2017	Michigan, USA	3	1	2	7	7	8	NR	NR	30 days	Yes	NR
Peterson	2012	Ohio, USA	3	1	2	451	451	NR	NR	NR	1 year	Yes	CDC
Piazza	2011	Minnesota, USA	3	1	2	162	162	248	0.5	50.2	Mean 3.54 years	No	NR
Pitt	1980	Dublin, Ireland	1	1	2	205	205	231	2.7	59.8	28 days	Yes	Szilagyi
Pleger	2017	Siegen, Germany	1	1	3	100	100	129	2.6	68.8	30 days	Yes	Szilagyi
Ploeg	2009	The Hague, Netherlands	1	1	3	171	171	198	1.7	68.0	6 weeks	Yes	Szilagyi
Reifsnyder	1992	Milwaukee, USA	3	1	2	117	114	123	n/a	65.5	NR	Yes	Author defined
Rezk	2019	Lund, Sweden	3	1	3	189	NR	163	1.6	73.5	1 year	Yes	Szilagyi
Ricco	2006	Poitiers, France	3	1	3	289	149	298	NR	NR	3 years (30 days for SSI)	No	Szilagyi
Risberg	1995	Malmo, Sweden	1	2	2	580	580	631	NR	72.0	30 days	Yes	NR
Robbs	1988	Durban, South Africa	2	1	3	124	124	168	4.4	55.9	30 days	Yes	Szilagyi
Sabat	2016	New York, USA	1	1	3	49	49	63	NR	NR	4 months	Yes	NR
Santin	2013	Wilmington, USA	3	1	1	30	30	60	2.3	70.0	NR	Yes	NR
Saratzis	2008	Thessaloniki, Greece	2	1	1	100	100	193	11.5	NR	30 days	Yes	NR
Simó	2011	Budapest, Hungary	3	1	2	155	155	155	2.2	62.0	Median 21 (30 days for SSI)	No	NR
Siracuse	2014	New York, USA	3	2	2	1513	1513	1513	1.6	68.7	30 days	No	CDC
Stavorovsky	1980	Tel-Aviv, Israel	2	1	2	45	45	45	NR	NR	NR	Yes	NR

TABLE 1 (Continued)

1st Author	Year	Location	Study type[a]	Centres[b]	Pathology[c]	N patients total	N patients with groin incision	N groin incisions total	M:F ratio	Mean age	Follow up	SSI a primary outcome	SSI definition
Swinnen	2010	Westmead, Australia	1	2	NR	88	88	116	2.5	NR	28 days	Yes	CDC
Teixeira	2015	Porto, Portugal	3	1	3	279	279	358	3.9	69.0	30 days	Yes	CDC
Torsello	2003	Munster, Germany	1	1	1	30	15	NR	NR	71.0	NR	No	NR
Trinidad	2019	Tuscon, USA	3	2	1	14 868	14 868	29 736	4.3	73.6	30 days	Yes	CDC
Turtiainen	2011	Joensuu, Finland	1	2	2	274	103	103	1.5	72.5	30 days	Yes	CDC
Uhl	2018	Regensburg, Germany	3	1	2	108	108	115	1.4	65.0	30 days	No	NR
Uhl	2020	Regensburg, Germany	3	1	2	20	20	23	1.2	59.0	30 days	No	NR
van der Slegt	2014	Breda, Netherlands	3	1	2	255	255	292	2.1	71.9	90 days	Yes	CDC
van Himbeeck	1992	Nijmegen, Netherlands	2	1	2	603	NR	452	NR	NR	Median 45 months	Yes	Szilagyi
Vierhout	2014	Assen, Netherlands	1	1	2	47	47	47	1.5	NR	6 weeks	Yes	Southampton Wound Scale
Vierhout	2018	Assen, Netherlands	1	2	1	137	137	137	9.0	72.0	2 weeks	Yes	Southampton Wound Scale
Walker	1998	Nottingham, UK	2	1	3	136	136	272	NR	NR	Median 7 months	Yes	Author defined
Watson	2004	Columbus, USA	2	1	1	134	134	278	8.5	71.6	30 days	Yes	Author defined
Wengrovitz	1990	Hershey, USA	3	1	2	163	163	163	2.5	NR	NR	Yes	Szilagyi
Worning	1986	Copenhagen, Denmark	1	1	3	155	NR	164	NR	NR	NR	Yes	Szilagyi
Wubbeke	2020	Maastricht, Netherlands	1	2	3	288	288	288	2.5	69.5	6 weeks	Yes	CDC
Youssef	2005	London, UK	1	1	2	73	73	106	1.2	72.0	5 days	No	Author defined
Zamani	2018	Houston, USA	3	1	2	338	NR	317	165.7	65.2	30 days	Yes	CDC

Abbreviations: CDC, Centers for Disease Control and prevention; NR, not reported; SSI, surgical site infection.

[a]1: Randomised Controlled Trial; 2: Prospective observational; 3: Retrospective observational.

[b]1: Single; 2: Multiple.

[c]1: Aneurysmal; 2: Occlusive; 3: Aneurysmal and occlusive.

that only included patients undergoing intervention for aneurysmal disease (1.5%) compared with studies that only included patients undergoing intervention for occlusive disease (9.9%) or studies that included patients undergoing both aneurysmal and occlusive disease (11.0%).

The incidence of SSIs was higher in studies that used a previously published definition for SSI diagnosis (10.7%) compared with studies that either report an author definition or do not report how SSI was defined (6.0%). Incidence was almost double when observing studies where SSI was a primary outcome (9.1%) compared with studies where SSI was not a primary outcome (5.2%).

SSI incidence was reported on a 'per patient' basis for 37 565 patients, of which 1902 patients developed a groin SSI (giving an SSI incidence of 5.1% 'per patient'). Within this cohort, the ratio of groin incisions to patients with a groin incision was 1.6. An estimated SSI rate per incision would, therefore, be 5.1% multiplied by 1.6, which equals 8.16%. This is almost exactly the same rate captured by the studies reporting SSIs per incision (8.1%).

3.3 | Randomised controlled trials

The overall incidence of SSIs in RCTs was 11.9% (477/4007). Superficial SSIs (15.8%) occurred more frequently than deep SSIs (1.7%). The control arms of RCTs experienced a higher incidence of SSIs (16.0%) than the intervention arms (9.1%). This was a consistent finding when looking at subgroups of studies based on pathology and SSI definition; but was more prominent in studies where SSI was a primary outcome (Table 2).

SSI incidence was lower in studies that only included patients undergoing intervention for aneurysmal disease (1.5%) compared with studies that only included patients undergoing intervention for occlusive disease (10.2%) or studies that included patients undergoing both aneurysmal and occlusive disease (13.1%). Similarly, SSI incidence was higher in studies where SSI was a primary outcome (12.7%) compared with studies where SSI was not a primary outcome (5.7%). Overall and superficial SSI incidence was lower when the authors did not report an existing definition for SSI compared with studies where SSI was defined according to an existing definition/grading system (overall SSI incidence: 9.8% and 12.9% respectively, and superficial SSI incidence: 11.1% and 18.0% respectively), but deep SSI incidence was lower (2.6% and 1.3% respectively). Several RCTs, 78.8% (26/33) evaluated an intervention aimed at reducing SSIs in groin wounds. Closed incision negative pressure wound therapy (ciNPWT) was evaluated in 7 (26.9%) studies, intravenous antibiotics (versus oral or other intravenous preparations) was evaluated in 3 (11.5%) studies, local/topical antibiotics placed into the wound before closure was evaluated in 2 (8.0%) studies. The following interventions were evaluated in single studies: platelet-rich plasma, twice-daily skin preparation for 2 days preoperatively versus standard skin prep, subcuticular suture versus transcutaneous, silver alginate dressing, lateral dissection, supplemental oxygen, and cryanocrylate skin sealant.

3.4 | Observational

Overall SSI incidence in observational studies was 7.2% (1253/17 424). Superficial SSIs (4.8%) were more frequent than deep SSIs (1.9%). The incidence of SSIs was lower in studies that only included patients undergoing intervention for aneurysmal disease (1.5%) compared with studies that only included patients undergoing intervention for occlusive disease (9.8%) or studies that included patients undergoing both aneurysmal and occlusive disease (10.0%). Studies that used an existing SSI definition reported a higher SSI incidence (9.8%) compared with studies that did not report an SSI definition or used an author definition (5.6%). Studies that had SSI as a primary outcome, when compared with studies where SSI was not a primary outcome, had a higher overall SSI incidence (8.1% and 5.1% respectively) but lower incidence of superficial (4.6% and 5.7% respectively) and deep SSIs (2.0% and 1.5% respectively).

3.5 | Meta-regression

Meta-regression results are presented in Table 3. Univariate analysis identified the following variables as significantly associated with a lower reported SSI incidence: increasing mean age, only aneurysmal pathology (relative to only occlusive), prospective observational design (relative to RCT), retrospective observational design (relative to RCT), CDC definition (relative to no reported definition), SSI being a primary outcome, and more recent year of publication. The variables identified as significantly associated with a higher incidence of SSIs in univariate analysis were: increasing male to female ratio and Szilagyi definition (relative to no reported definition).

Multivariate analysis identified aneurysmal pathology (reference: occlusive, $\beta = -10.229$, 95% CI -12.585 to -7.873, $P < .001$) and retrospective observational study design (reference: RCT, $\beta = -1.118$, 95% CI -1.800 to -0.436, $P = .002$) as independent predictors of a lower reported SSI incidence, whereas SSI being a primary

TABLE 2 Incidences of surgical site infection (number of infections/number of incisions [%])

Variable	Observational study and RCT	Observational study	RCT both arms	RCT intervention arm	RCT control arm
All studies					
SSI	1730/21 431 (8.1)	1253/17 424 (7.2)	477/4007 (11.9)	168/1838 (9.1)	289/1807 (16.0)
Superficial SSI	804/12 786 (6.3)	526/11 024 (4.8)	278/1762 (15.8)	115/849 (13.6)	166/915 (18.1)
Deep SSI	241/12 863 (1.9)	211/11 101 (1.9)	30/1762 (1.7)	11/849 (1.3)	20/915 (2.2)
Studies that include aneurysmal pathology only					
SSI	88/5888 (1.5)	86/5751 (1.5)	2/137 (1.5)	0/73 (0)	2/73 (3.1)
Superficial SSI	20/3638 (0.6)	20/3638 (0.6)	NR	NR	NR
Deep SSI	7/3638 (0.2)	7/3638 (0.2)	NR	NR	NR
Studies that include occlusive pathology only					
SSI	751/7600 (9.9)	621/6322 (9.8)	130/1278 (10.2)	41/561 (7.3)	73/561 (13.9)
Superficial SSI	304/3894 (10.0)	253/3360 (7.5)	51/534 (9.6)	26 (10.5)	28/213 (9.5)
Deep SSI	86/3971 (2.2)	79/3437 (2.3)	7/534 (1.3)	5/247 (2.0)	3/296 (1.0)
Studies that include aneurysmal and occlusive pathology					
SSI	803/7300 (11.0)	500/4981 (10.0)	303/2319 (13.1)	108/1068 (10.1)	191/1080 (17.7)
Superficial SSI	475/5224 (9.1)	253/4026 (6.3)	222/1198 (18.5)	85/586 (14.5)	137/605 (22.7)
Deep SSI	147/5224 (2.8)	125/4026 (3.1)	22/1198 (1.8)	5/586 (0.9)	17/605 (2.8)
Studies that use the author's definition of SSI or not reported					
SSI	725/12 004 (6.0)	595/10 681 (5.6)	130/1323 (9.8)	36/513 (7.0)	88/614 (14.3)
Superficial SSI	288/7870 (3.7)	224/7294 (3.1)	64/576 (11.1)	15/215 (7.0)	47/329 (14.3)
Deep SSI	123/7870 (1.6)	108/7294 (1.5)	15/576 (2.6)	4/215 (1.9)	11/329 (3.3)
Studies that use a formal definition of SSI					
SSI	1005/9427 (10.7)	658/6743 (9.8)	347/2684 (12.9)	132/1325 (10.0)	201/1193 (16.9)
Superficial SSI	516/4916 (10.5)	302/3730 (8.1)	214/1186 (18.0)	100/634 (15.8)	119/586 (20.3)
Deep SSI	118/4993 (2.4)	103/3807 (2.7)	15/1186 (1.3)	7/634 (1.1)	9/586 (1.5)
Studies that include SSI as a primary outcome					
SSI	1430/15 638 (9.1)	979/12 086 (8.1)	451/3552 (12.7)	164/1706 (9.6)	283/1673 (16.9)
Superficial SSI	671/10 283 (6.5)	401/8812 (4.6)	270/1471 (18.4)	111/717 (15.5)	164/781 (21.0)
Deep SSI	205/10 360 (2.0)	179/8889 (2.0)	26/1471 (1.8)	11/717 (1.5)	16/781 (2.1)
Studies where SSI not a primary outcome					
SSI	300/5793 (5.2)	274/5338 (5.1)	26/455 (5.7)	4/132 (3.0)	6/134 (4.5)
Superficial SSI	133/2503 (6.8)	125/2212 (5.7)	8/291 (2.8)	4/132 (3.0)	2/134 (1.5)
Deep SSI	36/2503 (1.4)	32/2212 (1.5)	4/291 (1.4)	0/132 (0)	4/134 (3.0)

Abbreviations: RCT, randomised controlled trials; SSI, surgical site infection.

outcome ($\beta = 3.429$, 95% CI 0.645 to 6.212, $P = .017$) was an independent predictor of a higher reported SSI incidence.

3.6 | Comorbidities and practices that may impact SSI incidence

Information regarding comorbidities and surgical practice relevant to SSI prevention was generally infrequently, and heterogeneously, reported (Supplementary material 5). Little's MCAR test P-value = .015. Owing to the high proportion of missing data and that data were not missing completely at random, they could not be included in meta-regression using case-wise deletion and were not appropriate for multiple imputation.

The median (interquartile range [IQR]) proportion of patients that: were current smokers = 50.0% (33.6%-70.0%), had ischaemic heart disease = 41.0% (27.1%-48.8%), had diabetes = 28.6% (17.7%-37.8%), had a body

TABLE 3 Results of meta-regression analyses to predict an increase in the reported Surgical Site Infection incidence

Variable	β	95% CI	P
Univariate analysis			
Male:Female ratio	.111	−0.020 to 0.243	.095*
Mean age	−1.177	−1.471 to −0.883	<.001*
Pathology: occlusive	Reference		
Pathology: aneurysmal	−8.930	−11.710 to −6.149	<.001*
Pathology: aneurysmal and occlusive	3.395	−0.880 to 7.669	.118
Randomised controlled trial	Reference		
Prospective observational	−6.001	−13.089 to 1.087	.096*
Retrospective observational	−12.025	−16.313 to −7.738	<.001*
SSI definition: Not reported	Reference		
SSI definition: Author defined	2.846	−5.176 to 10.868	.482
SSI definition: CDC	−6.191	−9.949 to −2.433	.002*
SSI definition: Szilagyi	6.861	0.349 to 13.373	.039*
SSI definition: ASESPSIS	7.072	−16.440 to 30.585	.551
SSI definition: Southampton wound scale	−2.670	−19.431 to 14.092	.752
SSI not a primary outcome	Reference		
SSI a primary outcome	−5.360	−10.241 to −0.451	.033*
Year of publication	−.234	−0.438 to −0.030	.025*
Multivariate analysis			
Pathology: occlusive	Reference		
Pathology: aneurysmal	−10.229	−12.585 to −7.873	<.001
RCT	Reference		
Retrospective observational	−1.118	−1.800 to −0.436	.002
SSI not a primary outcome	Reference		
SSI a primary outcome	3.429	0.645 to 6.212	.017

Abbreviations: CDC, Centers for Disease Control and Prevention; RCT, randomised controlled trial; SSI, surgical site infection; 95% CI, 95% confidence interval.
Note: * indicates significance at $P < .1$ level.

mass index of over 30 kg/m^2 = 32.0% (21.0%-40.9%), had a prosthetic bypass/patch = 25.4% (0.0%-55.4%). The number of studies with missing data for smoking status, ischaemic heart disease, diabetes, body mass index, and bypass/patch material were: 58 (49.6%), 67 (57.3%), 37 (31.6%), 94 (80.3%), 55 (47.0%).

Incision type was only longitudinal in 21 studies (18.0%), only oblique in 9 studies (7.7%), either longitudinal or oblique in 7 studies (6.0%), and not reported in 80 studies (68.4%). Antibiotic prophylaxis was given as standard in 45 studies (38.5%), not standardised in 13 studies (11.1%), and not reported in 59 studies (50.4%). Skin preparation was standardised in 21 studies (18.0%), not standardised in 4 studies (3.4%), and not reported in 92 studies (78.6%). Of studies where skin preparation was standardised, 6 used an iodine-based solution, 6 used a chlorhexidine-based solution, 1 used denatured ethanol, 1 used hexachlorophene, 1 used Kodan Tinkfur Forte, 1 study standardised the solution but did not report the name, and 3 studies allowed a choice between an iodine-based solution and chlorhexidine-based solution. There was no reporting of details regarding pre-operative bathing/showering in 106 (90.6%) and pre-operative shaving in 99 (84.6%).

The incidence of seroma, haematoma, lymphatic leak, and re-intervention to manage SSI were infrequently reported. The overall incidence of each were 5.7% (157/2734), 2.5% (171/6696), 4.5% (298/6589) and 2.5% (205/8373) per incision respectively.

4 | DISCUSSION

This systematic review identified 117 studies that reported an overall groin wound SSI incidence of 8.1% after arterial intervention. SSIs were more frequently

superficial (6.3%) than deep (1.9%). Studies only including patients undergoing procedures for aneurysmal pathology reported a lower SSI incidence when compared with studies only including patients with occlusive pathology and with studies including patients with aneurysmal or occlusive pathology. This was consistent when examining RCTs and observational subgroups separately. The control arms of RCTs were consistently reported as experiencing more SSIs when compared with the intervention arms of RCTs. Aneurysmal pathology (in relation to occlusive) and retrospective observational study design (in relation to RCT) were identified as predictors of a lower reported SSI incidence. SSI being a primary outcome was identified as a predictor of a higher reported SSI incidence.

This review highlights that clinicians should be aware of study-level factors that influence the reported incidence of SSIs. Those wishing to benchmark their own practice should identify studies where the pathology being treated most closely aligns with their practice and include SSI as a primary outcome. Clinicians whose surveillance of SSIs does not include community/primary care surveillance should be aware that the pooled incidence from observational studies is the figure most likely to be representative of their observed incidence, and therefore likely to be approximately 8.0%. These SSIs may well be those which become apparent to the vascular surgeon[22,23]; however, it appears many superficial SSIs are missed by observational studies, despite being a potential source of morbidity and increased health care costs.[24] Studies on SSIs following general surgical procedures report that approximately half of all SSIs are diagnosed in the community and that many were managed completely by primary care.[24,25] Further observational studies with robust follow-up data capture are needed to quantify post-discharge vascular groin wound SSI and the impact on patients and health care costs. Other methods of community surveillance such as wound questionnaires are an attractive, resource-efficient concept that show promising accuracy and reliability but require validation in a vascular surgery specific cohort.[26]

Results concerning the control arms of the RCTs will be valuable to researchers aiming to evaluate groin wound SSI preventing interventions/strategies. These results can be used to inform power calculations when designing future trials. Insight into the superficial and deep SSI incidences identified in this review could inform the design of trials that evaluate more expensive prophylactic interventions, the cost-efficiency of which are not yet determined[9]; it may be appropriate to use these selectively in patients most at risk of deep SSIs. However, predicting vascular groin wound SSIs reliably is challenging,[27] with few, if any, robust risk prediction tools in this cohort. Most of the included RCTs evaluate an intervention aimed at preventing groin wound SSIs and most have been included in previous reviews and subjected to meta-analyses.[9,28] Most of the RCTs evaluating prophylactic antibiotics were published over 20 years ago and were heterogenous in design. Several evaluate regimes that continues for at least 24 h postoperatively but, crucially, none compare extended regimes with what would be considered standard practice (one-off dose preoperatively/on induction). A recent RCT demonstrated that an extended course of antibiotic prophylaxis reduced SSIs following minor and major amputation, it is currently unknown whether a similar intervention would be efficacious in preventing groin wound SSIs.[29]

There were differences in the incidences of SSIs between studies using different SSI definitions. Univariate analyses demonstrated that when compared with studies not reporting how SSI was defined; studies using the CDC criteria reported a lower SSI incidence and studies using the Szilagyi classification reported a higher SSI incidence. Differences in results based on differing SSI definitions have been demonstrated before.[30] This could have resulted from the key differences between the two: the Szilagyi description is less detailed and more likely to introduce subjectivity, and the CDC criteria exclude certain complications (eg, stitch abscess). However, multivariate meta-regression results did not find that this variable remained significant.

Observational studies reported lower incidences of SSIs compared with RCTs, with the exception of when SSI was not a primary outcome. This finding is likely to be heavily influenced by differences in follow-up data capture between study types. Observational studies are more likely to rely on medical records as source data as opposed to dedicated follow-up patient review or interview, either because of design choice in prospective studies,[31] or necessity in the case of retrospective registry studies.[2] Both administrative and clinical registry data are known to have inaccuracies.[32] In addition, milder SSIs which commonly occur post-discharge,[24] especially given that some definitions include infections up to 90 days postoperatively,[19] are potentially identified and treated entirely in primary care.[24] This compounds data inaccuracy especially in single health care systems or organisations that have a disconnect between their own primary and secondary care data.[33-35] The difference in ratio of superficial to deep SSIs between observational studies and RCTs identified in this review highlight that it is the superficial SSIs (rather than deep SSIs) which are underreported by observational studies.

SSI being a primary outcome was an independent predictor of a higher incidence of SSIs. This is likely the result of study design ensuring robust data collection and accuracy of the primary outcome.[36] If SSI was not a primary

outcome in RCTs the ratio of superficial to deep infections suggest that the 'missed cases' were mostly superficial. Deep infections are more likely to require hospitalisation and operative re-intervention,[23,37] and are therefore, more readily apparent to the treating (and study) team. The finding that reported SSI rates in RCTs are higher if SSI is a primary outcome (compared with a secondary outcome) is congruent with findings from a review of RCT data on SSIs following gastrointestinal surgery.[38]

It was not surprising that studies only including patients with aneurysmal pathology reported a lower incidence of SSIs compared with studies only including patients with occlusive pathology or a mix of patients with aneurysmal and occlusive pathology. A lower incidence can likely be attributed, in part, to studies that include cut-downs for endovascular aneurysm repair, in which SSIs are infrequent. In addition, peripheral arterial disease itself and factors that commonly accompany the disease (relative to aneurysmal pathology) such as diabetes mellitus, obesity and presence of peripheral wounds (with/without active infection) are well recognised risk factors for SSI.[12,39,40]

A limitation of this review is that several patient-level variables could not be captured in detail, which prevents a more detailed description of how study population can influence the observed SSI incidence, and a more robust meta-regression. Most groin incisions included in this review were from observational studies, therefore, the overall calculated SSI incidences are heavily weighted by studies that are incompletely capturing SSIs; the true incidence of groin wound SSI after arterial intervention is likely higher and closer to that of our reported RCT incidence. There was inconsistent reporting of SSI incidence as 'per incision', some studies only reported the incidence on a 'per patient' basis; therefore, this result could not be calculated using data from all studies. The regression analyses were limited to a relatively low number of predictor variables because of the relatively low number of 'cases' (studies), there are other potentially relevant study-level variables such as geographical location and funding source that could not be explored for this reason.

5 | CONCLUSION

The overall incidence of groin wound SSI after arterial intervention reported in the literature is 8.1% (6.3% superficial and 1.9% deep). Studies that only include patients with aneurysmal pathology (relative to occlusive) and retrospective observational study design (relative to RCT) was associated with a lower reported incidence of SSIs. SSI being a primary outcome was associated with a higher reported incidence of SSIs. Our results concerning RCT data could be used to inform trial design, whilst results concerning observational studies suggest that a significant proportion of superficial SSIs occur in the community and are missed by many observational studies and vascular teams.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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