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# BMJ Open

## Spontaneous Bladder Rupture and Associated Factors During Pregnancy: A Systematic Review and Metanalysis Protocol

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Keywords:	Maternal medicine < OBSTETRICS, Prenatal diagnosis < OBSTETRICS, Adult urology < UROLOGY, Bladder disorders < UROLOGY

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Manuscripts

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3 **1 Spontaneous Bladder Rupture and Associated Factors During Pregnancy: A Systematic**  
4  
5 **2 Review and Metanalysis Protocol**  
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## 22 Abstract

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

27 **Methods and analysis:** This protocol was designed based on the Preferred Reporting Items for  
28 Systematic Review and Meta-Analysis Protocols. The primary objective is to identify and  
29 summarize the associated factors with spontaneous bladder rupture during pregnancy. The  
30 secondary outcome was to determine the diagnostic and treatment approach. Databases that will  
31 be used include the Cochrane Central Register, PubMed, MEDLINE (Via PubMed), EMBASE  
32 (Via Ovid), ProQuest, Scopus, WOS and search engine Google Scholar. All observational studies  
33 focusing on spontaneous bladder rupture during pregnancy will be included. Non-English articles  
34 and articles unrelated to the topic will be rejected. Letters to the editor and reviews will also be  
35 excluded. There is no time limit for publication. Two authors will review the studies based on  
36 inclusion and exclusion criteria. Three authors will independently extract data using a researcher-  
37 created checklist. In the event of a disagreement, an external reviewer will be used. The NOS  
38 checklist will be used by two authors to assess the quality of the studies independently. Data  
39 analysis will be carried out using STATA 16.

40 **Ethics and dissemination:** Ethical approval is not required, as our review will include published  
41 and publicly accessible data. This systematic review discusses the factors contributing to bladder  
42 rupture during pregnancy, a rare but pernicious occurrence. The findings of this study can aid in  
43 the development of new diagnostic and therapeutic strategies by introducing factors that influence  
44 bladder rupture.

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3 45 **Systematic review registration:** The protocol for this review was submitted at PROSPERO on  
4  
5 46 20/03/2022 with ID number 319511 [<https://www.crd.york.ac.uk/prospERO/#myprospERO>].  
6  
7

### 8 47 **Strengths and limitations of this study**

- 9  
10  
11 48 • To the best of our knowledge, this review will be the first to determine the risk factors of  
12  
13 bladder rupture in pregnancy.
- 14 49
- 15  
16 50 • Systematic reviews and meta-analyses will provide the most evidence for developing  
17  
18 51 diagnostic and therapeutic algorithm.
- 19  
20  
21 52 • This review will be thorough, utilizing independent dual review at each stage and adhering  
22  
23 53 to best-practice guidelines.
- 24  
25  
26 54 • There may only be a few articles in the literature regarding this topic.
- 27

### 28 55 **Introduction**

29  
30  
31 56 Spontaneous bladder rupture during pregnancy, childbirth and postpartum is a potentially life-  
32  
33 57 threatening event requiring immediate surgery to reduce morbidity and mortality (1,2). Although  
34  
35 58 the majority of bladder ruptures have been reported following childbirth (3,4), there have been a  
36  
37 59 few cases of bladder rupture during pregnancy reported in the literature (1,5). Supra-pubic pain,  
38  
39 60 anuria, hematuria, ascites and acute abdominal pain are typical signs and symptoms (3). According  
40  
41 61 to some case reports, necrotizing cystitis (6) and a previous cesarean section (7) could result in  
42  
43 62 spontaneous bladder rupture during pregnancy. However, most bladder rupture cases have been  
44  
45 63 reported as a result of trauma (8,9). The few data available in the literature do not allow us to  
46  
47 64 understand the causes of this adverse event. This systematic review aims to identify associated  
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49 65 factors of spontaneous bladder rupture during pregnancy and propose a diagnostic and therapeutic  
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51 66 algorithm.  
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## 67 **Methods/design**

68 This protocol was designed based on the Preferred Reporting Items for Systematic Review and  
69 Meta-Analysis Protocols (PRISMA-P 2015). (Additional file 1)

70 The protocol for this review was submitted at PROSPERO on 20/03/2022 with ID number 319511  
71 [<https://www.crd.york.ac.uk/prospero/#myprospero>].

## 72 **Objectives**

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

## 75 **Review question**

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

## 78 **Eligibility criteria**

### 79 **Population**

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

81 1-Women above 18 years old

82 2- Any trimester in pregnancy

83 3- Spontaneous bladder rupture diagnoses with any method

84 4- Spontaneous bladder rupture diagnoses with any treatment approach

### 85 **Exposure**

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

## 96 **Outcomes**

### 97 **Primary outcome**

98 To determine the factors associated with bladder rupture during pregnancy.

### 99 **Secondary outcome**

100 1. To identify the diagnostic approach

101 2. To identify a treatment approach

### 102 **Search strategy**

103 This strategy will include the search for published and unpublished studies. Databases that will be  
104 used include the Cochrane Central Register, PubMed, MEDLINE (Via PubMed), EMBASE (Via  
105 Ovid), ProQuest, Scopus, WOS and search engine Google Scholar. Keywords will be selected  
106 based on the MeSH terms and include "bladder rupture" , "spontaneous bladder rupture", "SRUB",

1  
2  
3 107 "Urinary bladder rupture", "rupture of the urinary bladder", "ruptured urinary bladder", "rapture of  
4  
5 108 bladder", "Pregnancy", "Gestation", "Pregnant Women", "Birth", "Childbirth", "Parturition",  
6  
7  
8 109 "Gravidity" and "Parity" will combine with Boolean "OR" and "AND" operators. In addition, the  
9  
10 110 reference lists of the identified articles will also search along with hand-searching to ensure that  
11  
12 111 all documents were retrieved, which will combine using Boolean "OR" and "AND" operators.  
13  
14 112 Words and expressions will be chosen from a controlled vocabulary (MeSH, ENTREE, and others)  
15  
16  
17 113 and free text searching for each database. An information specialist will devise the search strategy.  
18  
19 114 Additional file 2 will contain the details of the search strategy. A snowballing method will also be  
20  
21 115 used to identify other studies from the references of the selected studies.  
22  
23  
24 116 The search strategy will seek out both published and unpublished research. An initial search of  
25  
26 117 MEDLINE and EMBASE will be conducted to identify articles on the topic. Following text  
27  
28 118 analysis, titles, abstracts, and keywords will be reviewed. The search strategy, which includes all  
29  
30 119 specified keywords and index terms, will be tailored to each information source included. Using  
31  
32  
33 120 similar keywords from the search strings, researchers will search for additional studies from grey  
34  
35 121 literature from government departments, international agencies, academic institution repositories,  
36  
37  
38 122 and Key Journals such as Obstetrics & Gynecology, American Journal of Obstetrics &  
39  
40 123 Gynecology, BMC Women's Health, Human Reproduction Update, and BJOG: an International  
41  
42 124 Journal of Obstetrics & Gynecology. Furthermore, we will use snowballing to search the  
43  
44 125 references of identified articles for potentially relevant studies. Furthermore, the identified  
45  
46 126 searching strategy will be retrieved and managed using Endnote X8 (Thomson Reuters,  
47  
48 127 Philadelphia, PA, USA) software.

51 **Study type**  
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129 All observational studies focusing on spontaneous bladder rupture during pregnancy will be  
130 included. Non-English articles and articles unrelated to the topic will be rejected. Letters to the  
131 editor and reviews will also be excluded. There is no time limit for publication.

### 132 **The study selection method**

133 Two authors (VM and FD) will review the studies based on inclusion and exclusion criteria. The  
134 review will be conducted in two stages. In the first stage, reviewers will look over the titles and  
135 abstracts of the studies found through the search. The second stage will use the full-text screening  
136 to screen the full texts chosen in the previous stage. For articles not accessible through online  
137 databases, an extended reference search of included studies will be considered. We will contact  
138 the corresponding author three times if the articles are not open access. We will exclude an article  
139 if the authors are unwilling to provide the full text. In the PRISMA-2009 flow diagram, we will  
140 provide reasons for excluding all excluded studies. Finally, we will compile a list of articles for  
141 data extraction.

### 142 **Data extraction**

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

- 146 1. General items (Author, publication year, article ID, country)
- 147 2. Type of Study
- 148 3. Sampling location
- 149 4. Sample size and participant group

- 150 5. Subject characteristics (demographics, ages, past medical histories, obstetrical histories,
- 151 drug usage during pregnancy, symptoms, type of diagnosis, and outcome.)
- 152 6. Type of treatment
- 153 7. Result

### 154 **Quality assessment of studies**

155 The NOS checklist will be used by two authors (NR and MB) to assess the quality of the studies  
156 independently. The purpose of this checklist is to evaluate the quality of observational studies.  
157 This instrument assesses each study using eight items divided into three categories: selecting study  
158 groups, comparing groups, and proving the exposure or expected outcome. Each approved quality  
159 item is given a star, with a maximum score of 9 (10). This checklist will be used to score all  
160 studies, and the results will be presented in the form of a table for each article. If there are  
161 disagreements about the scores assigned to published articles, the discussion method and an  
162 outside referee will be used to decide.

### 163 **Data analysis**

164 Data analysis will be carried out using STATA 16. The binomial distribution will calculate the  
165 standard error for each study. The chi-square test will investigate the heterogeneity level using  
166 Cochran's Q statistic and I<sup>2</sup> index at a significance level of 1.1. If the sample homogeneity  
167 hypothesis is rejected, the random-effects model will be used to estimate the share ratio using an  
168 inverse variance method. The results will be displayed using a forest plot.

169 Furthermore, moment-based meta-regression will be used to investigate the effects of potential  
170 factors influencing heterogeneity in the prevalence of bladder rupture during pregnancy. Egger's  
171 correlation and Begg's regression intercept tests will detect publication bias at a 5% significance

172 level. If there is evidence of publication bias in our analysis, we will conduct a non-parametric  
173 'trim and fill' analysis using Duval and Tweedie to formalize the use of funnel plot, estimate the  
174 number and outcome of missing studies, and adjust for theoretically missing studies. If possible,  
175 sub-group analysis will be performed based on ages, previous medical histories, obstetrical  
176 histories, drug use during pregnancy, symptoms, type of diagnosis, and outcome.

#### 177 **Pateint and public involvement**

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

#### 179 **Ethics and dissemination**

180 Ethical approval is not required, as our review will include published and publicly accessible data.  
181 This systematic review discusses the factors contributing to bladder rupture during pregnancy, a  
182 rare but pernicious occurrence. Given the rarity of the event, treatment for this problem has been  
183 sought infrequently in recent years. The findings of this study can aid in the development of new  
184 diagnostic and therapeutic strategies by introducing factors that influence bladder rupture.

#### 185 **Ethics approval and consent to participate**

186 Not applicable.

#### 187 **Consent for publication**

188 Not applicable.

#### 189 **Availability of data and materials**

190 Not applicable.

#### 191 **Competing interests**

192 The authors declare that they have no competing interests.

### 193 **Funding**

194 No funding.

### 195 **Authors contributions**

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

### 200 **Acknowledgment**

201 All of the authors acknowledged the Hormozgan University of Medical Sciences.

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39 227 [Ottawa\\_Scale\\_NOS\\_for\\_Assessing\\_the\\_Quality\\_of\\_Non-Randomized\\_Studies\\_in\\_Meta-](https://www.researchgate.net/publication/261773681_The_Newcastle-Ottawa_Scale_NOS_for_Assessing_the_Quality_of_Non-Randomized_Studies_in_Meta-Analysis)  
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41 228 [Analysis](https://www.researchgate.net/publication/261773681_The_Newcastle-Ottawa_Scale_NOS_for_Assessing_the_Quality_of_Non-Randomized_Studies_in_Meta-Analysis)  
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## PRISMA-P 2015 Checklist

This checklist has been adapted for use with systematic review protocol submissions to BioMed Central journals from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 4:1

An Editorial from the Editors-in-Chief of *Systematic Reviews* details why this checklist was adapted – Moher D, Stewart L & Shekelle P: Implementing PRISMA-P: recommendations for prospective authors. *Systematic Reviews* 2016 5:15

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
<b>ADMINISTRATIVE INFORMATION</b>					
<b>Title</b>					
Identification	1a	Identify the report as a protocol of a systematic review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<b>Registration</b>	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	<input checked="" type="checkbox"/>	<input type="checkbox"/>	48
<b>Authors</b>					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3-14
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	187-191
<b>Amendments</b>	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<b>Support</b>					
Sources	5a	Indicate sources of financial or other support for the review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	186
Sponsor	5b	Provide name for the review funder and/or sponsor	<input checked="" type="checkbox"/>	<input type="checkbox"/>	186
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	<input checked="" type="checkbox"/>	<input type="checkbox"/>	186
<b>INTRODUCTION</b>					
<b>Rationale</b>	6	Describe the rationale for the review in the context of what is already known	<input checked="" type="checkbox"/>	<input type="checkbox"/>	51-61
<b>Objectives</b>	7	Provide an explicit statement of the question(s) the review will address with reference to	<input checked="" type="checkbox"/>	<input type="checkbox"/>	67-71

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		participants, interventions, comparators, and outcomes (PICO)			
<b>METHODS</b>					
<b>Eligibility criteria</b>	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	70-95
<b>Information sources</b>	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	<input checked="" type="checkbox"/>	<input type="checkbox"/>	97-99
<b>Search strategy</b>	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	100-122
<b>STUDY RECORDS</b>					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	124-126
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	128-131
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	<input checked="" type="checkbox"/>	<input type="checkbox"/>	138-140
<b>Data items</b>	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	<input checked="" type="checkbox"/>	<input type="checkbox"/>	140-148
<b>Outcomes and prioritization</b>	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	<input checked="" type="checkbox"/>	<input type="checkbox"/>	90-95
<b>Risk of bias in individual studies</b>	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	<input checked="" type="checkbox"/>	<input type="checkbox"/>	150-157
<b>DATA</b>					
<b>Synthesis</b>	15a	Describe criteria under which study data will be quantitatively synthesized	<input checked="" type="checkbox"/>	<input type="checkbox"/>	159-163
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., $I^2$ , Kendall's tau)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	160-167
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	164-166

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	<input type="checkbox"/>	<input checked="" type="checkbox"/>	NA
<b>Meta-bias(es)</b>	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	167-171
<b>Confidence in cumulative evidence</b>	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	150-157

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**Additional file 2: PubMed search string**

Search	Query	Items found	Date	Time
#1	Search ("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")	809	03/19/2022	11:54:43
#2	Search ("Pregnancy" OR "Gestation" OR "Pregnant Women" OR "Birth" OR "Childbirth" OR "Parturition" OR "Gravidity" OR "Parity")	1,301,215	03/19/2022	11:56:03
#1 and #2	Search ("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")	61	03/19/2022	11:57:53

# BMJ Open

## Spontaneous Bladder Rupture and Associated Factors During Pregnancy: A Systematic Review and Metanalysis Protocol

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Manuscript ID	bmjopen-2022-063955.R1
Article Type:	Protocol
Date Submitted by the Author:	25-Jul-2022
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<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Urology
Keywords:	Maternal medicine < OBSTETRICS, Prenatal diagnosis < OBSTETRICS, Adult urology < UROLOGY, Bladder disorders < UROLOGY

SCHOLARONE™  
Manuscripts

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3 **1 Spontaneous Bladder Rupture and Associated Factors During Pregnancy: A Systematic**  
4  
5 **2 Review and Metanalysis Protocol**  
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## 22 Abstract

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

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

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

43 **Systematic review registration:** The protocol for this review was submitted at PROSPERO on  
44 20/03/2022 with ID number CRD42022319511.

#### 45 **Strengths and limitations of this study**

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

#### 54 **Introduction**

55 Spontaneous bladder rupture during pregnancy, childbirth, and postpartum is a potentially life-  
56 threatening event requiring immediate surgery to reduce morbidity and mortality (1,2). Although  
57 the majority of bladder ruptures have been reported following childbirth (3,4), there have been a  
58 few cases of bladder rupture during pregnancy reported in the literature (1,5). Supra-pubic pain,  
59 anuria, hematuria, ascites, and acute abdominal pain are typical signs and symptoms (3).  
60 According to some case reports, necrotizing cystitis (6) and a previous cesarean section (7) could  
61 result in spontaneous bladder rupture during pregnancy. However, most bladder rupture cases have  
62 been reported as a result of trauma (8,9). The few data available in the literature do not allow us to  
63 understand the causes of this adverse event. This systematic review aims to identify associated

64 factors of spontaneous bladder rupture during pregnancy and propose a diagnostic and therapeutic  
65 algorithm.

## 66 **Methods/design**

67 To improve the reporting of this protocol, the Preferred Reporting Items for Systematic Review  
68 and Meta-Analysis PRISMA 2020 statement was used (10). (Additional file 1). The protocol for  
69 this review was submitted at PROSPERO on 20/03/2022 with CRD42022319511.

## 70 **Patient and public involvement**

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

## 72 **Objectives**

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

## 75 **Review question**

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

## 78 **Eligibility criteria**

### 79 **Population**

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

81 1- Any trimester in pregnancy

82 2- Spontaneous bladder rupture diagnoses with any method

83 3- Spontaneous bladder rupture management with any treatment approach

## 84 **Exposure**

85 The term 'exposure' in this study refers to 'factors' linked to spontaneous bladder rupture during  
86 pregnancy. As a result, studies focusing on the various risks associated with spontaneous bladder  
87 rupture during pregnancy will be examined. The Strengthening Reporting of Observational Studies  
88 in Epidemiology (STROBE) checklist contains 22 items that will be used to investigate study  
89 reporting standards (11). This checklist evaluates the title and purpose of the articles, the  
90 population and research samples, the sampling methods, how the sources of bias were controlled  
91 for, the validity and reliability of the instruments used in the research, data analysis, results, and  
92 discussion of a study in the best way possible. The STROBE checklist categorizes studies into  
93 three levels: weak, moderate, and strong. The study includes studies that received 70% of the  
94 checklist score (10) or higher.

## 95 **Outcomes**

### 96 **Primary outcome**

97 To determine the factors associated with bladder rupture during pregnancy.

### 98 **Secondary outcome**

- 99 1. To identify the diagnostic approach
- 100 2. To identify a treatment approach

### 101 **Search strategy**

102 This strategy will include the search for published and unpublished studies. From inception to June  
103 2022, a systematic search of the following electronic databases of peer-reviewed journal articles  
104 and online search records will be conducted: the Cochrane Central Register, PubMed, MEDLINE

1  
2  
3 105 (Via PubMed), EMBASE (Via Ovid), ProQuest, Scopus, WOS and search engine Google Scholar.  
4  
5 106 Keywords will be selected based on the MeSH terms and include "bladder rupture" , "spontaneous  
6  
7 107 bladder rupture", "SRUB", "Urinary bladder rupture", "rupture of the urinary bladder", "ruptured  
8  
9 108 urinary bladder", "rapture of bladder", "Pregnancy", "Gestation", "Pregnant Women", "Birth",  
10  
11 109 "Childbirth", "Parturition", "Gravidity" and "Parity" will combine with Boolean "OR" and "AND"  
12  
13 110 operators. In addition, the reference lists of the identified articles will also search along with hand-  
14  
15 111 searching to ensure that all documents were retrieved, which will combine using Boolean "OR"  
16  
17 112 and "AND" operators.  
18  
19 113 Words and expressions will be chosen from a controlled vocabulary (MeSH, ENTREE, and others)  
20  
21 114 and free text searching for each database. An information specialist will devise the search strategy.  
22  
23 115 Additional file 2 will contain the details of the search strategy. A snowballing method will also be  
24  
25 116 used to identify other studies from the references of the selected studies.  
26  
27 117 The search strategy will seek out both published and unpublished research. An initial search of  
28  
29 118 MEDLINE and EMBASE will be conducted to identify articles on the topic. Following text  
30  
31 119 analysis, titles, abstracts, and keywords will be reviewed. The search strategy, which includes all  
32  
33 120 specified keywords and index terms, will be tailored to each information source included. Using  
34  
35 121 similar keywords from the search strings, researchers will search for additional studies from grey  
36  
37 122 literature from government departments, international agencies, academic institution repositories,  
38  
39 123 and Key Journals such as Obstetrics & Gynecology, American Journal of Obstetrics &  
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41 124 Gynecology, BMC Women's Health, Human Reproduction Update, and BJOG: an International  
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43 125 Journal of Obstetrics & Gynecology. Furthermore, we will use snowballing to search the  
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45 126 references of identified articles for potentially relevant studies. Furthermore, the identified  
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47 127 searching strategy will be retrieved and managed using Endnote X8 (Thomson Reuters,  
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3 128 Philadelphia, PA, USA) software. Potential publication bias may limit the scope of the review;  
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5 129 therefore, databases will be searched for unpublished studies such as thesis dissertations and  
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8 130 conference proceedings to reduce the risk of publication bias.  
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### 10 131 **Study type**

11  
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13 132 All types of studies focusing on spontaneous bladder rupture during pregnancy in all languages  
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15 133 will be included. There is no time limit for publication.  
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### 18 134 **The study selection method**

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22 135 Two authors (VM and FD) will review the studies based on inclusion and exclusion criteria. The  
23  
24 136 review will be conducted in two stages. In the first stage, reviewers will look over the titles and  
25  
26 137 abstracts of the studies found through the search. The second stage will use the full-text screening  
27  
28 138 to screen the full texts chosen in the previous stage. For articles not accessible through online  
29  
30 139 databases, an extended reference search of included studies will be considered. We will contact  
31  
32 140 the corresponding author three times if the articles are not open access. We will exclude an article  
33  
34 141 if the authors are unwilling to provide the full text. In the PRISMA-2020 flow diagram, we will  
35  
36 142 provide reasons for excluding all excluded studies. Finally, we will compile a list of articles for  
37  
38 143 data extraction.  
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### 43 144 **Data extraction**

44  
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46 145 Three authors will independently extract data using a researcher-created checklist. In the event of  
47  
48 146 a disagreement, an external reviewer will be used. The following items will be included on this  
49  
50 147 checklist:

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53 148 1. General items (Author, publication year, article ID, country)
- 54  
55 149 2. Type of Study
- 56  
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- 150 3. Sampling location
- 151 4. Sample size and participant group
- 152 5. Subject characteristics (demographics, ages, past medical histories, obstetrical histories,  
153 drug usage during pregnancy, symptoms, type of diagnosis, and outcome.)
- 154 6. Type of treatment
- 155 7. Result

### 156 **Quality assessment of studies**

157 The Newcastle-Ottawa scale (NOS) checklist (12) will be used by two authors (NR and MB) to  
158 assess the quality of the studies independently. The purpose of this checklist is to evaluate the  
159 quality of observational studies. This instrument assesses each study using eight items divided into  
160 three categories: selecting study groups, comparing groups, and proving the exposure or expected  
161 outcome. Each approved quality item is given a star, with a maximum score of 9 (12). This  
162 checklist will be used to score all studies, and the results will be presented in the form of a table  
163 for each article. If there are disagreements about the scores assigned to published articles, the  
164 discussion method, and an outside referee will be used to decide.

### 165 **Data analysis**

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

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3 173 Furthermore, moment-based meta-regression will be used to investigate the effects of potential  
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5 174 factors influencing heterogeneity in the prevalence of bladder rupture during pregnancy (13).  
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8 175 Egger's correlation (14) and Begg's regression intercept tests (15) will detect publication bias at a  
9  
10 176 5% significance level. If there is evidence of publication bias in our analysis, we will conduct a  
11  
12 177 non-parametric 'trim and fill' analysis using Duval and Tweedie (16) to formalize the use of funnel  
13  
14 178 plot, estimate the number and outcome of missing studies, and adjust for theoretically missing  
15  
16 179 studies. If possible, sub-group analysis will be performed based on ages, previous medical  
17  
18 180 histories, obstetrical histories, drug use during pregnancy, symptoms, type of diagnosis, and  
19  
20 181 outcome.  
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## 23 24 182 **Statements**

## 25 26 27 183 **Contributorship**

28  
29  
30 184 AR and FD were in charge of protocol design and manuscript conception. VM is in charge of  
31  
32 185 determining study eligibility and reviewing collected data. The full text of papers and data  
33  
34 186 collection is the responsibility of FD, NR, and MB. The authors also read the manuscript, provided  
35  
36 187 significant revisions, and approved the final version.  
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## 40 188 **Funding statements**

41  
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43 189 There are no funders to report for this submission.  
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## 45 190 **Competing of Interests**

46  
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48 191 No, there are no competing interests for any author.  
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## 51 192 **Ethics approval**

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54 193 Ethical approval is not required, as our review will include published and publicly accessible data.  
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3 194 **Data sharing**  
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6 195 Not applicable.  
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9 196 **References**  
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226 [Ottawa\\_Scale\\_NOS\\_for\\_Assessing\\_the\\_Quality\\_of\\_Non-Randomized\\_Studies\\_in\\_Meta-](https://www.researchgate.net/publication/261773681_The_Newcastle-Ottawa_Scale_NOS_for_Assessing_the_Quality_of_Non-Randomized_Studies_in_Meta-Analysis)  
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For peer review only

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## PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
<b>TITLE</b>			
Title	1	Identify the report as a systematic review.	1
<b>ABSTRACT</b>			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
<b>INTRODUCTION</b>			
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
<b>METHODS</b>			
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

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Section and Topic	Item #	Checklist item	Location where item is reported
<b>RESULTS</b>			
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
<b>DISCUSSION</b>			
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
<b>OTHER INFORMATION</b>			
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 peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>  
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

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3 ("Pregnancy" OR "Gestation" OR "Pregnant Women" OR "Birth" OR "Childbirth" OR "Parturition" OR  
4 "Gravidity" OR "Parity") AND ("bladder rupture" OR "spontaneous bladder rupture" OR "SRUB" OR  
5 "Urinary bladder rupture" OR "rupture of the urinary bladder" OR "ruptured urinary bladder" OR "rapture  
6 of bladder")  
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### 9 **Cochrane library**

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