

# Few complications after paracentesis in patients with cirrhosis and refractory ascites

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## ABSTRACT

**INTRODUCTION:** The relevance of needle type and ultrasound guidance in connection with complications and technical problems in paracentesis in cirrhotic patients has only been sparsely described. The aim of this study was to evaluate paracentesis in cirrhotic patients with refractory ascites, focusing on technique, complications, amount of ascites drained and prognosis.

**MATERIAL AND METHODS:** This was a retrospective study based on 51 cirrhotic patients with refractory ascites undergoing paracentesis. A total of 209 paracenteses were performed using a pigtail catheter and an intravenous catheter. Ultrasound-guided puncture or no ultrasound-guided puncture were compared with regard to amount of drained ascites, technical problems and complications both immediate and within a week of the procedure. The impact of coagulopathy was also investigated.

**RESULTS:** 12% immediate and 5% late complications occurred, most of which were minor. No significant differences in the frequency of complications were found when comparing a pigtail to an intravenous catheter (8% versus 21%, OR = 2.81 95% CI (0.86; 9.13)), nor did the amount of drained ascites differ significantly. Ultrasound guidance did not significantly decrease the frequency of complications (7% versus 9%, OR 1.34 95% CI (0.37; 4.84)). Coagulopathy did not significantly affect the risk of complications.

**CONCLUSION:** Paracentesis in patients with cirrhosis is associated with a low frequency of serious complications, regardless of the technique deployed. Although the material is of limited size, it appears that coagulopathy does not increase the risk of complications following this procedure.

Cirrhosis is a common disease in the Western world. In Denmark, the prevalence of deaths due to cirrhosis is increasing [1]. Many cirrhotic patients will progress to a decompensated state within years, most often due to complications such as variceal haemorrhage, hepatic encephalopathy and ascites. Among these, ascites is the most common, as 50% of the patients will develop ascites within a period of ten years from diagnosis [2]. International studies have shown that the survival among cirrhotic patients with ascites is poor with a three year mortality of approximately 50% [3].

Refractory ascites – i.e. ascites not responding to di-

uretic therapy [4] – may be treated in several ways and the choice of treatment depends on the severity of the liver disease, the speed of ascites reaccumulation and the presence of any comorbidity. Large volume paracentesis (LVP) is the recommended first-choice treatment. Although a transjugular intrahepatic portosystemic shunt (TIPS) can prevent recurrence of ascites, it apparently does not improve survival, and the incidence of hepatic encephalopathy is significantly increased compared to LVP [5]. The only curative treatment of cirrhosis is a liver transplant.

The literature only provides limited data substantiating whether a specially designed needle or an intravenous catheter should be preferred when performing LVP, and although ultrasound has been introduced at many centres, only limited data are available on complications and the effect on the volume of drained ascites in paracentesis. The aim of this study is to evaluate the impact of the choice of needle type and usage of ultrasound on complications, the amount of drained ascitic fluid and prognosis.

## MATERIAL AND METHODS

A retrospective study was performed including a total of 95 patients referred for paracentesis to Hvidovre Hospital between January 2007 and December 2008. The inclusion criteria of the present study were cirrhosis and presence of refractory ascites requiring therapeutic paracentesis (**Figure 1**). The diagnosis of cirrhosis was based on liver histology or classical clinical and laboratory data. Refractory ascites was defined as a lack of response to intensive diuretic therapy (weight loss below 200 g/day during four days on spironolactone up to 400 mg/day in combination with furosemide up to 240 mg/day), but patients with recurrent side effects on lower diuretics doses were also considered to have refractory ascites.

A total of 44 patients were excluded, 27 due to other diseases causing ascites (e.g. cancer, heart failure and pancreatitis), 14 were still responding sufficiently to diuretic therapy and in three cases the medical charts could not be produced.

For each case of paracentesis performed on the 51 included patients, the following data were collected

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**FIGURE 1**

Utensils used in paracentesis.



from a data sheet filled in at each procedure: coagulation parameters prior to paracentesis, volume of drained ascitic fluid, needle type, ultrasound guidance, immediate complications and dose of infused albumin.

Coagulopathy was defined as prothrombin index < 0.40; platelet count  $\leq$  40 billion/l or both according to local definitions [6].

The primary endpoint was occurrence of complications related to paracentesis, which was defined as immediate complications including outflow of ascitic fluid from the puncture site, local bleeding, technical problems (e.g. need for repuncture, slipping of the catheter from the abdominal wall, incomplete procedure) or complications requiring hospitalization within a week after the procedure. Complications requiring hospitalization included large haematomas, hepatorenal syndrome (HRS), hepatic encephalopathy and spontaneous bacterial peritonitis (SBP). Cases of SBP which developed within 30 days of the procedure were only registered if the neutrophil count of the ascitic fluid was normal (< 250 cells/microlitre) on the day of paracentesis. Secondary endpoints were defined as: (i) the volume of drained ascites expressed as mean volume in ml; and (ii) the patient's prognosis, which was defined as the patient's status on 1 August 2009. The cause of death was determined from the patient's record.

Data were statistically analyzed by using t-test on mean values and  $\chi^2$  test and Fisher's exact test on binary outcomes depending on sample size. All tests were two-sided and p-values below 0.05 were considered significant. 95% confidence interval (CI) was used.

## RESULTS

The population's age ranged from 44 to 81 years, and it mainly comprised males with cirrhosis due primarily to alcohol (**Table 1**). The majority of the patients had ad-

vanced cirrhosis with a high Child-Pugh score (mean 10.6, 95% CI (10.0; 11.1)) – 67% being Child-Pugh class C. Besides refractory ascites, 80% of the patients had experienced  $\geq$  2 other cirrhosis-related complications (e.g. oesophageal varices, hepatic encephalopathy, hepatocellular carcinoma, HRS or SBP) at the time of inclusion. Additionally, more than half of the patients suffered from other significant comorbidities, the most frequent of which were cardiac disease, hypertension, diabetes and cancer. 20% of the patients suffered from  $\geq$  2 comorbid diseases.

At the cut-off date (1 August 2009), 18 patients (35%) were alive, 27 patients (53%) had died due to cirrhosis and four patients (8%) had died from other diseases, while two patients (4%) had died from causes not specified in the medical chart (**Figure 2**).

A total of 209 paracenteses were performed on the 51 patients (median 2, (1;57)) with a mean volume of drained ascites of  $6,822 \pm 2,698$  ml. Immediate complications occurred in 12% of the procedures. The most frequent complication was local bleeding, but 5% were technical problems. Late complications occurred in 16 procedures; however, in five cases it was unlikely that the complication was related to the paracentesis (two cases of SBP due to variceal haemorrhage, two cases of HRS caused by increased doses of diuretics and a case of


**TABLE 1**

Clinical and laboratory data at baseline.

Variable	Patients (n = 51)
Age, years, median (range)	58 (44-81)
Sex, n (%)	
Male	33 (65)
Female	18 (35)
Aetiology, n (%)	
Alcoholic	47 (92)
Hepatitis C-related <sup>a</sup>	2 (4)
Hepatitis B-related	2 (4)
Cryptogenic	1 (2)
Serum albumin, g/dl	27 (14.7-38.0)
Serum bilirubin, micromol/l, median (range)	30.5 (3.0-304.0)
Serum creatinine, micromol/l, median (range)	83 (36-382)
International Normalised Ratio, median (range)	1.5 (1.0-3.0)
Child-Pugh score <sup>b</sup> , median (range)	10 (8-15)
Model For End-stage Liver Disease score <sup>c</sup> , median (range)	13.5 (6.4-27.7)

a) One patient had both alcoholic and hepatitis C aetiology.

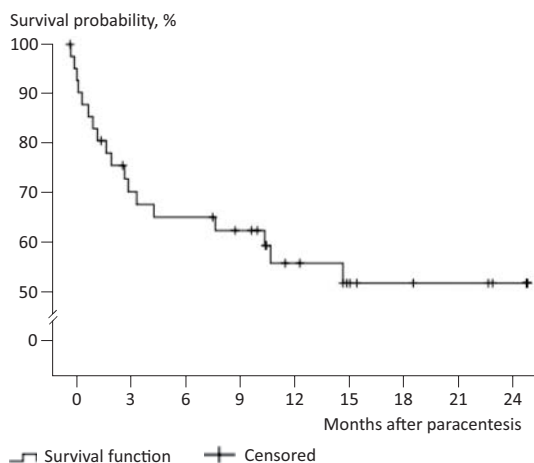
b) The Child-Pugh score (range 5-15) was calculated on the basis of the presence and degree of hepatic encephalopathy, presence and degree of ascites, bilirubin and albumin concentration in serum, and International Normalized Ratio.

c) The Model For End-stage Liver Disease score was calculated on the basis of bilirubin and creatinine concentrations in serum, and International Normalized Ratio.



FIGURE 2

Survival probability. Patients with hepatocellular carcinoma ( $n = 7$ ) and patients who died due to other causes than cirrhosis ( $n = 6$ ) have been excluded.



fever due to erysipelas); hence, late complications due to paracentesis occurred in 5% of cases (Table 2).

Paracentesis was performed using a pigtail catheter (size seven French) in 71 of the procedures, while an intravenous catheter (venflon size 16 G) was used in 34 procedures. In 104 paracenteses, information about type of needle was lacking. The rate of immediate complications was greater in procedures performed by venflon than by pigtail (21% versus 8%), although there was no statistically significant difference with regard to risk, odds ratio (OR) 2.81, 95% CI (0.86; 9.13). Particularly the number of repunctures was increased when venflon was used (five versus none). Late complications occurred more often when a pigtail catheter was used (eight versus none). The mean volume of drained ascitic fluid did not differ significantly between the two types of needles (Table 3).

Ultrasound was used to locate a proper puncture site in 101 of the paracenteses, while 44 procedures were performed without this technique. Documentation concerning ultrasound lacked in 64 procedures. The rate of immediate complications was marginally smaller when ultrasound was used (7% vs. 9%), but there was no significant difference in risk, OR 1.34, 95%CI (0.37; 4.84). Also, no significant difference was found for the mean volume of drained ascitic fluid.

Coagulopathy was present prior to paracentesis in 40 of the procedures (19%). In 45 paracenteses, the coagulation status had not been obtained within a week prior to the procedure. In 70% of the cases, a low prothrombin index was the cause of coagulopathy, a low platelet count was the cause in 15% and in another 15% both parameters fulfilled local coagulopathy criteria. The

risk of immediate complications did not differ significantly between paracenteses performed in patients with coagulopathy prior the procedure compared with those performed in the absence of coagulopathy, OR 2.71, 95%CI (0.94; 7.81).

## DISCUSSION

Therapeutic paracentesis in cirrhotic patients with refractory ascites is the recommended first line treatment, but although intravenous albumin infusions have been demonstrated to reduce the rate of complications by preventing post-paracentesis induced circulatory dysfunction (PICD), the procedure is still associated with complications [7].

The immediate complications seen in this study match the findings reported in a recent prospective study [8] where minor complications occurred in 9% of the procedures and technical problems in another 6%. Bleeding is considered to be one of the most serious complications to paracentesis [9, 10], but was only observed in < 1% of the procedures (one patient).

Well-known late complications of paracentesis include SBP, HRS and hepatic encephalopathy [4, 8]. In the present study, these conditions were also observed after paracentesis, although rarely. Given the trial's design, it cannot be determined whether these conditions were associated with paracentesis, or if they were simply unrelated events occurring in this population of patients with advanced cirrhosis.

There was a tendency towards a higher incidence of subsequent repunctures when venflon was used than



TABLE 2

Data on all paracenteses regarding volume of drained ascitic fluid and complications.

Variable	Paracenteses (n = 209)
Mean volume $\pm$ SD of drained ascitic fluid, ml	6,821,5 $\pm$ 2,698
<i>Immediate complications, n (%)</i>	
Outflow of ascites from the puncture site	4
Local bleeding from the puncture site	7
Pain located to the puncture site	3
Slipping of the catheter from the abdominal wall	2
Repuncture	6
Incomplete drainage	2
Total	24 (12)
<i>Late complications, n (%)</i>	
Spontaneous bacterial peritonitis	5
Hepatorenal syndrome	4
Encephalopathy	2
Fever	4
Abdominal haematoma	1
Total	16 (8)

SD = standard deviation.

 TABLE 3

Comparison of pigtail catheter to intravenous catheter and ultrasound-guided puncture to blind puncture.

Variable	Pigtail catheter (n = 71)	Intravenous catheter (n = 34)	Ultrasound-guided (n = 101)	Blind (n = 44)
<i>Immediate complications, n</i>				
Outflow of ascites from the puncture site	0	1	1	0
Local bleeding from the puncture site	5	0	3	2
Pain located to the puncture site	0	0	0	0
Slipping of the catheter from the abdominal wall	1	1	0	0
Repuncture	0	5	3	1
Incomplete drainage	0	0	0	1
Rate of complications, %	8	21	7	9
Mean volume ± SD of drained ascitic fluid, ml	6,872,6 ± 3,243	6,679,4 ± 2,390	6,712,1 ± 2,755	7,031,3 ± 2,425

SD = standard deviation.

when the pigtail catheter was used. This observation is supported by the results from two randomized studies comparing intravenous catheters with specially designed paracentesis needles [11, 12]: Schlottmann et al found a higher success rate when they used the special paracentesis needle (93% versus 30%,  $p < 0.001$ ) to perform a complete drainage of ascites with no need of repuncture; and Shaheen et al found a significantly lower rate of repunctures (one versus six,  $p = 0.046$ ) when using a special paracentesis needle. In our study, the pigtail catheter was associated with more severe complications such as HRS and SBP. One explanation may be that this needle was often used in hospitalized patients; hence, their risk of developing these conditions was already increased. Some of these patients were hospitalized due to variceal haemorrhage, which is a known risk factor for the development of both SBP and HRS [2, 13]. It would be relevant to perform a larger randomized study aimed at investigating if the needle type affects the risk of developing severe complications. Furthermore, the significant number of procedures deployed and the lack of data on needle type demand that conclusions be cautious.

The mean volume of drained ascitic fluid did not differ significantly between the two needle types, as we observed a difference of only 193 ml in favour of the pigtail catheter. In the studies mentioned above [11, 12], the specially designed paracentesis needle yielded in a more complete ascites drainage than intravenous catheters. It was not possible to investigate residual ascites in this retrospective study. Nor was it possible to monitor the time used for paracentesis or patients' satisfaction with the procedure.

As the needles appear to be equally good in terms of safety and volume, the choice of needle may be based either on price or on time-efficacy. Thus, a larger caliber may decrease the time required for the procedure, which is particularly advantageous in outpatient clinics.

Ultrasound guidance had no beneficial effect on the volume of drained ascites. In the present population, ultrasound may primarily have been applied in the following situations: When access to ascites was judged difficult, on suspicion of a limited amount of ascites, when complications were expected with regard to drainage of the ascitic fluid; as described in De Gottardi et al [8], this could explain the recorded lack of benefits. Given the retrospective design of our study, we cannot rule out that this was, indeed, the case. Further studies are needed to evaluate the possible benefit of ultrasound in paracentesis. However, since ultrasound is a non-invasive procedure without known risks and may be of benefit to selected patients, its continued use seems warranted.

In 19% of the paracenteses, the coagulation parameters met local coagulopathy criteria [6] without increasing significantly the risk of complications associated with the procedure; however, bleedings did, in fact, occur. Other studies have reached the same conclusions and the absolute contraindications to paracentesis continue to be persisting disseminated intravascular coagulation or fibrinolysis [8-10].

Mortality due to cirrhosis was 53% during the period of observation – a surprisingly low share as most of the patients had advanced cirrhosis and half of the population had significant comorbidities associated with an unfavorable prognosis [14].

## CONCLUSION

Paracentesis in cirrhotic patients is a fairly safe procedure. Neither the choice of needle type nor the usage of ultrasound significantly changed the severity or the frequency of complications or the volume of drained ascites. Coagulopathy did not significantly increase the risk of procedure-related complications.

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