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# Unsuspected Infection Is Infrequent in Asymptomatic Outpatients With Refractory Ascites Undergoing Therapeutic Paracentesis

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**OBJECTIVE:** Large-volume paracentesis is a safe and effective means of treating patients with refractory ascites. However, there is limited information regarding the need for ascitic fluid studies in asymptomatic outpatients presenting for therapeutic paracentesis. The aim of this prospective study was to define the incidence and natural history of peritoneal fluid infection in asymptomatic outpatients undergoing therapeutic paracentesis.

**METHODS:** Over a 13-month period, 118 therapeutic paracenteses were performed in 29 outpatients with decompensated cirrhosis (Child-Pugh class B = 38%, C = 62%). After a brief medical history and physical examination, ascitic fluid cell count with differential and culture were obtained from all participating subjects. Seven (24%) of the subjects were receiving norfloxacin prophylaxis, accounting for antibiotic coverage during 40% of the procedures performed. The clinical course and outcome of study subjects during a mean follow-up of 137 days was reviewed.

**RESULTS:** All 118 (100%) of the ascitic fluid samples demonstrated absolute neutrophil counts of $<250/mm^3$ (mean = 6.5 ± 22.5 pmn/$mm^3$). Asymptomatic bacterascites was identified from three of the 118 (2.5%) fluid samples, but all of these subjects spontaneously recovered without treatment or sequelae. During follow-up, six episodes of symptomatic or hospital-associated peritoneal fluid infection were identified in study participants, emphasizing the importance of fluid studies in other clinical settings.

**CONCLUSIONS:** Although further studies are needed, the routine culture of ascitic fluid in asymptomatic outpatients with refractory ascites requiring therapeutic paracentesis may not be necessary when there is a low index of suspicion for occult infection. In circumstances of clinical uncertainty, however, obtaining ascitic fluid cell counts with differential is recommended to insure patient safety. (Am J Gastroenterol 1999;94:2972–2976. © 1999 by Am. Coll. of Gastroenterology)

## INTRODUCTION

Refractory ascites (RA), defined as fluid overload that is unresponsive to sodium restriction and high-dose diuretics, is estimated to occur in <10% of patients with cirrhotic ascites (1). In light of the poor short-term survival in these individuals, it is currently recommended that patients with RA be considered for liver transplantation (2, 3). In both transplant candidates and other patients with RA, intermittent therapeutic large-volume paracentesis (LVP) is considered a safe, simple, and effective treatment strategy (3, 4).

Patients with advanced and severe liver disease such as those with refractory ascites appear to be at increased risk of developing peritoneal fluid infection (5). Although the outcome with spontaneous bacterial peritonitis (SBP) and SBP variants has improved over the last decade, the in-hospital and 1-yr mortality of patients with SBP remain approximately 30% and 50%, respectively (6–8). At presentation, as many as one-third of patients with infected peritoneal fluid do not manifest overt signs or symptoms such as fever or abdominal pain (6). Furthermore, 7–27% of patients with cirrhotic ascites harbor occult peritoneal fluid infection at the time of hospital admission (6, 9, 10). Therefore, a high index of suspicion with a low threshold to perform a diagnostic paracentesis is required to make a rapid diagnosis of this potentially life-threatening infection in various clinical settings.

With an increasing emphasis on cost containment in the delivery of medical care, many patients with RA are undergoing LVP in the outpatient setting. Although many of these patients are at increased risk for SBP due to their advanced liver disease, low protein ascites, and prior episode(s) of SBP, the need for routine ascitic fluid analysis in the outpatient setting remains unclear (11). The issue is further complicated by the fact that some patients are now receiving primary or secondary antibiotic prophylaxis to prevent SBP. In our experience, there is considerable variability in clinical practice with regards to the need and type of diagnostic ascitic fluid studies to perform in the outpatient setting. Therefore, the aim of this study was to prospectively determine the incidence and natural history of peritoneal fluid

infection in asymptomatic outpatients with RA presenting for therapeutic paracentesis.

## MATERIALS AND METHODS

### *Patient Population*

Outpatients with cirrhosis and RA presenting to the Medical Procedure Unit at the University of Michigan Medical Center for LVP were invited to participate in this study from April 1, 1997 to May 15, 1998. A brief medical history and physical exam was performed before each LVP by a gastroenterology fellow or attending physician. Inclusion criteria were age ≥18 yr with diuretic refractory or intolerant (*i.e.*, develop prerenal azotemia or electrolyte imbalance) cirrhotic ascites requiring therapeutic LVP. Exclusion criteria included symptoms of possible peritonitis such as recent fever, chills, or abdominal pain not thought to be related to fluid accumulation alone. Subjects with moderate to severe abdominal tenderness or peritoneal signs on examination were excluded. Other exclusion criteria included evidence of acute decompensation in liver disease with gastrointestinal bleeding, worsening hepatic encephalopathy, or acute renal insufficiency with a serum creatinine >2.5 mg/dl. In addition, subjects with malignant ascites and noncirrhotic ascites were excluded. Any subject receiving prescription antibiotics for a documented bacterial infection within 2 wk of LVP were excluded. Subjects receiving oral antibiotics for primary or secondary prophylaxis for SBP were included. The protocol was reviewed by the local Institutional Review Board and written informed consent was obtained from all participating subjects.

During the study period, 227 outpatient paracenteses were performed at our institution. Twenty-nine eligible subjects were enrolled at the time of 118 therapeutic paracenteses and form the basis of this report.

### *Procedure*

Large-volume paracentesis was performed in the standard fashion. A site in the midline suprapubic or lower quadrant area was localized by percussion and prepped using sterile technique. A 14-gauge catheter was inserted into the peritoneal cavity until a free flow of ascitic fluid was obtained. The needle trocar was removed and fluid samples for diagnostic studies were obtained. The catheter was connected to a wall-mounted suction unit with the intent to drain the peritoneal cavity to the greatest extent possible, or total paracentesis. In most instances, ascitic fluid was drained within 30–90 min of needle insertion. Details of the procedure, including the number of needle passes, fluid appearance, volume removed, and complications, were prospectively recorded. Immediate periprocedural complications included hypotension, defined as a decrease in systolic blood pressure of >20 mm Hg or a systolic blood pressure <90 mm Hg upon completion of the procedure, intraperitoneal or site bleeding requiring transfusion or hospitalization, new-onset abdominal pain, or leakage at the needle-insertion site. Human serum albumin was infused per predetermined dosing guidelines at the discretion of the attending physician.

Laboratory test charges for ascitic fluid studies at the University of Michigan Hospitals were obtained from the Department of Laboratory Services. Estimates of the corresponding Medicare reimbursement for the fluid studies performed were obtained from published fee schedules for CPT codes 89051 (fluid cell count with differential), 87075 (anaerobic culture), and 87070 (aerobic culture).

### *Ascitic Fluid Analysis*

Using sterile technique, 10 ml of ascitic fluid was inoculated at the bedside into Bactec-T/Alert FAN aerobic and anaerobic blood culture bottles (Organon Teknika, Durham, NC) (12). Ascitic fluid cell counts with manual differential of the white blood cell count was performed on all specimens using standard laboratory techniques. Peritoneal fluid results were categorized as follows: spontaneous bacterial peritonitis (SBP) = fluid cell count of ≥250 polymorphonuclear leukocytes (PMN)/$mm^3$ with a positive culture; culture-negative neutrocytic ascites (CNNA) = fluid cell count of ≥250 PMN/$mm^3$ and a negative culture after 7 days; monomicrobial nonneutrocytic bacterascites (MNB) = fluid cell count of <250 PMN/$mm^3$ and a single positive bacterial culture result; normal or uninfected = fluid cell count of <250 PMN/$mm^3$ and a negative culture after 7 days. All subjects with MNB underwent repeat diagnostic paracentesis within 5 days of a positive culture report to detect progression to SBP or resolution of bacterascites.

### *Subject Follow-Up*

The cumulative incidence of peritoneal fluid infection and the clinical outcome of study participants during the 13-month study period were determined by chart review.

### *Statistics*

Statistical analysis of the data was performed using StatView 4.5 (Abacus Concepts Inc., Berkeley, CA). Values are expressed as the mean ± SD.

## RESULTS

Clinical characteristics of the 29 eligible subjects with refractory cirrhotic ascites undergoing 118 therapeutic paracenteses are summarized in Table 1. All subjects entered into the protocol had a low ascitic fluid albumin and a serum-ascites albumin gradient >1.1 g/dl (10). The etiology of cirrhosis was related to alcohol and hepatitis C in the majority of subjects. All subjects had evidence of advanced liver disease with 38% Child-Pugh class B and 62% Child-Pugh class C. In addition, 17% had a documented episode of prior SBP and 38% were awaiting liver transplantation. Overall, 24% of the subjects were receiving oral antibiotics for primary or secondary prevention of SBP, accounting for antibiotic coverage during 40% of the procedures performed.

**Table 1.** Clinical Characteristics of Study Subjects (n = 29)

| | |
|---|---|
| Mean age, yr | 55 ± 11.4 (range, 37–76 yr) |
| Gender | 23 men, 6 women |
| Etiology of cirrhosis | |
| Alcohol | 12 (41.4%) |
| Alcohol and hepatitis C | 6 (20.7%) |
| Hepatitis C | 5 (17.2%) |
| Cryptogenic | 2 (6.9%) |
| Other | 4 (13.8%) |
| Child-Pugh class | |
| B | 11 (38%) |
| C | 18 (62%) |
| Transplant candidates | 11 (38%) |
| Antibiotic prophylaxis | 7 (24%) |

The results from the 118 paracenteses with ascitic fluid analysis are summarized in Table 2. Therapeutic paracentesis was performed with the intent of total paracentesis whenever possible. The procedure was well tolerated by study subjects, with no serious complications identified. In all cases, the fluid cell count was $<250$ PMN/mm$^3$. Three of the 118 fluid specimens grew *Micrococcus*, *Klebsiella Oxytoca*, and coagulase-negative *Staphylococcus* species, respectively. All of the positive cultures exhibited growth within 4 days of inoculation. A careful review of the procedure notes failed to identify any technical difficulties encountered during these procedures. Two of the three positive cultures occurred in a 47-yr-old man with cryptogenic cirrhosis receiving norfloxacin 400 mg per day for primary SBP prophylaxis. This patient underwent a total of 38 LVPs over the study period. Subject follow-up after the report of a positive culture included a repeat paracentesis with fluid studies within 5 days. In each instance, the subject remained asymptomatic and follow-up fluid studies revealed no evidence of progressive or persistent infection.

The clinical course and outcome of the 29 study subjects followed during the study period are summarized in Table 3. With a mean follow-up of 137 ± 103 days, seven (24%) subjects died, six (21%) underwent liver transplantation, 11 (38%) were alive at their last visit, and five (17%) were lost to follow-up. The identified causes of death included hepatorenal syndrome in three subjects and progressive liver failure in the remaining four. During follow-up, six subjects (21%) developed discrete episodes of symptomatic peritoneal fluid infection that were diagnosed under clinical circumstances independent of a study-related paracentesis.

**Table 2.** Ascitic Fluid Analysis at LVP (n = 118)

| | |
|---|---|
| Mean no. of LVP/subject | 4.1 ± 7.5 (range, 1–36) |
| Mean volume removed | 9.4 ± 4.9 L (range, 2–20.8) |
| No. receiving albumin | 103 (87%) |
| Mean albumin infused | 24.2 ± 16.0 g |
| Mean fluid WBC/mm$^3$ | 107 ± 94.5/mm$^3$ (range, 8–538/mm$^3$) |
| Mean fluid PMN/mm$^3$ | 6.5 ± 22.5/mm$^3$ (range, 0–204/mm$^3$) |
| Positive cultures* | 3 (2.5%) |

* See *Results* for bacterial pathogens isolated.

LVP = large-volume paracentesis; WBC = white blood cell count; PMN = polymorphonuclear leukocytes.

**Table 3.** Ascitic Fluid Infection Identified at the Time of a Non-study-related Paracentesis*

| Infection† | Presentation | Culture Results |
|---|---|---|
| CNNA | Fever, abdominal pain | No growth |
| SBP | Fever, abdominal pain | *Escherchia coli* |
| MNB‡ | Encephalopathy, N/V | *Streptococcus sp.* |
| MNB | At admission | *Serratia sp.* |
| MNB | Abdominal pain | *Staphylococcus sp.* |
| MNB | Fever, other infection | *Pseudomonas sp.* |

* Mean follow-up, 137 ± 103 days (range, 7–338).

† Additional episodes of ascitic fluid infection were identified under clinical circumstances independent of a study-related outpatient therapeutic paracentesis.

‡ Receiving prophylactic antibiotics.

CNNA = culture-negative neutrocytic ascites; SBP = spontaneous bacterial peritonitis; MNB = monomicrobial nonneutrocytic bacterascites; N/V = nausea and vomiting.

Four cases of MNB and one case each of SBP and CNNA were diagnosed immediately before or upon admission to the hospital in patients with clinical symptoms (Table 3). Only one of the six subjects was receiving prophylactic antibiotics. All of these episodes of symptomatic peritoneal fluid infection were successfully treated with antibiotics without any associated in-hospital mortality. There was no apparent temporal relationship between these episodes of infection and the performance of an outpatient therapeutic LVP.

The hospital charges and Medicare reimbursement for the ascitic fluid cell counts and culture are summarized in Table 4. Assuming that the incidence of peritoneal fluid infection is 2.5% in asymptomatic outpatients, the estimated cost to diagnose a single case of monomicrobial bacterascites in a comparable patient population would be $1320–$9600 using Medicare reimbursement and University of Michigan Medical Center institutional charges, respectively.

## DISCUSSION

Patients with refractory ascites are at increased risk of developing potentially serious and life-threatening spontaneous peritoneal fluid infection, but little information regarding the need for routine ascitic fluid analysis at the time of outpatient therapeutic paracentesis is available. We set out to prospectively study ascitic fluid cell counts and cultures obtained at the time of therapeutic LVP in outpatients

**Table 4.** Estimated Hospital Charges and Medicare Reimbursement for Ascitic Fluid Studies

| Ascitic Fluid Test | UMMC* | Medicare† |
|---|---|---|
| Fluid cell count with differential | $ 92 | $ 8 |
| Fluid culture (aerobic/anaerobic) | $ 148 | $ 25 |
| Total charge per procedure | $ 240 | $ 33 |
| Cost per case of MNB identified = Total charge per procedure/ (2.5 case of MNB identified/ 100 procedures) | $9600 | $1320 |

* Charges estimated from University of Michigan Hospitals laboratory fee schedule.

† Medicare laboratory fee reimbursement for CPT codes 89051 (fluid cell count with differential), 87075 (anaerobic culture), and 87070 (aerobic culture).

**Table 5.** Studies of Ascitic Fluid Analysis During Outpatient Large-Volume Paracentesis

| Study | % Patients With Cell Count ≥250 PMN/mm$^3$ | % Patients With Positive Cultures | Outcome of Patients With Positive Cultures |
|---|---|---|---|
| Stern *et al*. (21)* | 0% | 0% (0/37) | |
| Kolle *et al*. (22) | 0% | 2.3% (4/173) | No treatment or sequelae |
| Jeffries *et al*.† | 0% | 2.5% (3/118) | No treatment or sequelae |

* Includes only patients in whom both cell count and culture results were reported.
† Current publication.

with refractory ascites. We found that none of the 118 fluid specimens demonstrated elevated neutrophil counts suggestive of bacterial peritonitis. Furthermore, the bedside inoculation of blood culture bottles grew bacterial microorganisms in only three of 118 (2.5%) samples. With fluid cell counts of <250 PMN/mm$^3$, these cases were classified as MNB, an SBP variant with a more favorable prognosis than SBP or CNNA (13, 14). Close monitoring of subjects with MNB demonstrated spontaneous clearance of bacterascites in all three cases. This favorable outcome in subjects with asymptomatic MNB is consistent with prior studies that demonstrate a favorable prognosis in the absence of symptoms (14, 15).

The low rate of peritoneal fluid infection observed in our study may be due to several factors. Subjects with overt signs or symptoms suggestive of peritoneal fluid infection, acute decompensation in liver disease, and those being admitted to the hospital for other reasons were excluded from this protocol, as it is standard of care to perform a diagnostic paracentesis in these high-risk settings (16). Secondly, antibiotic prophylaxis with norfloxacin was used by 24% of study subjects, accounting for antibiotic coverage during 40% of the procedures performed. This may have resulted in a lower-than-expected rate of peritoneal fluid infection, as previous studies have demonstrated the efficacy of antibiotic prophylaxis in high-risk patient populations (17, 18).

It is unlikely that the low rate of peritoneal fluid infection observed was due to suboptimal culture methods and techniques. Ten milliliters of ascitic fluid was directly inoculated into aerobic and anaerobic blood culture bottles at the bedside using sterile technique. This culture method has been previously shown to be superior to standard culture methods in the detection of ascitic fluid pathogens (12, 19). Conversely, highly sensitive culture techniques may theoretically overestimate the prevalence of true peritoneal fluid infection due to growth of contaminants. The three cases of bacterascites were classified as MNB, as prior reports have identified the isolated microorganisms as potential pathogens (20). However, the clinical significance of a culture growing coagulase-negative *staphylococci*, a frequent skin contaminant, remains unclear.

Despite the low incidence of peritoneal fluid infection at the time of outpatient LVP, the study population represented a high-risk group. All of the study subjects had RA, 62% were Child-Pugh class C cirrhotics, and 17% had a prior history of documented SBP. During a mean follow-up of 137 days, six subjects (21%) were diagnosed with symptomatic SBP or SBP variants under clinical circumstances independent of a study-related procedure (Table 3). Fortunately, all six cases were successfully treated with antibiotics without any associated in-hospital mortality. Nonetheless, overall mortality remained predictably high in our study population, with only 55% of subjects surviving without liver transplantation.

Only two other studies published in abstract form have addressed the issue of whether ascitic fluid should be analyzed at the time of therapeutic paracentesis in asymptomatic outpatients (Table 5). In a retrospective study of 37 outpatient LVPs performed at Emory University, ascitic fluid cell counts and cultures revealed no evidence of peritoneal fluid infection (21). Similarly, in a prospective study from Barcelona, 173 ascitic fluid samples were analyzed from 51 asymptomatic stable cirrhotics with RA (22). All ascitic fluid cell counts were <250 PMN/mm$^3$ and only four cultures (2.3%) grew bacterial microorganisms. These infections, classified as asymptomatic MNB, reportedly cleared without treatment or sequelae. The incidence of MNB and the favorable clinical course of infected patients was remarkably similar to that observed in the present study.

The low incidence of peritoneal fluid infection reported in these studies should not overshadow the importance of diagnostic fluid studies in the inpatient or ambulatory outpatient setting under other circumstances. For example, patients with cirrhosis and new-onset ascites, acute decompensation of liver disease, or signs and symptoms of peritonitis should undergo expedient evaluation of ascitic fluid to exclude potentially serious and life-threatening infection. In clinical practice, patients requiring therapeutic LVP may present with less ominous but concerning symptoms of vague abdominal discomfort, mild tenderness on exam, or subtle changes in affect that may be suggestive of occult infection. It would be reasonable in such instances of clinical uncertainty to obtain ascitic fluid cell count with differential. This approach would rapidly screen for SBP and CNNA, which require immediate intervention without the additional expense of cultures. However, if the ascitic fluid were cloudy at the time of therapeutic paracentesis, it would be prudent to obtain not only cell counts but a bacterial culture as well.

Our study results demonstrate that unsuspected ascitic fluid infection in asymptomatic outpatients with refractory

ascites is uncommon (2–3%). Because the outcome of patients with asymptomatic MNB was favorable and comparable to that reported in the literature, minimal risk would be incurred if ascitic fluid cultures were not routinely performed. Furthermore, with estimated charges of $240 per procedure for diagnostic fluid studies (Medicare reimbursement of $32), it would cost ~$9600 (Medicare reimbursement of $1320) to diagnose each case of asymptomatic MNB in a comparable patient population (Table 4). Although further studies are needed, the routine culture of ascitic fluid in asymptomatic outpatients frequently receiving prophylactic antibiotics may not be necessary when there is a low index of suspicion for occult infection. In circumstances of clinical uncertainty, however, obtaining an ascitic fluid cell count with differential is recommended to insure patient safety.

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