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Title

The incidence of wound infection and dehiscence following childbirth-related perineal trauma: A systematic review of the evidence

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Abstract

Objectives

Approximately 85% of vaginal births are affected by childbirth related perineal trauma, either spontaneously or as a result of an episiotomy. Perineal infection in the postnatal period is associated with wound dehiscence, granulation tissue formation, dyspareunia and pelvic floor dysfunction. Despite leading to long-term physical and psychological problems, the incidence of infection continues to remain unclear. This review is designed to determine the incidence of childbirth related perineal wound infection and dehiscence.

Study design

A systematic review to determine the incidence of wound infection and dehiscence associated with childbirth-related perineal trauma. Medline, Embase and Cinahl databases were searched from inception to September 2018 using MeSH, textwords and appropriate word variants to ensure capturing all relevant studies. No restrictions were placed on birth mode, degree of trauma, parity, country or language.

Results

23 studies were included (11 cohort, 2 case control and 10 reporting incidence). Reported incidence of childbirth-related perineal trauma wound infection ranged from 0.1% - 23.6% and wound dehiscence from 0.21% - 24.6%. Quality assessment of included studies exposed inadequacies in several methodological areas. There was great clinical heterogeneity amongst the studies, particularly regarding perineal wound infection definition and confirmation, making effective synthesis of the data almost impossible.

Conclusion

Despite the known high occurrence of perineal trauma during childbirth and associated long-term morbidities, this review clearly demonstrates the true incidence of infection remains largely unknown. This can be attributed to multiple factors including lack of high level evidence around understanding ‘normal’ perineal wound healing, absence of a core outcome set for childbirth-related perineal trauma and that women present to a variety of healthcare settings for treatment. It is vital that a validated childbirth-related perineal trauma diagnostic tool and core outcome set are developed for use in future studies to facilitate improved diagnosis and treatment and reduce long term morbidities of women affected by childbirth-related perineal trauma wound infection and dehiscence.

Key words

Childbirth related perineal trauma ; Wound infection ; Wound dehiscence ; Incidence ; Systematic review

Introduction

Every year up to 85% of women who give birth vaginally in the UK will experience trauma to the perineum (1). Childbirth-related perineal trauma (CRPT) is defined as an injury to the perineal skin, muscles or, in more severe cases, the anal sphincter complex and anal epithelium. Injury occurs as a result of spontaneous tearing or episiotomy (surgical incision to the perineum) during a vaginal birth (2).

Consequences of CRPT include dyspareunia, urinary and faecal incontinence, granulomas and pain all of which may become long-term problems (3). For some women postnatal recovery is delayed by perineal infection and/or wound dehiscence (4, 5). Morbidity associated with CRPT wound infection and dehiscence elicits highly upsetting and emotional responses from mothers, negatively affecting their physical, psychological and sexual recovery (6).

Postnatal perineal infection and wound dehiscence also have repercussions for the NHS at a wider financial and service-provision level. Women with infection or dehiscence will, in many cases, require treatment such as antibiotics, more effective analgesia or readmission to hospital. In severe cases it may be necessary to return to theatre for debridement and re-suturing or at a later date for perineal revision. The risk of needing additional surgery following perineal wound dehiscence may be as high as 13.2% (7). These additional treatments incur extra costs, apply further pressure on an already stretched service and do little to reduce the use of antibiotics.

Despite the known morbidities, the number of women affected by CRPT infection is difficult to determine. The incidence of postnatal perineal infection has been reported as anything between 0.8% to 11% in western healthcare settings and up to 23% in low and middle income countries (4, 5, 8, 9). Currently, there is no core outcome set for CRPT or an agreed definition of a clinically relevant infection of the perineum in the postnatal period. This, combined with the potential for researchers to only use the data of women who present to hospital for treatment may impact on the ability to determine a clear incidence of infection and dehiscence(10, 11). Given the known negative health implications for women with CRPT wound infection it is imperative that the extent of the issue is accurately assessed in order to support and guide much needed research into CRPT wound infection prevention and treatment.

This review aimed to systematically assess the current available evidence to determine the incidence of wound dehiscence or infection associated with CRPT.

Materials and Methods

A protocol using recommended methods for the structuring of systematic reviews was developed and registered with PROSPERO (12). The PRISMA statement and check-list were followed throughout review preparation (13).

Medline, CINAHL, EMBASE and Web of Science databases were searched from inception through to May 2019 and search strategies adapted for each. The search of the databases used MESH terms *childbirth* *perineum injury* *anus injury* *episiotomy* *puerperal infection* *wound infection *wound breakdown* and *wound dehiscence* (Appendix 1 and 2). No restrictions were placed on language, country of origin, date of publication, participants, degree of postnatal trauma, mode of delivery, settings and design of study, other than the exclusion of case series and reports. Exclusions were made after reviewing the abstracts if the full text was unobtainable or if it was not possible to acquire a suitable English language translation. Two, independent reviewers (KJ and MM) studied the included full text papers and assessed them for eligibility according to the pre-defined inclusion/exclusion criteria. Questions of suitability for inclusion were referred to a third reviewer for resolution (SW). If any clarification was required about the content of a paper then efforts were made to contact the corresponding author. Studies were included if they stated a measure of the incidence of postnatal perineal infection, wound dehiscence or wound breakdown. Studies were excluded if they only reported data from women in experimental studies of an intervention designed to reduce perineal infection and/or breakdown/dehiscence, either with or without a randomisation element, to avoid intervention bias.

For definition of the outcome, all outcomes reported by the authors were included. It was decided *a priori* to exclude studies that used pain in isolation as the only indicator of infection or REEDA as tools to measure infection as an outcome (14). The REEDA (Redness, oEdema, Ecchymosis, Discharge and Approximation) wound assessment scoring tool uses five components to evaluate postpartum healing of the perineum following an episiotomy. REEDA was not designed as a tool to diagnose infection, only to assess healing, and pain as a lone outcome was deemed insufficient to diagnose infection for the purpose of this review.

Data were extracted by three independent reviewers using a pre-designed data extraction form (KJ, MM and SD). Any discrepancies or queries raised during data extraction were resolved by a fourth person (SW). Data was extracted on general study information (year of publication, study setting), demographic characteristics of the population being studied, methodological details and outcome measures (incidence of infection or dehiscence). Extracted data were entered into a database and a comprehensive table of study characteristics constructed.

Quality assessment of non-randomised studies (NRS) (cohort studies, case control and studies reporting incidence) was undertaken using the appropriate tool from The Joanna Briggs Institute. (15). Quality assessment was then used to assess the methodological adequacies of the included studies and assist with interpretation of meta-analysis findings and possible bias resultant from study heterogeneity.

Data were extracted on the number of study participants and the number of perineal wound infection or dehiscence cases for each included study, presented as a percentage figure and, where appropriate, with 95% confidence intervals (CI). Visual inspection of data was planned in Forest plots of the studies with similar characteristics and outcome. A meta-analysis was planned including studies with similar populations and outcome measures. I^2 was used as the statistical measure of heterogeneity (16). Values below 25% were considered low, around 50% moderate, and above 75% high (17). Potential sub-group analyses were planned for mode of vaginal birth, degree of classification of CRPT, suture repair methods and suture type used and healthcare setting and country if the data allowed. (12)

Results

23 Non-Randomised Studies (NRS) from seven countries were included (10 Cohort, 2 Case Control and 11 papers reporting on incidence). (Fig. 1) (Table 1) (Appendix 3)

All articles were published in English, ranging in year of publication from 1965 to 2018, with 65% of the papers published after 2000. Three of the studies were from Low/Middle Income Countries. Sample populations varied across the studies to include nulliparous and multiparous women, women giving birth spontaneously and women having an operative vaginal delivery, women with episiotomies and women with spontaneous perineal trauma of all classifications. The majority of studies collected data retrospectively with only six studies reporting a prospective approach and most frequently wound infection or wound dehiscence were identified as a primary outcome.

There was no identifiable, uniform set of outcome measures used across the included studies and no two studies used exactly the same outcome set. Outcomes included heat, erythema, oedema and purulent discharge (18), cellulitis at the wound site (9) and in 8 studies there was no clear explanation given of how infection was diagnosed. Many of the included studies used dehiscence as an interchangeable outcome with infection to demonstrate the extent and degree of perineal healing problems. Each of the studies measured outcomes at different postnatal time points ranging from day

1 (19) to 7 years postpartum (20), and in 10 studies the time point at which measurement of infection were made was not reported.

The included papers were generally poor in both reporting and methodological quality. None used a valid, reliable tool for assessing clinical outcomes, attrition was poor in many cases and 15 of the studies used insufficient or inappropriate statistical analysis to present their findings. No studies were excluded from the systematic review for failure to fulfil the quality criteria. (Fig. 2)

Overall incidence rates from the included studies ranged from 0.1% to 23.6% (4, 5, 9, 11, 18-31) for wound infection and 0.21% to 24.6% (4, 5, 7, 9, 11, 18, 22, 28, 29, 32-35) for wound dehiscence. (Table 2)

In relation to the planned meta-analyses, only five studies demonstrated sufficient similarities of design, setting and population making them potentially suitable (4, 21, 27, 32, 33). Of these, three reported incidence of CRPT wound infection (4, 21, 27) and two reported incidence of CRPT wound dehiscence (32, 33). Four of the studies displayed high or unclear levels of bias across all assessed elements (21, 27, 32, 33), with lack of detail about the study population, absence of a valid and reliable tool to measure outcomes and minimal statistical analysis of results.

Further analysis of these five studies revealed a marked clinical heterogeneity between them. None of the studies used the same outcome set for a definitive diagnosis of infection or of clinically significant wound dehiscence. Three of the papers did not provide adequate detail about participant demographics to allow for a reliable assessment of the level of clinical heterogeneity amongst study populations (21, 27, 32). Consequently, in view of the high level of bias and significant heterogeneity meta-analysis was deemed inappropriate (36) and the planned sub group analyses were not possible thus a narrative account of the data extracted and table of individual results is presented (37). Forest plots are not drawn and data is displayed in tabular form only. (Table 2) A sensitivity analysis by date of publication (pre 2000 vs post 2000) and retrospective vs prospective demonstrated no effect on infection or dehiscence rates. Only 5 papers reported suture type use in repair and this subgroup analysis was not possible.

There were 19 interventional studies that were excluded due to their experimental design (RCT, quasi-experimental). Of these, 9 had sufficient data to calculate the incidence of infection and dehiscence

with a range of 0%-17% and 0.05%-37.5% respectively. Thus these results were similar to those from the observational studies without intervention.

Comment

This systematic review summarises the available evidence regarding the incidence of CRPT wound infection and dehiscence. This is based on data from 23 NRS, across 7 countries, predominantly with methodological inadequacies.

The incidence varied from 0.1% (24) to 23.6% (5) for infection and 0.21% (7) to 24.6% (18) for dehiscence and demonstrated little consistency or similarity between the studies, with respect to population, setting or timing. Despite the comprehensive nature of this systematic review it is not possible to give a clear and definitive estimate of the incidence of CRPT wound infection and wound dehiscence.

The strengths of our review come from its robust methodological design, its transparent and rigorous search of the literature and its number of included studies. At the time of writing we are unaware of any other systematic reviews investigating the incidence of CRPT wound infection and dehiscence.

The potential limitations of this review lie predominantly with the high levels of clinical heterogeneity and high risk of bias amongst included studies. There was wide variation in wound infection diagnosis, management, recording and reporting, meaning further data meta-analyses were not possible. Critics may argue that this raises questions over the validity of our presented findings. By excluding all studies that had a potential for intervention bias there is a risk that some relevant data may have been lost. However, this is outweighed by the potential risk posed from selection and intervention bias, were they included. A further limitation of this systematic review may be from the date of publication and setting (country) of some of the included studies. Three of the included papers were written over 40 years ago and medical and technological advancements may mean the results are now of little value (23, 24, 26). Two papers were centred in Nigeria and that may limit applicability of their findings when viewed in the context of the Western world (5, 34); in view of the limited number of papers that met the inclusion criteria and the general clinical heterogeneity across the included studies we felt it was acceptable to include these studies. Ideally sub-group analysis of other potentially relevant factors would have been performed as discussed in our methods and protocol.

This would have helped identify groups at greater risk of infection or dehiscence. Unfortunately the poor quality and heterogeneity of the included studies meant this was not possible.

Our systematic review highlights the lack of standardised outcome reporting in observational studies of CRPT infection. A systematic review of RCTs in CRPT research by Pergialiotis et al (2018), which was not restricted to infection as an outcome had similar findings, highlighting the heterogeneous nature of outcome reporting in this area which is suggestive of high levels of reporting bias amongst studies in this area (38).

This systematic review has identified a wide range for the incidence of CRPT infection and a varied set of outcomes (including stitches breaking down and wound dehiscence, purulent discharge, pain or a 'positive swab') used as a diagnostic measure, (4, 27, 33). This current lack of an agreed definition of clinically relevant infection and a core outcome set for CRPT presents a significant challenge when attempting to measure the incidence of CRPT wound infection and poses a challenge in estimating the incidence of outcomes e.g. in control group for an intervention study. Also, CRPT infection is often reported as a secondary outcome or in the broader context of puerperal infection or genital tract sepsis, thus making it difficult to extract clear and quantifiable data. Consequently there is a clear and urgent need for a core outcome set for CRPT to be designed, defined and rigorously tested.

The difficulty in identifying an accurate figure for incidence of CRPT wound infection and/or dehiscence is also partly explained by the fact that women will present to a variety of primary and secondary health care facilities to receive assessment and treatment (4), making it almost impossible to accurately capture the total number of women seeking treatment. There is scope for future research to develop a more sophisticated and cohesive pathway for women with suspected or confirmed CRPT wound infection or dehiscence, facilitating a more accurate account of the incidence of infection, with the potential to be rolled out as a national service improvement measure. This would enable NHS Trusts to monitor their performance in relation to CRPT infection prevention and treatment and ensure a high level of care is provided to all women, irrespective of where they initially present for assessment.

This systematic review has also identified a noticeable lack of Patient Reported Outcomes (PRO) and Patient Reported Outcome Measures (PROM) within the included studies. For a clinical condition that has been described as potentially so debilitating as to reduce a woman's ability to enjoy motherhood, the lack of public and patient involvement in CRPT research is concerning (4) . Consequently, any future CRPT clinical trial/study must include an element of PRO's (39) .

Conclusion

This systematic review highlights the current gap in our understanding about the size and consequently the potential impact of CRPT wound infection for women. This is in part due to the current lack of a core outcome set, validated CRPT wound infection diagnostic tool and an agreed definition of clinically relevant infection. The true incidence and ultimately the impact of wound infection and dehiscence associated with childbirth related perineal trauma remains largely unknown and quite probably underestimated. It is vital that a validated CRPT diagnostic tool and core outcome set are developed for use in future studies to facilitate improved diagnosis and treatment and to reduce the long term morbidities of women affected by CRPT wound infection and dehiscence.

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Figure 1

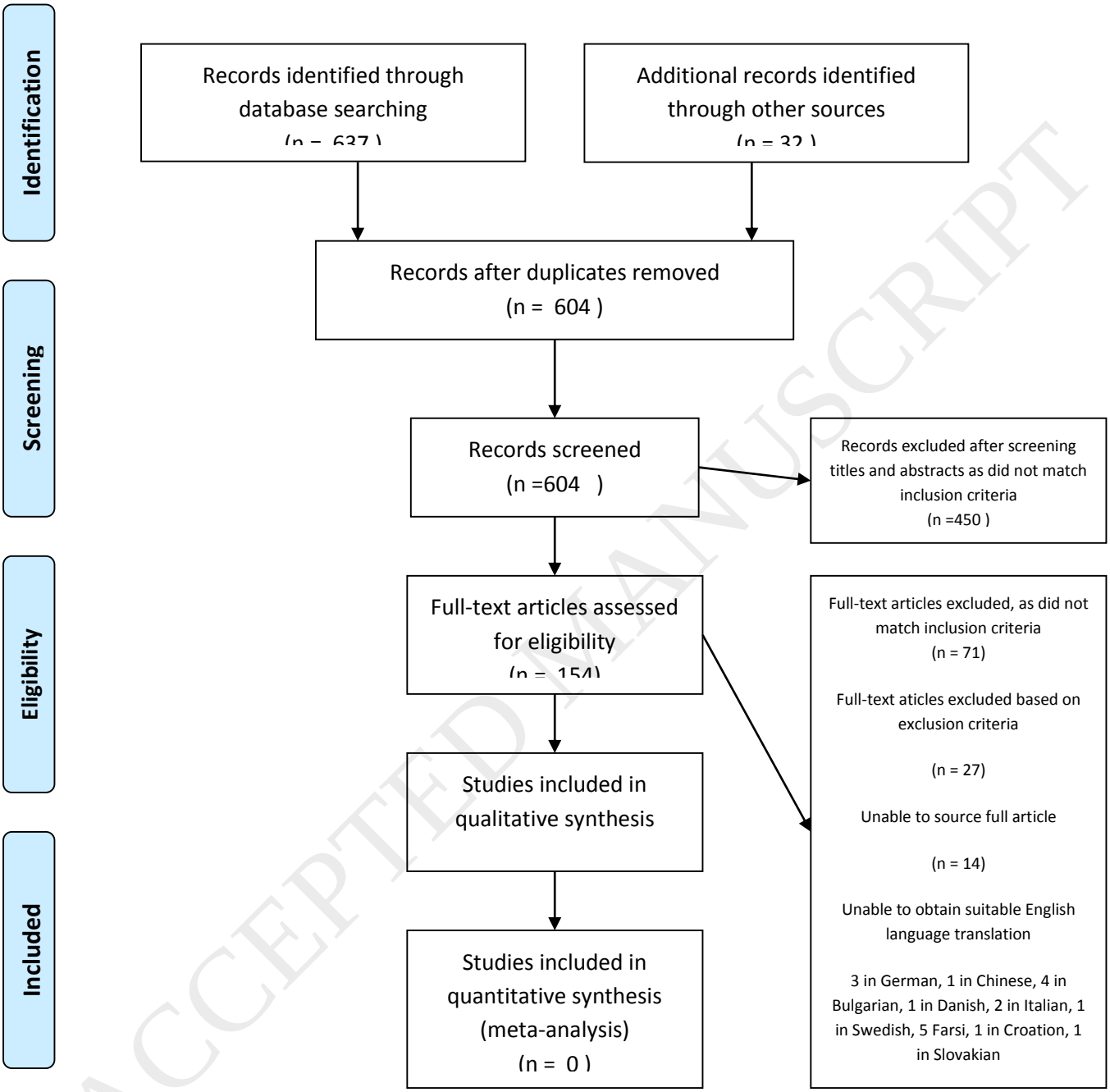
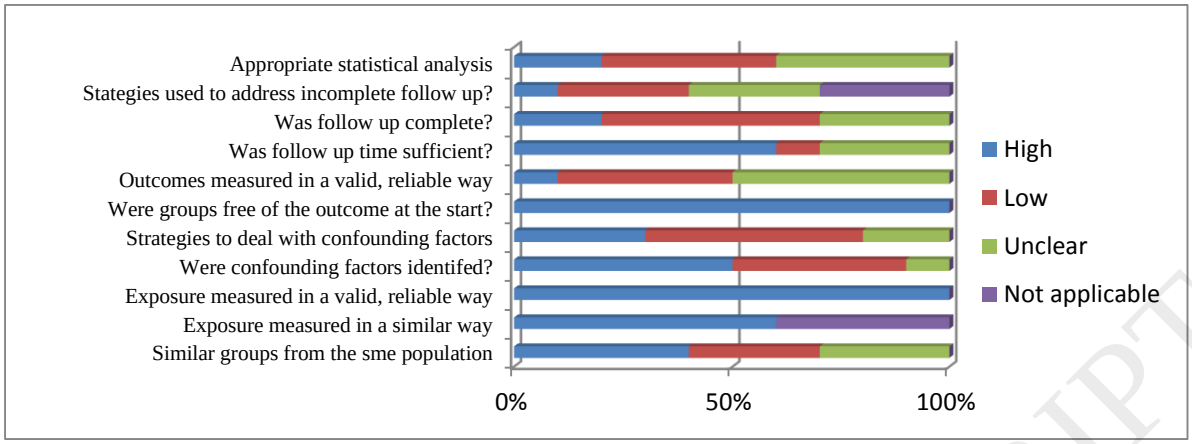
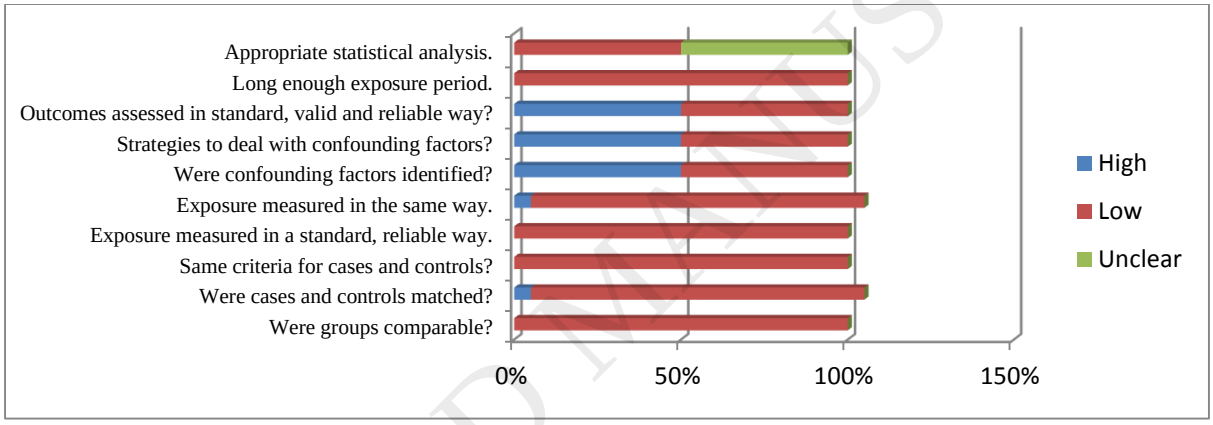


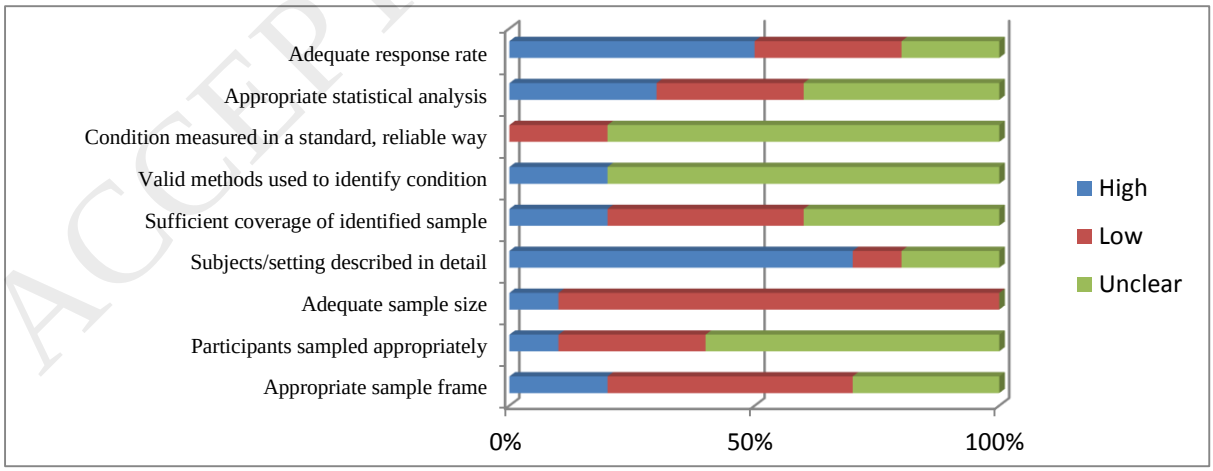
Figure 2



a) Studies reporting incidence



b) Cohort studies



c) Case control studies

Table 1

Author, date, country, language	Study design, method and population	Study objectives relevant to CRPT wound infection and/or dehiscence	Outcome	Outcome definition[b]	Method of obtaining outcome
Ajibade, 2013, UK, English	Study reporting incidence. All degrees of CRPT[a] included. Women giving birth at Royal Berkshire Hospital, UK	Problems relating to perineal repair	Wound dehiscence	Unclear	Medical notes review, healthcare professional reported
Allen, 2006, Canada, English	Cohort study. Degree of included CRPT unreported. Data of women recorded by the Nova Scotia Atlee Perineal Network	Maternal morbidity	Wound infection	Unclear	Medical notes review, healthcare professional reported
Calvia, 2016, UK, English	Study reporting incidence. All degrees of CRPT included. Women giving birth at Luton and Dunstable NHS Trust	Infection of perineal wounds, wound healing	Wound infection	Unclear	Telephone call, patient reported
Clement, 1999, UK, English	Cohort study. First and second degree spontaneous trauma and episiotomy included. Women who had given birth under the care of one midwifery team in South East London	Long term perineal health of women with unsutured perineal trauma	Wound infection	Unclear	Postal questionnaire, patient reported
Edwards, 1978, USA, English	Case control study. Degree of included CRPT unreported. Women giving birth at St Paul-Ramsey Hospital, Minnesota, USA	Wound or episiotomy infection	Wound infection	Unclear	Unreported
Fodstad, 2014, Norway,	Cohort study. Episiotomy only	Puerperal wound infection	Wound infection	Unclear	Postal questionnaire, patient

English	included. Women giving birth at Oslo Hospital, Norway				reported
Glazener, 1995, UK, English	Study reporting incidence. Degree of included CRPT unreported. Women giving birth in 4 settings in Aberdeen, UK	Maternal morbidity	Wound dehiscence	Unclear	Postal questionnaire, patient reported
Goldaber, 1992, USA, English	Cohort study. 4th degree tear only included. Women giving birth at Parkland Memorial Hospital, Texas, USA	Postpartum perineal complications including dehiscence	Wound infection and wound dehiscence	Unclear	Medical notes review, healthcare professional reported
Harris, 1970, USA, English	Cohort study. Obstetric anal sphincter injury (OASI) only included. Women giving birth at the Malcolm Grow Clinical Center, USAF Hospital, Andrews AFB, USA	Complications of the episiotomy	Wound infection	Unclear	Outpatient clinic, healthcare professional reported
Jallad, 2016, USA, English	Case control study. All degrees of CRPT included. Women giving birth at 3 tertiary care centres in Cleveland, Ohio, USA	Perineal wound breakdown	Wound dehiscence	Unclear	Notes review, healthcare professional reported
Johnson, 2012, UK, English	Study reporting incidence. All degrees of CRPT included. Women giving birth at Croydon Hospital, London, UK	Incidence and risk factors for perineal wound infection	Wound infection and wound dehiscence	Two of the following : pain, wound dehiscence, purulent vaginal discharge	Telephone call, patient and healthcare professional reported
Lam, 2006, Hong Kong, English	Cohort study. All degrees of CRPT included. Women giving birth in the public	Perineal wound infection	Wound infection	Unclear	Medical notes review, healthcare professional reported

	hospitals of Hong Kong				
Lewicky-Gaupp, 2015, USA, English	Cohort study. OASI only included. Women giving birth at Northwestern Medicine's Prentice Women's Hospital, Chicago, USA	Wound complications with OASI	Wound infection and wound dehiscence	Three or more of the following : heat, erythema, oedema, purulent discharge	Outpatient clinic, healthcare professional reported
O'Leary, 1965, USA, English	Cohort study. Episiotomy and OASI only included. Women giving birth at an unreported centre	Unclear	Wound infection	Unclear	Unreported
Otoide, 1999, UK, English	Study reporting incidence. All degrees of CRPT included. Women giving birth at the University of Benin Teaching Hospital, Benin City, Nigeria	Post-episiotomy complications	Wound dehiscence	Unclear	Medical notes review, healthcare professional reported
Ridley, 2015, UK, English	Study reporting incidence. All degrees of CRPT included. Women giving birth in a consultant led unit and a free standing midwifery-led unit in Lancashire, UK	Perineal wound infections	Wound infection	Positive swab within 28 days of giving birth	Swab result, healthcare professional reported
Stock L, 2013, USA, English	Study reporting incidence. OASI only included. Women giving birth at Prentice Women's Hospital, Chicago, USA	Perineal wound complications in OASI	Wound infection	Unclear	Medical notes review, healthcare professional reported
Stock SJ, 2013, UK, English	Study reporting incidence. Episiotomy and OASI only	Early maternal complications	Wound infection and wound dehiscence as a	Unclear	Medical notes review, healthcare professional reported

	included. Women giving birth at the Simpson Centre for Reproductive Health, Scotland, UK		combined outcome		
Sule, 2003, Nigeria, English	Cohort study. Episiotomy only included. Women giving birth at the Ahmadu Bello University Teaching Hospital, Zaria, Nigeria	Episiotomies and their puerperal complications	Wound infection and wound dehiscence	Wound discharge with or without tenderness	Outpatient clinic, healthcare professional reported
Wilkie, 2018, USA, English	Cohort study. Degree of included CRPT unreported. Women giving birth at an unnamed centre	Poor perineal outcome	Wound dehiscence	Unclear	Unreported
Wiseman, 2018, UK, English	Prospective, observational cohort study. Second degree tear only included. Women giving birth in an urban tertiary National health Service hospital in the South of England, UK	Wound infection/breakdown associated with spontaneous second degree tears	Wound infection and wound dehiscence	Inclusion criteria adapted from Public Health England's Surgical Site Infection Surveillance Survey (multiple combination factors of spontaneous dehiscence, antibiotic prescription, positive swab, offensive discharge/smell, pain/redness/swelling/heat)	Medical notes review, healthcare professional reported
Yokoe, 2001, USA, English	Study reporting incidence. Episiotomy only included. Women giving birth at Brigham Women's Hospital, Boston, USA	Postpartum infections	Wound infection	Unclear	Medical notes review, healthcare professional reported
Zhang, 2017, China, English	Study reporting incidence. Episiotomy only included. Women giving birth at an unnamed centre	Postoperative infection in episiotomy	Wound infection	Incision secretions	Unreported

Table 2

Author	Date	Country	Outcome	Time point	No. of participants	No. of cases	%
Allen	2006	Canada	Infection	Unclear	24,609	188	0.76%
Calvia	2016	UK	Infection	Up to 28 days	36	5	14%
Clement	1999	UK	Infection	Unclear	106	2	2%
Edwards	1978	USA	Infection	Unclear	416	10	2.40%
Fodstad	2014	Norway	Infection	Unclear	179	17	9.40%
Goldaber	1992	USA	Infection	Unclear	390	14	3.58%
Harris	1970	USA	Infection	Unclear	870	1	0.10%
Johnson	2012	UK	Infection	Up to 21 days	341	39	11%
Lam	2006	Hong Kong	Infection	Unclear	6167	13	0.20%
Lewicky-Gaupp	2015	USA	Infection	Day 7	268	53	19.77%
O'Leary	1965	USA	Infection	Unclear	1224	9	0.73%
Ridley	2015	UK	Infection	Within 28 days	262	31	11.83%
Stock L	2013	USA	Infection	Unclear	909	39	4.20%
Sule	2003	Nigeria	Infection	Day 7	76	18	23.68%
Wiseman	2018	UK	Infection	Unclear	828	14	1.7%
Yokoe	2001	USA	Infection	Unclear	2301	7	0.30%
Zhang	2017	China	Infection	Unclear	1200	30	2.50%
Ajibade	2013	UK	Dehiscence	Unclear	3218	19	0.59%
Glazener	1995	UK	Dehiscence	0 - 13 days	1068	18	1.68%
Goldaber	1992	USA	Dehiscence	Unclear	390	18	4.61%
Jallad	2016	USA	Dehiscence	Unclear	68,839	144	0.21%
Johnson	2012	UK	Dehiscence	Up to 21 days	341	35	10%
Lewicky-Gaupp	2015	USA	Dehiscence	Unclear	268	66	24.60%
Otoide	1999	Nigeria	Dehiscence	Unclear	627	36	5.70%
Stock L	2013	USA	Dehiscence	Unclear	909	36	3.96%
Sule	2003	Nigeria	Dehiscence	Day 7	76	11	14.40%
Wilkie	2018	USA	Dehiscence	Unclear	334	7	2.10%
Wiseman	2018	UK	Dehiscence	Unclear	828	2	0.24%
Stock SJ	2013	UK	Combined[a]	Unclear	848	12	1.40%