

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

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# Is perioperative pregabalin effective for reducing postoperative pain in major surgery?

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### Abstract

#### INTRODUCTION

Pregabalin is a structural analog of  $\gamma$ -aminobutyric acid that may have a role in acute pain management. It has been used in the perioperative context, but there is controversy regarding its real clinical utility.

#### METHODS

To answer this question we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

#### RESULTS AND CONCLUSIONS

We identified 21 systematic reviews including 77 randomized trials. We concluded the use of perioperative pregabalin in major surgeries probably does not produce a clinically important decrease in acute postoperative pain. Although it could decrease nausea, postoperative vomiting and opioid requirements, it also produces an increase in sedation.

### Problem

Postoperative pain management is an important aspect of anesthesiology practice. Among the most commonly used drugs to manage acute pain are opioids, which despite being very effective have adverse effects such as nausea, vomiting, sedation and respiratory depression. One of the strategies to reduce these unwanted effects is to use adjuvant analgesics that act through different pathways involved in pain response.

Pregabalin is a structural analog of  $\gamma$ -aminobutyric acid (GABA) that binds to the  $\alpha 2\delta$  subunit of voltage-dependent calcium channels in the central nervous system decreasing

the release of various neurotransmitters. Although it is usually used as an antiepileptic and for chronic pain management, its role for acute postoperative management has also been raised. However, is it not clear if it constitutes an effective alternative in this context.

### Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to

identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) 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 when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

### Key messages

- Perioperative pregabalin probably does not produce a clinically significant reduction of acute postoperative pain in major surgeries.
- Perioperative pregabalin increases postoperative sedation.
- Perioperative pregabalin could decrease postoperative opioid consumption and the incidence of nausea and vomiting, but the certainty of this evidence is low.

### About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found twenty one systematic reviews [1],[2],[3],[4],[5],[6],[7],[8],[9],[10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21] that include seventy seven randomized trials [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],[87],[88],[89],[90],[91],[92],[93],[94],[95],[96],[97],[98].</p>
<p>What types of patients were included*</p>	<p>Sixteen trials included patients undergoing abdominal surgery [22],[23],[24],[26],[29],[30],[31],[35],[37],[42],[69],[78],[82],[86],[88],[89], twenty one trials included patients undergoing pelvic or gynecological surgery [28],[39],[43],[45],[49],[50],[52],[56],[58],[59],[60],[65],[68],[73],[76],[80],[81],[82],[84],[90],[97], thirty trials included patients undergoing trauma surgery [25],[32],[33],[34],[36],[38],[40],[41],[44],[48],[51],[53],[54],[55],[57],[62],[63],[67],[70],[71],[72],[74],[75],[77],[82],[83],[91],[93],[95],[96], five trials included patients undergoing thoracic surgery [46],[61],[79],[92],[98]; and seven trials included patients undergoing other types of surgery [27],[47],[64],[66],[85],[87],[94].</p>
<p>What types of interventions were included*</p>	<p>In all trials oral pregabalin was administered. In forty-nine trials pregabalin was administered during the preoperative period [23],[24],[25],[26],[27],[28],[29],[31],[35],[38],[39],[42],[43],[44],[46],[48],[49],[50],[51],[52],[54],[55],[56],[60],[64],[65],[67],[68],[69],[70],[71],[72],[73],[75],[76],[80],[82],[84],[85],[86],[87],[88],[89],[91],[92],[93],[94],[97],[98], in twenty six trials during both the preoperative and the postoperative period [22],[30],[32],[33],[34],[36],[37],[40],[41],[45],[47],[53],[57],[58],[59],[61],[62],[63],[66],[77],[78],[79],[83],[90],[95],[96] and in the rest this data was not reported. Forty-six trials used a single dose of pregabalin [23],[24],[25],[26],[27],[28],[29],[31],[35],[38],[39],[42],[43],[46],[48],[50],[51],[54],[55],[56],[60],[64],[65],[67],[68],[69],[70],[71],[72],[73],[75],[76],[80],[82],[85],[87],[88],[89],[91],[92],[93],[94],[95],[96],[97],[98], twenty-seven trials used multiple doses [22],[30],[32],[33],[34],[36],[37],[40],[41],[44],[45],[47],[49],[52],[53],[57],[58],[59],[61],[62],[63],[66],[77],[78],[79],[83],[90] and in the rest this data was not reported. The dose of pregabalin varied between 50 mg and 600 mg. Dexamethasone was coadministered in one trial [51], remifentanyl infusion in two trials [58],[69], nonsteroidal anti-inflammatory drugs in two trials [60],[70], acetaminophen in one trial [73], acetaminophen and diclofenac in one trial [55], and in the rest of the trials there was no coadministration of drugs. Regarding postoperative analgesia, acetaminophen with nonsteroidal anti-inflammatory drugs were used in two trials [36],[95], acetaminophen with opioids were used in twelve trials [45],[46],[52],[55],[60],[61],[72],[73],[78],[79],[86],[93], nonsteroidal anti-inflammatory drugs alone were used in nine trials [22],[24],[28],[37],[39],[42],[51],[80],[87], nonsteroidal anti-inflammatory drugs and opioids were used in thirteen trials [27],[30],[35],[49],[50],[53],[54],[57],[63],[64],[67],[69],[70], opioids alone were used in thirty trials [23],[25],[26],[29],[31],[33],[34],[38],[40],[43],[44],[47],[56],[58],[62],[66],[68],[71],[75],[77],[82],[83],[84],[88],[89],[90],[92],[94],[97],[98], acetaminophen, nonsteroidal anti-inflammatory drugs and opioids were used in three trials [76],[91],[96] and in three trials this data was not reported [74],[81],[85]. Sixty eight trials compared against placebo [22],[23],[25],[26],[27],[29],[30],[31],[32],[33],[34],[35],[36],[37],[38],[39],[40],[41],[42],[43],[44],[45],[46],[48],[49],[50],[51],[52],[53],[54],[55],[57],[58],[61],[62],[63],[64],[65],[66],[67],[68],[71],[72],[73],[74],[75],[76],[77],[78],[79],[80],[81],[82],[83],[84],[85],[86],[88],[89],[90],[91],[92],[93].</p>

	[94],[95],[96],[97],[98], twenty trials compared against another drug [24],[30],[36],[38],[47],[50],[56],[58],[59],[60],[62],[67],[69],[70],[71],[75],[77], [80],[82],[87], three trials compared against pregabalin with another drug [72],[73],[83] and in the rest this data was not reported.
What types of outcomes were measured	The main outcomes analyzed by the systematic reviews were postoperative pain, sedation, opioid consumption, stay in a postoperative care unit, preoperative anxiety, adverse effects, postoperative nausea and vomiting, and morbidity. The average follow-up of the trials was 24 hours, with a range that fluctuated between 2 and 72 hours postoperatively.

\* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

### Summary of Findings

The information regarding the effects of perioperative pregabalin is based on 53 randomized trials that include 3543 patients in total [23],[26],[29],[30],[31],[32],[33],[34],[35],[36],[37],[38],[40],[41],[44],[45],[49],[50],[52],[53],[54],[56],[57],[58],[59],[60],[61],[63],[64],[65],[66],[69],[70],[72],[73],[74],[75],[76],[77],[78],[79],[81],[84],[85],[86],[90],[91],[92],[93],[94],[95],[96],[97]. The rest of the trials did not report any of the outcomes of interest or did it in a way that it was not possible to incorporate into a meta-analysis.

Forty-six trials reported the outcome pain at 24 hours after surgery (3037 patients) [23],[26],[30],[31],[32],[33],[34],[35],[36],[37],[38],[40],[41],[44],[45],[49],[50],[53],[54],[56],[57],[58],[59],[60],[61],[63],[64],[66],[69],[70],[72],[73],[75],[76],[77],[78],[81],[85],[86],[90],[91],[92],[93],[94],[96],[97], 27 trials the outcome opioid consumption (1712 patients) [23],[31],[35],[37],[44],[45],[49],[50],[52],[53],[56],[58],[59],[60],[63],[66],[72],[73],[77],[78],[79],[84],[91],[92],[96],[97], 31 trials the outcome nausea and vomiting (2461 patients) [23],[29],[31],[32],[33],[35],[37],[38],[50],[53],[56],[57],[59],[60],[64],[65],[69],[72],[73],[74],[77],[78],[79],[84],[86],[90],[91],[93],[95],[96],[97]; and 18 trials the outcome sedation (1587 patients) [23],[31],[33],[36],[37],[38],[53],[56],[61],[63],[64],[65],[72],[73],[90],[91],[95],[96]. The summary of findings is the following:

- Perioperative pregabalin probably does not produce a clinically significant reduction of acute postoperative pain after major surgeries. The certainty of this evidence is moderate.
- Perioperative pregabalin could decrease postoperative opioid consumption in major surgeries, but the certainty of this evidence is low.
- The use of perioperative pregabalin in major surgeries could decrease the incidence of postoperative nausea and vomiting, but the certainty of this evidence is low.
- Perioperative pregabalin in major surgeries produces an increase in postoperative sedation. The certainty of this evidence is high.

Perioperative pregabalin for postoperative pain				
Patients	Patients undergoing major surgery			
Intervention	Perioperative oral pregabalin			
Comparison	Placebo or other drugs / analgesics			
Outcome	Absolute effect*		Relative effect (95% CI)	Certainty of evidence (GRADE)
	WITHOUT Pregabalin	WITH Pregabalin		
	Difference: patients per 1000			
Postoperative pain at 24-hours (VAS 0-10)	2.61**	2.16	--	⊕⊕⊕○ <sup>1</sup> Moderate
	DM: 0.45 less (Margin of error: 0.25 to 0.64 less)			
Opioid consumption (morphine mg equivalents) ***	38.14**	28.99	--	⊕⊕○○ <sup>2</sup> Low
	DM: 9.15 less (Margin of error: 7.09 to 11.22 less)			
Nausea and vomiting	426 per 1000	311 per 1000	RR 0.73 (0.62 to 0.86)	⊕⊕○○ <sup>1,3</sup> Low
	Difference: 115 patients less per 1000 (Margin of error: 60 to 162 less)			
Sedation	133 per 1000	193 per 1000	RR 1.45 (1.04 to 2.03)	⊕⊕⊕⊕ High
	Difference: 60 patients more per 1000 (Margin de error: 5 to 137 more)			

Margin of error: 95% confidence interval (CI).  
 RR: Risk ratio.  
 MD: Mean difference.  
 GRADE: Evidence grades of the GRADE Working Group (see later).

\*The risk **WITHOUT pregabalin** is based on the risk in the control group of the trials. The risk **WITH pregabalin** (and its margin of error) is calculated from relative effect (and its margin of error).

\*\* The value was calculated using the approximate median of the control group of the trials

\*\*\* The consumption of opioids is described in milligrams of intravenous morphine. When an opioid other than morphine was administered, the trials calculated the dose of equianalgesic morphine according to conversion tables.

<sup>1</sup> The certainty of evidence was reduced in one level given the inconsistency of the results obtained (I<sup>2</sup> 50-89%)  
<sup>2</sup> The certainty of evidence was reduced in one level given the inconsistency of the results obtained (I<sup>2</sup> >90%)  
<sup>3</sup> The certainty of evidence was reduced in one level due to publication bias according to the funnel plot.

About the certainty of the evidence (GRADE)*
<p>⊕⊕⊕⊕</p> <p><b>High:</b> This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.</p>
<p>⊕⊕⊕○</p> <p><b>Moderate:</b> This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate</p>
<p>⊕⊕○○</p> <p><b>Low:</b> This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.</p>
<p>⊕○○○</p> <p><b>Very low:</b> This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.</p>
<p>*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.</p> <p>† Substantially different = a large enough difference that it might affect a decision.</p>

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## Other considerations for decision-making

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### To whom this evidence does and does not apply

- The evidence presented in this summary applies to adult patients undergoing abdominal, pelvic or gynecological, trauma, thoracic and other major surgeries; and who receive general or neuraxial anesthesia.
- It is not possible to determine if there is a different effect in any of the subgroups evaluated in this summary.

### About the outcomes included in this summary

- The outcomes presented in the summary of findings table are those considered critical for health decision-making by the authors of this article. These generally coincide with those evaluated in the systematic reviews identified.

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

- Perioperative pregabalin probably produces a decrease of acute postoperative pain of 0.45 points (VAS 0-10), which is below the minimally important difference established in the literature in a perioperative pain context [99].
- Perioperative pregabalin may decrease opioid consumption and the incidence of postoperative nausea and vomiting, however, the certainty of the evidence is low.
- In addition, perioperative pregabalin probably produces an increase in sedation.
- It is not possible to make an adequate balance between benefits and risks, due to the uncertainty associated to the benefits. However, considering that it has no clinically important benefit on the main outcome, and that it has adverse effects, it is probably an intervention whose balance is not favorable.

### Resource considerations

- It is a relatively low-cost intervention in the perioperative context.
- It is not possible to make an adequate balance between benefits and costs, due to the uncertainty associated to the benefits. However, it is probably an intervention whose balance is not favorable.

### What would patients and their doctors think about this intervention

- Faced with the evidence presented in this summary, most clinicians should lean against the use of pregabalin for postoperative pain.
- Variability in decision-making for this intervention can be expected, considering there is some possibility of benefit, and the adverse effects are not severe. This could be reinforced by the existence of recommendations in favor of this intervention in the main clinical guidelines.

### Differences between this summary and other sources

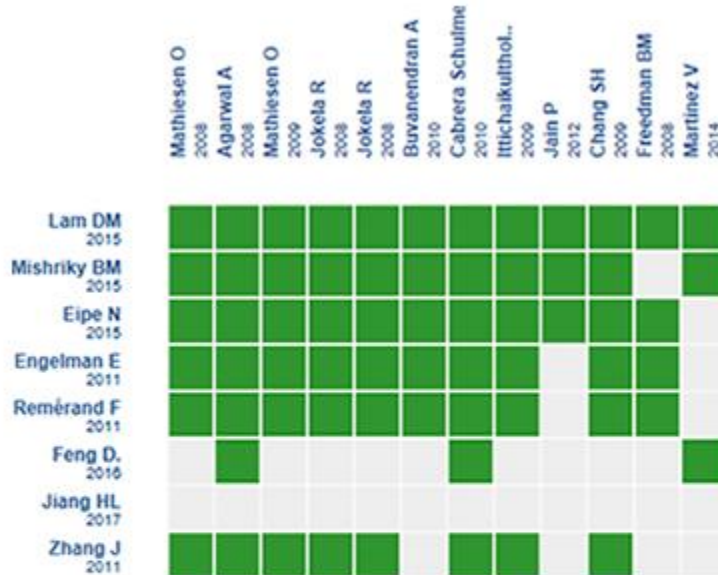
- The conclusions of this summary coincide with the different systematic reviews identified, which propose that the use of pregabalin could have a role in postoperative pain management, but which is of low impact and depends on the type of surgery. Its indication for routine use is discussed and must take into account the associated risks and benefits. They also emphasize that the quality of existing evidence is low.
- Regarding the main clinical guidelines, The American Society of Anesthesiologists Practice Guidelines for Acute Pain Management in the Perioperative Setting states that pregabalin should be considered in post-operative multimodal analgesia, since pain reduction and reduced postoperative opioid consumption have been described [100]. On the other hand, the Australian and New Zealand College of Anaesthetists (ANZCA) Acute pain management: scientific evidence guideline mentions pregabalin as part of the options for acute neuropathic pain treatment in surgery and trauma context [101].

### Could this evidence change in the future?

- The likelihood that future evidence changes the conclusion of this summary is low, due to the certainty of the evidence involving some of the outcomes.
  - In a search in the Prospective register of systematic reviews (PROSPERO), we did identify at least seven ongoing reviews addressing this question [102],[103],[104],[105],[106],[107],[108]. Their conclusions could provide relevant clinical information.
  - Also, there are at least 6 ongoing trials addressing this question according to the International Clinical Trials Registry Platform of the World Health Organization [109],[110],[111],[112],[113],[114].
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## 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.



An evidence matrix is a table that compares systematic reviews that answer the same question.

Rows represent systematic reviews, and columns show primary studies.

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

The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the **interactive version**: [Perioperative pregabalin for acute postoperative pain in major surgeries](#)

## 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.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using

Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here

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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 ([www.epistemonikos.org](http://www.epistemonikos.org)).

### Potential conflicts of interest

The authors do not have relevant interests to declare.

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