The incidence of wound complications following primary repair of obstetric anal sphincter injury: a systematic review and meta-analysis

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OBJECTIVE: We aimed to systematically determine the incidences of wound infection and dehiscence after primary obstetric anal sphincter injury repair.

DATA SOURCES: MEDLINE, Embase, CINAHL, EmCare, the Cochrane Library, and Trip Pro databases were searched from inception to February 2021.

STUDY ELIGIBILITY CRITERIA: We included observational clinical studies reporting the incidences of wound infection and dehiscence after primary obstetric anal sphincter injury repair. Case series and reports were excluded. Conference articles and observational study abstracts were included if they contained enough information regarding study design and outcome data.

METHODS: Data were analyzed as incidence (percentage) with 95% confidence intervals. Moreover, the prediction intervals were calculated to provide a predicted range for the potential incidence of wound complications when applied to an individual study setting. Study quality and risk of bias were assessed using the relevant tool from the Joanna Briggs Institute.

RESULTS: Of 956 studies found, 39 were selected for full-text review. Moreover, 10 studies (n=4767 women) were eligible and included in the meta-analysis. All 10 studies were conducted in high-income countries (Denmark [n=1], the United Kingdom [n=3], and the United States [n=6]). The incidences of wound infection (n=4593 women) and wound dehiscence (n=3866 women) after primary obstetric anal sphincter injury repair ranged between 0.1% to 19.8% and 1.9% to 24.6%, respectively. The overall incidences were 4.4% (95% confidence interval, 0.4–8.4) for wound infection and 6.9% (95% confidence interval, 1.6–12.2) for wound dehiscence. The prediction intervals were wide and suggested that the true incidences of wound infection and dehiscence in future studies could lie between 0.0% to 11.7% and 0.0% to 16.4%, respectively. Overall, 8 studies had a high or unclear risk of bias across ≥1 assessed element. None of the studies used the same set of clinical parameters to define wound infection or dehiscence. Furthermore, microbiological confirmation with wound swabs was never used as a diagnostic measure.

CONCLUSION: This was a systematic review and meta-analysis of wound infection and dehiscence incidences after primary obstetric anal sphincter injury repair. The incidence estimates from this review will be useful for clinicians when counseling women with obstetric anal sphincter injury and when consenting them for primary surgical repair.

Key words: antibiotics, meta-analysis, obstetric anal sphincter injuries, perineal wound dehiscence, perineal wound infection, systematic review, third-degree tears, wound complications

Introduction

Approximately 3 million women will deliver vaginally in the United States.[1] The 1998–2010 Nationwide Inpatient Sample reported an obstetric anal sphincter injury (OASI) incidence in the United States of 4.4%.[2] In addition, a national survey in the United Kingdom between 2009 and 2010 reported an incidence of 2.9%.[3] However, in primiparous women, the incidence of OASI may be as high as 19% in centers where midline episiotomy is performed and 6.1% where mediolateral episiotomy alone is practiced.[4,5] Because of the involvement of the anal

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International Prospective Register of Systematic Reviews registration was completed on February 26, 2021 (CRD 42021239678).

This study has been presented at the 46th annual general meeting of the International Urogynaecology Association, held virtually, December 10, 2021.

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AJOG at a Glance

Why was this study conducted?

A paucity of evidence in the literature surrounding the administration of antibiotics immediately after delivery after primary obstetrical anal sphincter repair means that there is a disparity in management globally. It is important that clinicians appreciate the incidence of wound complications after obstetric anal sphincter injury (OASI) so preventative measures can be considered.

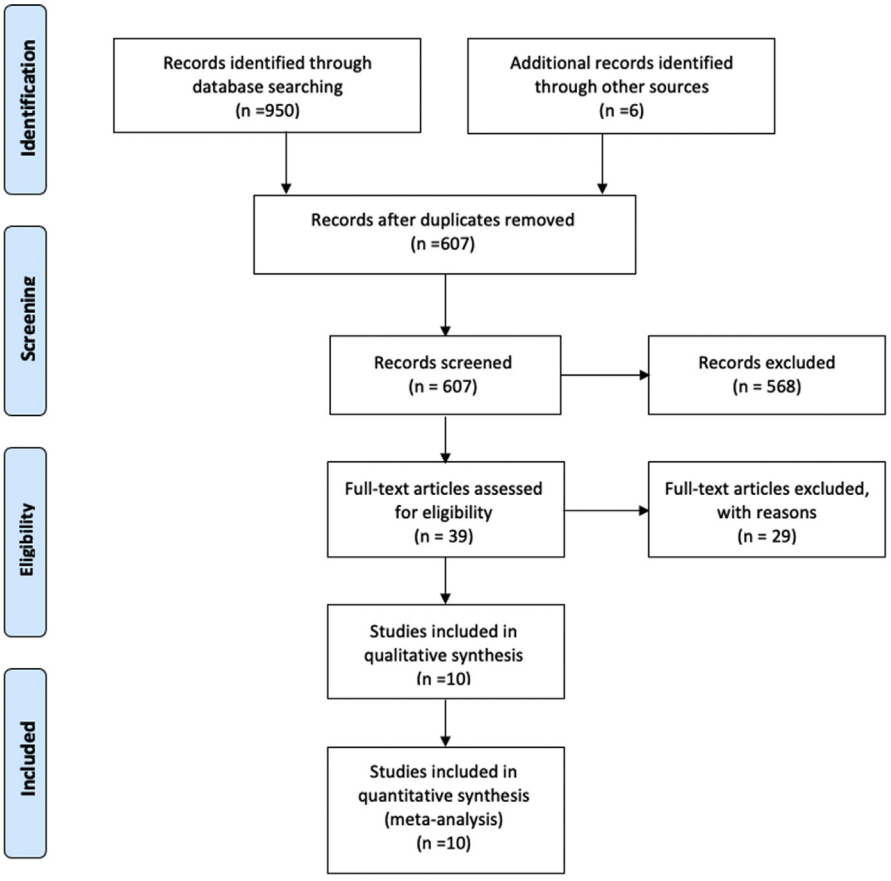
Key findings

The incidences of wound infection and wound dehiscence after primary repair of OASIs were 4% and 7%, respectively. Prediction intervals suggested that their true incidence in future studies could lie between 0.0% to 11.7% and 0.0% to 16.4%, respectively.

What does this add to what is known?

Wound infection and dehiscence occur commonly after primary repair of OASIs. The calculated prediction interval estimates could be used to guide sample size and statistical power calculations for future epidemiologic studies.

FIGURE 1
A PRISMA flow diagram of the study selection process



PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

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sphincter complex and the anatomic location of these tears, which are close to the rectum, organisms from the skin surrounding the perineum and endogenous mucosal surfaces (genitourinary tract and gastrointestinal tract) can contaminate the wound.[6,7] This can result in wound infection and breakdown of the primary OASI repair.[8] Perineal wound infection and dehiscence are associated with peripartum morbidity and prolonged postnatal recovery. This can adversely affect women's quality of life and general well-being because of symptoms, such as pain, dyspareunia, voiding dysfunction, defecatory problems, and body image concerns.[9,10] Moreover, this can negatively affect relationships with the newborn, partner, and relatives.[9–11] Moreover, distress caused by the management of perineal injury and its complications can potentially lead to an increase in the number of women electing for cesarean deliveries in future pregnancies.[12,13]

Because of the risk of wound complications after primary OASI repair, the Royal College of Obstetricians and Gynaecologists (RCOG) recommends prophylactic broad-spectrum antibiotic administration to reduce the risk of these postoperative complications.[14] However, the American College of Obstetricians and Gynecologists (ACOG) does not, because of the lack of high-quality research evidence supporting the postpartum clinical benefit of antibiotic administration.[15] Few studies have identified risk factors for wound complications after primary OASI repair, such as operative vaginal delivery, increasing body mass index, smoking, and fourth-degree tear.[16,17] However, no meta-analysis has been conducted to determine the epidemiologic incidence of wound complications after primary OASI repair. Knowing the true incidence of these complications will encourage clinicians to modify the practice to prevent them and will provide further evidence to support postnatal antibiotic administration after OASI.

Objectives

Given the paucity of evidence, the primary objective of this review was to systematically determine the incidence of wound infection and wound

TABLE 1
Overview of included studies

Author, y	Country	Study design	Sample size (n)	Outcome	Outcome definition	Outcome follow-up	Wound infection incidence (%)	Wound dehiscence incidence (%)
Ajibade et al,[32] 2013	United Kingdom	Study reporting incidence	171	Wound dehiscence	Unclear	Unclear	NA	2.3
Goldaber et al,[30] 1993	United States	Retrospective cohort	390	1. Wound infection 2. Wound dehiscence	1. Presence of purulence and cellulitis at the repair site was usually accompanied by a temperature of 38.0°C. 2. Complete or partial separation of the layers of the repair site. Vaginal mucosal or superficial perineal skin separation was not considered dehiscence.	Unclear	3.6	4.6
Gommesen et al,[25] 2019	Denmark	Prospective cohort	200	1. Wound infection 2. Wound dehiscence	1. Presence of purulent discharge or a wound abscess according to the CDC definition for episiotomy site infection 2. Gap of >0.5 cm between wound edges	11–21 d	3.0	12.5
Groves et al,[29] 2007	United States	Retrospective case-control	62	1. Wound infection 2. Wound dehiscence	Unclear	5 wk	4.8	11.3
Harris et al,[27] 1970	United States	Prospective cohort	870	1. Wound infection	Unclear	6 wk	0.1	NA
Johnson et al,[26] 2012	United Kingdom	Prospective cohort	29	1. Wound infection 2. Wound dehiscence	1. Presence of ≥2 of the following markers: perineal pain, wound dehiscence, and/or purulent vaginal discharge 2. Unclear	21 d	10.3	3.4
Kaltreider et al,[31] 1948	United States	Retrospective cohort	710	1. Wound infection 2. Wound dehiscence	1. Unclear 2. Skin separation to complete breakdown of incision	Unclear	2.5	6.3
Lewicky-Gaupp et al,[17] 2015	United States	Prospective cohort	268	1. Wound infection 2. Wound dehiscence	1. Of note, ≥3 of the following on examination: heat, erythema, edema, or purulent discharge 2. Wound breakdown of at least 1 cm	1 wk	19.8	24.6
Stock et al,[16] 2013	United States	Retrospective cohort	909	1. Wound infection 2. Wound dehiscence	Unclear	Unclear	4.3	1.9
Wan et al,[28] 2020	United Kingdom	Retrospective cohort	1147	1. Wound infection 2. Wound dehiscence	1. Perineal tenderness, erythema, exudate, odor, and edema 2. Gaping of the perineal wound >0.5 cm with or without pyrexia	3 mo	2.7	3.3

CDC, Centers for Disease Control and Prevention; *NA*, not applicable.

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dehiscence after primary OASI repair. Our secondary objective was to determine the prediction intervals associated with wound infection and dehiscence after primary OASI repair, to guide sample size calculations for future studies.

Methods

This systematic review and meta-analysis was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[18] Moreover, the meta-analysis of Observational Studies in Epidemiology guidelines for reporting meta-analyses of observational studies were observed (Appendix 1).[19] The protocol was developed (CRD 42021239678) and registered on February 26, 2021, with the International Prospective Register of Systematic Reviews.[20]

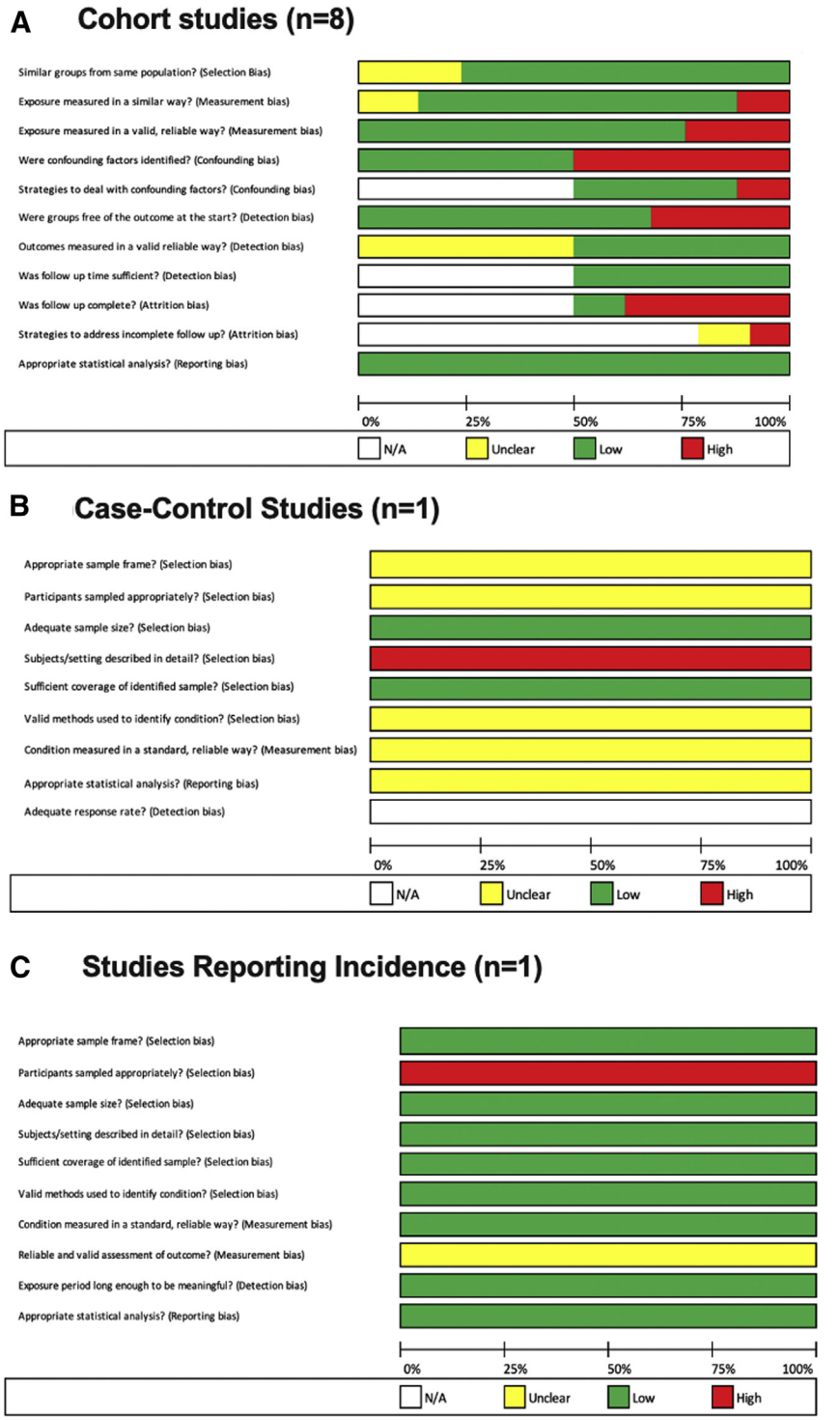
Search strategy and eligibility criteria

Our primary review question was "What is the incidence of wound infection and wound dehiscence after primary repair of OASIs?" Medline, Embase, CINAHL, EmCare, the Cochrane Library, and Trip Pro databases were searched from inception to February 2021 using the terms "wound infection," "wound dehiscence," "wound breakdown," "obstetric anal sphincter injury," "third-degree perineal laceration," "fourth-degree perineal laceration," and "severe perineal trauma," including Medical Subject Headings terms, with no restriction on language or year of publication (Appendix 2). The results were exported to Zotero reference management system and deduplicated. Additional references were manually searched from identified studies to find other relevant studies. There was no restriction placed on the date of publication or language. No funding was required to complete this review. However, the Croydon Childbirth Charitable Trust provided an educational grant for the first author.

Inclusion and exclusion criteria

We included randomized control trials (RCTs) and observational studies reporting the incidence of wound

FIGURE 2
Quality assessment and risk of bias of the studies



A, Cohort studies. **B,** Case-control studies. **C,** Studies reporting incidence.

NA, not available.

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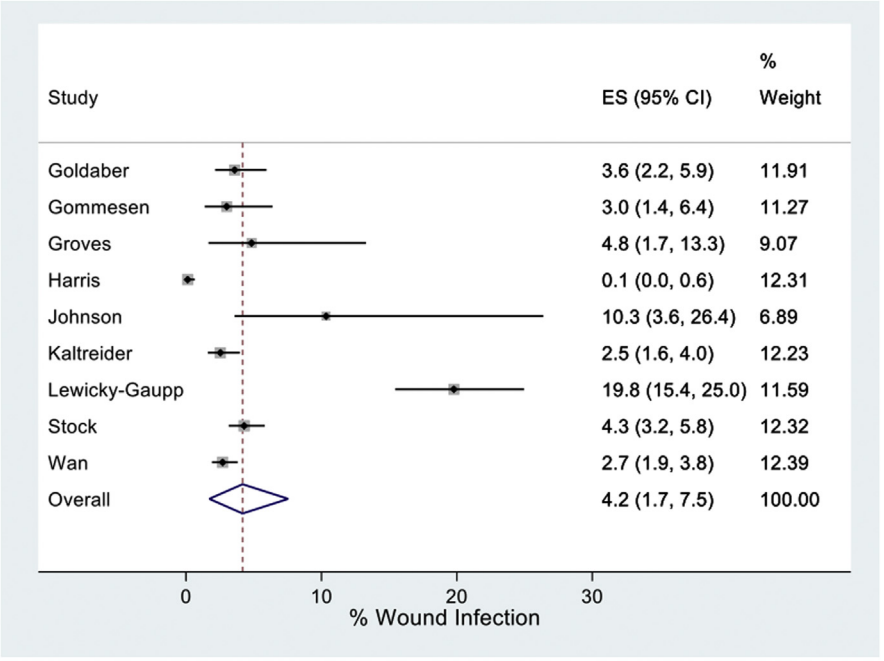
FIGURE 3
The pooled incidence of wound infection following primary OASI repair



Patient group	Number studies	Heterogeneity p-value	Heterogeneity I^2	Pooled Incidence (%) (95% CI)
Wound infection	9	<0.001	95%	4.2% (1.7%, 7.5%)

CI, confidence interval; *OASI*, obstetric anal sphincter injury.

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infection and dehiscence after primary OASI repair. Case series and case reports were excluded. However, conference articles and abstracts were included if they contained enough information regarding study design and outcome data. Of note, 2 independent reviewers (N.A.O. and K.W.W.) screened the titles and abstracts of all retrieved studies to obtain studies for full-text assessment. Any disagreements surrounding eligibility for full-text assessment were resolved by the senior reviewers or through consensus-based discussion. Authors of included studies were contacted if the full text was unobtainable and if the data reported was published in a manner that was unclear or not extractable. To avoid potential intervention bias, RCTs, which were designed to investigate the effect of an intervention on wound complications after primary OASI repair, were excluded. Full-text articles, which met the inclusion criteria, were assessed by the 2 reviewers (N.A.O. and K.W.W.) independently.

Data extraction

Data were collected and managed using a standardized electronic data extraction form on Microsoft Excel. Data extracted included study characteristics (first author, publication year, study design, setting, and sample size), outcome measures (incidence of wound infection or wound dehiscence) and outcome definition. Of note, 2 investigators (N.A.O. and K.W.W.) performed the data extraction to prevent errors. Any disagreements were resolved through consensus.

Risk of bias of included studies

The methodological quality of the selected studies and risk of bias were assessed at an outcome level by the 2 reviewers (N.A.O. and K.W.W.) independently using the relevant tool from the Joanna Briggs Institute (JBI).[24] Any disagreements surrounding eligibility for full-text assessment were resolved by the senior reviewers or through consensus-based discussion. These results were integrated into the data analysis when interpreting and drawing conclusions from the meta-analysis findings.

Data synthesis

Stata (version 15.1; StataCorp, College Station, TX) and Meta-Essentials (version 1.5)[21] were used to analyze the data. For each outcome (wound infection or wound dehiscence), the incidence rates (percentage) with 95% confidence intervals (CIs) were calculated. Moreover, the prediction interval was calculated to provide a predicted range for the potential incidence of wound complications when applied to an individual study setting.[22] Heterogeneity in the effect estimates of the individual studies was calculated using the I^2 statistic. An I^2 of >50% was considered significant heterogeneity. The results were pooled, and a meta-analysis was performed if each outcome was represented in at least 2 studies. The random-effects model (DerSimonian and Laird) was used if heterogeneity was significant (I^2>50%). In addition, Tau2 values were reviewed to assess the effect size variance among studies.[23]

Results

Study selection

Overall, 956 articles were initially identified. After removal of duplicates and screening of study titles and abstracts, 39 articles were selected for full-text review. Of note, 10 studies were eligible and included in the meta-analysis (Figure 1). A full list of excluded studies is provided in Appendix 3.

Study characteristics

Table 1 describes the methodological characteristics of the included studies in further detail and their reported incidence of wound infection and wound dehiscence. The mean sample size was 476 women, and the studies were published between 1970 and 2020. The design of

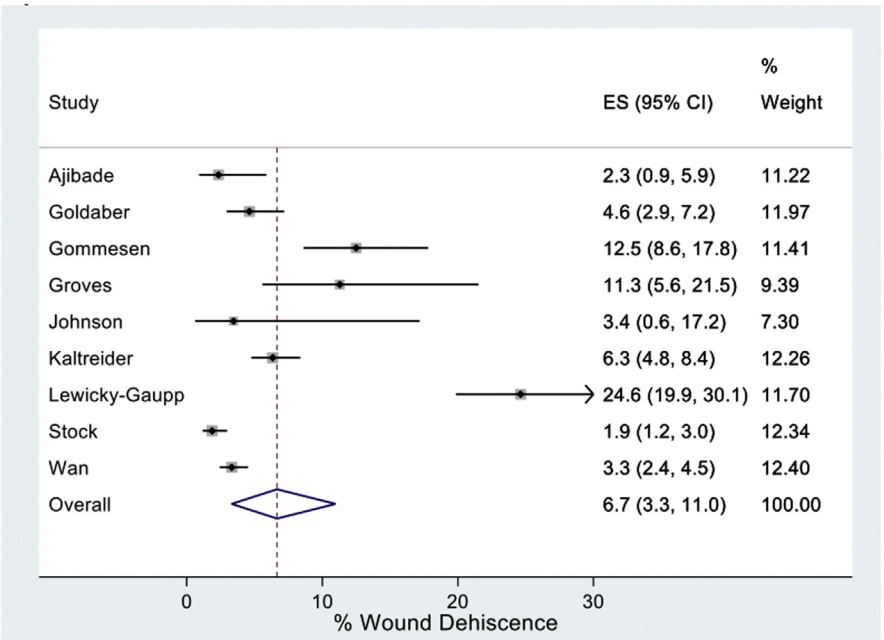
these studies included 4 prospective observational studies,[17,25–27] 5 retrospective observational studies,[16,28–31] and 1 reporting on incidence.[32] Among the included studies, all were conducted in high-income countries, with 1 completed in Denmark,[25] 3 in the United Kingdom,[26,28,32] and 6 in the United States.[16,17,27,29–31]

Risk of bias of included studies

Concerning study quality, 6 studies[16,26,27,29,31,32] were unclear with the reliability and validity of the outcome measurement: wound dehiscence or wound infection (measurement bias). Of the 4 prospective studies,[17,25–27] follow-up time was sufficient (range, 1–6 weeks). However, follow-up was incomplete in 3 studies[26,27,30] and unclear in 1 study[32] (attrition bias). Overall, 8 studies[16,17,25–27,29,32] had a high or unclear risk of bias across ≥1 assessed element. Figure 2 demonstrates the results of the methodological assessment of the included studies using the relevant tool from the JBI. In the cohort studies, a high risk of bias was evident in 7 assessed components (64%). In the case-control study, a high risk of bias was present in 1 assessed component (11%). In the study reporting incidence, a high risk of bias was present in 1 assessed component (10%).

Although each study reported the outcomes of wound infection and dehiscence separately, none of the studies used the same set of clinical parameters to define wound infection or dehiscence. In addition, although the clinical assessment of the signs and symptoms of infection was used in diagnosis, microbiological confirmation with wound swabs was not used as a diagnostic measure. Wound infection was defined in 5 studies[17,25,26,28,30] and wound dehiscence in 4 studies.[17,25,28,30] Johnson et al[26] included wound dehiscence as a marker of wound infection. However, Johnson et al[26] reported the incidence of wound infection in wounds that were intact and those that had dehisced. The definition of wound infection or wound dehiscence was not given in 6 studies.[16,26,27,29,31,32] Concerning the definition of wound infection, the most common clinical sign included was the presence of purulent discharge.[17,25,26,28,30] Wound dehiscence was defined as a separation of the wound edges of ≥0.5 cm in 2 studies[25,28] and ≥1 cm in 1 study.[17] Kaltreider et al[31] referred to dehiscence as either skin separation or complete breakdown of the incision. Goldaber et al[30] defined wound dehiscence as "complete or partial separation of the layers of the repair site." However, the authors did not consider vaginal mucosal or superficial perineal skin separation as dehiscence (Table 1).

FIGURE 4
The pooled incidence of wound dehiscence following primary OASI repair



Patient group	Number studies	Heterogeneity p-value	Heterogeneity I^2	Pooled Incidence (%) (95% CI)
Wound dehiscence	9	<0.001	95%	6.7% (3.3%, 11.0%)

CI, confidence interval; *OASI*, obstetric anal sphincter injury.

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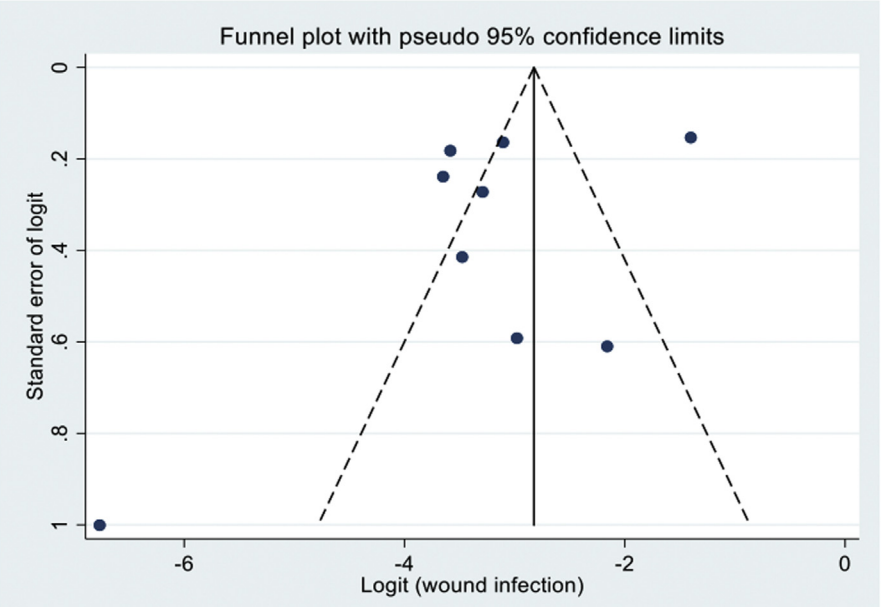
Synthesis of results

Based on the inclusion criteria, 4764 patients from 10 studies were pooled for meta-analysis, with substantial heterogeneity, as measured by I^2 (>80%). The incidence of wound infection and wound dehiscence after primary OASI repair ranged between 0.1% to 19.8% and 1.9% to 24.6% respectively. The incidence of wound infection was pooled from 9 studies (n=4593 patients), and the incidence of wound dehiscence was pooled from 9 studies (n=3886 patients). This meta-analysis showed that the overall incidence rates were 4.2% (95% CI, 1.7–7.5) for wound infection (Figure 3) and 6.7% (95% CI, 3.3–11.0) for wound dehiscence (Figure 4). The prediction intervals were wide and suggested that the true incidence of wound infection and dehiscence in future studies could lie between 0.0% to 11.7% and 0.0% to 16.4%, respectively, with a confidence of 95%. Tau2 was low for both outcomes (<.0001), which may be more appropriate to consider with a random-effects model, as it measures the actual variance among the studies and, unlike I^2, does not systematically increase with the number or size of studies in a meta-analysis.[33]

The presence of publication bias was assessed using the Egger regression analysis. The results suggested some

FIGURE 5
Funnel plot analysis of publication bias



Outcome	Egger test p-values	
	Slope	Bias
Wound infection	0.02	0.31

The outcome assessed was wound infection.

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evidence of bias for the slope measure for both outcomes. This was significant for wound infection and approaching significance for wound dehiscence. However, the bias results were not statistically significant. The graphical illustration of the association between the results and the standard error of the measurements is shown in Figures 5 and 6 for the 2 outcomes. In both plots, the figures are based on the logit of the proportion of patients with each outcome.

Comment

Principal findings

This meta-analysis of 4764 women with a history of OASIs in 9 studies from 3 countries found an overall incidence of wound infection and wound dehiscence after 4 and 7 per 100 primary surgical repairs.

Comparison with existing literature

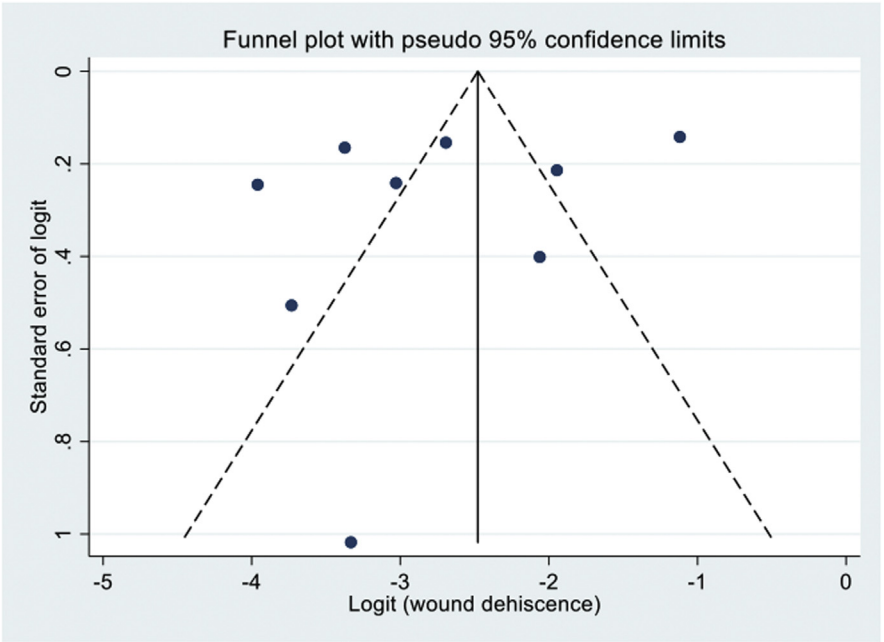
A recently published review of the incidence of wound infection and dehiscence after childbirth-related perineal trauma, irrespective of tear grade, showed that the range of infection and dehiscence ranged between 0.1% to 23.6% and 0.2% to 24.6%, respectively.[37] However, the authors did not perform a meta-analysis and subsequently subgroup analysis based on tear grade because of the high risk of bias and significant study heterogeneity. Despite this, their results were similar to those from our review, where the range of wound infection and wound dehiscence in women with only OASI was 0.1% to 19.8% and 1.9% to 24.6%, respectively. Moreover, the authors highlighted that in their systematic review, there was no standardized outcome measure of wound infection or dehiscence.[37] In addition, we acknowledge that this was the case in our review, as the outcome definitions were often not reported.[16,27,29,32] In the studies where definitions were provided, the combination of clinical signs to define wound infection varied, including pain, erythema, edema, and purulent discharge,[17,25–28] or the definition of wound dehiscence varied: >0.5 cm or >1 cm separation, complete separation, or partial separation.[17,25,28,30,31] This use of varied outcome definitions may result in an overestimation or underestimation of wound infection or wound dehiscence incidence by the individual included studies. However, it is important to note that, overall, each study aimed to measure the same outcome measure separately (wound infection or wound dehiscence); therefore, our average incidence of wound complications after primary OASI repair remains useful. This average estimate could be used to guide sample size and statistical power calculations for future epidemiologic studies in similar settings. Prediction intervals must be reported in meta-analyses as they guide clinical decision-making by demonstrating what the expected true treatment effects would be in a future setting and patients. This means that outliers to this interval can be highlighted and addressed. In the presence of heterogeneity, prediction intervals are always wider than 95% CIs.[38] Therefore, it was unsurprising that the prediction intervals in our study were wide.

Wound infection and dehiscence in the context of OASIs can result in complications, such as anal incontinence and fistula formation.[8] Prophylactic antibiotics at the time of primary OASI repair have been shown to reduce perineal wound complications 2 weeks after delivery.[34,35] However, no RCT has been performed to investigate the benefits of postoperative antibiotics after repair. Although the RCOG recommends the use of prophylactic antibiotics after OASI repair based on expert opinion,[14] the ACOG does not, because of the lack of research evidence.[15] Therefore, an RCT is needed to evaluate the true effect of postoperative antibiotics on wound outcomes after primary OASI repair. There are inconsistencies among the studies currently available in the literature concerning antibiotic administration after primary OASI repair. The rate of antibiotic administration was reported in 3 studies.[16,17,25] At the time of surgical repair, the rate of antibiotic administration ranged between 0%[16] and 18%.[17] Although postoperative

antibiotics were given in 16%.[17] The Antibiotics for Severe Perineal Laceration to Prevent Infection Following Repair RCT (identifier: NCT04573504) is currently being undertaken in the United States to investigate the use of postoperative broad-spectrum antibiotics (co-amoxiclav and metronidazole or co-amoxiclav and clindamycin) and wound complications after primary OASI repair. They are estimated to enroll 274 participants.[36]

Perineal wound infection and dehiscence can have a significant physical, psychosocial, and sexual effect on women.[10] In addition, in the context of a primary OASI repair, complications because of infection or wound breakdown, such as anal incontinence and fistulae, can be devastating for women, causing them embarrassment, feeling socially isolated, breakdown in relationships, and reduced employment opportunities.[39–41] Therefore, because of these potential clinical implications, it is important that a standardized definition of wound infection and dehiscence is designed and validated to allow accurate comparisons to be drawn among different studies.

FIGURE 6
Funnel plot analysis of publication bias



Outcome	Egger test p-values	
	Slope	Bias
Wound dehiscence	0.06	0.41

The outcome assessed was wound dehiscence.

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Strengths and limitations

The main strength of our study was that this was a meta-analysis reporting the incidence of wound complications after primary OASI repair. In addition, the search was extensive, across several databases with no restriction on language or date of publication.

This study did have some limitations. First, the included studies were from 3 high-income countries alone. This means that our results may not reflect the true global incidence of wound complications after primary OASI repair. The incidence of peripartum infections, such as chorioamnionitis, endometritis, wound infection (perineal and cesarean delivery), and sepsis, has been shown to be higher in low- and middle-income countries (including Tanzania, Nigeria, Egypt, Bangladesh, India, Pakistan, Argentina, Guatemala, Kenya and Zambia) than in high-income countries (including North America, Europe, Japan, and Thailand).[42] For example, the overall incidence rates of maternal peripartum infection are 1.9% (95% CI, 0.9–3.2) in North America and Europe, 3.8% (95% CI, 2.2–5.8) in Central Asia and Southern Asia, and 2.4% (95% CI, 2.3–2.5) in Latin America and the Caribbean. Other limitations included the significant heterogeneity among the studies as measured by I^2, although this was controlled by using a random-effects model when pooling data for meta-analysis. Sensitivity analyses to assess for methodological heterogeneity by removing high or critical bias studies were not performed, as 8 of 10 included studies had a high or unclear risk of bias. We acknowledge that some may argue that estimates should not be pooled together in the meta-analysis when there is significant heterogeneity. However, it has been described that the decision to pool studies should not be based on I^2 alone, as it is not useful in evaluating clinically relevant heterogeneity.[33] Tau2 has been described to be a more appropriate estimate of the absolute between-study variance when a random-effects model is used and is a direct measure of study variability, as it is measured on the same scale as the outcome.[23,33] In our meta-analysis, the Tau2 values were small for both outcome measures (<.0001). However, the quality of most studies was poor, with potential measurement bias present in 6 studies (60%),[16,26,27,29,31,32] because the outcome measures, wound infection and dehiscence, were not clearly defined. It is important to note that 2 of these studies were dated 50 years ago.[27,31] In addition, there was potential attrition bias in 4 studies (40%),[25,26,31,32] as follow-up was either incomplete or unclear if complete.

Conclusions and implications

This study was a systematic review and meta-analysis of wound infection and dehiscence incidence after primary OASI repair. The incidence estimates

from this review could be used as a guide by clinicians when counseling women with OASIs and when consenting them for primary surgical repair. However, this study has highlighted that standardized criteria are required to define perineal wound infection and dehiscence to improve the reporting of these complications in future studies. Moreover, further studies are required to evaluate the risk of these complications in different healthcare settings, including low- and middle-income countries. ■

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