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[Intervention Review]

# Antibiotic prophylaxis for spontaneous bacterial peritonitis in cirrhotic patients with ascites, without gastro-intestinal bleeding

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## ABSTRACT

### Background

Spontaneous bacterial peritonitis is frequent among cirrhotic patients, associated with significant morbidity and mortality. Selective intestinal decontamination employing antibiotics is a proposed prophylactic measure. While data regarding this modality among cirrhotic patients with gastrointestinal bleeding exist, there is insufficient data synthesis regarding cirrhotic patients with ascites and no gastrointestinal bleeding.

### Objectives

To assess whether antibiotic prophylaxis decreases spontaneous bacterial peritonitis and mortality among cirrhotic patients with ascites and no gastrointestinal bleeding.

### Search methods

We identified relevant randomised trials by searching trial registries of The Cochrane Hepato-Biliary Group and The Cochrane Collaboration, medical literature search engines, and reviewing all literature we found on the topic until February 2009.

### Selection criteria

We searched for randomised clinical trials assessing prophylactic treatment among adult cirrhotic patients with ascites and no gastrointestinal bleeding, comparing antibiotic therapy with no intervention, placebo, or with another antibiotic regimen.

### Data collection and analysis

Three independent authors searched for and collected the trials and extracted relevant data. Four other independent authors validated the findings and assessed them. The studies were assessed for design, patient and intervention characteristics, and quality. A meta-analysis was performed to estimate measures of association between antibiotic prophylaxis and spontaneous bacterial peritonitis or mortality.

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## **Main results**

Nine trials were included in the review. Seven trials, comparing antibiotics to placebo or no treatment, were meta-analysed. Systematic bias in design or publication is suggested by trial results. The randomisation results suggest that the probability that true randomisation took place in all trials is very small and the report of most trials regarding design was poor. The proportion of participants with spontaneous bacterial peritonitis varied between the trials from 15% to 50%. The calculated relative risks (95% confidence interval) of spontaneous bacterial peritonitis and mortality among patients treated with antibiotics compared with no treatment/placebo were 0.20 (0.11 to 0.37) and 0.61 (0.43 to 0.87). There were very few reports of adverse events.

## **Authors' conclusions**

The pooled estimates suggest that antibiotic prophylaxis might be prudent among cirrhotic patients with ascites and no gastrointestinal bleeding. However, poor trial methodology and report coupled with findings suggesting systematic bias in publication and design reflect the fragility of these findings. Potential hazard to society and the patients themselves from resistant pathogens should be considered when promoting long-lasting antibiotic prophylaxis. It seems that recommending antibiotic prophylaxis is still far from being a substantiated prevention strategy. Trials of better design, well reported, and of longer follow-up are greatly needed.

## **PLAIN LANGUAGE SUMMARY**

### **Existing trials, of poor quality, indicate that antibiotic prophylaxis reduces spontaneous bacterial peritonitis among cirrhotic patients with ascites and no gastrointestinal bleeding**

Spontaneous bacterial peritonitis (infection and inflammation of the membrane lining the abdominal cavity) is a frequent complication among cirrhotic patients (patients with end-stage liver disease marked by irreversible scarring of liver tissue) and is associated with significant morbidity and mortality. Selective intestinal decontamination, employing antibiotics, is a proposed prophylactic (preventive) measure. This systematic review of randomised clinical trials assesses whether antibiotic prophylaxis prevents spontaneous bacterial peritonitis and mortality among cirrhotic patients with ascites (excess fluid in the abdominal cavity) and no gastrointestinal bleeding. Nine trials are included in the review. The pooled rates of spontaneous bacterial peritonitis and mortality indicate that antibiotic prophylaxis reduces both. There are very few reports of adverse events. Reviewing these trials, we found poor methodology, evidence suggesting publication bias, and limited follow-up periods. Thus, the recommendation to prescribe prophylactic antibiotics to cirrhotic patients without gastrointestinal bleeding is hampered by quality of the trials that generated the data. Due to potential hazards, both to society as a whole and the patients, as individuals, before antibiotic prophylaxis can be confidently recommended, trials of better design, well reported, and of longer follow-up are required.