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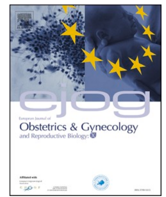

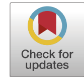

Variation in outcome reporting in studies comparing vacuum-assisted birth versus second-stage caesarean section: A systematic review

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ABSTRACT

Objective: To assess the variations and quality of maternal and neonatal outcomes reported in studies on vacuum devices vs second-stage caesarean section through a systematic review.

Methods: We searched major databases were searched from inception to January 2025. Two reviewers independently screened studies and extracted data. We grouped maternal and perinatal outcomes were grouped into mortality or morbidity and process or care-related categories, with 33 predefined categories and 62 subcategories. Frequencies were summarised as proportions, and outcome reporting quality was assessed using a modified Harman's questionnaire. We determined the associations between study characteristics and reporting quality through multilevel mixed-effects models. The protocol was registered (PROSPERO CRD42024469164).

Results: Twenty-three studies including over 2.6 million women reported 352 outcomes (132 primary; 220 secondary). The frequently reported maternal outcomes were urogenital tract injury (40/137, 29.2%) and postpartum haemorrhage (32/137, 23.4%), while Apgar score (24/215, 7%) and musculoskeletal injury (22/215, 6%) were the most common neonatal outcomes. Most outcomes scored 2/3 on the modified Harman's questionnaire, with no significant improvement in reporting quality over time. Maternal outcomes had significantly higher quality scores than neonatal outcomes ($\beta = 0.18$, $p = 0.002$, 95% CI 0.06–0.29). Study setting was significantly associated with total quality scores, with studies from middle-income countries showing lower scores compared with those from high-income countries ($\beta = -1.73$, $p = 0.003$, 95% CI –2.88 to –0.57). There was no association between reporting quality and study size, outcome type (primary or secondary), or journal impact factor.

Conclusions: Outcomes reporting quality varied considerably. Standardisation through a core outcome set is needed to improve comparability, evidence synthesis, and research quality on outcomes of vacuum-assisted births.

Background

Despite advances in quality of care, there are approximately 260,000 maternal deaths every year [1]. The second stage of labour, when the cervix is fully dilated, poses significant risks to both mother and fetus [2]. Assisted vaginal birth using forceps or a vacuum can expedite birth

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in the second stage and can be lifesaving [3, 4]. Rates of assisted vaginal birth have been declining worldwide. Assisted vaginal birth counts for < 1% of hospital births, particularly in low- or middle-countries (LMICs), compared to 5–10% in high-income countries due to inadequate training and lack of equipment [5, 6]. In the absence of assisted vaginal birth, a second-stage caesarean section is performed to expedite delivery. This carries the risk of additional complications due to the low fetal head in the maternal pelvis [2]. We need high-quality evidence to demonstrate the effectiveness and safety of assisted vaginal birth [7].

Amongst assisted vaginal births, vacuum devices are used more often than forceps [7]. However, the rate of vacuum assisted births is extremely low in many countries, particularly in low- and middle-income countries, where paradoxically the complications from caesarean sections are also the highest [8]. Studies have compared the effects, safety, and acceptability of vacuum vs second stage caesarean section. There is a need to assess if these report the clinically relevant outcomes, and if there are variations in the outcomes according to the setting and study characteristics. The lack of consistency in outcome reporting impedes researchers' abilities to conduct meaningful evidence synthesis [9]. Initiatives such as the Core Outcome Measures in Effectiveness Trials (COMET) and Core Outcomes in Women's Health (CROWN) work towards developing core outcome sets, to standardise outcome measurement and reporting [11, 12]. This helps ensure that the research provides clinicians and patients with complete information [10]. To our knowledge, there is currently no core outcome set for assisted vaginal birth [9, 13].

We systematically assessed the outcomes and their quality and variations in reporting on studies comparing vacuum vs second stage caesarean section through a systematic review.

Methods

We registered our systematic review with PROSPERO (registration number: CRD42024469164) and reported as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [11].

Search strategy

We searched major databases: PubMed, Global Index Medicus, Cochrane Central Register of Controlled Trials (CENTRAL), and Embase from inception to 17 January 2025. We adapted the search strategy used by Thierens et al., who evaluated the clinical effectiveness of vacuum extraction versus caesarean section during the second stage of labour [9]. Search terms included a combination of free-text keywords and Medical Subject Headings related to women in the second stage of labour and vacuum-assisted vaginal birth. Filters were applied to include only human studies, with no restrictions on language or date. The full search strategy can be found in Appendix A.

Eligibility criteria for selecting studies

A two-stage selection process was used to identify relevant studies. Titles and abstracts were screened using pre-defined inclusion and exclusion criteria (see Appendix B). Subsequently, full-text articles were assessed. Screening was conducted using the online software Covidence [12] with two reviewers (MH and EG) independently assessing each article [13]. Any disagreement was resolved through discussion with a third reviewer (AW).

Studies were eligible if they included pregnant women in the second stage of labour who had a vacuum-assisted birth as an intervention with a caesarean section group as the comparator. The second stage of labour was defined as full cervical dilatation, as reported in the original studies. The studies had to report at least one clinical maternal or perinatal outcome. Studies were excluded if they were case reports, expert opinions, or literature reviews, and if the intervention was not in the second stage of labour. This review focused exclusively on outcomes following vacuum-assisted vaginal birth; studies that included only forceps-assisted births were excluded [7]. The vacuum device is generally easier to operate than forceps and may be more readily available or preferred in certain settings, particularly where forceps expertise is limited [13]. As vacuum and forceps differ in both mechanism of action and outcome profile, it is methodologically appropriate to assess them separately. Studies that only reported psychological outcomes or long-term maternal outcomes were excluded, as the focus of this review was on the quality of immediate and short-term clinical outcomes.

Data extraction

Data were extracted using a standardised, pre-piloted data extraction form in Microsoft Excel. During the pilot phase, if an outcome materialised in the data that was not included in the data extraction sheet, the reviewers adapted the data extraction sheet to ensure that all outcomes were included. The clinical outcome data extraction categories were selected to ensure comprehensive coverage of all relevant outcomes. The current available childbirth and labour core outcome sets were used to guide the categories that were included [10, 13].

We recorded baseline characteristics of the studies, including study design, sample size, participant inclusion criteria, type of instrument used, and indications for intervention. Other factors such as geographical and income region of the study, journal type and impact factor, number of caesarean sections and assisted vaginal births were also collected. We documented whether the study pre-specified its primary outcomes, with a yes or no question. Two reviewers (MH and EG) independently extracted all data. Discrepancies were resolved through discussion with a third reviewer (AW). All reported outcomes, were recorded and categorised into one of the 33 outcome categories.

Outcomes were categorised as maternal or neonatal, and as mortality/morbidity or process and care-related outcomes. Full outcome definitions and measures are provided in Appendix E. Selected outcomes (postpartum haemorrhage (PPH), maternal infection, and Apgar score) were further subcategorised. The majority of subcategorisation was based on established clinical groupings and physiological systems. Outcomes with no clear similarities were grouped into an 'other' category. No hierarchy was applied to outcomes with differing thresholds and time points (e.g. Apgar scores). These were recorded separately to avoid masking heterogeneity arising from differences in outcome definitions and timing.

Assessment of outcome reporting quality

We used a modified version of the Harman questionnaire to assess and grade the extracted outcomes, as it is a simple, reproducible, and feasible tool that can be applied to any study reporting at least one outcome (see Appendix C) [14, 15]. This scoring system was adapted from a tool developed in a systematic review on caesarean section outcome reporting, and assesses outcomes based on three key criteria, awarding one point for each criterion met [15].

The first criterion is that the outcome had to be clearly defined, with a stated definition if required. The second criterion is a description of how an outcome would be statistically analysed. Thirdly, the studies were evaluated on whether they described steps taken to enhance the quality of outcome measurement. If met, each criterion scored one point, meaning that a maximum score of 3 could be awarded to each outcome and a minimum score of 0 points. An outcome score of ≥ 2 was considered high quality, having reported 2 parts of the Harman questionnaire. Scores of < 2 were considered poorer quality. Similar thresholds have been used in other reviews looking at outcome reporting [15]. Reviewers (MH and EG) performed independent assessments, and disagreements were resolved through discussion, with input from a third reviewer (AW).

Data analysis

Descriptive statistics were used to summarise the frequency and quality of the outcomes reported in the included studies using percentages, mean, median and interquartile range (IQR). Outcomes were classified as primary or secondary, outcomes not explicitly defined as primary were treated as secondary. We fitted separate mixed-effects models with the individual outcome as the unit of analysis and the Harman outcome quality score as the dependent variable. Each model included fixed effects for one outcome-level characteristic (outcome type) and for study-level characteristics (journal impact factor, country of the study, authorship income region, journal type, study design—prospective vs retrospective—and sample size). Study-level predictors were constant across outcomes within each study, and their effects were therefore estimated at the between-study level. To account for the non-independence of multiple outcomes contributed by the same study, all models included random intercepts for study.

No ethical approval was required for this work and individual patient data were not accessed.

Results

From 3162 citations, we included 23 studies (Fig. 1); study characteristics are summarised in Table 1. Most of the studies (n = 20) were

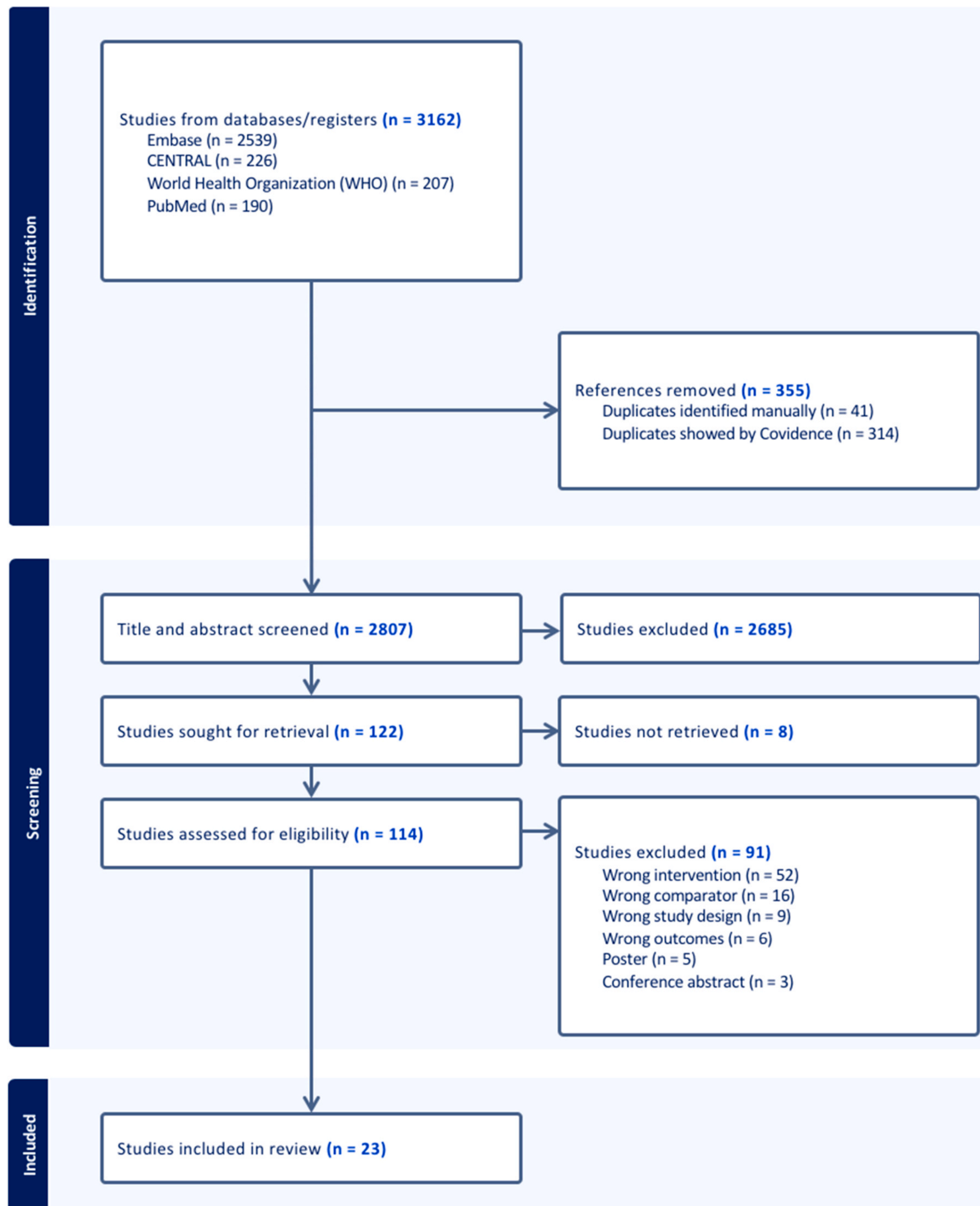

Fig. 1. PRISMA flowchart for study selection.

Table 1
Study characteristics of included studies.

Author, year	Study period	Country	World Bank Country Income	Study design	Sample size	Number of caesarean sections (n)	Number of vacuum-assisted births (n)	Type of vacuum device	Journal impact factor
Åberg, 2016 [31]	1999–2012	Sweden	High	Retrospective cohort	1030,775	60,008	85,919	*NR	4.3
Auger, 2023 [26]	2006–2019	Canada	High	Retrospective cohort	1080,503	265,390	71,315	NR	1.6
Bailit, 2016 [28]	2008–2011	USA	High	Retrospective cohort	2531	131	1382	NR	9.8
Baloch, 2008 [29]	2005–2006	Pakistan	Middle	Retrospective cohort	400	240	64	NR	0.6
Contag, 2010 [30]	2002–2005	USA	High	Retrospective cohort	990	190	333	NR	2
Eze, 2020 [32]	2012–2016	Nigeria	Middle	Retrospective cohort	559	348	211	Kiwi®; Omnicup	3.1
Freeman, 2017[33]	2010–2012	USA	High	Case-control	376,325	142,670	18,393	NR	3.8
Giacchino, 2020[34]	2010–2018	UK	High	Retrospective cohort	23,786	9465	344	NR	1.6
Gurney, 2021 [35]	2014–2018	UK	High	Retrospective cohort	971	107	116	Kiwi®; Omnicup	5.8
Halscott, 2015[36]	2002–2008	USA	High	Retrospective cohort	2518	222	1598	NR	7.2
Hendler, 2017[37]	2011–2013	Israel	High	Retrospective cohort	547	197	200	Metal cup	1.8
Kessous, 2013[38]	1993–2010	Israel	High	Retrospective cohort	319	135	184	NR	2.6
Krizman, 2017[39]	1996–2002	USA	High	Retrospective cohort	1837	468	608	NR	0.9
Levin, 2021 [40]	2011–2019	Israel	High	Retrospective cohort	611	46	565	NR	1.9
Levin, 2022 [41]	2011–2019	Israel	High	Retrospective cohort	60	35	25	Kiwi®; Omnicup & Medela Malmström (metallic)	1.8
Muraca, 2018[42]	2004–2014	Canada	High	Retrospective cohort	10,901	4524	1913	NR	5.8
Muraca, 2019[43]	2003–2013	Canada	High	Retrospective cohort	55,450	15,034	24,854	NR	1.8
Nolens, 2018 [8]	2014–2015	Uganda	Low	Prospective cohort	783	425	358	Kiwi®; Omnicup; Bird and silicone cups	3.8
Polkowski, 2017[44]	2004–2014	Germany	High	Retrospective cohort	1971	1420	393	Metal ventouse cup & Kiwi® Omnicup	1.8
Shmueli, 2017[45]	2007–2014	Israel	High	Retrospective cohort	3449	356	3093	NR	5.8
Tempest, 2013[46]	2006–2010	UK	High	Retrospective cohort	1291	146	107	NR	3.7
Tempest, 2017[47]	2006–2013	UK	High	Prospective and retrospective cohort	2426	790	171	NR	7.2
Walsh, 2013 [48]	2000–2009	Ireland	High	Retrospective cohort	64,555	509	7579	Kiwi®; Omnicup; metal cup & silastic cup	4.3

* NR – not recorded

retrospective cohort studies, with the remaining studies comprising one prospective, one prospective and retrospective and one case-control study.

Study characteristics

Studies were published between 2008 and 2023. Three studies took place in low- and middle-income countries, and 20 in high-income countries as classified by the World Bank region (Table 1). Most studies were published in specialist obstetrics and gynaecology journals (n = 20, 87.0%). Eighteen studies reported on indication for intervention and included; prolonged second stage/labour dystocia (n = 14), fetal distress (n = 12), maternal indications (n = 6) and other indications (n = 4). Seven studies reported the type or brand of vacuum device used; Kiwi® Omnicups (n = 6); other brands mentioned were Medela (n = 1) and Bird cups (n = 1). Three studies reported the use of metal cups but did not provide further details.

Frequency of reported outcomes

The 352 outcomes were grouped into 33 categories and 62 subcategories. A table with all subcategories is included in Appendix E. More outcomes were reported in the mortality and morbidity group (n = 291) than in the process and care outcomes group (n = 61). The most frequently reported outcome category was ‘urogenital tract injury’, the subcategories of which were reported 40 times across 16 studies. The main subcategory within this was ‘anal sphincter injury’, defined as 3rd and 4th degree perineal tear, which was reported 28 times across the 16 studies. The second most reported maternal outcome was postpartum haemorrhage, which was reported 32 times across 14 studies. The least reported maternal outcome was ‘maternal admission to intensive care unit’ (n = 1). Apgar score was the most frequently reported neonatal

outcome, reported 24 times and appearing in 18 (78.3%) of the studies. The least reported neonatal outcome was neurodevelopmental anomalies reported twice in one study and respiratory concerns, reported twice across two studies. See Table 2 for the breakdown of reported outcomes.

Variations in outcome reporting

Neonatal outcomes accounted for 61.1% (n = 215) of all reported outcomes, while the remaining 38.9% (n = 137) were maternal outcomes. All studies reported neonatal outcomes, but only 73.9% (n = 17 studies) reported maternal outcomes. No outcome was reported by all studies, with the most widely reported outcome ('Apgar score') present in 18 studies (78.3%). 20 outcomes (5% of the total outcomes reported) were only reported by one study, examples include: 'maternal admission to intensive care unit', 'maternal faecal and urinary incontinence', 'neonatal pyrexia' and 'neonatal skin lacerations' (Table 2). The maternal category with the most variation, with 6 subcategories, was urogenital tract injury. (see Appendix D1). Apgar score was the most widely reported outcome (78.3%) across the 23 studies, but there was heterogeneity in how the outcome was reported and measured (see table in Appendix D2). The most frequently reported subcategory was 5-minute Apgar score < 7, reported by 10 studies.

Quality of outcome reporting

All outcomes were assessed for quality using the modified Harman questionnaire. Overall, 61.1% of outcomes were 'clearly defined so that other researchers would be able to reproduce its measurement', and most outcomes (98.0%) described how the outcome would be statistically analysed. Fewer outcomes (58.8%) scored a point for describing the 'methods to enhance the quality of measures' (Table 3)

The two highest scoring neonatal outcomes were 'perinatal hypoxic ischaemic encephalopathy' and 'neonatal skull fractures', both with a median score of 3 (IQR 3–3; IQR 3–3). The highest scoring maternal outcome was 'uterine rupture' with a median score of 3 (IQR 2–3). The lowest-scoring outcomes were 'infant feeding' and 'neonatal neurodevelopmental anomalies', both with a median Harman score of 1.5 and an IQR of 1–2 (Table 2).

Of the 215 neonatal outcomes, 34.8% (n = 75) scored the full three points on the modified Harman's questionnaire. Similarly, 37.2% (n = 51) of the 137 maternal outcomes achieved the maximum score. Multilevel analysis results showed that maternal outcomes were associated with significantly higher quality scores compared to neonatal outcomes ($\beta = 0.18$, $p = 0.002$, 95% CI 0.06–0.29).

Across the 352 outcomes, 132 were reported as primary and 220 as secondary. 39% of studies did not clearly define their outcomes as primary and were therefore defined as secondary. 81.1% of primary and 82.4% of secondary outcomes scored 2 or higher on the modified Harman's questionnaire. Although a greater number of secondary outcomes received a score of zero, there was no meaningful difference in the overall Harman score distribution between primary and secondary outcomes, with both having a median score of 2. Table 2 shows a breakdown of the median Harman scores according to outcome type, with the score as a categorical variable: < 2 considered low quality and ≥ 2 high quality. Appendix F presents the distribution of median Harman scores across the major outcome categories, demonstrating the heterogeneity in outcomes reported with high quality.

The median journal impact factor was 2.6, ranging from 9.8 to 0.6. There was no correlation found between the journal impact factor and the Harman score of reported outcomes. Furthermore, mixed-effects analyses revealed that certain study characteristics were significantly associated with the total quality score of outcomes. Specifically, studies conducted in South Asia (compared with Europe and Central Asia) and studies from middle-income countries (compared with high-income countries) had significantly different scores ($\beta = -1.73$, $p = 0.003$, 95% CI –2.88 to –0.57). No significant associations were observed for

Table 2
Distribution of the main categories of outcomes by number of times reported and number of studies that reported outcomes, including Harman questionnaire score; see Appendix E for the full breakdown of outcomes.

Category	Total times outcome reported per outcome category (% of total outcomes)	Total number of studies that reported (% of total studies)	Median Harman score (IQR (p25-p75))
Maternal outcomes	137 (38.9%)	17 (73.9%)	2 (2–3)
Mortality and morbidity outcomes	114 (32.3%)	16 (69.6%)	2 (2–3)
Urogenital tract injury	40 (11.4%)	16 (69.6%)	3 (2–3)
Postpartum haemorrhage	32 (9.1%)	14 (60.9%)	2 (2–3)
Maternal infection	18 (5.1%)	10 (43.5%)	2 (1–2)
Other maternal morbidity	17 (4.3%)	6 (26.1%)	2 (2–2)
Maternal mortality	4 (1.1%)	4 (17.4%)	2 (2–2)
Uterine rupture	3 (0.9%)	3 (13.0%)	3 (2–3)
Incontinence	2 (0.6%)	1 (4.3%)	2 (2–2)
Process and care-related outcomes	23 (6.5%)	11 (47.8%)	2 (2–3)
Wound complications*	9 (2.6%)	7 (30.4%)	2 (1–3)
Failed instrumental delivery	5 (1.4%)	5 (21.7%)	2 (2–3)
Prolonged hospitalisation	3 (0.9%)	3 (13.0%)	2 (2–3)
Return to theatre for surgery (unspecified)	3 (0.9%)	3 (13.0%)	2 (2–2)
Infant feeding by the mother	2 (0.6%)	2 (8.7%)	1.5 (1–2)
Maternal admission to ICU**	1 (0.3%)	1 (4.3%)	2 (2–2)
Neonatal outcomes	215 (61.1%)	23 (100%)	2 (2–3)
Mortality and morbidity outcomes	177 (50.3%)	23 (100%)	2 (2–3)
Apgar score***	24 (6.8%)	18 (78.3%)	3 (2–3)
Musculoskeletal injury	22 (6.3%)	15 (65.2%)	2 (2–3)
Perinatal death	22 (6.3%)	14 (60.9%)	2 (2–3)
Intracranial haemorrhage	14 (4.0%)	12 (52.2%)	2 (2–2)
Nerve injuries	14 (4.0%)	6 (26.1%)	2 (1–2)
Umbilical vessel pH/ base excess	13 (3.4%)	9 (39.1%)	3 (2–3)
Subgaleal haemorrhage	9 (2.6%)	9 (39.1%)	3 (2–3)
Neonatal infection	8 (2.3%)	6 (26.1%)	3 (2–3)
Birth injuries	7 (2.0%)	7 (30.4%)	2 (1–2)
Brachial plexus palsy	7 (2.0%)	7 (30.4%)	2 (1–3)
Cephalohaematoma	7 (2.0%)	7 (30.4%)	2 (2–3)
Metabolic complications	7 (2.0%)	6 (26.1%)	2 (1–3)
Neonatal seizure	7 (2.0%)	7 (30.4%)	2 (1–2)
Hypoxic ischaemic encephalopathy	5 (1.4%)	5 (21.7%)	3 (3–3)
Neonatal asphyxia	4 (1.1%)	4 (17.4%)	2 (1.5–2)
Respiratory distress syndrome	4 (1.1%)	4 (17.4%)	3 (2–3)
Neurodevelopmental anomalies (long-term)	2 (0.6%)	1 (4.3%)	1.5 (1–2)
Respiratory problems	2 (0.6%)	2 (8.6%)	2.5 (2–3)
Process and care-related outcomes	38 (10.8%)	18 (78.3%)	2 (2–2.5)
Perinatal admission to NICU****	15 (4.3%)	15 (65.2%)	2 (1–2)
Ventilation support	10 (2.8%)	10 (43.5%)	2 (2–3)
Neonatal scalp trauma	5 (1.4%)	5 (21.7%)	2 (2–2)
Skull fractures	5 (1.4%)	5 (21.7%)	3 (3–3)
Neonatal resuscitation	2 (0.6%)	2 (8.7%)	2 (1–3)
Total	**352 (100%)**	**23 (100%)**	**2 (2–3)**

* Tear extension and wound dehiscence

** Intensive care unit

*** Scoring system that looks at five key areas of a neonate's condition: heart rate, breathing, muscle tone, reflex irritability and skin colour, each scored from 0 to 2, allowing quick assessment of the neonate's condition at birth [16].

**** Neonatal intensive care unit

Table 3
The Harman questionnaire with the number of outcomes that achieved each component.

COMPONENTS OF THE SCORE	FREQUENCY
1. Clearly defined	215 (61.1%)
2. Mentioned in the statistical analysis	345 (98.0%)
3. Description of methods to enhance the quality	207 (58.8%)

journal type. Study design (prospective vs. retrospective; $\beta = 0.3$, $p = 0.650$, 95% CI –1.0–1.61) and the logarithm of sample size ($\beta = -0.08$, $p = 0.145$, 95% CI –0.19–0.03) were not significantly associated with the total quality score of reported outcomes.

The mixed-effects analysis of total quality score by publication year ($\beta = 0.06$, $p = 0.083$, 95% CI –0.01–0.14) indicates no statistically significant improvement in outcome reporting over time. This suggests that, while there may be a slight upward trend, there is currently insufficient evidence to conclude that reporting quality has improved consistently across the years.

We further evaluated whether the number of outcomes reported per study (i.e. breadth of outcome reporting) was associated with the Harman outcome quality score using mixed-effects models. No significant association was observed between the number of outcomes reported per study and outcome reporting quality ($\beta = 0.01$, $p = 0.44$, 95% CI −0.02–0.04). In contrast, the number of outcomes reported per study varied according to study-level characteristics. Studies conducted in high-income countries reported a greater number of outcomes than those conducted in middle-income countries ($\beta = 5.5$, $p = 0.01$, 95% CI 1.3–9.7). Additionally, larger study sample size (log-transformed) was associated with fewer reported outcomes ($\beta = -0.56$, $p = 0.003$, 95% CI −0.93 to −0.19).

Discussion

There is substantial variation and little consistency in how outcomes are reported in studies comparing vacuum-assisted vaginal births with second stage caesarean sections. No outcome was reported across all studies, highlighting limited coherence in current reporting practices. Most outcomes met the predefined threshold for high-quality reporting (score ≥ 2), with the majority achieving a score of 2 out of a possible 3 points on the modified Harman scale. Maternal outcomes had significantly higher quality scores than neonatal outcomes, and studies from middle-income countries had lower scores compared with those from high-income countries. There was no association between reporting quality and study size, outcome type (primary/secondary), or journal impact factor.

Importantly, increasing the number of reported outcomes was not associated with improved reporting quality, suggesting that broader outcome reporting does not equate to better-quality reporting and reinforcing the need for prioritised and standardised outcome selection.

Anal sphincter injury was the most frequently reported outcome category, likely due to the well-established association between assisted vaginal birth and obstetric anal sphincter injury. These outcomes also demonstrated relatively high reporting quality, which may reflect their clearly defined clinical nature and established diagnostic criteria. The least reported outcome was maternal intensive care unit admission, only reported once. Although this is rare [17] it is a significant clinical event and should be recorded even when no events occur [18]. Although neonatal Apgar scores were commonly reported, there was substantial heterogeneity in the cut-off and timing used to define the Apgar score across the included studies, with seven different reporting measures used, limiting comparability and the ability to synthesise findings and draw meaningful conclusions. A 5-minute threshold of < 7 is associated with an increased risk of neonatal and infant mortality and morbidity [17,19–22].

Studies conducted in middle-income settings had lower Harman scores compared with high-income settings. Given the 0–3 range of the Harman scale, this difference corresponds to the absence of approximately one to two key components of outcome reporting quality, indicating substantially poorer reporting quality in middle-income settings. This gap may reflect differences in research infrastructure. Poorer outcome reporting from these settings potentially reinforces global inequities. These findings may highlight the need for targeted efforts to strengthen reporting practices in middle-income settings [14].

To our knowledge, this is the first study to quantify reported outcomes for vacuum-assisted vaginal birth. This review was conducted using rigorous methodology, including double independent screening and data extraction using predefined inclusion and exclusion criteria. The search strategy was comprehensive, drawing from previously piloted methods and incorporating multiple databases without language restrictions, enhancing global inclusivity.

A further strength of this review is the use of the modified Harman questionnaire to assess outcome reporting at the level of individual outcomes. Unlike broader tools such as CONSORT [18] and GRADE [19], which focus on study-level reporting and overall quality of evidence, this approach enabled a more granular evaluation of how outcomes are defined and measured. however, these focus primarily on the overall study-level quality or the quality of evidence reporting, rather than on the assessment of individual outcome reporting.

A key limitation is the exclusion of studies evaluating forceps assisted birth, which reduced the number of eligible studies, breadth of analysis and limited the generalisability of findings to all assisted vaginal births. In addition, only a small number of the included studies were conducted in low- and middle-income countries, limiting the generalisability of our results in countries where assisted vaginal birth could have the most impact. These settings may have limited resources to measure outcomes, and so it would be important when developing a global core outcome set to consider these restraints and identify essential outcomes that can be assessed in LMIC.

There was considerable diversity across studies in indications for intervention and types of vacuum device used. This was not formally analysed in this review, and therefore its influence on outcome selection and reporting could not be assessed.

This review focused on clinical outcomes and did not include psychological or long-term maternal outcomes of assisted vaginal birth. These outcomes are important to women and essential for understanding the full impact of mode of birth. Future research should incorporate these domains to provide a more comprehensive assessment of outcome reporting.

Previous work has highlighted similar challenges related to the heterogeneity in outcome measurement and definitions, Thierens et al. were unable to perform a meta-analysis to synthesise research comparing vacuum-assisted vaginal birth with caesarean section in the second stage [9]. Wilson et al. also performed a review assessing the quality of outcome reporting in caesarean sections, piloting the adapted Harman's questionnaire [14]. They found great variability in both the frequency and reporting of outcomes, with very few of them achieving the maximum score of 3 on the Harman score.

Together, these findings suggest that inconsistency in outcome reporting remains a persistent barrier to evidence synthesis across obstetrics. Outcomes should be identified a priori as they are the structure around which methods, analysis, and results are crafted. [29] Outcomes should be clearly defined to limit heterogeneity in measurement methods. This is especially important as we found that the poorest aspect of component reporting was descriptions of the methods taken to enhance the quality of outcome measures.

We recommend a Delphi study as well as qualitative work to support the development of a comprehensive core outcome set including long term and psychological outcomes. In developing such a core outcome set, we encourage adherence to established guidance, including the COMET initiative, and standards such as COS-STAD (Core Outcome Set–STAndards for Development) and COS-STAR (Core Outcome

Set–STAndards for Reporting) to ensure methodological rigour [23–25].

Conclusion

Our systematic review demonstrates substantial variation and the need for standardisation in outcome reporting in studies of vacuum-assisted vaginal birth. The absence of consistent outcome definitions limits comparability and hinders reliable evidence synthesis. The development and implementation of a core outcome set for second stage of labour interventions is essential to improve research quality, support clinical decision-making, and ultimately improve outcomes for women and neonates.

Author roles

MH, EG, and AW designed the search strategy. MH and EG conducted the searches. MS, AW, JV, and ST designed the data extraction form. MH and EG extracted data. AW and SS provided senior support to MH and EG. GRC, JCC, and JZ conducted the analysis. MH and EG wrote the manuscript. SS, ST, SD, CH, SJ and CK provided critical feedback on the manuscript.

MH and EG contributed equally to this work and share first authorship.

CRediT authorship contribution statement

Javier Chaves Cordero: Formal analysis. **Mohammed Sheraz:** Resources, Methodology. **Javier Zamora:** Methodology, Formal analysis. **Gabriel Ruiz Calvo:** Formal analysis. **Claudia Hanson:** Writing – review & editing. **Carol Kingdon:** Writing – review & editing. **Soha Sobhy:** Writing – review & editing, Supervision, Project administration. **Martha Hahn:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Soo Downe:** Writing – review & editing. **Amie Wilson:** Writing – review & editing, Supervision, Conceptualization. **Shakila Thangaratinam:** Writing – review & editing, Supervision, Project administration, Funding acquisition, Conceptualization. **Emily Grace:** Writing – review & editing, Writing – original draft, Resources, Methodology, Investigation, Data curation, Conceptualization. **Sian Jenkins:** Writing – review & editing.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. Martha Hahn, Soo Downe, Carol Kingdon, Amie Wilson, Shakila Thangaratinam, Sian Jenkins, Claudia Hanson reports financial support and article publishing charges were provided by UK Research and Innovation Medical Research Council. Soha Sobhy reports financial support and article publishing charges were provided by UK Research and Innovation Medical Research Council. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. – Search strategies

PubMed: initial search 13/12/2023, updated 16/01/2025; 190 results identified

((human AND ((women) OR (woman) OR (female) OR (birthing person) OR (birthing people))) AND (((obstetric delivery[Text Word]) OR (partuition[Text Word]) OR (childbirth[Text Word]) OR (labour stage second[Text Word])) AND ((vacuum extraction[Text Word]) OR (assisted delivery[Text Word]) OR (operative delivery[Text Word]) OR (vacuum assisted delivery[Text Word]) OR (ventouse[Text Word]) OR (instrumental delivery[Text Word])) AND ((cesarean section[Text Word]) OR (caesarean section[Text Word]) OR (caesarean delivery[Text Word]) OR (caesarean delivery[Text Word]) OR (c section[Text Word]) OR (caesarian delivery[Text Word]) OR (ceasarian delivery[Text Word]) OR (caesarian section[Text Word]) OR (ceasarian section[Text Word])))

Global Index Medicus: initial search 13/12/2023, updated 16/01/2025; 207 results identified

(human AND ((women) OR (woman) OR (female) OR (birthing person) OR (birthing people))) AND (((obstetric delivery) OR (partuition) OR (childbirth) OR (labour stage second)) AND ((vacuum extraction) OR (assisted delivery) OR (operative delivery) OR (vacuum assisted delivery) OR (ventouse) OR (instrumental delivery)) AND ((cesarean section) OR (caesarean section) OR (caesarean delivery) OR (caesarean delivery) OR (c section)))

Cochrane Register of Controlled Trials (CENTRAL): initial search 13/12/2023, updated 16/01/2025; 226 results identified

((Labour stage, second) OR (second stage of labour) OR (child birth) OR (parturition)):ti,ab,kw AND ((vacuum extraction, obstetrical) OR (assisted delivery) OR (operative delivery) OR (vacuum assisted delivery) OR (ventouse) OR (instrumental delivery)):ti,ab,kw AND ((cesarean section) OR (caesarean section) OR (caesarean delivery) OR (cesarean delivery) OR (c section) OR (caesarian section) OR (cesarian section) OR (caesarian delivery) OR (cesarian delivery)):ti,ab,kw AND ((female) OR (females) OR (woman) OR (women) OR (birthing person) OR birthing people)) AND ((human) OR (humans)

Embase (Ovid): initial search 13/12/2023, updated 16/01/2025; 2539 results identified

1.	exp female/
2.	('Female*' or 'Wom?n' or 'birthing person' or 'birthing people').mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
3.	exp human/
4.	('Human' or 'humans').mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
5.	1 or 2
6.	3 or 4
7.	5 and 6

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(*continued*)

8.	exp labor stage 2/
9.	('Labo?r stage, second' or 'second stage of labo?r' or 'child birth' or 'obstetric delivery' or 'parturition').ab,ti.
10.	8 or 9
11.	exp vacuum extraction/
12.	exp instrumental delivery/
13.	('Vacuum extraction' or 'instrumental delivery' or 'operative delivery' or 'vacuum assisted delivery' or 'assisted delivery' or 'ventouse').ab,ti.
14.	11 or 12 or 13
15.	exp cesarean section/
16.	('C?esarean section' or 'c?esarean delivery' or 'c section').ab,ti.
17.	15 or 16
18.	7 and 10 and 14 and 17

Appendix B. – Study selection criteria

Inclusion criteria	Exclusion criteria
• Pregnant women in the second stage of labour undergoing vacuum extraction as an intervention with a caesarean section group as the comparator	• Case reports, expert opinions, literature reviews and systematic reviews
• Comparative studies	• No full text available
• At least one clinical maternal or perinatal/neonatal outcome in terms of morbidity and mortality	• Interventions not executed in the second stage of labour
	• Studies including only forceps as the instrument for assisting delivery
	• Only psychological outcomes reported

Appendix C

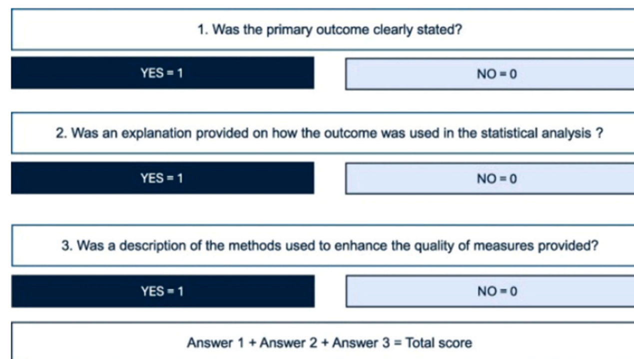


Fig. C1. Modified Harman questionnaire [1]

Appendix D

TAble D1
subcategories by which maternal urogenital tract injury was reported

	Frequency of outcome reporting	Number of studies that reported outcome
3rd degree perineal tear	14	13
4th degree perineal tear	14	13
Cervical injury	7	7
High vaginal tear	2	2
Operational complications	2	2
Obstetric fistula	1	1
Total (urogenital tract injury)	40	16

TAble D2
Apgar score reporting

Reported Outcome	Frequency of reporting
5 min Apgar < 5	2
Mean Apgar score	1
5 min Apgar < 4	6
5 min Apgar < 7	10
1 min Apgar < 7	3
5 min Apgar 4–6	1
5 min Apgar < 3	1

Appendix E. : All outcomes, including subcategories, collected

Maternal outcomes		Frequency of outcome reporting	Number of studies that reported outcome
Mortality and morbidity outcomes		114	16
Urogenital tract injury		40	16
	3rd degree perineal tear	14	13
	4th degree perineal tear	14	13
	Cervical injury	7	7
	High vaginal tear	2	2
	Operational complications	2	2
	Obstetric fistula	1	1
Postpartum haemorrhage		32	14
	Postpartum haemorrhage	15	14
	Blood transfusion	10	10
	Hysterectomy	5	5
	Anaemia	1	1
	Manual removal of the placenta	1	1
Maternal infection		18	10
	Pyrexia	4	4
	Sepsis	4	4
	Wound infection	4	4
	Endometritis	3	3
	Other infection	3	3
Other maternal morbidity		15	6
	Acute renal failure	2	2
	Amniotic fluid embolism	2	2
	Cardiac complications	2	2
	Injury to pelvic organs	2	2
	Venous thromboembolism	2	2
	Shock	2	2
	Anaesthesia complications	1	1
	Pelvic haematoma	1	1
	Paralytic ileus	1	1
Maternal mortality		4	4
Uterine rupture		3	3
Incontinence		2	1
	Faecal	1	1
	Urinary	1	1
Process and care-related outcomes		23	11
Wound complications*		9	7
Failed instrumental delivery		5	5
Prolonged hospitalisation		3	3
	Hospitalisation > 5 days	2	2
	Unspecified length of hospitalisation	1	1
Return to theatre for surgery (unspecified)		3	3
Infant feeding by the mother		2	2
Maternal admission to ICU		1	1
Total maternal outcomes		137	17
Total of all outcomes		352	23

*Tear extension and wound dehiscence

Neonatal outcomes		Frequency of outcome reporting	Number of studies that reported outcome
Mortality and morbidity outcomes		162	23
Musculoskeletal Injury		22	21
	Long bone fracture or dislocation	9	8
	Shoulder dystocia	7	7
	Clavicle fracture	6	6
Metabolic complications		7	7
	Jaundice	6	6

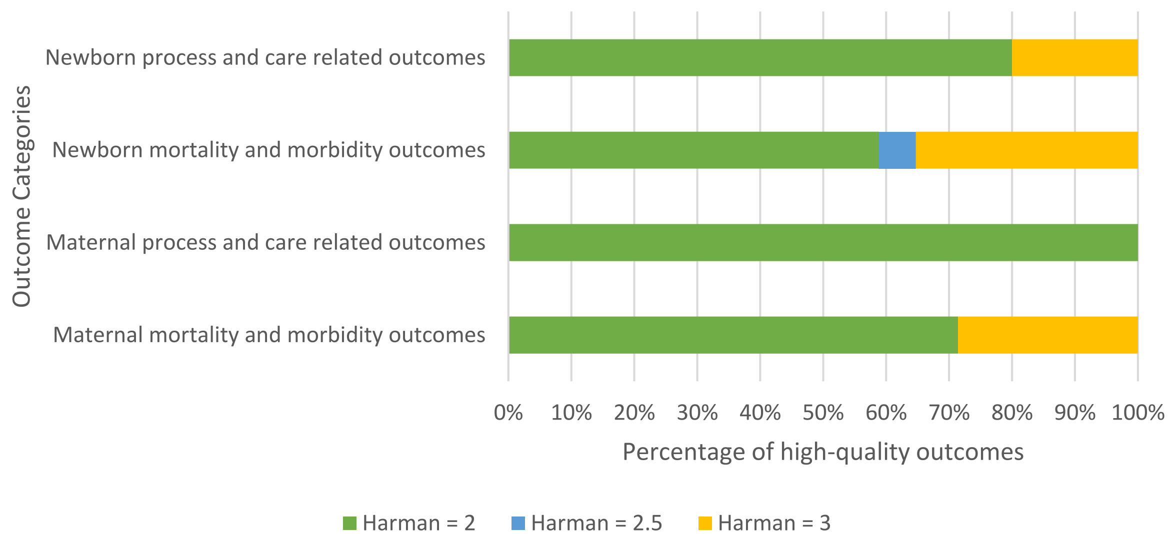
(*continued on next page*)

(*continued*)

	Hypoglycaemia	1	1
Birth injuries		7	7
	Liver or spleen injury	3	3
	Birth injury	2	2
	Skin laceration	1	1
	Facial injury	1	1
Respiratory problems		2	2
	Breathing difficulties	1	1
	Transient tachypnea of the newborn	1	1
Apgar score*		24	18
	5 min Apgar < 7	10	10
	5 min Apgar < 4	6	6
	1 min Apgar < 7	3	3
	5 min Apgar < 5	2	2
	5 min Apgar 4–6	1	1
	5 min Apgar < 3	1	1
	Mean Apgar	1	1
Perinatal death		22	14
	Perinatal death	8	8
	Neonatal death	8	8
	Stillbirth	5	5
	Infant death	1	1
Intracranial haemorrhage		14	12
Nerve injuries		14	6
	Central nervous system	5	3
	Peripheral nervous system	5	3
	Facial nerve palsy	4	4
Umbilical vessel pH/base excess		12	9
	Arterial pH < 7.1	6	6
	Base excess < -12.0	2	2
	Median arterial pH	2	2
	Mean arterial pH	1	1
	Arterial pH < 7.2	1	1
Subgaleal haemorrhage		9	9
Neonatal infection		8	6
	Sepsis	6	6
	Pyrexia	1	1
	Other infection	1	1
Brachial plexus palsy		7	7
Cephalohaematoma		7	7
Neonatal seizure		7	7
Hypoxic ischaemic encephalopathy		5	5
Neonatal asphyxia		4	4
Respiratory distress syndrome		4	4
Neurodevelopmental anomalies (long-term)		2	1
Process and care-related outcomes		37	18
Perinatal admission to NICU		15	15
Ventilation support		10	10
	Mechanical ventilation	5	5
	Intubation	3	3
	Non-invasive supplementary oxygen	2	2
Neonatal scalp trauma		5	5
Skull fractures		5	5
Neonatal resuscitation		2	2
Total neonatal outcomes		215	23
Total of all outcomes		352	23

* Scoring system that looks at five key areas of a neonate's condition: heart rate, breathing, muscle tone, reflex irritability and skin colour, each scored from 0 to 2, allowing quick assessment of the newborn [17].

Appendix F. : Distribution of Harman scores among high-quality (≥2) outcomes by outcome category. Bars are the proportion of outcomes within each major category scoring Harman 2, 2.5, 3. Percentages calculated using total high-quality outcomes as the denominator



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