

# Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

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# Is electroconvulsive therapy during pregnancy safe?

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# **Abstract**

Therapeutic options for psychiatric conditions are limited during pregnancy because many drugs are restricted or contraindicated. Electroconvulsive therapy constitutes an alternative, however there is controversy over its safety. Using the Epistemonikos database, which is maintained by searching multiple databases, we found five systematic reviews, including 81 studies overall describing case series or individual cases. Data were extracted from the identified reviews and summary tables of the results were prepared using the GRADE method. We concluded it is not clear what are the risks associated with electroconvulsive therapy during pregnancy because the certainty of the existing evidence is very low. Likewise, existing systematic reviews and international clinical guidelines differ in their conclusions and recommendations.

#### **Problem**

Many of the drugs that are used to treat psychiatric conditions have restrictions or even contraindications during pregnancy, which limit the therapeutic options in this group of patients. Electroconvulsive therapy is one of the interventions that are usually considered as a safe and effective alternative for the treatment of severe or resistant conditions during pregnancy, mainly in depression. There is consensus that it is the therapy of choice in such cases, especially when there is a vital risk to the mother or the fetus. However, in less serious cases where this treatment could also be an option to consider, there is controversy, largely because it is unclear what the risks are. On the other hand, the recommendations given by different clinical guidelines differ among them.

# **Methods**

We used Epistemonikos database, which is maintained by screening multiple databases, to identify systematic reviews and their included primary studies. With this information, we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

#### Key messages

- It is unclear what are the risks associated with electroconvulsive therapy during pregnancy because the certainty of the evidence is very low.
- Systematic reviews and existing clinical guidelines differ in their conclusions and recommendations.



# About the body of evidence for this question

What is the evidence. See evidence matrix in Epistemonikos later	We found five systematic reviews [1],[2],[3],[4],[5] which include 81 primary studies overall [6],[7],[8],[9],[10],[11],[12],[13],[14],[15],[16],[17],[18], [19],[20],[21],[22],[23],[24],[25],[26],[27],[28],[29],[30],[31],[32],[33], [34],[35],[36],[37],[38],[39],[40],[41],[42],[43],[44],[45],[46],[47],[48], [49],[50],[51],[52],[53],[54],[55],[56],[57],[58],[59],[60],[61],[62],[63], [64],[65],[66],[67],[68],[69],[70],[71],[72],[73],[74],[75],[76],[77],[78], [79],[80],[81],[82],[83],[84],[85] [86], all corresponding to series or case reports that answer the question of interest. No randomized controlled trials were identified, neither any other studies comparing against a control group.	
What types of patients were included	Seventeen studies included patients requiring electroconvulsive therapy during the first trimester of pregnancy [12],[13],[16],[19],[30],[34],[36], [38],[44], [62],[64],[67],[68],[74],[77],[81],[84], 45 studies during the second trimester [6],[7],[8],[9],[11],[12],[13],[14],[15],[17],[18],[19],[21], [24],[25],[29],(30],[31],[32],[33],[35],[37],[41],[43],[45],[47],[49],[50], [51],[54],[56],[60],[61],[63],[66],[67],[69],[71],[73],[74], [78],[83], [84], [85],[86], and 30 during the third [12],[13],[17],[19], [22],[23],[26], [27], [29],[37],[39],[40],[42],[46],[52],[57],[58],[59], [65],[66],[70],[72], [73], [75],[76],[78],[79], [80],[82],[84]. In 11 studies the time of gestation when electroconvulsive therapy was applied was not clear, [10],[16],[20],[21], [28],[29], [32],[48],[53],[55],[84]. The diagnosis for which electroconvulsive therapy was required was a major depressive episode in 43 studies [9],[10], [11],[12],[13],[14],[18],[19],[21],[22],[23],[24],[28],[29],[30],[31], [33], [35],[37],[39],[40],[41],[42],[43],[44],[45],[47],[48],[50],[51],[52], [57], [59],[62],[63],[65], [67],[69],[72], [73],[76], [80],[81],[82], [84],[85], bipolar disease in 16 [6],[7],[12],[13],[21], [26],[34],[56],[60],[64],[66], [70],[71],[73],[79], [83] and schizophrenia in 18 studies [6],[12],[15],[19], [23],[25],[27], [28],[40],[41], [42],[53],[54],[55],[58], [61],[84],[86]. Other reported diagnoses were psychosis, confusional state, schizoaffective and schizophreniform disorder, neuroleptic malignant syndrome and obsessive-compulsive disorder [6],[13], [17],[19],[32],[36],[38],[49],[54], [63],[67]. In 12 studies the diagnosis was not reported [8],[16],[20],[29], [46],[66],[68],[74],[75],[77],[78],[84]. In 11 studies patients also received medications to manage their psychiatric disorders during pregnancy, mainly antipsychotics, benzodiazepines and antidepressants [13],[34],[38],[49],[50],[55],[55],[60],[67],[71],[82],[86].	
What types of interventions were included	In all studies, patients received electroconvulsive therapy sessions. In two studies [33],[70] reported unilaterally and in 16 studies [11],[22],[23], [24],[25],[35],[38],[50], [52],[61],[62],[64],[76],[79],[80],[82] bilateral. The total number of sessions ranged from 1 to 35. The timing of electroconvulsive therapy sessions fluctuated between week two of gestation through week 40. The frequency of electroconvulsive therapy was reported in 22 studies [9],[11],[22],[23],[24],[25],[27],[29],[31], [33],[35],[39],[52],[60],[61], [62],[64],[66],[67],[76],[79],[80] and varied between 1 time every 2 weeks and 3 times a week. 37 studies refer to the type of anesthesia they used [7],[9],[11],[18],[19],[22],[23],[24],[27],[33],[34],[35],[38],[40],[43], [44],[45],[46],[48],[49],[50],[51],[52],[56],[60],[61],[62],[63],[69],[70], [71],[76],[79],[80],[82],[83],[84]. No study had a control group.	
What types of outcomes were measured	<ul> <li>The studies measured multiple outcomes, however, different systematic reviews grouped them as follows:</li> <li>Maternal adverse effects: respiratory alkalosis, vaginal bleeding, abdominal pain, contractions, premature labor, aspiration.</li> <li>Fetal adverse effects: Abortion, fetal stillbirth, complications after birth, fetal arrhythmia, malformations.</li> <li>Clinical improvement, symptom remission measured by score variation at different scales.</li> </ul>	



# **Summary of findings**

The information on the use of electroconvulsive therapy during pregnancy is based on 81 studies reporting case series or isolated cases, corresponding to 404 patients. The summary of the results is as follows:

• It is unclear what are the risks associated with electroconvulsive therapy during pregnancy because the certainty of the evidence is very low.

Patients Intervention Comparison	Pregnant women with some psychiatric pathology requiring electroconvulsive therapy (ECT) ECT Usual treatment without ECT	
Outcomes	Effects	Certainty of the evidence (GRADE)
Perinatal mortality	Different reviews provide different estimates. Some estimate there would be no association, and others it could reach 7.1% [3].	⊕○○○¹,2,3 Very low
Other side effects	Different reviews estimate that maternal risk is between 4.6% [4] and 5.3% [2] and fetal risk between 6.3% [4] and 29% [3]. The risk of complications in general, both maternal and fetal, would be between 9.3% [2] and 64.7% [3].	⊕○○○¹,2,3 Very low

GRADE: evidence grades of the GRADE Working Group (see later in this article).

# About the certainty of the evidence (GRADE)\*

# $\oplus \oplus \oplus \oplus$

**High:** This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

#### (H)(H)(H)(C)

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

# $\oplus\oplus$

**Low:** This research provides some indication of the likely effect. However, the likelihood that it will be substantially different<sup>†</sup> is high.

#### (H)()()

**Very low:** This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

- \*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.
- † Substantially different = a large enough difference that it might affect a decision.

<sup>&</sup>lt;sup>1</sup> All studies are observational.

<sup>&</sup>lt;sup>2</sup> The certainty of the evidence was downgraded for risk of bias, since none of the studies has a control group, so there is a very high risk of bias.

<sup>&</sup>lt;sup>3</sup> The certainty of the evidence was reduced due to indirectness, since most cases were performed decades ago, when both electroconvulsive therapy and anesthetic technique were very different.



# Other considerations for decision-making

## To whom this evidence does and does not apply

- This evidence applies to pregnant women during any gestation period who are undergoing psychiatric disorders for which electroconvulsive therapy is required.
- This summary does not address the efficacy of electroconvulsive therapy in the different pathologies in which it is used, which might not differ between pregnant women and the non-pregnant population.
- This summary does not address the safety of electroconvulsive therapy in the non-pregnant population, but focuses on maternal-fetal complications and on the newborn.

# About the outcomes included in this summary

According to the opinion of the authors of this summary, perinatal mortality is one of the critical
outcomes for decision making, but not the only one. Unfortunately, the studies, and therefore the
reviews, provide a very general synthesis of these effects, so it has been presented in this way in
the summary of findings table.

## Balance between benefits and risks, and certainty of the evidence

- It is not clear whether the use of electroconvulsive therapy is completely safe for the management of psychiatric pathology in pregnant women, because the certainty of the evidence is very low.
- The most frequently reported adverse events in the studies are vaginal bleeding, abdominal pain, contractions, premature labor, aspiration, and fetal complications such as abortion, stillbirth, complications after birth, fetal arrhythmia, and malformations.
- It is not possible to estimate the balance between benefits and risks, due to the existing uncertainty.

# What would patients and their doctors think about this intervention

• In cases where the psychiatric condition threatens the life of the mother or the child, there is probably little doubt about the need to use this measure. At the other extreme, in cases where the benefits are minor, or questionable, it is reasonable to abstain. The vast majority of the time the balance between benefits and risks will be uncertain, so it is important to evaluate this measure with caution. Regardless of the decision to be made, it is particularly important to report the uncertainty to patients, their relatives or caregivers.

#### **Resource considerations**

- It is not possible to make an appropriate balance between benefits and costs, due to the current uncertainty.
- While electroconvulsive therapy is associated with generally high costs, in most cases this factor should not be the primary determinant in decision-making.

#### Differences between this summary and other sources

- The conclusions of this summary partially disagree with the systematic reviews identified, which in turn come to different conclusions. Most indicate that electroconvulsive therapy is relatively safe, and that its benefits outweigh the risks, without putting a clear accent on the certainty of the evidence. One of the reviews concluded that this therapy should be used only as a last resort and under strict clinical criteria [3].
- With regard to international clinical guidelines, both the APA guideline on the use of electroconvulsive therapy [87] and the Australian and New Zealand guidelines for the management of mood disorders [88] partially disagree with the conclusions of this summary. Both indicate electroconvulsive therapy is generally safe for both the fetus and the mother, and even the Australian guideline indicates that electroconvulsive therapy may be the therapy of choice in patients with severe mood disorders. On the other hand, the NICE Guideline [89] of electroconvulsive therapy argues that given the poor quality of the evidence regarding the safety of this therapy, it should be used with caution.

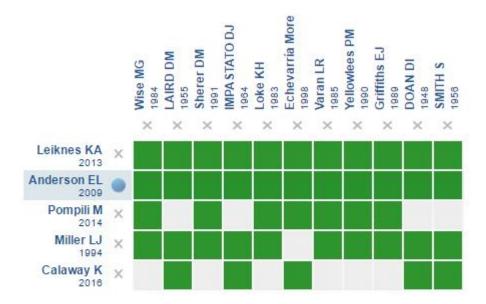
#### Could this evidence change in the future?

- It is very likely that the conclusions of this summary will change with future studies, due to the high degree of uncertainty.
- We did not identify ongoing studies that address the subject at the International Clinical Trials Registry Platform of the World Health Organization.



## How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The rows represent systematic reviews that share at least one primary study, and columns display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version**: Electroconvulsive therapy during pregnancy

## **Notes**

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears. The details about the methods used to produce these summaries are described here

http://dx.doi.org/10.5867/medwave.2014.06.5997.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database (<a href="www.epistemonikos.org">www.epistemonikos.org</a>).

These summaries follow a rigorous process of internal peer review.

#### **Conflicts of interest**

The authors do not have relevant interests to declare.

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