


BMJ Open Spontaneous bladder rupture and associated factors during pregnancy: a systematic review and metanalysis protocol

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ABSTRACT

Introduction Spontaneous bladder rupture during pregnancy is a potentially life-threatening event requiring immediate surgery to reduce morbidity and mortality. This systematic review aims to identify associated factors of spontaneous bladder rupture during pregnancy and propose a diagnostic and therapeutic algorithm.

Methods and analysis To improve the reporting of this protocol, the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 statement was used. The primary objective is to identify and summarise the associated factors with spontaneous bladder rupture during pregnancy. The secondary outcome was to determine the diagnostic and treatment approach. From inception to June 2022, a systematic search of the following electronic databases of peer-reviewed journal articles and online search records will be conducted: the Cochrane Central Register, PubMed, Medline (Via PubMed), Embase (Via Ovid), ProQuest, Scopus, WOS and search engine Google Scholar. All types of studies focusing on spontaneous bladder rupture during pregnancy will be included. Two authors will review the studies based on inclusion and exclusion criteria. Three authors will independently extract data using a researcher-created checklist. In the event of a disagreement, an external reviewer will be used. The Newcastle-Ottawa Scale checklist will be used by two authors to assess the quality of the studies independently. Data analysis will be carried out using STATA V.16.

Ethics and dissemination Ethical approval is not required, as our review will include published and publicly accessible data. Findings from this review will be disseminated via publication in a peer-review journal.

PROSPERO registration number The protocol for this review was submitted at PROSPERO on 20 March 2022 with ID number CRD42022319511.

INTRODUCTION

Spontaneous bladder rupture during pregnancy, childbirth and postpartum is a potentially life-threatening event requiring immediate surgery to reduce morbidity and mortality.^{1 2} Although the majority of bladder ruptures have been reported following childbirth,^{3 4} there have been a few cases of bladder rupture during

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Systematic reviews and meta-analyses will provide the most evidence for developing the diagnostic and therapeutic algorithm.
- ⇒ This review will be thorough, using independent dual review at each stage and adhering to best-practice guidelines.
- ⇒ There may only be a few articles in the literature regarding this topic.
- ⇒ Potential publication bias may limit the scope of the review; therefore, databases will be searched for unpublished studies such as thesis dissertations and conference proceedings to reduce the risk of publication bias.

pregnancy reported in the literature.^{1 5} Suprapubic pain, anuria, haematuria, ascites and acute abdominal pain are typical signs and symptoms.³ According to some case reports, necrotising cystitis⁶ and a previous caesarean section⁷ could result in spontaneous bladder rupture during pregnancy. However, most bladder rupture cases have been reported as a result of trauma.^{8 9} The few data available in the literature do not allow us to understand the causes of this adverse event. This systematic review aims to identify associated factors of spontaneous bladder rupture during pregnancy and propose a diagnostic and therapeutic algorithm.

METHODS/DESIGN

To improve the reporting of this protocol, the Preferred Reporting Items for Systematic Review and Meta-Analysis PRISMA 2020 statement was used (online supplemental file 1).¹⁰ The protocol for this review was submitted at PROSPERO on 20 March 2022 with CRD42022319511.

Patient and public involvement

Patients and/or the public were not involved in this research.

Objectives

To identify and summarise the associated factors with spontaneous bladder rupture during pregnancy and propose a diagnostic and therapeutic algorithm.

Review question

Are there any predisposing factors that can help predict the diagnosis in pregnant women who present with spontaneous or idiopathic urinary bladder rupture?

Eligibility criteria

Population

Studies will be considered if they contain data on spontaneous bladder rupture during pregnancy.

1. Any trimester in pregnancy.
2. Spontaneous bladder rupture diagnoses with any method.
3. Spontaneous bladder rupture management with any treatment approach.

Exposure

The term 'exposure' in this study refers to 'factors' linked to spontaneous bladder rupture during pregnancy. As a result, studies focusing on the various risks associated with spontaneous bladder rupture during pregnancy will be examined. The Strengthening Reporting of Observational Studies in Epidemiology (STROBE) checklist contains 22 items that will be used to investigate study reporting standards.¹¹ This checklist evaluates the title and purpose of the articles, the population and research samples, the sampling methods, how the sources of bias were controlled for, the validity and reliability of the instruments used in the research, data analysis, results and discussion of a study in the best way possible. The STROBE checklist categorises studies into three levels: weak, moderate and strong. The study includes studies that received 70% of the checklist score¹⁰ or higher.

Outcomes

Primary outcome

To determine the factors associated with bladder rupture during pregnancy.

Secondary outcome

1. To identify the diagnostic approach.
2. To identify a treatment approach.

Search strategy

This strategy will include the search for published and unpublished studies. From inception to June 2022, a systematic search of the following electronic databases of peer-reviewed journal articles and online search records will be conducted: the Cochrane Central Register, PubMed, Medline (Via PubMed), Embase (Via Ovid), ProQuest, Scopus, WOS and search engine Google Scholar. Keywords will be selected based on the MeSH terms and include "bladder rupture", "spontaneous bladder rupture", "SRUB", "Urinary bladder rupture", "rupture of the urinary bladder", "ruptured urinary bladder", "rapture of bladder", "Pregnancy", "Gestation", "Pregnant Women", "Birth",

"Childbirth", "Parturition", "Gravidity" and "Parity" will combine with Boolean "OR" and "AND" operators. In addition, the reference lists of the identified articles will also search along with hand-searching to ensure that all documents were retrieved, which will combine using Boolean "OR" and "AND" operators.

Words and expressions will be chosen from a controlled vocabulary (MeSH, ENTREE and others) and free text searching for each database. An information specialist will devise the search strategy. Online supplemental file 2 will contain the details of the search strategy. A snowballing method will also be used to identify other studies from the references of the selected studies.

The search strategy will seek out both published and unpublished research. An initial search of Medline and Embase will be conducted to identify articles on the topic. Following text analysis, titles, abstracts and keywords will be reviewed. The search strategy, which includes all specified keywords and index terms, will be tailored to each information source included. Using similar keywords from the search strings, researchers will search for additional studies from grey literature from government departments, international agencies, academic institution repositories, and Key Journals such as Obstetrics & Gynecology, American Journal of Obstetrics & Gynecology, BMC Women's Health, Human Reproduction Update, and BJOG: an International Journal of Obstetrics & Gynecology. Furthermore, we will use snowballing to search the references of identified articles for potentially relevant studies. Furthermore, the identified searching strategy will be retrieved and managed using Endnote V.X8 (Thomson Reuters, Philadelphia, Pennsylvania, USA) software. Potential publication bias may limit the scope of the review; therefore, databases will be searched for unpublished studies such as thesis dissertations and conference proceedings to reduce the risk of publication bias.

Study type

All types of studies focusing on spontaneous bladder rupture during pregnancy in all languages will be included. There is no time limit for publication.

The study selection method

Two authors (VM and FD) will review the studies based on inclusion and exclusion criteria. The review will be conducted in two stages. In the first stage, reviewers will look over the titles and abstracts of the studies found through the search. The second stage will use the full-text screening to screen the full texts chosen in the previous stage. For articles not accessible through online databases, an extended reference search of included studies will be considered. We will contact the corresponding author three times if the articles are not open access. We will exclude an article if the authors are unwilling to provide the full text. In the PRISMA-2020 flow diagram, we will provide reasons for excluding all excluded studies. Finally, we will compile a list of articles for data extraction.

Data extraction

Three authors will independently extract data using a researcher-created checklist. In the event of a disagreement, an external reviewer will be used. The following items will be included on this checklist:

1. General items (author, publication year, article ID, country).
2. Type of study.
3. Sampling location.
4. Sample size and participant group.
5. Subject characteristics (demographics, ages, past medical histories, obstetrical histories, drug usage during pregnancy, symptoms, type of diagnosis and outcome).
6. Type of treatment.
7. Result.

Quality assessment of studies

The Newcastle-Ottawa Scale checklist¹² will be used by two authors (NR and MB) to assess the quality of the studies independently. The purpose of this checklist is to evaluate the quality of observational studies. This instrument assesses each study using eight items divided into three categories: selecting study groups, comparing groups and proving the exposure or expected outcome. Each approved quality item is given a star, with a maximum score of 9.¹² This checklist will be used to score all studies, and the results will be presented in the form of a table for each article. If there are disagreements about the scores assigned to published articles, the discussion method, and an outside referee will be used to decide.

Data analysis

Data analysis will be carried out using STATA V.16. The binomial distribution will calculate the SE for each study. The χ^2 test will investigate the heterogeneity level using Cochran's Q statistic and I² index at a significance level of 1.1. The level of heterogeneity is defined as low (0%–40%), moderate (30%–60%), significant (50%–90%) and 75%–100% may represent significant heterogeneity.¹³ If the sample homogeneity hypothesis is rejected, the random-effects model will be used to estimate the share ratio using an inverse variance method. The results will be displayed using a forest plot.

Furthermore, moment-based meta-regression will be used to investigate the effects of potential factors influencing heterogeneity in the prevalence of bladder rupture during pregnancy.¹³ Egger's correlation¹⁴ and Begg's regression intercept tests¹⁵ will detect publication bias at a 5% significance level. If there is evidence of publication bias in our analysis, we will conduct a non-parametric 'trim and fill' analysis using Duval and Tweedie¹⁶ to formalise the use of funnel plot, estimate the number and outcome of missing studies, and adjust for theoretically missing studies. If possible, subgroup analysis will be performed based on ages, medical histories, obstetrical histories, drug use during pregnancy, symptoms, type of diagnosis and outcome.

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Contributors AR and FD were in charge of protocol design and manuscript conception. VM is in charge of determining study eligibility and reviewing collected data. The full text of papers and data collection is the responsibility of FD, NR and MB. The authors also read the manuscript, provided significant revisions and approved the final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	3
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	3,4
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	4
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	5,6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	5,6
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	7
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	7,8
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	7,8
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	8
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	8
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	8
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	8
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	8
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	8
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	8
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	8
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	8
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	9
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	8,9



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	NA
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	NA
Study characteristics	17	Cite each included study and present its characteristics.	NA
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	NA
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	NA
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	NA
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	NA
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	NA
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	NA
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	NA
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	NA
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	NA
	23b	Discuss any limitations of the evidence included in the review.	NA
	23c	Discuss any limitations of the review processes used.	NA
	23d	Discuss implications of the results for practice, policy, and future research.	NA
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	3,4
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	3,4
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	NA
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	10
Competing interests	26	Declare any competing interests of review authors.	10
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	9

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: <http://www.prisma-statement.org/>

Search strategy

PubMed

(("bladder rupture"[Title/Abstract] OR "spontaneous bladder rupture"[Title/Abstract] OR "SRUB"[Title/Abstract] OR "Urinary bladder rupture"[Title/Abstract] OR "rupture of the urinary bladder"[Title/Abstract] OR "ruptured urinary bladder"[Title/Abstract] OR "rapture of bladder"[Title/Abstract]) AND ("Pregnancy"[Title/Abstract] OR "Gestation"[Title/Abstract] OR "Pregnant Women"[Title/Abstract] OR "Birth"[Title/Abstract] OR "Childbirth"[Title/Abstract] OR "Parturition"[Title/Abstract] OR "Gravidity"[Title/Abstract] OR "Parity"[Title/Abstract]))

Embase

(Pregnancy:ti,ab,kw OR Gestation:ti,ab,kw OR Pregnant Women:ti,ab,kw OR Birth:ti,ab,kw OR Childbirth:ti,ab,kw OR Parturition:ti,ab,kw OR Gravidity:ti,ab,kw OR Parity:ti,ab,kw) AND (bladder rupture:ti,ab,kw OR spontaneous bladder rupture:ti,ab,kw OR SRUB:ti,ab,kw OR Urinary bladder rupture:ti,ab,kw OR rupture of the urinary bladder:ti,ab,kw OR ruptured urinary bladder:ti,ab,kw OR rapture of bladder:ti,ab,kw)

Scopus

(TITLE-ABS-KEY((Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity))) AND (TITLE-ABS-KEY(("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))

Web Of Science

(TS=((Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity))) AND (TS=(("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))

ProQuest

(ab((Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity))) AND (ab(("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))

Google Scholar

("Pregnancy" OR "Gestation" OR "Pregnant Women" OR "Birth" OR "Childbirth" OR "Parturition" OR "Gravidity" OR "Parity") AND ("bladder rupture" OR "spontaneous bladder rupture" OR "SRUB" OR "Urinary bladder rupture" OR "rupture of the urinary bladder" OR "ruptured urinary bladder" OR "rapture of bladder")

Cochrane library

((("Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity)) AND (("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))) in Title Abstract Keyword



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Competing interests	26	Declare any competing interests of review authors.	10
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	9

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For more information, visit: <http://www.prisma-statement.org/>

Search strategy

PubMed

(("bladder rupture"[Title/Abstract] OR "spontaneous bladder rupture"[Title/Abstract] OR "SRUB"[Title/Abstract] OR "Urinary bladder rupture"[Title/Abstract] OR "rupture of the urinary bladder"[Title/Abstract] OR "ruptured urinary bladder"[Title/Abstract] OR "rapture of bladder"[Title/Abstract]) AND ("Pregnancy"[Title/Abstract] OR "Gestation"[Title/Abstract] OR "Pregnant Women"[Title/Abstract] OR "Birth"[Title/Abstract] OR "Childbirth"[Title/Abstract] OR "Parturition"[Title/Abstract] OR "Gravidity"[Title/Abstract] OR "Parity"[Title/Abstract]))

Embase

(Pregnancy:ti,ab,kw OR Gestation:ti,ab,kw OR Pregnant Women:ti,ab,kw OR Birth:ti,ab,kw OR Childbirth:ti,ab,kw OR Parturition:ti,ab,kw OR Gravidity:ti,ab,kw OR Parity:ti,ab,kw) AND (bladder rupture:ti,ab,kw OR spontaneous bladder rupture:ti,ab,kw OR SRUB:ti,ab,kw OR Urinary bladder rupture:ti,ab,kw OR rupture of the urinary bladder:ti,ab,kw OR ruptured urinary bladder:ti,ab,kw OR rapture of bladder:ti,ab,kw)

Scopus

(TITLE-ABS-KEY((Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity))) AND (TITLE-ABS-KEY(("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))

Web Of Science

(TS=((Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity))) AND (TS=(("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))

ProQuest

(ab((Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity))) AND (ab(("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))

Google Scholar

("Pregnancy" OR "Gestation" OR "Pregnant Women" OR "Birth" OR "Childbirth" OR "Parturition" OR "Gravidity" OR "Parity") AND ("bladder rupture" OR "spontaneous bladder rupture" OR "SRUB" OR "Urinary bladder rupture" OR "rupture of the urinary bladder" OR "ruptured urinary bladder" OR "rapture of bladder")

Cochrane library

((("Pregnancy) OR (Gestation) OR ("Pregnant Women") OR (Birth) OR (Childbirth) OR (Parturition) OR (Gravidity) OR (Parity)) AND (("bladder rupture") OR ("spontaneous bladder rupture") OR (SRUB) OR ("Urinary bladder rupture") OR ("rupture of the urinary bladder") OR ("ruptured urinary bladder") OR ("rapture of bladder")))) in Title Abstract Keyword