



## Complete Summary

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### GUIDELINE TITLE

Management of adult patients with ascites due to cirrhosis.

### BIBLIOGRAPHIC SOURCE(S)

Runyon BA. Management of adult patients with ascites due to cirrhosis. Hepatology 2004 Mar;39(3):841-56. [110 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Runyon BA. Management of adult patients with ascites caused by cirrhosis. Hepatology 1998 Jan;27(1):264-72.

### \*\* REGULATORY ALERT \*\*

### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse (NGC):** This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [July 08, 2008, Fluoroquinolones \(ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin\)](#): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

### COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

### **DISEASE/CONDITION(S)**

Ascites caused by cirrhosis

### **GUIDELINE CATEGORY**

Diagnosis  
Evaluation  
Management  
Prevention  
Treatment

### **CLINICAL SPECIALTY**

Family Practice  
Gastroenterology  
Internal Medicine

### **INTENDED USERS**

Physicians

### **GUIDELINE OBJECTIVE(S)**

To provide a data-supported approach to care of patients with ascites caused by cirrhosis

### **TARGET POPULATION**

Adults with ascites caused by cirrhosis

### **INTERVENTIONS AND PRACTICES CONSIDERED**

#### **Initial Assessment and Diagnosis**

1. History
2. Physical examination
3. Abdominal ultrasound
4. Abdominal paracentesis
5. Ascitic fluid analysis including a cell count and differential, ascitic fluid total protein, and serum-ascites albumin gradient
6. Culture of ascitic fluid at bedside in blood culture bottles

#### **Treatment/Management**

NOTE: Refer to the "Major Recommendations" field for appropriate clinical context.

#### **Tense Ascites**

1. Abstinence from alcohol
2. Sodium-restricted diet
3. Oral spironolactone and furosemide
4. Serial paracenteses
5. Liver transplantation

### **Refractory Ascites**

1. Serial paracentesis;
2. Post-paracentesis albumin infusion for large-volume paracentesis
3. Referral for liver transplantation
4. Transjugular intrahepatic portosystemic stent-shunt (TIPS)
5. Peritoneovenous shunt

### **Hepatorenal Syndrome**

1. Albumin infusion plus administration of vasoactive drugs (octreotide, midodrine) for type I hepatorenal syndrome
2. Expedited referral for liver transplantation for patients with cirrhosis, ascites, and type I hepatorenal syndrome

### **Spontaneous Bacterial Peritonitis (SBP)**

1. Abdominal paracentesis
2. Empiric antibiotic therapy (e.g., cefotaxime)
3. Total protein, lactate dehydrogenase (LDH), glucose, and Gram's stain to differentiate between SPB and secondary peritonitis
4. Oral ofloxacin
5. Albumin

### **Prevention of Spontaneous Bacterial Peritonitis**

1. Short term prophylaxis (norfloxacin, trimethoprim/sulfamethoxazole)
2. Long-term prophylaxis (norfloxacin, trimethoprim/sulfamethoxazole)

### **MAJOR OUTCOMES CONSIDERED**

- Accuracy of diagnostic tests
- Serum and urine levels of sodium
- Health care costs
- Fluid retention
- Spontaneous bacterial peritonitis
- Survival rates

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Searches of Electronic Databases

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

A Medline search from 1966 through 2002 was performed; search terms included ascites, diet therapy, drug therapy, radiotherapy, surgery, and therapy. The search involved only papers published in English and involving humans. A manual search of the author's files was also performed. The search yielded 1,867 papers including 411 published since a similar search was performed in 1997 in preparation for writing the previous guideline on ascites.

## **NUMBER OF SOURCE DOCUMENTS**

A total of 1,867 papers, including 411 published since the release of the original guideline, were identified in the literature search.

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

**Grade I:** Randomized controlled trials

**Grade II-1:** Controlled trials without randomization

**Grade II-2:** Cohort or case-control analytic studies

**Grade II-3:** Multiple time series, dramatic uncontrolled experiments

**Grade III:** Opinions of respected authorities, descriptive epidemiology

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

The guideline developers reviewed a published cost-analysis.

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

This guideline was commissioned and approved by the American Association for the Study of Liver Diseases (AASLD).

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Recommendations are followed by quality of evidence ratings (Grades I, II-1, II-2, II-3, III) which are defined at the end of the "Major Recommendations" field.

### **Evaluation and Diagnosis**

1. Abdominal paracentesis should be performed and ascitic fluid should be obtained from inpatients and outpatients with clinically apparent new-onset ascites **(Grade II-3)**.
2. Since bleeding is sufficiently uncommon, the prophylactic use of fresh frozen plasma or platelets before paracentesis is not recommended **(Grade III)**.

### **Ascitic Fluid Analysis**

3. The initial laboratory investigation of ascitic fluid should include an ascitic fluid cell count and differential, ascitic fluid total protein, and serum-ascitic albumin gradient (SAAG) **(Grade II-2)**.
4. If ascitic fluid infection is suspected, ascitic fluid should be cultured at the bedside in blood culture bottles **(Grade II-2)**.
5. Other studies can be ordered based on pretest probability of disease (Refer to Table 2 in the original guideline document for ascitic fluid laboratory data) **(Grade III)**.

### **Treatment of Ascites**

6. Patients with ascites who are thought to have an alcohol component to their liver injury should abstain from alcohol consumption **(Grade II-2)**.
7. First-line treatment of patients with cirrhosis and ascites consists of sodium restriction (88 mmol per day [2,000 mg per day]) and diuretics (oral spironolactone and furosemide) **(Grade I)**.
8. Fluid restriction is not necessary unless serum sodium is less than 120 to 125 mmol/L **(Grade III)**.
9. An initial therapeutic abdominal paracentesis should be performed in patients with tense ascites. Sodium restriction and oral diuretics should then be initiated **(Grade II-3)**.

10. Diuretic-sensitive patients should preferably be treated with sodium restriction and oral diuretics rather than with serial paracenteses (**Grade III**).
11. Liver transplantation should be considered in patients with cirrhosis and ascites (**Grade II-3**)

### **Treatment of Refractory Ascites**

12. Serial therapeutic paracenteses may be performed in patients with refractory ascites (**Grade III**).
13. Post-paracentesis albumin infusion may not be necessary for a single paracentesis of less than 4 to 5 L. For large-volume paracenteses, an albumin infusion of 8 to 10 g per liter of fluid removed can be considered (**Grade II-2**).
14. Referral for liver transplantation should be expedited in patients with refractory ascites (**Grade II-3**).
15. Transjugular intrahepatic portosystemic stent-shunt (TIPS) should be considered in appropriately selected patients who meet criteria similar to those of published randomized trials (**Grade I**).
16. Peritoneovenous shunt should be considered for patients with refractory ascites who are not candidates for paracenteses, transplant, or TIPS (**Grade I**).

### **Hepatorenal Syndrome**

17. Albumin infusion plus administration of vasoactive drugs such as octreotide and midodrine should be considered in the treatment of type I hepatorenal syndrome (**Grade II-1**).
18. Patients with cirrhosis, ascites, and type I hepatorenal syndrome should have an expedited referral for liver transplantation (**Grade II-3**).

### **Spontaneous Bacterial Peritonitis (SBP)**

19. Patients with ascites admitted to the hospital should undergo abdominal paracentesis. Paracentesis should be repeated in patients (whether in the hospital or not) who develop signs or symptoms or laboratory abnormalities suggestive of infection (e.g., abdominal pain or tenderness, fever, encephalopathy, renal failure, acidosis, or peripheral leukocytosis) (**Grade III**).
20. Patients with ascitic fluid polymorphonuclear leukocyte (PMN) counts greater than or equal to 250 cells/mm<sup>3</sup> (0.25 X 10<sup>9</sup>/L) should receive empiric antibiotic therapy (e.g., intravenous cefotaxime 2 g every 8 hours) (**Grade I**).
21. Patients with ascitic fluid PMN counts less than 250 cells/mm<sup>3</sup> (0.25 X 10<sup>9</sup>/L) and signs and symptoms of infection (temperature >100 degrees F or abdominal pain or tenderness) should also receive empiric antibiotic therapy (e.g., intravenous cefotaxime 2 g every 8 hours) while awaiting results of cultures (**Grade II-3**).
22. When the ascitic fluid of a patient with cirrhosis is found to have a PMN count greater than or equal to 250 cells/mm<sup>3</sup> (0.25 X 10<sup>9</sup>/L), it should also be

- tested for total protein, lactic dehydrogenase (LDH), glucose, and Gram's stain to assist with the distinction of SBP from secondary peritonitis (**Grade II-2**).
23. Oral ofloxacin (400 mg twice per day.) can be considered a substitute for intravenous cefotaxime in inpatients without vomiting, shock, grade II (or higher) hepatic encephalopathy, or serum creatinine greater than 3 mg/dL (**Grade I**).
24. Patients with ascitic fluid PMN counts greater than or equal to 250 cells/mm<sup>3</sup> (0.25 X 10<sup>9</sup>/L) and clinical suspicion of SBP should receive 1.5 g albumin per kg body weight within 6 hours of detection and 1.0 g/kg on day 3 (**Grade I**).

### **Prevention of SBP**

25. Short-term (7 days) inpatient twice-daily norfloxacin (or trimethoprim/sulfamethoxazole) should be given to prevent bacterial infections in patients with cirrhosis and gastrointestinal hemorrhage; a quinolone antibiotic can be given intravenously while the patient is actively bleeding (**Grade I**).
26. Patients who have survived an episode of SBP should receive long-term prophylaxis with daily norfloxacin (or trimethoprim/sulfamethoxazole) because this is the most data-supported indication for long-term outpatient prophylaxis (**Grade I**).
27. In patients with cirrhosis and ascites but no gastrointestinal bleeding, either short-term (inpatient-only) or long-term outpatient use of daily norfloxacin (or trimethoprim/sulfamethoxazole) can be justified when the ascitic fluid total protein is less than or equal to 1 g/dL or serum bilirubin greater than 2.5 mg/dL (**Grade I**).

### **Definitions:**

#### **Quality of Evidence**

**Grade I:** Randomized controlled trials

**Grade II-1:** Controlled trials without randomization

**Grade II-2:** Cohort or case-control analytic studies

**Grade II-3:** Multiple time series, dramatic uncontrolled experiments

**Grade III:** Opinions of respected authorities, descriptive epidemiology

#### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate management of patients with ascites caused by cirrhosis

#### **Subgroups Most Likely to Benefit:**

Patients with a high serum-ascites albumin gradient have portal hypertension and usually are responsive to salt restriction and diuretics.

### POTENTIAL HARMS

- Complications of abdominal paracentesis have been reported in only about 1% of patients (abdominal wall hematomas), despite the fact that 71% of the patients had an abnormal prothrombin time. Although more serious complications (hemoperitoneum or bowel entry by the paracentesis needle) occur, they are sufficiently unusual (
- The chronic hyponatremia that is usually seen in patients with cirrhotic ascites is seldom morbid. Rapid attempts to correct hyponatremia in this setting can lead to more complications than the hyponatremia itself.
- Patients with parenchymal renal disease (e.g., diabetic nephropathy or immunoglobulin A nephropathy) may tolerate less spironolactone than usual because of hyperkalemia.
- Peritoneovenous shunt placement is associated with poor long-term patency and excessive complications.

## QUALIFYING STATEMENTS

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Intended for use by physicians, these recommendations suggest preferred approaches to the diagnostic, therapeutic, and preventative aspects of care. They are intended to be flexible, in contrast to standards of care, which are inflexible policies designed to be followed in every case. These guidelines were developed for the care of adult patients with clinically detectable ascites. Although the general approach may be applicable to children, the pediatric data base is much smaller and there may be unanticipated differences between adults and children. Patients with ascites that is detected by imaging modalities alone, but not yet clinically evident, are not included because of the lack of published information regarding the natural history of this entity.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## **IMPLEMENTATION TOOLS**

Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Living with Illness  
Staying Healthy

### **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

Runyon BA. Management of adult patients with ascites due to cirrhosis. Hepatology 2004 Mar;39(3):841-56. [110 references] [PubMed](#)

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

1998 Jan (revised 2004 Mar)

### **GUIDELINE DEVELOPER(S)**

American Association for the Study of Liver Diseases - Private Nonprofit Research Organization

### **SOURCE(S) OF FUNDING**

American Association for the Study of Liver Diseases

### **GUIDELINE COMMITTEE**

Practice Guidelines Committee

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Runyon BA. Management of adult patients with ascites caused by cirrhosis. *Hepatology* 1998 Jan;27(1):264-72.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [American Association for the Study of Liver Diseases Web site](#).

Print copies: Available from the American Association for the Study of Liver Diseases, 1729 King Street, Suite 200; Alexandria, VA 22314; Phone: 703-299-9766; Web site: [www.aasld.org](http://www.aasld.org); e-mail: [aasld@aaasld.org](mailto:aasld@aaasld.org).

## **AVAILABILITY OF COMPANION DOCUMENTS**

This guideline is available as a Personal Digital Assistant (PDA) download via the APPRISOR™ Document Viewer from [www.apprisor.com](http://www.apprisor.com).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on May 9, 2003. The information was verified by the guideline developer as of June 12, 2003. The guideline was updated by ECRI on July 27, 2004. The updated information was verified by the guideline developer as of August 25, 2004. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

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