## Title

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Original Article

# Incidence and risks of complication following 2,230 image-guided abdominal paracentesis

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A B S T R A C T

*Background:* Routine use of ultrasound (US) guidance for abdominal paracentesis has not gained consensus due to a lack of clinical data demonstrating greater safety relative to paracentesis performed without bedside imaging. While many studies have described complication rates after blind paracentesis, there have been limited reports describing incidence and risk factors for major complications following image-guided abdominal paracentesis in large cohorts. Here, we report an institutional experience of a large number of US-guided abdominal paracentesis performed.
*Methods:* For each paracentesis, we obtained relevant clinical, laboratory, and procedural variables to identify factors associated with major complications. Data was collected for 389 consecutive patients undergoing 2,230 abdominal paracentesis.
*Results:* Overall, 35 subjects experienced 56 major complications, representing a 2.5% complication rate. Of note, the complication rates for pain, bleeding, and perforation were 0.13%, 0.18%, and 0%, respectively. Mortality following paracentesis was recorded in three cases or 0.13% of procedures. Greater serum sodium levels and larger diameter catheters were associated with a lower risk of complication, while ascites related to malignancy were associated with a greater risk of complication. Indicators of coagulopathy, such as low platelet count or prolonged prothrombin time, did not correlate with risk of complication.
*Conclusion:* Our cohort's relatively low complication rate supports that US-guided paracentesis is safe and well-tolerated. The administration of coagulation factors or blood products to prevent US-guided paracentesis-related complications is unlikely to be beneficial.



Keywords: Ascites; Complications; Paracentesis; Ultrasound

## Introduction

Ascites is a frequent complication of portal hypertension related to increased sinusoidal hydrostatic pressure and vasodilation within splanchnic capillaries. The development of ascites is associated with poor prognosis in patients with advanced liver disease.[1,2] Paracentesis enables the cytological and chemical evaluation of ascitic fluid, which is often critical to diagnosing the etiology and complications of ascites.[3] Furthermore, large-volume ascites is associated with several complications, including discomfort, early satiety, and dyspnea. Treatment of ascites revolves around a low salt diet and the use of diuretics; therapeutic paracentesis is used for the treatment of ascites not easily mobilized.[4,5] When compared to diuretic therapy alone, paracentesis has been associated with a lower incidence of systemic and hemodynamic disturbance, encephalopathy, electrolyte abnormalities, and renal impairment.[4,6] Other benefits include improved cardiac output and lung volumes and reductions in intra-abdominal, portal intrathoracic, and pulmonary pressures.[6] Patients with medically refractory ascites, despite multiple large-volume paracentesis, can benefit from surgical or interventional portosystemic shunts.[7]

There are a number of well described complications related to

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the use of paracentesis such as bleeding, infection, and intestinal perforation.[1,8,9] Although ultrasonography (US) is recognized as a procedural adjunct to improve safety of central venous catheter insertion and thoracentesis, there is no consensus for routine use of US guidance during paracentesis due to lack of clinical data demonstrating greater safety relative to paracentesis performed without bedside imaging.[10–12] While many studies have described complications after blind paracentesis, there have been limited reports describing incidence and risk factors for major complications following US guided abdominal paracentesis in large cohorts.[9,13–15] Here, we report an institutional experience of a large number of US-guided abdominal paracentesis performed within the department of interventional radiology.

## Methods

### *Patient selection*

The UCLA institutional review board (IRB#10-000464) approved the design of this retrospective study. Patients were selected from a population of two academic hospitals and affiliated outpatient centers. All sites are affiliated with a single nationally accredited liver transplant program. The electronic medical record was used to acquire demographic, medical, and procedural information during a 41-month period between January 2016 and May 2019. For each procedure, we obtained the indication (diagnostic, therapeutic, or both), volume of fluid collected, and type and diameter of needle used. Additionally, pre-procedure values for prothrombin time (PT), platelet count, total serum bilirubin, serum sodium, and serum creatinine were collected within 4 weeks of paracentesis when available.

### *Procedure*

Ultrasound was used to identify the area of free-flowing abdominal fluid prior to marking entry point of the abdomen. Next, color Doppler was utilized to ensure absence of vessels along the planned trajectory of the needle. Paracentesis was conducted in one of two ways. In the majority of cases, the aspiration catheter consisted of a metal introducer needle with an outer plastic sheath with diameter of 4 to 6 Fr (Yueh; Cook Medical) or 6 to 8 Fr (Safe-T-Centesis; Becton Dickinson). In a minority of cases, an angiocatheter with introducer needle, 25 G (1.5 Fr) to 14 G (6.3 Fr), was used. Needle choice was based on provider preference. The cannula was secured to the abdominal wall and connected with plastic tubing to a graduated canister. Peritoneal fluid was evacuated by declivity until cessation of flow.

### *Complications*

The primary endpoint was occurrence of major complications within 7 days of paracentesis.[6] Major complications were defined according to the Society of Interventional Radiology (SIR) guidelines, and included those requiring major therapy, escalation of care, or prolonged hospitalization, and those resulting in permanent adverse sequelae or death.[16] The SIR defines minor complications as those requiring nominal therapy with no lasting consequences.[16] Given that the majority of our paracentesis were performed in the outpatient setting, there was inadequate sensitivity for detection and inclusion of minor complications.

### *Statistical analysis*

A generalized mixed effects logistic regression model was created to test correlations between clinical variables and complications while accounting for confounding effects related to variable interaction and repeated measures within subjects. In this model, patient and treatment characteristics were included as fixed effects, while subject identification was included as random effects. Only patients with complete data for all model parameters could be included in this portion of the analysis.

*P*-values < 0.05 were regarded as statistically significant. All statistical tests were performed with R (RStudio Team v2.1, 2015; Integrated Development for R. RStudio, Inc., http://www.rstudio.com/). Descriptive statistics were also used to describe the distribution of the data.

## Results

Data was collected for 389 patients undergoing 2,230 abdominal paracentesis. Overall, 35 subjects experienced 56 major complications, representing a 2.51% complication rate. The most common complications were acute hepatic encephalopathy (HE) and acute hyponatremia, occurring in 1.43% and 0.22% of cases, respectively. Iatrogenic hemorrhage occurred in 4 cases, representing a bleeding complication rate of 0.18%. All of these cases required blood transfusions. Other interventions included transfer to intensive care unit, upgrade to telemonitored bed, or interven-

**Table 1 Complication Type, Frequency, and Time Until Occurrence**

| Complication type | Count | Complications (%) | All paracentesis (%) | Days until complication (mean ± standard deviation) |
|---|---|---|---|---|
| Any complications | 56 | 100 | 2.51 | 2.7 ± 1.7 |
| Hepatic AMS/encephalopathy | 32 | 57.1 | 1.43 | 3.1 ± 1.7 |
| Acute hyponatremia | 5 | 8.9 | 0.22 | 2.2 ± 1.6 |
| Post-procedural intra-abdominal infection* | 4 | 7.1 | 0.18 | 2.5 ± 1.0 |
| Acute kidney injury | 4 | 7.1 | 0.18 | 2.3 ± 1.5 |
| Iatrogenic bleeding/hemoperitoneum | 4 | 7.1 | 0.18 | 2.5 ± 3.0 |
| Leaking ascitic fluid | 3 | 5.4 | 0.13 | 2.4 ± 0.9 |
| Abdominal pain | 3 | 5.4 | 0.13 | 2.3 ± 1.5 |
| Tachycardia upgrade to ICU | 1 | 1.8 | 0.04 | $n = 1$ |

AMS, altered mental status; ICU, intensive care unit.
*Two instances of mortality. Overall procedural mortality rate of 0.08%.

tional radiology embolization procedure. Mortality occurred in three cases, or 0.13% of procedures. One death occurred 3 days after paracentesis causing hemoperitoneum and hemorrhagic shock. Two additional cases of mortality occurred in the setting of post-procedural intra-abdominal infection, with initial presentation 2 days after paracentesis. A summary of major complications is provided in Table 1.

Baseline clinical, treatment, and laboratory characteristics amongst complicated and uncomplicated paracentesis are shown in Table 2. Causes of cirrhosis were alcohol, viral hepatitis, non-alcoholic steatohepatitis, and malignancy in 45.5%, 22.0%, 34.3%, and 7.1% of patients, respectively. More than one etiology underlying liver disease was present in 105 patients, or 26.9% of the cohort. The median platelet count was 99 × $10^3$/uL and

**Table 2 Summary of Patient, Procedural, and Laboratory Factors Across Patients With and Without Post-Paracentesis Complications**

| Variable | No Complications ($n$ = 2,174) | Any complication ($n$ = 56) |
|---|---|---|
| Patient | | |
| Sex, male | 1,457 (67.1) | 38 (67.9) |
| Age (yr) | 62.7 ± 10.2 | 61.6 ± 8.3 |
| Context | | |
| Outpatient | 1,719 (79.1) | 46 (82.1) |
| Inpatient | 436 (20.1) | 9 (16.1) |
| Emergency | 19 (0.9) | 1 (1.8) |
| Volume (L) | 4.4 ± 1.8 | 4.6 ± 1.6 |
| Needle | | |
| Yueh | 1,148 (52.8) | 37 (66.1) |
| Safe-T-Centesis | 1,001 (46.0) | 19 (33.9) |
| Other | 25 (1.1) | 0 (0.0) |
| Needle size (Fr) | 5.4 ± 0.7 | 5.2 ± 0.6 |
| Volume (L) | 4.4 ± 1.8 | 4.6 ± 1.6 |
| Etiology | | |
| Alcohol | 877 (45.5) | 34 (60.7) |
| NASH | 743 (34.3) | 14 (25.0) |
| Viral | 478 (22.0) | 11 (19.6) |
| HCC/malignant | 155 (7.1) | 13 (23.2) |
| Other | 242 (11.1) | 13 (23.2) |
| History | | |
| Anticoagulation | 149 (6.9) | 2 (3.6) |
| Prior GI bleed | 631 (29.0) | 18 (32.1) |
| Prior TIPS | 156 (7.2) | 3 (5.4) |
| Post-transplant | 86 (4.0) | 1 (1.8) |
| Dialysis > 2/week | 412 (29.0) | 10 (17.9) |
| Laboratory studies | | |
| Platelet (1e3/uL) | 126.9 ± 84.3 ($n$ = 1,911) | 105.6 ± 57.5 ($n$ = 55) |
| PT (sec) | 14.0 ± 3.7 ($n$ = 1,730) | 14.9 ± 2.9 ($n$ = 56) |
| Na (mEq/L) | 135.0 ± 5.3 ($n$ = 1,916) | 132.9 ± 6.4 ($n$ = 55) |
| Cr (mg/dL) | 1.8 ± 1.5 ($n$ = 1,912) | 1.9 ± 1.5 ($n$ = 55) |
| T. bili (mg/dL) | 2.7 ± 4.8 ($n$ = 1,781) | 3.3 ± 2.5 ($n$ = 53) |

Values are presented as number (%) or mean ± standard deviation.
NASH, non-alcoholic steatohepatitis; HCC, hepatocellular carcinoma; GI, gastrointestinal; TIPS, transjugular intrahepatic portosystemic shunt; PT, prothrombin time; Na, sodium; Cr, creatine; T. bili, total bilirubin.

**Table 3 Results of a Generalized Mixed Effects Regression Model for Prediction of Any Complication Following Paracentesis**

| Predictors | Any complication | | |
|---|---|---|---|
| | AOR | 95% CI | $P$-value |
| Patient | | | |
| Sex | | | |
| Female | ref | | |
| Male | 0.77 | 0.30–1.97 | 0.58 |
| Age (per year) | 1.00 | 0.96–1.04 | 0.98 |
| Context | | | |
| Emergency | ref | | |
| Inpatient | 0.32 | 0.03–3.15 | 0.33 |
| Outpatient | 0.12 | 0.01–1.31 | 0.08 |
| Volume (per L) | 1.13 | 0.92–1.40 | 0.25 |
| Needle | | | |
| Safe-T-Centesis | ref | | |
| Yueh | 0.50 | 0.12–2.11 | 0.34 |
| Needle size (per Fr) | 0.30 | 0.10–0.97 | 0.05* |
| Etiology | | | |
| Alcohol | 1.64 | 0.53–5.05 | 0.39 |
| NASH | 0.75 | 0.22–2.51 | 0.64 |
| Viral | 0.58 | 0.19–1.83 | 0.36 |
| Malignant | 3.67 | 1.18–11.37 | 0.03* |
| Other | 1.19 | 0.2–6.95 | 0.85 |
| History | | | |
| Anticoagulation | 1.38 | 0.22–8.64 | 0.73 |
| Prior GI bleed | 1.17 | 0.47–2.95 | 0.73 |
| Prior TIPS | 0.38 | 0.08–1.81 | 0.22 |
| Post-transplant | 1.06 | 0.09–11.95 | 0.96 |
| Dialysis > 2/week | 0.35 | 0.09–1.33 | 0.12 |
| Laboratory studies | | | |
| Platelet (per 1e3/uL) | 1.00 | 0.99–1.00 | 0.19 |
| PT (per second) | 1.08 | 0.98–1.19 | 0.15 |
| Na (per mEq/L) | 0.93 | 0.88–0.99 | 0.03* |
| Cr (per mg/dL) | 1.30 | 0.97–1.73 | 0.07 |
| T. bili (per mg/dL) | 0.97 | 0.88–1.07 | 0.54 |
| Random effects | | | |
| $\sigma^2$ | 3.3 | | |
| NID | 342 | | |
| Observations | 1,624 | | |
| Marginal $R^2$/conditional $R^2$ | 0.19/0.42 | | |

Continuous variables are reported as change in AOR with each integer step of the predictive variable. Categorical variables are reported as adjusted odds ratios (AOR) relative to a reference level or to the binary complement.
AOR, adjusted odds ratio; CI, confidence interval; NASH, non-alcoholic steatohepatitis; GI, gastrointestinal; TIPS, transjugular intrahepatic portosystemic shunt; PT, prothrombin time; Na, sodium; Cr, creatine; T. bili, total bilirubin; NID, Natural InDirect effect.
*$P$ < 0.05.

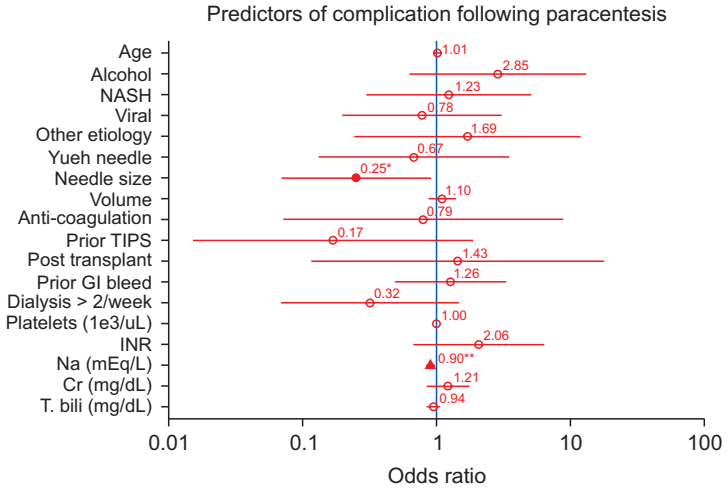


**Fig. 1.** Predictors of complication following paracentesis: Plot of AOR derived from generalized mixed effects regression model for prediction of any complication following paracentesis. Continuous variables are plotted as change in AOR with each integer step of the predictive variable. Categorical variables are reported as AOR relative to a reference level or to the binary complement. AOR, adjusted odds ratio; NASH, non-alcoholic steatohepatitis; TIPS, transjugular intrahepatic portosystemic shunt; GI, gastrointestinal; INR, international normalized ratio; Na, sodium; Cr, creatine; Bili, bilirubin. *$P < 0.05$, **$P < 0.05$.

PT was 13.0 seconds. Amongst all cases, 29.0% were performed in patients with a previous episode of gastrointestinal bleeding, 29.0% were receiving regular hemodialysis, 7.2% had an intrahepatic portosystemic shunt, and 4.0% had undergone orthotopic liver transplantation.

Results of a mixed effects logistics regression model are shown in Table 3. Greater serum sodium levels and larger diameter catheters were associated with lower risk of complication. Ascites related to malignancy was associated with greater risk of complication. Notably, laboratory values associated with coagulopathy did not correlate with risk of complication. Adjusted odds ratios are plotted in Fig. 1.

## Discussion

Prior studies describing paracentesis related complications use variable inclusion criteria. For example, a recent comparable large retrospective series reported a major complication rate of 16.8% amongst paracentesis mostly performed without imaging guidance.[6] Conversely, a smaller prospective cohort reported a far lower complication rate of 1.6%. However, this study excluded complications related to large fluid shifts such as acute hyponatremia, acute kidney injury (AKI), or acute HE and limited follow up time to 3 days.[1] Thus, comparability between previous reports and the present study are limited. Overall, the 2.5% complication rate and 0.13% mortality rate observed within our cohort are well within the range of previous reports, and supports the notion that paracentesis is a safe and well tolerated procedure.[17,18]

### *Bleeding complications*

Bleeding events were extremely rare, occurring in 0.18% of cases. Iatrogenic vascular injury in these often coagulopathic patients can be catastrophic, given the large size of potential bleeding space and inability to achieve hemostasis with direct pressure. Hemorrhagic complications of paracentesis have been associated with a three-fold increase in hospital mortality.[18] In general, bleeding complications of paracentesis have been reported in the range of 1%–3.3% for blind procedures and 0.3%–1% for US guided procedures.[1,17–20] The largest study to directly compare these methods reported a 32% relative risk of hemorrhage with imaging guidance.[18] However, this study relied on administrative claims database and these authors could not ascertain whether indexed complications occurred preceding or following paracentesis, nor could they categorically determine if image guidance was indeed used.[18] To our knowledge, we describe one of the largest single center cohorts for image guided paracentesis to date, and therein provide unique and complementary perspective to recent large multi-site database studies.[18,19] Our relatively low bleeding rate contributes to a growing body of evidence for the support of US guidance in mitigating risk of hemorrhagic complications.[6,15,18,19] Furthermore, we report no association between hematological abnormalities related to the clotting cascade, namely PT and platelet count, and an increase risk of post-paracentesis complications, including bleeding. We confirm the paradigm that administration of coagulation factors or blood products to prevent paracentesis related complications is unlikely to be beneficial.[21]

### *Sodium, creatinine, and volume status*

Cirrhotic patients with ascites have marked alterations in the splanchnic and systemic hemodynamics, related to central hypovolemia and arterial hypotension with consequent vasoconstriction and activation of renin-angiotensin and sympathetic systems.[22] Paracentesis induced circulatory dysfunction (PICD) is likely caused by large post-procedural fluid shifts, commonly manifesting as effective hypovolemia and renal impairment.[23] Resultant increased vasopressin secretion and free water retention, may explain serum chemistry abnormalities which are typically observed within 6 days of paracentesis. PICD has been reported to occur in 19%–75% of cases following paracentesis.[23–26] The administration of albumin, volume re-expansion, or administration of splanchnic vasoconstrictors prior to or immediately following paracentesis may help mitigate the risk of complications. In the present study, we show that each 1 mEq increase in pre-procedural sodium provides a 94% relative odd reduction in any complication. Future study should be performed to identify the effects of close pre-procedural sodium management for mitigation of paracentesis related complications.

Interestingly, advanced renal disease has been previously associated with paracentesis related complications, especially hemorrhage.[1,13,15] Although we discovered a trend linking elevated pre-procedural creatinine to increased odds of complication ($P = 0.067$), this correlation was not statistically significant.

### *Needle size*

Amongst procedural variables, larger catheter diameter de-

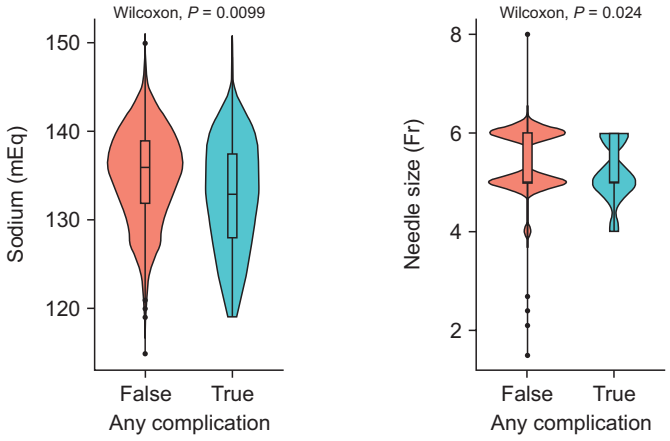


**Fig. 2.** Comparison of sodium level and needle gauge across groups: Plot of bivariate Wilcoxon rank sum tests comparing pre-procedural sodium and gauge of paracentesis needle used across any complication and no-complication groups.

creased risk of complication, whereas needle type and volume drained demonstrated no significant effect. We hypothesize that larger needles are less likely to become obstructed, and would therefore be associated with less need to reposition the needle or re-puncture the patient. Additionally, our institution uses a larger gauge pigtail catheter found in the Safe-T-Centesis system, which may help stabilize the catheter after placement. Prior studies have reported greater rates of immediate complication, particularly necessity for re-punctures, when using a smaller diameter needle.[12] Also, smaller catheters may cause premature procedural termination as indicated by obstructive cessation of flow, which could be difficult to differentiate from complete ascites drainage. It would be relevant to perform a larger randomized study aimed at investigating if needle parameters affect the risk of developing major complications. Notably, the observed effect was likely related to frequency of use of 6 Fr catheter in the non-complicated group (Fig. 2), and results should not be extrapolated to larger gauge catheters.

### *Malignancy*

Abdominal ascites related to malignancy significantly increases risk for complication. In most cases, malignancy was a primary hepatocellular carcinoma (HCC), although biliary carcinoma and metastatic liver disease were also included in this category. Given that HCC may be considered a late complication of chronic liver cirrhosis, regardless of original etiology, it is possible that the observed effect was driven by chronicity and severity of liver disease.[2] Although not assessed here, advanced liver disease, as scored by Childs-Pugh grade, has been shown to correlate with increased complication rate following paracentesis.[1] Furthermore, patients with metastatic liver disease necessitating paracentesis could have poor performance status (i.e. Eastern Cooperative Oncology Group Performance Status, Karnofsky, etc.), increasing risk for complication. Thus, these results should be interpreted cautiously, and future study should examine ascitic etiologies in the context of underlying disease duration, severity, and overall patient level of functioning.

### *Limitations*

The retrospective nature of this study presents several major limitations to the interpretation of results. First, many recorded complications may not be attributable to abdominal paracentesis. For example, HE, acute hyponatremia, spontaneous bacterial peritonitis, and AKI, frequently spontaneously occur in patients with decompensated liver disease. Given the trial design, it cannot be determined whether these conditions were associated with paracentesis, or if they were spontaneous unrelated events occurring in this population of patients with advanced liver disease. Furthermore, HE was the most common complication of abdominal paracentesis within our cohort. Although diuresis and hyponatremia have been shown to exacerbate HE, it is unclear whether paracentesis directly arbitrates this risk and no causative mechanism has been identified. In keeping with prior literature,[6,12,25,27] HE was included amongst post-procedural complications; however, it should be noted that overall complication rate was 1.1% when this subset was excluded. As there is minimal evidence directly linking large volume paracentesis to HE, future study should consider excluding these events as possible complications of paracentesis.

Additionally, there was limited follow up for detection of minor complications, especially in the outpatient settings. The majority of minor complications that did not require patients to return to urgent clinic, emergency department, or require readmission were likely not recorded. To eliminate bias in complication rates, only major complications were recorded. However, minor complications remain relevant considerations for paracentesis related management, and prospective study should be performed to account for this group.

### *Conclusions*

US guided paracentesis is an effective and well tolerated procedure, especially when performed by well-experienced providers within academic liver transplant centers. Although variable methodology limits comparability across studies, we report an overall complication rate of US guided paracentesis that is relatively low compared to prior reports of blind procedures. We confirm that aberrant coagulation parameters do not affect the risk of complication. Hyponatremia increases risk for complication and warrants further study for identification of risk mitigation strategies.

## Funding

None.

## Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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