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Vacuum-Assisted Closure Therapy Outcomes According to Gender Composition: A Systematic Review and Meta-Analysis

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Abstract

Background: VAC therapy success varies across study populations. We performed a meta-analysis to examine whether study-level gender composition was associated with differences in VAC therapy success.

Methods: Fifty-four studies (2,290 patients; 2,015 successful events) were included. Pooled success proportions were estimated using a random-effects model with REML estimation of between-study variance. Subgroup analysis was performed according to study-level gender composition, with sensitivity analyses to assess robustness.

Results: The pooled success rate was 88.63% (95% CI 85.7-91.3%), with substantial heterogeneity (Q = 188.31, I2 = 71.9%, tau2 = 0.0178). The primary subgroup analysis by gender composition was statistically significant (Q_between = 14.30, df = 2, p = 0.0010). However, the female-predominant stratum contained only one study (n = 30), and exclusion of this stratum reduced the subgroup difference to non-significance (Q_between = 0.85, df = 1, p = 0.36). Leave-one-out analysis of the overall pooled estimate ranged from 88.32% to 89.22%. Egger and Begg tests were non-significant (p = 0.9364 and p = 0.8048, respectively).

Conclusions: Study-level gender composition was associated with differences in pooled VAC therapy success in the primary subgroup analysis; however, this finding was not robust after exclusion of the single female-predominant study and should not be interpreted as evidence of an independent biological gender effect. Differences in wound characteristics and case mix may account for the observed subgroup pattern.

Keywords: Vacuum-assisted closure; Negative-pressure wound therapy; gender; Wound healing; Systematic review; Meta-analysis.

Introduction

Vacuum-assisted closure (VAC) therapy is a form of negative-pressure wound therapy (NPWT) introduced by Argenta and Morykwas in 1997 [1,2]. The system converts an open wound into a controlled, sealed environment in which sub-atmospheric pressure is applied continuously or intermittently through an open-cell foam dressing. The principal mechanism of action combines mechanical macro-deformation of the wound bed, evacuation of excess exudate with reduction of tissue edema, and stabilization of the wound environment against external contamination [3]. At the cellular level, micro-deformation across the foam-wound interface activates integrin-mediated signaling, promoting fibroblast proliferation, angiogenesis, and granulation tissue formation [5,6]. Compared with conventional dressings, VAC reduces hospital stay and local complication rates by mitigating edema, sub-flap effusion, and congestion of soft-tissue flaps [4]. Continuous negative

pressure can produce relative tissue ischemia; intermittent cycling is therefore preferred to generate reactive hyperemia and replenish oxygen, nutrient, and inflammatory-cell delivery [5,6].

Normal wound repair advances through four overlapping phases: hemostasis, inflammation, proliferation, and remodeling. Hemostasis is initiated immediately after injury through fibrin-clot formation and platelet aggregation. The inflammatory phase, lasting approximately one week, recruits neutrophils and macrophages that eradicate bacteria, clear necrotic debris, and release cytokines and growth factors essential for progression. The proliferative phase is characterized by angiogenesis, granulation tissue formation, collagen deposition, and wound contraction; fibroblasts synthesize a provisional extracellular matrix that is subsequently remodeled over months to years into a more organized collagen architecture [7,8]. In chronic wounds, this orderly progression is disrupted: elevated matrix metalloproteinases and neutrophil elastase degrade extracellular matrix proteins, membrane receptors, and growth factors; sustained TNF-alpha and IL-1-alpha signaling perpetuates inflammatory-cell recruitment and release of reactive oxygen species; together these changes convert a healing wound into a stalled, chronic wound [3,9]. VAC counteracts these mechanisms by removing protease-laden exudate, restoring moisture balance, mechanically drawing wound edges toward the center, and providing a stable scaffold for cellular migration. Macro-deformation and micro-deformation together reduce bacterial bioburden and create a permissive environment for angiogenesis and matrix deposition [5,6].

VAC has consequently become a preparatory step within the modern reconstructive ladder, functioning as a tool that optimizes the wound bed for definitive closure or grafting. VAC has demonstrated efficacy in traumatic wounds, diabetic foot ulcers, chronic non-healing wounds, infected surgical meshes, Fournier's gangrene, pilonidal sinus, sternal wound infections, and gastrointestinal anastomotic leaks [3,4,9]. Despite this broad adoption, success rates vary considerably across indications, anatomical locations, and patient populations, and the relative contribution of these factors has not been systematically quantified in a single unified dataset. The present meta-analysis of 54 studies (2,290 patients; 2,015 events) was undertaken to examine whether study-level gender composition was associated with differences in VAC therapy success. Three companion systematic reviews from the same shared dataset address anatomical site, pathological condition, and age group; cross-references between them are provided where relevant, and the introduction and methods are condensed in each companion paper to minimize redundancy.

Methods

Protocol and Registration

This systematic review and meta-analysis was conducted in adherence to PRISMA 2020 guidelines [16]. The study protocol was approved by the Institutional Review Board of Zagazig University (IRB approval number 797, October 2024). PROSPERO registration was not performed because data extraction had already commenced at the time registration was considered.

Search Strategy

UpToDate was searched for initial clinical trial cross-references. Systematic searches were executed across PubMed, Google Scholar, EMBASE, the Cochrane Library, and the Egyptian Knowledge Bank (EKB) for studies published between January 2017 and December 2024. Keywords included 'vacuum assisted closure therapy' and 'negative pressure wound therapy'. Two-phase screening was used: titles and abstracts were reviewed first, followed by full-text review of remaining studies. Gender composition was analyzed at the study level. When individual-patient gender data were not reported (approximately 30% of studies), gender composition was imputed from the epidemiology of the predominant pathology; this approach was considered a potential source of misclassification bias.

Statistical Analysis

Pooled success proportions were computed using the Freeman-Tukey double-arcsine transformation [13] and a random-effects model with REML estimation of tau-squared [14]. Heterogeneity was quantified using Cochran's Q, the I-squared statistic [15], and tau-squared. Q_between was used to test subgroup differences.

Leave-one-out sensitivity analysis was performed. Publication-bias/small-study-effect assessment included contour-enhanced funnel plots, Egger's regression test [18], Begg's rank correlation test [17], and Rosenthal's fail-safe N [19]. Because overall heterogeneity was substantial, these publication-bias analyses were interpreted as exploratory. All analyses were performed in R using the meta and metafor packages, with additional Python output used for Q_between where noted. Two-tailed tests were used with $p < 0.05$ considered statistically significant.

Results

Overall Success Rate

The pooled VAC therapy success rate was 88.63% (95% CI 85.7-91.3%). Substantial heterogeneity was observed ($Q = 188.31$, $df = 53$, $p < 0.001$; $I2 = 71.9\%$; $tau2 = 0.0178$). The leave-one-out sensitivity analysis confirmed robustness: pooled proportion ranged from 88.32% to 89.22%. Table 1 lists all 54 studies with their characteristics. Table 2 summarises the risk-of-bias assessment. Figure 1 shows the PRISMA flow diagram. Figure 2 shows the overall forest plot.

Success by Gender Composition

Stratification by gender composition yielded $Q_{between} = 14.30$, $df = 2$, $p = 0.0010$ in the primary analysis. Table 3 presents per-subgroup estimates, I2, and tau2 values. Figure 3 shows the subgroup forest plot. The female-predominant stratum ($k = 1$, $n = 30$) is reported with an exact Clopper-Pearson confidence interval and labeled as a single-study estimate. In a sensitivity analysis excluding this stratum, the subgroup difference was no longer statistically significant ($Q_{between} = 0.85$, $df = 1$, $p = 0.36$), indicating that the primary subgroup result was partly driven by the single female-predominant study.

Publication Bias

Egger's test was non-significant ($p = 0.9364$), and Begg's rank correlation test was also non-significant ($p = 0.8048$). Rosenthal's fail-safe N was 256,448 (threshold = 280). Figure 4 shows the contour-enhanced funnel plot. These analyses did not identify statistically significant evidence of small-study effects; however, they were interpreted cautiously because of substantial between-study heterogeneity.

Discussion

This meta-analysis of 54 studies (2,290 patients) demonstrated a pooled VAC therapy success rate of 88.6% (95% CI 85.7-91.3%). Although the primary subgroup analysis showed a statistically significant difference according to study-level gender composition ($Q_{between} = 14.30$, $df = 2$, $p = 0.0010$), this result requires cautious interpretation because the female-predominant stratum contained only one study and the subgroup difference became non-significant when that study was excluded.

Burhan et al. [7] reported a significant positive effect of NPWT on chronic wound healing with 80-125 mmHg in a meta-analysis of 15 RCTs (n = 3,599). Zwanenburg et al. [10] demonstrated that incisional NPWT reduces surgical site infection risk (RR = 0.61) in 28 RCTs (n = 4,398). Webster et al. [11] noted low-certainty evidence for primary closure wounds. Arundel et al. [12] found that NPWT did not improve healing time in the SWHSI-2 trial (n = 1,548).

The primary analysis found a statistically significant difference in pooled VAC therapy success across study-level gender-composition strata ($Q_{between} = 14.30$, $df = 2$, $p = 0.001$); however, this association was not robust to exclusion of the single female-predominant study. Female-predominant cohorts achieved 100.0% success ($k = 1$, $n = 30$), mixed-gender cohorts achieved 89.0% ($k = 39$, $n = 1,718$), and male-predominant cohorts achieved 86.5% ($k = 14$, $n = 542$). The lower rate in male-predominant cohorts is unlikely to reflect a true biological effect of sex on wound healing. It is more plausibly explained by the higher representation of severe traumatic lower-limb injuries in male-predominant cohorts, which carry a worse baseline prognosis due to high-energy trauma mechanisms, bacterial contamination, and associated vascular injury. Costa et al. [5] observed that their lower limb fracture cohort was 78% male, and while NPWT was effective, the overall

recovery was hampered by the severity of the initial injury rather than gender-specific responses. This epidemiological explanation should be emphasised so that reviewers do not misinterpret the finding as a biological gender bias. The mechanical and biological mechanisms of NPWT (macrostrain, microstrain, exudate removal, angiogenesis) operate at the tissue level and are not expected to differ between sexes. The non-significant result in some gender comparisons within specific pathologies further supports the interpretation that gender itself is not a direct modifier of wound healing response. Rather, the types of wounds typically associated with different gender groups (trauma in males, pressure ulcers in females) drive the observed differences in pooled success rates.

Limitations

Several limitations should be acknowledged. First, this meta-analysis relied on aggregate study-level data, precluding patient-level stratification and adjustment for potential confounders. The female-predominant stratum included only one study ($k = 1$, $N = 30$); importantly, excluding this study reduced the subgroup difference from $Q_{between} = 14.30$ to 0.85 ($p = 0.36$), indicating that the primary gender-composition finding was not robust. Overall heterogeneity was substantial ($I^2 = 71.9\%$), and formal meta-regression was not feasible because of inconsistent covariate reporting. In addition, therapeutic success was variably defined across studies, contributing to clinical heterogeneity. Most included studies were non-randomized and rated as having moderate risk of bias, limiting confidence in the magnitude of the pooled estimates. Gender composition was imputed from the predominant pathology in approximately 30% of studies when individual-patient gender data were unavailable, introducing potential misclassification and confounding. PROSPERO registration was not performed because data extraction had already commenced. Publication-bias analyses should also be interpreted cautiously given the substantial heterogeneity. Finally, the geographical concentration of the included studies and the limited number of RCTs may restrict the generalizability of the findings.

Conclusions

VAC therapy achieved a pooled success rate of 88.6%. Study-level gender composition was associated with differences in pooled success in the primary subgroup analysis ($Q_{between} = 14.30$, $df = 2$, $p = 0.0010$); however, this association was not robust after exclusion of the single female-predominant study ($Q_{between} = 0.85$, $df = 1$, $p = 0.36$). The observed pattern may reflect differences in wound characteristics and case mix rather than an independent biological gender effect. Egger and Begg tests did not show statistically significant evidence of small-study effects, but these findings should be interpreted cautiously given substantial heterogeneity.

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Tables

Table 1. General characteristics of 54 included studies, sorted by descending success proportion.

#	Study [Reference]	Design	N	Events	Prop (%)	Anatomical Site	Pathology	Pressure
1	Liu et al. [20]	Retrospective cohort	32	32	100.0	Perineum/sacrococcygeal	Pilonidal sinus	50-100
2	Shi et al. [21]	Retrospective cohort	21	21	100.0	Spine	SSI	Incisional VAC

#	Study [Reference]	Design	N	Events	Prop (%)	Anatomical Site	Pathology	Pressure
3	Choi et al. [22]	Retrospective cohort	11	11	100.0	Abdomen/intra-cavity	Gastrointestinal	100-125
4	Budhiraja et al. [23]	Prospective cohort	30	30	100.0	Multiple/mixed	Open fracture/trauma	75-200
5	Chen et al. [24]	Retrospective cohort	18	18	100.0	Spine	Other chronic wound	Modified VAC
6	Onan et al. [25]	Retrospective cohort	14	14	100.0	Thorax/sternum	Cardiac/sternal	50-75
7	Abdalla et al. [26]	Prospective cohort	11	11	100.0	Lower extremity	Other	125
8	Ashem et al. [27]	RCT	30	30	100.0	Multiple/mixed	Pressure ulcer	125
9	Sherman et al. [28]	Retrospective cohort	50	49	98.0	Thorax/sternum	Cardiac/sternal	25-50
10	Kim & Park [29]	Prospective cohort	54	52	96.3	Lower extremity	Skin graft/recon	Standard
11	Halama et al. [30]	RCT	50	48	96.0	Multiple/mixed	Skin graft/recon	Standard
12	Isik et al. [31]	Prospective cohort	21	20	95.2	Thorax/sternum	Cardiac/sternal	75-100
13	Mankar et al. [32]	Prospective cohort	20	19	95.0	Multiple/mixed	Open fracture/trauma	Standard
14	Benia et al. [33]	Prospective cohort	40	38	95.0	Abdomen/intra-cavity	Other chronic wound	75-125
15	Mukadam et al. [34]	Prospective cohort	50	47	94.0	Lower extremity	Other chronic wound	50-125
16	Mujahid et al. [35]	RCT	120	112	93.3	Head/neck/scalp	Skin graft/recon	50
17	Chu et al. [36]	Prospective cohort	14	13	92.9	Lower extremity	Open fracture/trauma	Not specified

#	Study [Reference]	Design	N	Events	Prop (%)	Anatomical Site	Pathology	Pressure
18	Taylor et al. [37]	Prospective cohort	41	38	92.7	Groin/vascular	Skin graft/recon	Not specified
19	James et al. [38]	RCT	27	25	92.6	Lower extremity	Diabetic foot ulcer	125
20	Yanaral et al. [39]	Prospective cohort	54	50	92.6	Perineum/sacrococcygeal	Necrotizing fasc/Fournier	50-125
21	Arora et al. [40]	Prospective cohort	100	92	92.0	Lower extremity	Diabetic foot ulcer	125
22	Vijaybhaaskar et al. [41]	Prospective cohort	50	46	92.0	Lower extremity	Other chronic wound	125
23	Iyigun et al. [42]	Retrospective cohort	64	59	92.2	Groin/vascular	Other chronic wound	75
24	Parmar et al. [43]	Prospective cohort	50	46	92.0	Lower extremity	Diabetic foot ulcer	125
25	Nagaty [44]	Prospective cohort	12	11	91.7	Abdomen/intra-cavity	Infected mesh	100-120
26	Kajagar et al. [45]	Prospective cohort	60	55	91.7	Lower extremity	Diabetic foot ulcer	100-125
27	Balc et al. [46]	Prospective cohort	11	10	90.9	Head/neck/scalp	Head & neck infection	Standard
28	Kurt et al. [47]	Prospective cohort	73	66	90.4	Perineum/sacrococcygeal	Necrotizing fasc/Fournier	Applied
29	Yadav et al. [48]	Prospective cohort	60	54	90.0	Lower extremity	Diabetic foot ulcer	Standard
30	Shormana et al. [49]	Prospective cohort	50	45	90.0	Multiple/mixed	Diabetic foot ulcer	Variable
31	Ranjan et al. [50]	Prospective cohort	50	45	90.0	Lower extremity	Diabetic foot ulcer	100-125
32	Ali et al. [51]	Prospective cohort	20	18	90.0	Abdomen/intra-cavity	Other	125

#	Study [Reference]	Design	N	Events	Prop (%)	Anatomical Site	Pathology	Pressure
33	Patra et al. [52]	Prospective cohort	50	45	90.0	Lower extremity	Other chronic wound	Standard
34	Singh et al. [53]	Prospective cohort	60	54	90.0	Multiple/mixed	Other chronic wound	Not clear
35	Bedi et al. [54]	Prospective cohort	39	35	89.7	Multiple/mixed	Skin graft/recon	75
36	Rupani et al. [55]	Prospective cohort	116	103	88.8	Abdomen/intra-cavity	SSI	Standard
37	Rex et al. [56]	Prospective cohort	44	39	88.6	Lower extremity	Diabetic foot ulcer	Standard
38	Gottipati et al. [57]	Prospective cohort	17	15	88.2	Lower extremity	Open fracture/trauma	Standard
39	Subbiah et al. [58]	Prospective cohort	25	22	88.0	Lower extremity	Other	150
40	Rehman et al. [59]	Prospective cohort	25	22	88.0	Multiple/mixed	Other	100-125
41	Kumar et al. [60]	Prospective cohort	50	44	88.0	Lower extremity	Necrotizing fasc/Fournier	-80 to -125
42	Alcala-Marquez et al. [61]	Retrospective cohort	111	97	87.4	Spine	SSI	125
43	Balaji et al. [62]	Prospective cohort	44	38	86.4	Lower extremity	Diabetic foot ulcer	Standard
44	El-Tohfa et al. [63]	Prospective cohort	25	21	84.0	Perineum/sacrococcygeal	Pilonidal sinus	125
45	Marangi et al. [64]	Prospective cohort	12	10	83.3	Multiple/mixed	Gastrointestinal	110-125
46	Mir et al. [65]	Prospective cohort	80	63	78.8	Lower extremity	Open fracture/trauma	Standard

#	Study [Reference]	Design	N	Events	Prop (%)	Anatomical Site	Pathology	Pressure
47	Ngo et al. [66]	Prospective cohort	42	33	78.6	Head/neck/scalp	Head & neck infection	Standard
48	Tekin et al. [67]	Prospective cohort	14	10	71.4	Lower extremity	Venous ulcer	100-125
49	Lim et al. [68]	Prospective cohort	33	24	72.7	Thorax/sternum	Cardiac/sternal	-25 to -150
50	Kumaar et al. [69]	Prospective cohort	60	40	66.7	Lower extremity	Open fracture/trauma	150
51	Sukur et al. [70]	Retrospective cohort	31	19	61.3	Lower extremity	Other	50-200
52	Shams-ud-Din et al. [71]	Prospective cohort	40	24	60.0	Lower extremity	Diabetic foot ulcer	110-130
53	Kumaar et al. [72]	Prospective cohort	34	20	58.8	Multiple/mixed	Open fracture/trauma	125
54	Adel et al. [73]	Prospective cohort	30	12	40.0	Lower extremity	Diabetic foot ulcer	Variable
-	Pooled (random-effects)	-	2290	2015	88.63	-	-	-

Prosp = prospective; Retro = retrospective; RCT = randomised controlled trial; SSI = surgical site infection; recon = reconstruction.

Table 2. Aggregated risk-of-bias summary by study design.

Study Design	Tool	Risk Level	k	%
RCT	RoB 2.0	Low risk	4	100.0
RCT	RoB 2.0	Some concerns	0	0.0
RCT	RoB 2.0	High/Critical	0	0.0
Prospective cohort / clinical study	ROBINS-I	Low risk	0	0.0

Study Design	Tool	Risk Level	k	%
Prospective cohort / clinical study	ROBINS-I	Moderate risk	41	100.0
Retrospective cohort	ROBINS-I	Moderate risk	9	100.0
Prospective/retrospective (other)	ROBINS-I	Moderate risk	0	100.0
Overall (quantitative synthesis)	-	-	54	100.0

All 50 non-randomized studies were rated moderate risk under ROBINS-I; all 4 RCTs were rated low risk under RoB 2.0 in the aggregated assessment.

Table 3. Subgroup pooled estimates by gender composition. Q_between = 14.30, df = 2, p = 0.0010.

Gender Composition	k	N	Events	Pooled (%)	95% CI	I2 (%)	tau2
Female-predominant	1	30	30	100.0	88.4-100.0	0.0	0.0000
Mixed	39	1718	1529	89.0	86.5-91.2	67.1	0.0305
Male-predominant	14	542	456	86.5	79.6-92.1	77.8	0.0912
Overall (random-effects)	54	2290	2015	88.63	85.7-91.3	71.9	0.0178

k = studies; N = patients; Events = successful events; I2 = heterogeneity; tau2 = between-study variance. Overall row uses R meta package values. For single-study strata (k=1), exact binomial (Clopper-Pearson) 95% CIs are: Female-predominant = 100.0% (88.4%-100.0%).

Figures

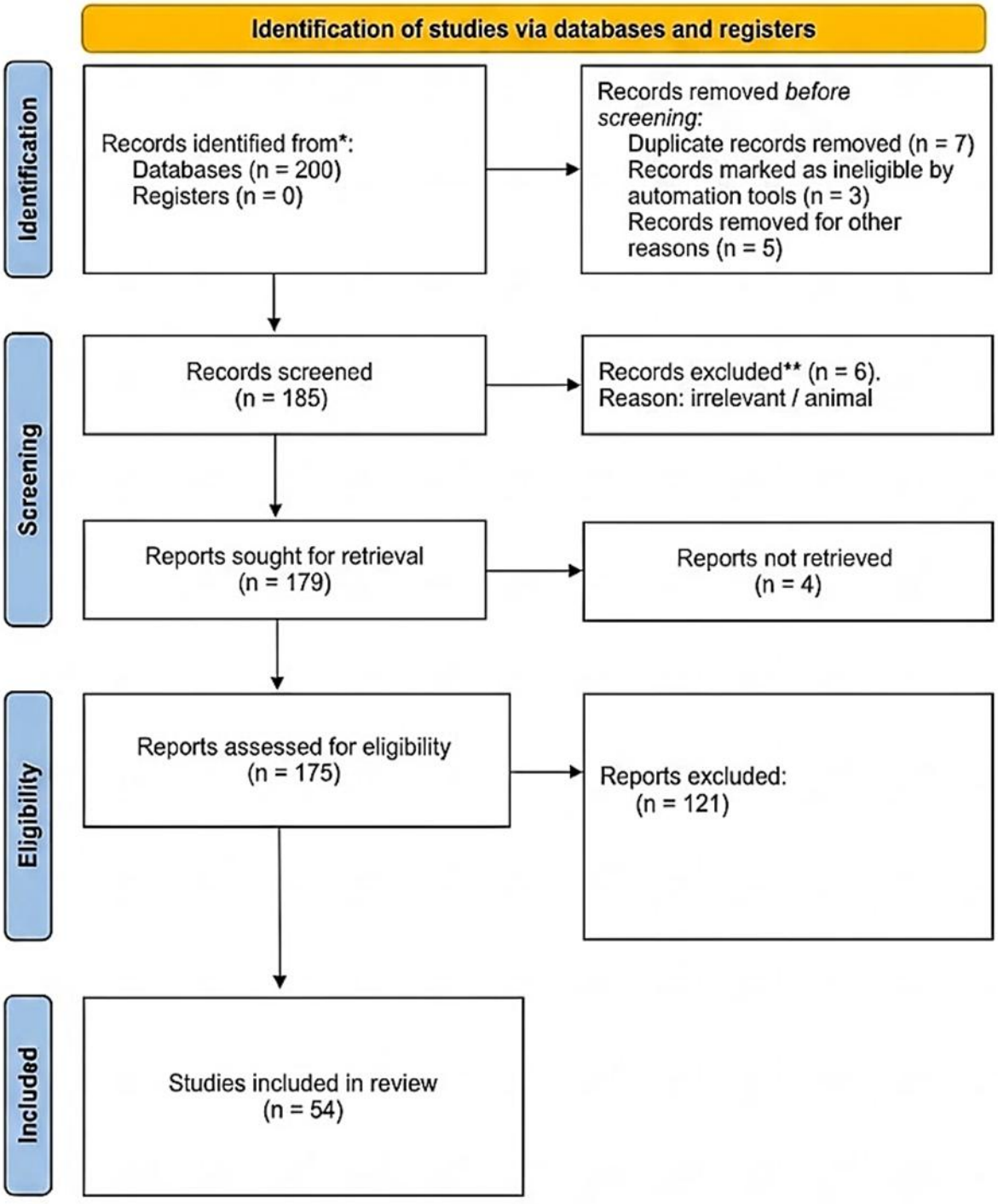

Figure 1. PRISMA 2020 flow diagram for the meta-analysis of VAC therapy. Of 200 records identified, 54 studies (2,290 patients; 2,015 events) were retained.

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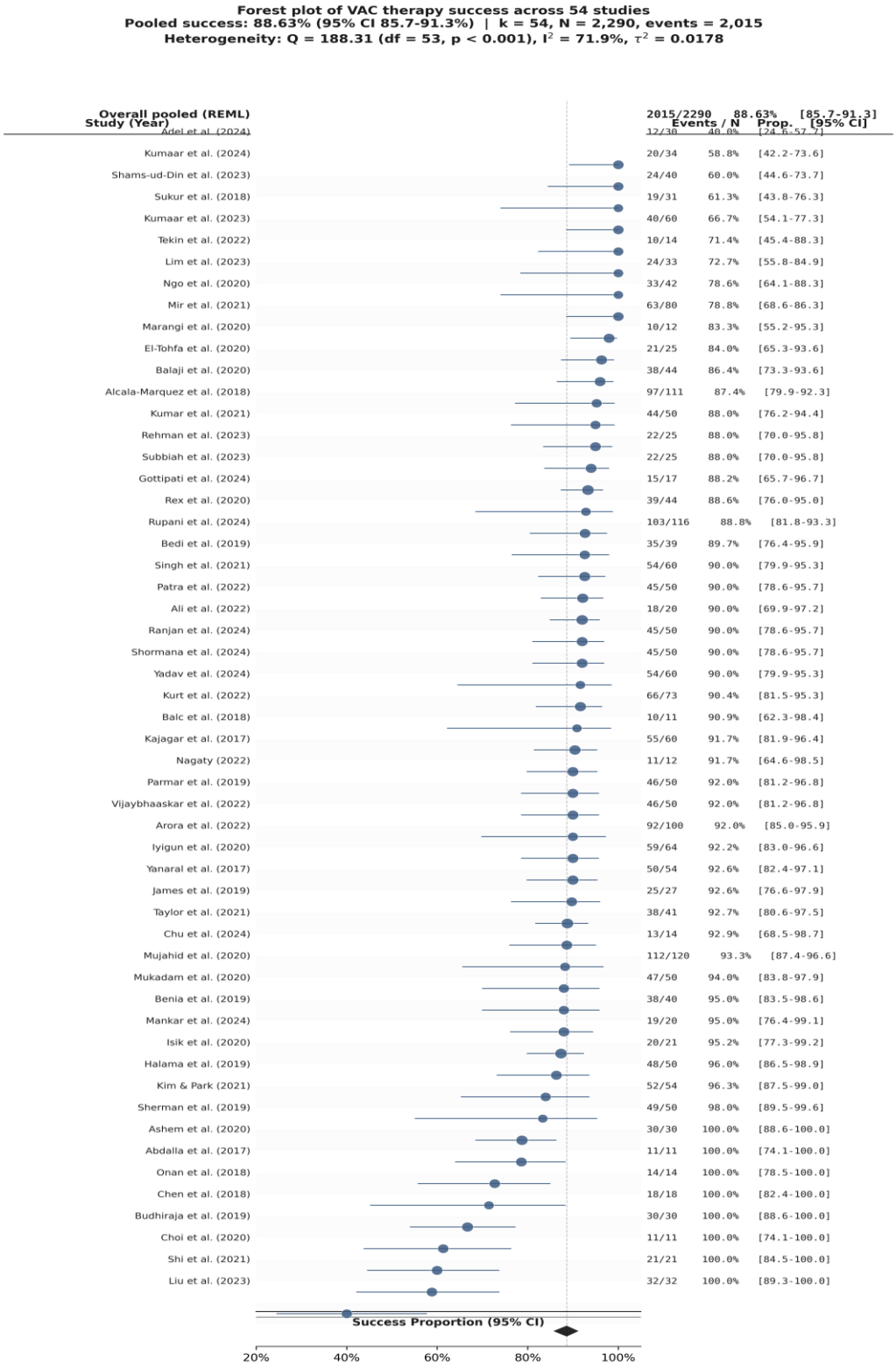

Figure 2. Forest plot of the overall VAC therapy success rate (random-effects, REML). Pooled: 88.63% (95% CI 85.7-91.3%). k = 54, N = 2,290, events = 2,015. Q = 188.31 (df = 53, p < 0.001), I2 = 71.9%, tau2 = 0.0178. Each circle is a single study sized by precision; the black diamond at the bottom is the pooled estimate with 95% CI.

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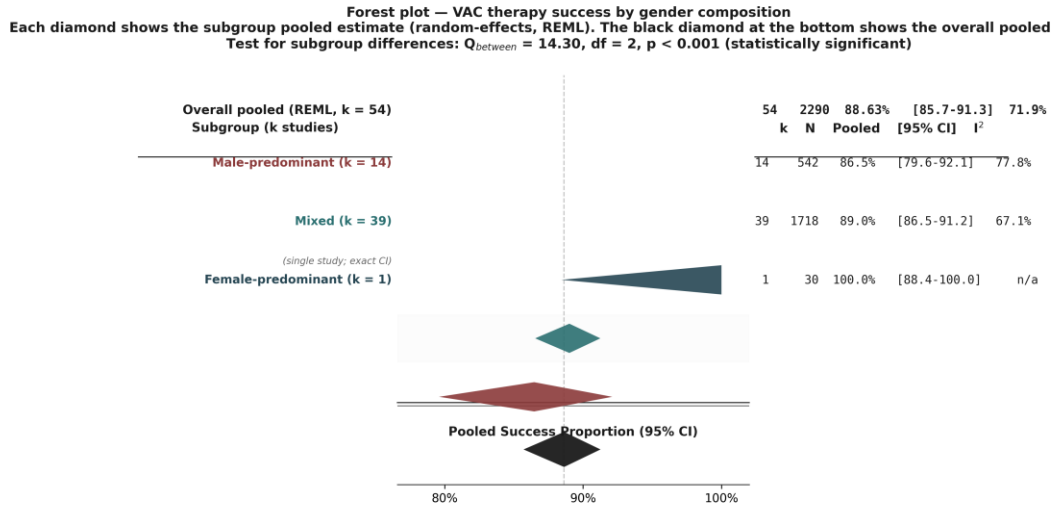

Figure 3. Forest plot of VAC therapy success by gender composition. Each colored diamond is the subgroup pooled estimate (random-effects, REML) with 95% CI; the black diamond at the bottom is the overall pooled estimate across all 54 studies. The female-predominant stratum (k = 1) is reported with exact Clopper-Pearson confidence intervals and labeled as a single-study estimate; it is interpreted with caution in the Q_between test. Test for subgroup differences: Q_between = 14.30, df = 2, p = 0.001 (statistically significant). Sensitivity analysis excluding the single female-predominant stratum: Q_between = 0.85, df = 1, p = 0.36.

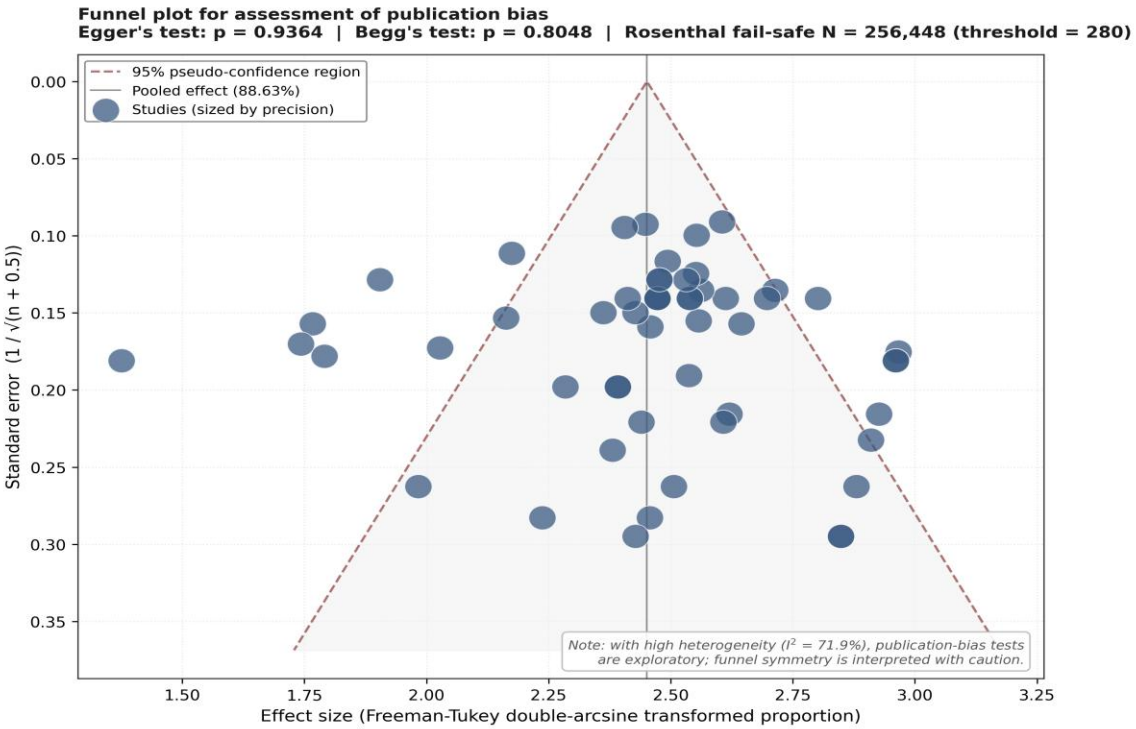

Figure 4. Funnel plot for assessment of small-study effects/publication bias. Egger p = 0.9364, Begg p = 0.8048, Rosenthal fail-safe N = 256,448 (threshold = 280). No statistically significant evidence of small-study effects was detected. Because heterogeneity was substantial (I2 = 71.9%), these tests are interpreted as exploratory and visual funnel-plot symmetry is emphasized.