

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

Amene Ranjbar,<sup>1</sup> Vahid Mehrnoush,<sup>2</sup> Nasibeh Roozbeh,<sup>2</sup> Mojdeh Banaei,<sup>2</sup> Fatemeh Darsareh <sup>2</sup>

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<sup>1</sup>Fertility and Infertility Research Center, Hormozgan University of Medical Sciences, Bandar-Abbas, Iran

<sup>2</sup>Mother and Child Welfare Research Center, Hormozgan University of Medical Sciences, Bandar-Abbas, Iran

## Correspondence to

Dr Fatemeh Darsareh; [famadarsareh@yahoo.com](mailto:famadarsareh@yahoo.com)

## 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.<sup>1 2</sup> Although the majority of bladder ruptures have been reported following childbirth,<sup>3 4</sup> 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.<sup>1 5</sup> Suprapubic pain, anuria, haematuria, ascites and acute abdominal pain are typical signs and symptoms.<sup>3</sup> According to some case reports, necrotising cystitis<sup>6</sup> and a previous caesarean section<sup>7</sup> could result in spontaneous bladder rupture during pregnancy. However, most bladder rupture cases have been reported as a result of trauma.<sup>8 9</sup> 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).<sup>10</sup> 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.<sup>11</sup> 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 score<sup>10</sup> 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 checklist<sup>12</sup> 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.<sup>12</sup> 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  $\chi^2$  test will investigate the heterogeneity level using Cochran's Q statistic and I<sup>2</sup> 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.<sup>13</sup> 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.<sup>13</sup> Egger's correlation<sup>14</sup> and Begg's regression intercept tests<sup>15</sup> 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 Tweedie<sup>16</sup> 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.

**Twitter** Fatemeh Darsareh @famadarsareh

**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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**Ethics approval** Not applicable.

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## ORCID iD

Fatemeh Darsareh <http://orcid.org/0000-0003-2644-792X>

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