# Are postoperative prophylactic antibiotics effective for orbital fracture?

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## Abstract

### Introduction

Infection is one of the main complications of orbital fracture, either because of the connection to the paranasal sinuses or as a postoperative complication. Despite the advances made in this condition, there is still controversy regarding the role of prophylactic antibiotics.

### 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 and generated a summary of findings table using the GRADE approach.

### Results and conclusions

We identified only one systematic review including four studies overall, of which only one was a randomized trial. We concluded that postoperative antibiotic prophylaxis might not decrease the risk of infection in orbital fracture, and probably increases the risk of diarrhea.

## Problem

An increase in the incidence of traumatic facial fracture has been reported in the last years, with 30-40% compromising the orbit[1]. While the risk of infection associated to this type of fracture is difficult to determine, it is estimated at less than 1%[2]. Because of the anatomical characteristics of the orbit and its proximity to the paranasal sinuses, the prophylactic use of postoperative antibiotics has been suggested, but it is not clear if they are actually effective.

## Key messages

- Postoperative antibiotic prophylaxis might not decrease the risk of infection in orbital fracture.
- Postoperative antibiotic prophylaxis probably increase the risk of complications, particularly diarrhea.

## About the body of evidence for this question

| | |
|---|---|
| What is the evidence.<br>See evidence matrix in Epistemonikos later | We found one systematic review[3] including four studies[4-7], of which only one corresponded to a randomized trial[4]. This table and the summary in general are based on the latter, since the observational studies did not increase the certainty of the existent evidence nor did they contribute any relevant additional information. |
| What types of patients were included* | The trial[4] included patients with orbital blow-out fracture that required surgical intervention and with no need of intensive care; without bacterial infection at the moment of the fracture, bullet wounds, pathological fracture, basilar skull fracture with cerebrospinal fluid rhinorrhoea or intracranial emphysema, history of malignancy or radiation in the head and neck area, known hypersensitivity or allergy to penicillin or other beta-lactam antibiotics, compromised host defense, severe renal insufficiency or lack of compliance. |
| What types of interventions were included* | The trial[4] compared the use of intravenous amoxicillin/clavulanic acid 1.2g every eight hours from the time of admission to 24 hours after the surgery, followed by four days of orally administered placebo every eight hours, versus the use of intravenous amoxicillin/clavulanic acid 1.2g every eight hours from the time of admission to 24 hours after the surgery, followed by four days of orally administered amoxicillin/clavulanic acid 625 mg every eight hours for four days. |
| What types of outcomes were measured | The outcomes reported by the systematic review were postoperative infections and adverse effects (skin rash and diarrhea).<br>The mean follow-up of the trial was six months[4]. |

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

## 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.

## Summary of Findings

The information about the effects of postoperative antibiotic prophylaxis in orbital fracture is based on one randomized trial[4] that included 62 patients.

This trial[4] reported the outcomes postoperative infection, diarrhea and skin rash (62 patients).

The summary of findings is the following:

- Postoperative antibiotic prophylaxis might not decrease the risk of infection in orbital fracture, but the certainty of the evidence is low.
- Postoperative antibiotic prophylaxis probably increases the risk of diarrhea. The certainty of the evidence is moderate.
- Postoperative antibiotic prophylaxis might not increase the risk of skin rash, but the certainty of the evidence is low.

**Postoperative antibiotic prophylaxis for orbital fracture**

**Patients** Orbital fracture
**Intervention** Antibiotic prophylaxis
**Comparison** Placebo

| Outcome | Absolute effect* | | Relative effect (95% CI) | Certainty of evidence (GRADE) |
|---|---|---|---|---|
| | **WITHOUT antibiotic prophylaxis** | **WITH antibiotic prophylaxis** | | |
| | Difference: patients per 1000 | | | |
| Postoperative infections | 30 per 1000 | 69 per 1000 | RR 2.28 (0.22 to 23,82) | ⨁⨁◯◯[1] Low |
| | Difference: 39 patients more (Margin of error: 24 less to 692 more) | | | |
| Diarrhea | 3 per 1000 | 10 per 1000 | RR 3.4 (0.14 to 80.36) | ⨁⨁⨁◯[2] Moderate |
| | Difference: 7 patients more (Margin of error: 3 less to 240 more) | | | |
| Skin rash | 30 per 1000 | 12 per 1000 | RR 0.38 (0.02 to 8.93) | ⨁⨁◯◯[1] Low |
| | Difference: 18 patients less (Margin of error: 30 less to 240 more) | | | |

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

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

[1] The certainty of the evidence was downgraded in two levels for imprecision, since the confidence interval is too wide, and providing from a single trial.
[2] The certainty of evidence was downgraded in only one level for imprecision due to abundant existing indirect evidence in other populations.

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

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

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

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

⊕◯◯◯
**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.

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* 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

## Other considerations for decision-making

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

The evidence presented in this summary applies to patients with a low-risk orbital fracture, since the trial included patients that did not require intensive care; without acute pre-existent bacterial infections at the moment of the fracture, bullet wounds, pathological fracture, basilar skull fracture with cerebrospinal fluid rhinorrhoea or intracranial emphysema, history of malignancy or radiation in the head and neck area, known hypersensitivity or allergy to penicillin or other beta-lactamic antibiotics, compromised host defense, severe renal insufficiency or lack of compliance.

### About the outcomes included in this summary

The outcomes presented in the summary of findings table are those considered critical for decision-making, according to the opinion of the authors of this summary. In general, they coincide with the outcomes reported by the systematic reviews identified.

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

There is a high degree of uncertainty regarding the possible effects of the intervention. ON the other hand, is is associated to adverse effects, which are not serious, but probably frequent.

It is not possible to make an adequate balance between benefits and risks, due to the uncertainty regarding the former.

### Resource considerations

Even though antibiotics are easily accessible, and of a relatively low cost, it is not possible to make an adequate cost-benefit balance, due to the existing uncertainty.

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

According to a report by the American Society of Ophthalmic Plastic and Reconstructive Surgery, 63% of the polled members do not use prophylactic antibiotics on patients with orbital fracture[2]. Among the reasons that may justify this practice are: the fact that most orbital fractures do not require surgical correction, a low incidence of infections associated to orbital fracture (the incidence of post-fracture orbital cellulitis is below 1%[2]); potential risks associated to using antibiotics without a clear justification and the increase in the costs associated to health services[2].

Faced with the evidence presented in this summary, most patients and physicians should lean towards not using postoperative prophylactic antibiotics for the prevention of infections associated to orbital fracture. However, in high-risk patients the decision may vary depending on the clinical conditions.

### Differences between this summary and other sources

The conclusions in this summary agree with the systematic reviews identified.

The guideline of the American Academy of Ophthalmology states that, at least in the case of orbital floor fractures, the use of antibiotics is subjected to physician's judgement[1]. Other guidelines also recognize the lack of evidence to inform the use of prophylactic antibiotics in orbital fracture[2,8].

### Could this evidence change in the future?

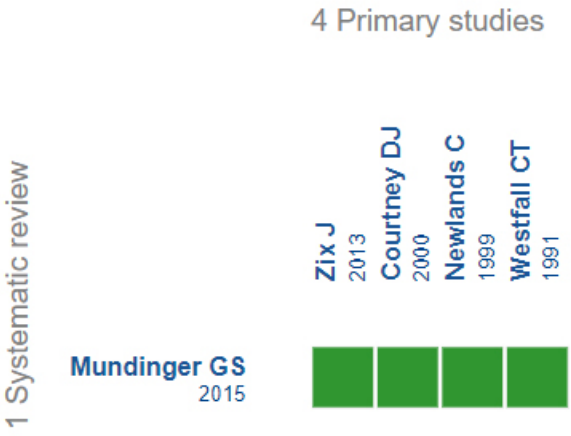
It is probable that the conclusions in this summary might be modified by future evidence, due to the uncertainty about the benefits of the intervention.

We identified one ongoing trial [9] in the International Clinical Trials Registry Platform of the World Health Organization.

We did not identify ongoing systematic reviews in the PROSPERO database.

## 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:** [Prophylactic antibiotics for orbital fractures]

## 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 (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

www.epistemonikos.org.

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