ABSTRACT

**Purpose:** To objectively evaluate the methodological quality and clinical heterogeneity robustness of the published clinical practice guidelines (CPGs) on the management of trauma in pregnancy.

**Materials and methods:** Pubmed, Google Scholar, UpToDate, and Scopus Database were searched. The risk of bias and quality assessment of the included CPGs were performed using “The Appraisal Of Guidelines for Research and Evaluation (AGREE II)” tool. The following points relating to the management of trauma during pregnancy were addressed: quality of evidence assessment, classification of recommendations, main causes of trauma in pregnancy, importance of correct use of seat belts, ultrasound scans and/or pregnancy test in every female of reproductive age, description of physiological changes in pregnancy, classification in primary and secondary survey, primary survey based on ABCD Approach, fetus viable based on the weeks, radiographic studies for maternal evaluation, duration of fetal monitoring, use of anti-D immunoglobulin in rhesus-D-negative pregnant trauma patients, description of dose of RhD-Ig, the way to define gestational age if it was undetermined, descriptions of obstetrical complications, use of tetanus vaccination, and timing to perimortem cesarean section (CS).

**Results:** Six CPGs were included. Quality of evidence assessment was described in 16.7% of CPGs (1/6), while it was not reported in 83.3% (5/6). Classification of recommendations was reported in 50% (3/6) of the CPGs. Motor vehicle crash was reported as the main cause of trauma in pregnancy in all the CPGs included in the present review, despite that the importance of a correct use of seat belts was described only in the 50% (3/6). Definition of fetal viability was also different among the included CPGs; in 50% (3/6) defined a fetus viable when it from 23 weeks, 33.3% (2/6) from 24 weeks, and 16.7% (1/6) from 20 weeks of gestation. Regarding the type of fetal monitoring, 33.3% (2/6) CPGs recommended CTG assessment at least every 4 h, 16.7% (1/6) at least every 6 h, 33.3% for 24 h if there are not reassuring signs and 16.7% (1/6) did not specify the duration of monitoring. Recommendations about the use of anti-D-immunoglobulin in rhesus-D-negative pregnant were also heterogeneous: 50% (3/6) of the CPGs suggested administration in all rhesus-D-negative pregnant women, 16.7% (1/6) only according to gestational age at trauma or in case of significant abdominal trauma, and 16.7% (1/6) only in case of positive Kleihauer test while 16.7% (1/6) did not specify it. Administration of tetanus vaccination was suggested in in 33.3% (2/6) of CPGs. Finally, there were different descriptions of timing to perimortem CS: 33.3% (2/6) of CPGs claims to do CS no later than 4 min, 50% (3/6) no later than 5 min, and 16.7% (1/6) does not describe timing for CS. The AGREE II standardized domain scores for the first overall assessment (OA1) had a mean of 69%. Only three CPGs scored more than 60% and revealed a consensus agreement between the reviewers on recommending the use of these CPGs.

**Conclusion:** There is clinical heterogeneity in some of the most relevant aspects of the management of pregnant women with trauma. The findings from this systematic review highlight the need for up to date and shared guidelines promoted by the main body societies in order make management of pregnant women with trauma homogenous.
Introduction

Trauma is the leading non-obstetric cause of maternal death during pregnancy [1], with 20% of deaths directly related to injury [2,3]. Motor vehicle crash (MVC), falls, and domestic violence represent the main causes of maternal trauma in pregnancy, with less frequent events represented by penetrating traumas such as ballistic or blade wounds [4–8].

Of women who experience trauma, about 87% receive medical treatment, and most hospital admissions involve pregnant women > 20 weeks of gestation [9].

The large majority of traumatic injuries during pregnancy are classified as minor. Despite that, 60% to 70% of fetal losses follow a trauma initially labeled as minor [10]. Emergency care of the pregnant trauma patient presents a unique set of circumstances and challenges for the physician. Physiological changes related to pregnancy occur in virtually all systems and can be directly or indirectly affected by a trauma. Therefore, knowledge of such changes is crucial when managing pregnant women with trauma and make management of such conditions extremely challenging [11]. Despite its complexity and clinical relevance, it has still to be ascertained whether the management of pregnant women with trauma is standardized among the different body societies.

Clinical practice guidelines (CPGs) are statements that include recommendations intended to optimize patient care. CPGs should follow a rigorous methodology to provide clinicians with the most-up to date and objective clinical evidence. The Appraisal of Guidelines for Research and Evaluation (AGREE II) tool is the most widely utilized tool to appraise the quality of CPGs, and It has been considered as the “Gold Standard” for CPG quality assessment. To date, no study has critically evaluated the methodological robustness and the clinical heterogeneity of CPGs on the management of Trauma in Pregnancy.

The primary aim of this systematic review was to objectively evaluate the robustness of the published CPGs on the management of Trauma in Pregnancy using the AGREE II tool. The secondary aim was to evaluate the clinical heterogeneity in the suggested management of pregnant women with trauma among the published CPGs.

Methods

Study protocol, search strategy, and study selection

This research was conducted by using PubMed, Google Scholar, UpToDate, and Scopus Database to identify local, national, and international guidelines, published before 14 April 2022. Combinations of the following keywords were used: “Trauma in Pregnancy” and “Injury in Pregnancy” and “Guidelines”. No restriction for geographic location were applied. Only English written CPGs were considered suitable for the inclusion in this review.

Three reviewers (MDV, GC, and SA) independently assessed the abstracts. Other two authors (GR and FDA) were involved in case of disagreements among the three reviewers. If more versions of the same guideline were available, the most recent and updated one was included.

Data extraction

The principal variables extracted for the present review included: Society/Main Author of Guidelines, country, year of last revision, scope of the CPGs, and type of methodology adopted. The outcomes were extracted and reported in an online Dropbox sheet for sharing among all authors.

Risk of bias assessment and quality appraisal of guidelines

The Appraisal of Guidelines for Research and Evaluation (AGREE II) tool was used to assess the quality and risk of bias of each guideline.

The AGREE II tool contains 23 items branched into 6 quality domains and 2 final overall assessment: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, editorial independence (Supplementary Table 1). The first domain regards the aim, the health questions covered by the guideline, and its target population; the second domain is concerned with the objective of its intended users; the third domain focuses on the method used for the formulation of each recommendation; the fourth domain is analyzed the language, structure, and format of the guideline; the fifth domain evaluates the facilities and/or difficulties on application of the CPG; and the sixth domain concerns biases with competing interests.

The last two domains regard a final overall assessment (OA1), which consists of the rating of the overall quality of the CPG and whether the CPG would be recommended for use in practice (OA2)

Each item was evaluated from two appraisers on a seven-point scale that ranges from 1 (strongly disagree) to 7 (strongly agree). The reviewers consulted each other after completing the AGREE II assessment.
to avoid discrepancies. If each appraiser scored 1 for all the items included in this domain the standardized domain score would be 0% (https://www.agreetrust.org/resource-centre/agree-ii) [12]. We applied the reaching consensus method to score the items. After reviewing 23 items and the comprehensive judgment of the reviewers, the evaluation of the CPGs was divided into three categories according to the AGREE II score (recommended, recommended after revision, and not recommended).

**Outcomes measures**

The following clinical points related to the management of trauma in pregnancies were analyzed:

1. Quality of evidence assessment
2. Classification of recommendations
3. Main cause of trauma in pregnancy
4. Importance of correct use of seat belts
5. Ultrasound scan and/or pregnancy test in every female of reproductive age
6. Description of physiological changes in pregnancy
7. Classification in primary and secondary survey
8. Primary survey based on ABCD approach
9. Fetus viable based on the weeks
10. Radiographic studies for maternal evaluation
11. Duration of electronic fetal monitoring
12. Use of anti-D immunoglobulin in rhesus-D-negative pregnant trauma patients
13. Description of dose RhD-Ig used
14. The way to define gestational age if it’s undetermined
15. Description of obstetrical complications
16. Tetanus vaccination
17. Timing of perimortem cesarean section (CS)

Each of the 17 items targets various aspects of CPGs quality of the practice guideline. Each item was evaluated on a seven-point scale from 1 (strongly disagree) to 7 (strongly agree).

A final overall assessment includes the rating of the overall quality of the CPGs (OA1) and whether the CPGs would be recommended for use in practice (OA2).

To begin the appraisal process, it is recommended that at least two, and preferably four, appraisers review each clinical guideline to increase the reliability of the assessment. The standardized domain score would be 0% if each appraiser scored 1 for all the items included in this domain (https://www.agreetrust.org/resource-centre/agree-ii).

**Data analysis**

It was performed a descriptive statistic in order to summarize the general characteristics of the guidelines included. Frequencies and raw proportions were carried out to summarize the main recommendations in managing trauma in pregnancy. It was calculated proportions and percentage for each different issue of the guidelines included. Moreover, the quality of CPGs was evaluated using AGREE II domain scores (Table 3). Mean ± standard deviation (SD) was used to summarize the scores across all the guidelines per domain. The AGREE II tool does not elicit any advises on how to define scores. To define a CPG as of good quality, we adopted the cutoff score according to Amer et al.: if the overall guideline score was >60%, CPGs was recommended; if the overall guideline score was 40% to 60%, CPGs was recommended after modification; and if the guideline score was <40%, it was not recommended. The analysis was performed using Excel 16.57 (© 2021 Microsoft Corporation. All rights reserved) and SPSS (version 26 IBM Corp., Armonk, NY) statistical softwares.

**Results**

**Study selection and characteristics**

A total of 42 articles were identified and screened and 6 CPGs were included in the analysis [13–18] (Figure 1). Table 1 describes general characteristics of the CPGs included in the present systematic review (SR).

The CPGs analyzed in this SR consisted in Expert opinion with review of literature, expert panel consensus, and review of literature; 1/6 (The Royal Melbourne Hospital) was first published in 2009 and revised in 2019; 1/6 (The EAST Practice Management Guidelines Work Group) was published in 2010; 2/6 (Trauma Victoria and Queensland Clinical Guidelines) were published in 2014 and the second CPG was revised in 2019; 1/6 (SOG) was published in 2015; and 1/6 (Birmingham, University Hospitals) was published in 2016.
Synthesis of results

Quality of evidence assessment was described in 16.7% of CPGs (1/6), while it was not reported in 83.3% (5/6) (Table 2). Classification of recommendations was reported in 50% (3/6) of the CPGs. MVC was reported as the main cause of trauma in pregnancy in all the CPGs included in the present review; despite >that the importance of a correct use of seat belts was described only in the 50% (3/6). There was heterogeneity as regard as the type of pregnancy confirmation to adopt in women in reproductive age experiencing a trauma; 66.7% (4/6) of CPGs suggested use the pregnancy test and 16.7% (1/6) recommend ultrasound assessment. Classification in primary and
Table 2. Critical evaluation of the different clinical aspects of the management of pregnancies complicated by trauma among the different CPGs.

| Issue                                                                 | N (%) |
|----------------------------------------------------------------------|-------|
| **Issue guidelines tot.:=6 (100%)**                                  |       |
| **Scope**                                                            |       |
| International                                                        | 0/6 (0%) |
| National                                                             | 1/6 (16.7%) |
| Local                                                                | 5/6 (83.3%) |
| **Method of development**                                            |       |
| Review of literature, expert panel consensus                         | 2/6 (33.3%) |
| Review of literature, expert opinion                                 | 4/6 (66.7%) |
| **Quality of evidence assessment (6/6)**                             |       |
| Yes                                                                  | 1/6 (16.7%) |
| No                                                                   | 5/6 (83.3%) |
| Not specified                                                        | 0/6 (0%) |
| **Classification of recommendations (6/6)**                          |       |
| Yes                                                                  | 3/6 (50%) |
| No                                                                   | 3/6 (50%) |
| Not specified                                                        | 0/6 (0%) |
| **Main cause of trauma in pregnancy (6/6)**                          |       |
| Motor vehicle collision                                              | 6/6 (100%) |
| Not specified                                                        | 0/6 (0%) |
| **Importance of correct use of seat belts (6/6)**                    |       |
| Yes                                                                  | 3/6 (50%) |
| No                                                                   | 3/6 (50%) |
| Not specified                                                        | 0/6 (0%) |
| **Ultrasound scan and/or pregnancy test in every female of reproductive age (5/6)** |       |
| Pregnancy test                                                       | 4/6 (66.7%) |
| Ultrasound scan                                                      | 1/6 (16.7%) |
| Not specified                                                        | 1/6 (16.7%) |
| **Description of physiological changes in pregnancy (6/6)**          |       |
| Yes                                                                  | 3/6 (50%) |
| No                                                                   | 3/6 (50%) |
| Not specified                                                        | 0/6 (0%) |
| **Classification in primary and secondary survey (6/6)**             |       |
| Yes                                                                  | 4/6 (66.7%) |
| No                                                                   | 2/6 (33.3%) |
| Not specified                                                        | 0/6 (0%) |
| **Primary survey based on ABCD approach (5/6)**                      |       |
| Yes                                                                  | 4/6 (66.7%) |
| No                                                                   | 1/6 (16.7%) |
| Not specified                                                        | 1/6 (16.7%) |
| **Fetus viable based on the weeks (6/6)**                            |       |
| ≥ 23 weeks                                                           | 3/6 (50%) |
| ≥ 24 weeks                                                           | 2/6 (33.3%) |
| ≥ 20 weeks                                                           | 1/6 (16.7%) |
| **Radiographic studies for maternal evaluation (5/6)**               |       |
| Yes                                                                  | 5/6 (83.3%) |
| No                                                                   | 0/6 (0%) |
| Not specified                                                        | 1/6 (16.7%) |
| **Duration of electronic fetal monitoring (5/6)**                    |       |
| At least 4h                                                           | 2/6 (33.3%) |
| At least 6h                                                          | 1/6 (16.7%) |
| For 24h if not reassuring signs                                     | 2/6 (33.3%) |
| Not specified                                                        | 1/6 (16.7%) |
| **Use of anti-D immunoglobulin in rhesus-D-negative pregnant trauma patients (5/6)** |       |
| Yes, always                                                          | 3/6 (50%) |
| Based on gestational age (If 13 weeks or less, only if abdominal trauma is significant) | 1/6 (16.7%) |
| Only if Kleihauer test is positive                                   | 1/6 (16.7%) |
| Not specified                                                        | 1/6 (16.7%) |
| **Description of dose of RhD-Ig (5/6)**                               |       |
| Yes, it depends on gestational age                                   | 2/6 (33.3%) |
| Yes, only one dose independently from gestational age                | 2/6 (33.3%) |
| No                                                                   | 1/6 (16.7%) |
| Not specified                                                        | 1/6 (16.7%) |
| **If gestational age is undetermined (3/6)**                         |       |
| Use of ultrasound scan                                               | 1/6 (16.7%) |
| Symphys fundal height                                                | 2/6 (33.3%) |
| Not specified                                                        | 3/6 (50%) |
| **Description of obstetrical complications (6/6)**                   |       |
| Yes                                                                  | 3/6 (50%) |
| No                                                                   | 3/6 (50%) |
| Not specified                                                        | 0/6 (0%) |

(continued)
secondary survey was reported in 66.7% (4/6) of the CPGs. In the context of the primary survey, 66.7% (4/6) of the CPGs was based on ABCD approach, 16.7% (1/6) did not use it, and 16.7% (1/6) did not specified about it. Definition of viability was also different among the included CPGs; 50% (3/6) defined a fetus viable when it from 23 weeks, 33.3% (2/6) from 24 weeks, and 16.7% (1/6) from 20 weeks of gestation. Regarding the type of fetal monitoring, 33.3% (2/6) CPGs recommended CTG assessment at least every 4 h, 16.7% (1/6) at least every 6 h, 33.3% for 24 h if there are not reassuring signs, and 16.7% (1/6) did not specify the duration of monitoring. Recommendations about the use of anti-D-immunoglobulin in rhesus-D-negative pregnant were also heterogeneous: 50% (3/6) of the CPGs suggested administration in all rhesus-D-negative pregnant women, 16.7% (1/6) only according to gestational age at trauma (before 13 weeks) or in case of significant abdominal trauma, and 16.7% (1/6) only in case of positive Kleihauer test while 16.7% (1/6) did not specify it. Likewise, the CPGs included in the present systematic review also differed as regard as the dose of anti-D prophylaxis; 33.3% (2/6) suggested to adjust the dose based upon the gestational age at trauma, 33.3% (2/6) recommended a standard dose independently from gestational age, while 33.2%/2/16) did not mention the actual dose to administer in case of trauma. Administration of tetanus vaccination was suggested in in 33.3% (2/6) of CPGs. Finally, there were different descriptions of timing to perimortem CS: 33.3% (2/6) of CPGs claims to do CS no later than 4 min, 50% (3/6) no later than 5 min, and 16.7% (1/6) does not describe timing for CS.

CPGs rated >60% were considered high-quality guidelines and were shown in green; medium-quality CPGs, rated with 40–59% cutoff, were shown in yellow and low-grade CPGs, rated <40%, were reported in red. The AGREE II standardized domain scores for the first overall assessment (OA1) had a mean of 69%. Only three CPGs scored more than 60% and revealed a consensus agreement between the reviewers on recommending the use of these CPGs.

**Discussion**

**Main findings**

The findings of this systematic review show that the published CPGs on trauma in pregnancy are generally of good quality as highlighted by the AGREE II assessment. There was a general agreement in the main reported causes for trauma and recommendation on the need for a multidisciplinary approach when managing pregnancies complicated by a trauma. Conversely, we reported a clinical heterogeneity among the published CPGs on several aspects of the management of pregnant women with trauma, including type and frequency of maternal monitoring, anti-D administration, and thresholds for fetal viability.

**Strengths and limitations**

This is, to the best of our knowledge, the first systematic review assessing the quality and clinical heterogeneity of CPGs on trauma in pregnancy. The strengths of the present systematic review rely in the thorough literature search and the multitude of clinical aspects on the management of trauma in pregnancy.

The weaknesses of CPGs rely in examined variables in particular Obstetric management: heterogeneity about definition of viability of the fetus, duration of monitoring, use of RhD-Ig, and tetanus vaccine. Exclusion of non-English written CPGs represents the main weaknesses of the present review. And they are based upon series published also decades ago, thus questioning on their full clinical applicability. Furthermore, we could not

**Methodological quality of CPGs**

Table 3 shows a summary of all the AGREE II domains and reports below each column the average AGREE II standardized score for each domain.
critically evaluate the different clinical aspects related to the type of trauma because most of the CPGs included in the present review did not report such differentiation. Finally, a comprehensive pooled data analysis was not possible for all the observed outcomes in view of the multitude of management options reported by the different CPGs.

**Implications and future perspectives**

Management of trauma in pregnancy is challenging. The lack of adequately powered randomized controlled trials (RCTs) on the management of trauma in pregnancy makes the clinical approach to these women difficult. Controversies regarding the management of pregnant women with trauma involves mainly the type and timing of fetal monitoring and the need for maternal hospitalization in mild to moderate events. About two thirds of maternal and fetal adverse events following a trauma occur in minor to moderate events, thus questioning whether these women should be hospitalized and undergo a strict monitoring irrespective of the magnitude of the trauma. Criteria for maternal hospitalization varies among the different guidelines, thus making difficult to extrapolate an objective evidence to sue in clinical practice. Designing an RCT on trauma in pregnancy is even more challenging, trauma is an acute event which can present with a large variety of clinical manifestations, and this makes difficult to establish objective inclusion criteria to apply to an RCT. More importantly, the acute nature of trauma makes also difficult for a researchers exposing the rationale for the study to the parents and obtaining the informed consent in these women. Therefore, the management of trauma in pregnancy is mainly based upon observation studies. However, these studies present several major biases mainly because of their small sample size and heterogeneous inclusion criteria and were published even decades ago, thus making their findings not entirely applicable to the era of modern obstetrics.

The severity of the trauma during MVC is related not only on the characteristics of the accident but also on the use of seat belts (these are a cause of complications from 21% to 98% [2]) and/or the opening of the airbags [19,20]. The most common complications arising from a blunt trauma include organ damage, pelvic fractures, uterine rupture, preterm birth, perinatal death, and placental abruption or severe maternal events such as cardiac arrest. In view of the multitude of adverse events potentially related to a maternal trauma, a multidisciplinary team should be immediately

| ID AGREE II | AGREE II Domain 1 (Items 1-3) | AGREE II Domain 2 (Items 4-6) | AGREE II Domain 3 (Items 7-14) | AGREE II Domain 4 (Items 15-17) | AGREE II Domain 5 (Items 18-21) | AGREE II Domain 6 (Items 22-23) |
|-------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| O2          | 100%                          | 100%                          | 100%                          | 100%                          | 100%                          | 100%                          |
| O1          | 100%                          | 86%                           | 50%                           | 86%                           | 14%                           | 10%                           |
| Domain 6    |                               |                               |                               |                               |                               |                               |
| Domain 5    |                               |                               |                               |                               |                               |                               |
| Domain 4    |                               |                               |                               |                               |                               |                               |
| Domain 3    |                               |                               |                               |                               |                               |                               |
| Domain 2    |                               |                               |                               |                               |                               |                               |
| Domain 1    |                               |                               |                               |                               |                               |                               |

Table 3. Summary of all the AGREE II domains.

Green: agree; yellow: neither agree nor disagree; red: disagree.
available to assess and monitor the pregnant woman with trauma, to promptly identify life-threatening complications which can be amenable of immediate treatment. Ideally, in view of their rare occurrence, specialized centers for trauma in pregnancy should be established to maximize the outcome of these women.

Another peculiar issue involves women education of the potential catastrophic effects of a trauma occurring in pregnancy. In the present systematic review, there was a general agreement among the different CPGs in recognized the car accidents as the primary cause of trauma in pregnancy. In this scenario, educational programs aimed at highlighting the for a safe driving and the correct use of seatbelts are needed in order to make them aware of the severe complications potentially occurring from a maternal trauma.

Conclusion

There is clinical heterogeneity in some of the most relevant aspects of the management of pregnant women with trauma. The findings from this systematic review highlight the need for up to date and shared guidelines promoted by the main body societies in order make management of pregnant women with trauma homogenous.

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