

Study on safety of large volume paracentesis under cover of intravenous polygeline in chronic liver disease

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Abstract

Objectives: This study had two objectives: 1. To observe effects of large volume paracentesis on hemodynamic status, renal function and electrolyte balance. 2. To observe the symptomatic relief induced in portal hypertensive patients.

Study design: This was a intervention quasi- experimental study.

Setting & duration: This study was conducted in Medical unit II of Abbasi Shaheed Hospital, a tertiary care public sector hospital in Karachi, and was carried out from January 2009 to January 2010.

Methodology: During the study period, 50 adult patients who had Stable blood pressure, Normal serum electrolytes, Tense ascites preferably with edema, Prothrombin time < 40% and diagnosed case of cirrhosis of liver of more than six months duration were included while the patients with a history of Hepato-cellular carcinoma, GI bleeding within previous month, encephalopathy or Child Pugs class C were excluded. The analysis was performed using SPSS version 16.0. Data expressed as mean \pm SD. All p-values were two sided and considered statistically significant if < 0.05.

Results: There were no significant changes noted in hemodynamic status, renal function and electrolytes of all the patients undergoing large volume paracentesis with intravenous polygeline but significant change noted in symptomatic relief.

Conclusion: Large volume paracentesis with intravenous polygeline is an effective and safe therapy of ascites in-patients with cirrhosis. It is more effective then diuretics in eliminating ascites and does not induce significant changes in hepatic and renal function, fluid and electrolyte balance.

Keywords: Ascites, Cirrhosis, Polygeline, Large volume paracentesis.

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Introduction:

Diseases involving liver are one of the commonest reasons for in-patients hospital care. Chronic liver disease is one of the most frequent medical problems encountered these days in a tertiary care hospital¹. The patients are admitted in medical ward due to one of its complications like hepatic encephalopathy, upper GI bleeding and portal hypertension, spontaneous bacterial peritonitis and ascites². Apart from mortality, the morbidity of chronic liver disease is a social dilemma like work loss due to prolonged hospital stay³⁻⁴.

Ascites is the pathological accumulation of fluid in the peritoneal cavity. Although a wide variety of disease processes may be associated with ascites. More than 90% of patients with ascites are found to have cirrhosis of liver (75%), neoplasm (10%), congestive heart failure (3%), tuberculosis (2%) or pancreatitis (1%)⁵. Portal hypertension due to chronic liver disease is the most common cause of ascites.

Small amount of ascites is usually asymptomatic and physical examination is not sensitive in detecting early small amount of ascites. Large accumulation, however, can cause uncomfortable

abdominal distention and inability to perform daily routine work. Ultrasound examination is gold standard in establishing the diagnosis and in locating the optimal site for paracentesis.

Traditional practice of categorizing ascitic fluid as exudate or transudate on the basis of total protein content has been replaced by more useful calculation of serum albumin & ascitic fluid albumin gradient (SAAG)⁶. Management of ascites depends on its etiology. Valuable treatment modalities include vasopressin diuretics and sodium restrictions, peritoneo-venous shunts; Transjugular intrahepatic portosystemic shunts (TIPS), liver transplant and large volume paracentesis⁷.

As the probability of readmission to the hospital due to re-accumulation of ascites is high for such patients, hence treatment offered should be safe, effective and cheaper. The surgical shunt procedures are costly and associated with serious complication, so are not advisable for routine use.

For many centuries paracentesis was the only effective way to relieve ascites, however, it was abandoned at the end of 1950 with the introduction of modern diuretics⁸. A critical analysis of literature indicated paracentesis adversely influenced systemic and portal haemodynamics and renal functions in cirrhotics in the past⁹. Now it has been shown that large volume paracentesis with intravenous plasma expander infusions (albumin, dextrans -70, polygeline) is a rapid effective and safe therapy⁴. It is more effective than conventional diuretic treatment and helps to relieve symptoms in a short period of time.

Large volume paracentesis with intravenous polygeline lowers the incidence of complications, considerably shortens the duration of hospital stay and is more effective than diuretics in eliminating ascites and does not induce significant changes in hepatic and renal functions, fluid and electrolyte balance, cardiac output, plasma volume, plasma renin activity and plasma concentration of Nor-adrenaline and ADH. Thus, the objectives of this study were:

1. To observe effects of large volume paracentesis on hemodynamic status, renal function and electrolyte balance
2. To observe the symptomatic relief induced by large volume paracentesis in portal hypertensive patients.

Patients and methods:

This intervention quasi-experimental study was conducted in Medical unit II of Abbasi Shaheed Hospital, a tertiary care public sector hospital in Karachi. The study was carried out from January 2009 to January 2010. It was prospective study that had been conducted according to the principles of good clinical practice.

During the study period, 50 adult patients who had Stable blood pressure (systolic not less than 90mm Hg & diastolic not less than 60mm Hg), Normal serum electrolytes, Tense ascites preferably with edema, Prothrombin time < 40% and diagnosed case of cirrhosis of liver of more than six months duration were included while the patients with a history of Hepato-cellular carcinoma, GI bleeding within previous month, Child Pugs class C, Serum bilirubin >10mg/dl, Serum creatinine >3mg/dl, Platelets count <40,000/mm, Urinary sodium <10 mEq/24 hour were excluded.

An informed consent was obtained from the patients before enrollment and after enrollment their biochemical and clinical profile assessed prior to large volume paracentesis.

Procedure was done at the bedside. The physician remained at the bedside throughout the procedure; urinary bladder was emptied prior to the procedure. Written inform consent was taken prior to the procedure. All necessary lab investigation was done before and after the procedure. After careful selection of patient a wide bore cannula was inserted in the lower abdomen after sterilization under local anesthesia. Once the needle entered the peritoneal cavity, the inner part was removed and cannula was connected to the drainage bag. Drainage of ascitic fluid was continued till tap became dry or patients became haemodynamically unstable. Patient

reclined for 2 hours on side opposite to paracentesis side to prevent leakage of ascitic fluid. The Intra-venous administration of polygeline was initiated at the end of the procedure; Intra-venous polygeline 125ml per liter of ascitic fluid drained was given. Hemodynamic status was checked before and after the procedure.

The analysis was performed using SPSS version 16.0. Data expressed as mean \pm SD. All p-values were two sided and considered statistically significant if < 0.05 .

Results:

During the study period, 50 adult patients had fulfilled the inclusion criteria, among them 20 (40%) were female and 30 (60%) were male. Mean age of the patients was 51.92 ± 6.91 years. 38 (76%) of patients were belong to 40-59 years age group where as 12 (24%) were 60-69 years age group.

Table-1 shows the base line data of the patients. The mean time required to perform the paracentesis was 126.50 ± 14.22 minutes. Minimum time was 90 minutes where as maximum was 150 minutes. Operator intervention was required only intermittently that is at the beginning and end of the procedure. The average volume of ascitic fluid removed was 4825 ± 970 ml. The minimal amount removed was 3750 ml while maximal amount was 7000 ml.

Table-2 depicts the comparison of their parameters before the procedure with day one and day six after the procedure. Despite a slight increased in pulse just after the procedure, pulse returned to baseline on day six, ($P > 0.947$). Similarly Systolic and diastolic blood pressure were slightly dropped after the procedure but they also returned to base line on day six ($p > 0.241$) and ($p > 0.593$) respectively. Paracentesis with intra-venous polygeline infusion did not induce significant changes in serum creatinine ($p > 0.239$) and blood urea concentration ($p > 0.608$). None of the patient in this study developed renal impairment. Large volume paracentesis with intra-venous polygeline infusion also causes no significant changes in the serum electrolytes. No

Table 1: Baseline Parameters before Paracentesis

Baseline parameters	Mean with SD
Weight (kg)	68.06 ± 10.67
Peripheral edema	1.00 ± 0.00
Pulse (min)	73.54 ± 3.91
Systolic blood pressure (mmHg)	114.90 ± 12.06
Diastolic blood pressure (mmHg)	71.60 ± 5.84
Abdominal girth (cm)	93.84 ± 6.20
S.creatinine (mg/dl)	0.962 ± 0.181
Blood urea (mg/dl)	29.00 ± 4.75
S. sodium (mEq/l)	137.16 ± 2.79
S. potassium (mEq/l)	$3.87 \pm .212$
Total protein (g/l)	$6.178 \pm .594$
S. albumin (g/l)	2.924 ± 0.115
Symptomatic relief (dyspnoea)	3.16 ± 0.37

significant changes were also noted in the liver function of all patients under going large volume paracentesis with intra-venous polygeline. There was insignificant ($P > 0.460$) and ($p > 0.394$) decrease in both total protein and serum albumin respectively after the procedure, which returned to baseline on day six (table-2). Symptomatic relief assessed by subjective scoring of dyspnoea was significant ($p < 0.00$) and most patients was discharge from hospital within week.

Discussion:

Chronic liver disease (CLD) is one of the most frequent medical problems leading to mortality and morbidity encountered these days in tertiary care hospital³. Hepatitis B and C are the most common cause of cirrhosis world wide and they can lead to hepatocellular carcinoma while ascites is the most common of the major complication of liver cirrhosis^{10,11,12}. Its presence indicates a poor prognosis. Effective management of ascites eliminates patient's risk for life threatening complication such as spontaneous bacterial peritonitis and improves patient's wellbeing and early resumption to work.

Tense and refractory ascites in hepatic cirrhosis always poses difficulties in the management and hence different treatment options have been tried with variable results¹³. Out of these the simplest and easy to perform is large volume paracentesis followed by volume expansion or transjugular intrahepatic portosystemic shunt¹⁴.

Table 2: Comparison of Baseline Parameter with Day One & Day Six after Paracentesis

Parameters	Base Line	Day-1	Result (p-value)	Day-6	Result (p-value)
Clinical Parameters					
Pulse (min)	73.54 ± 3.91	80.66 ± 6.08	0.66	79.58 ± 5.88	0.947
Systolic blood pressure (mmHg)	114.90 ± 12.06	111.30 ± 9.47	0.003	113.60 ± 9.32	0.241
Diastolic blood pressure (mmHg)	71.60 ± 5.84	70.10 ± 6.10	0.219	71.10 ± 4.87	0.593
Weight (kg)	68.06 ± 10.67	62.04 ± 9.66	0.00	63.74 ± 9.88	0.00
Abdominal girth (cm)	93.84 ± 6.20	84.38 ± 9.27	0.00	87.26 ± 5.84	0.00
Biochemical Parameters					
S.creatinine (mg/dl)	0.962 ± 0.181	0.926 ± 0.145	0.239	0.926 ± 0.145	0.239
Blood urea (mg/dl)	29.00 ± 4.75	29.98 ± 3.11	0.172	29.38 ± 2.28	0.608
S .sodium (mEq/l)	137.16 ± 2.79	137.10 ± 2.39	0.879	137.02 ± 02.26	0.693
S. potassium (mEq/l)	3.87 ± 0.212	3.854 ± 0.133	0.629	3.84 ± 0.136	0.427
Total protein (g/l)	6.17 ± 0.594	6.15 ± 0.588	0.471	6.15 ± 0.596	0.460
S. albumin (g/l)	2.92 ± 0.115	2.90 ± 0.206	0.430	2.90 ± 0.162	0.394
Symptomatic Relief					
Dyspnoea	3.16 ± 0.37	2.14 ± 0.35	0.00	2.14 ± 0.35	0.00

This treatment is more effective than conventional diuretic treatments and is associated with lower incidence of complication¹⁵. It also considerably shortens the duration of hospital stay of cirrhotic patients. This therapeutic procedure is recognized as a safe and effective treatment of massive ascites.

Results of the present study confirm that LVP associated with plasma expander is a fast, effective and safe method for treatment of tense ascites in cirrhotic patients¹⁶. This procedure eliminated ascites in all of our 50 patients. Paracentesis without infusion of plasma expander is associated with significant impairment of systemic hemodynamic and renal function¹⁷. Among different plasma expanders, although Albumin has been found very effective in the prevention of paracentesis induced circulatory dysfunction, it implies high cost and has a limited availability¹⁸. In addition, despite effective methods of virus inactivation the plasma derivative can never be considered as completely free of a residual hazard of virus transmission. Others valid alternative like Polygeline, Dextran-70, Mannitolum and even Saline have been found equally effective¹⁹⁻²⁰. Various studies have recently shown that reinfusion of ultrafiltrate of ascitic fluid after paracentesis is as effective as paracentesis with plasma expanders but because of the cost of in-

strument and allergic reaction causes by ascitic fluid, it can not be considered a real alternative to plasma expanders²¹⁻²².

We used Polygeline in our study and found it as effective as Albumin and due to its reduced cost it may be considered the treatment of choice in cirrhotic patients with massive ascites. In addition it is preferable for patients with severe liver disease because it does not affect platelet activity and clotting mechanism. The solution of polygeline is also iso-oncotic with normal plasma and therefore its administration does not induce shifting of fluid²³.

Our current study also confirm that large volume paracentesis with polygeline does not impair systemic hemodynamic in cirrhosis¹⁷. As shown in results that all patients had slight increase in pulse rate and decrease in blood pressure just after the procedure, these changes were insignificant and they returned to baseline level on the six-day of procedure. These changes can be explained by mechanical factors that are directly or indirectly related to relief of abdominal pressure because abrupt abdominal decompression plays an important role in the early post-paracentesis systemic hemodynamic changes.

This study also shows that large volume paracentesis with polygeline infusion does not induced

renal impairment and electrolyte derangement like hyponatremia as none of our patients showed any significant change in renal function and electrolyte balance²⁴. Patients with cirrhosis and tense ascites have circulatory dysfunction characterized by arteriolar vasodilatation, hypotension and decreased effective circulatory blood volume and also activation of renal vasoconstrictor. Large volume paracentesis without plasma expanders is associated with significant decrease in creatinine clearance and serum sodium concentration as shown by Simon et al²⁵ but as shown in our study none of the patients developed such complication. This protective effect of polygeline infusion could be, theoretically, due to diminution in the rate of ascites formation or expansion of effective circulatory blood volume or both. All patients in our study had significant symptomatic relief in shortness of breath after large volume paracentesis, because lung volume decreased by tense ascites and increase after large volume paracentesis.

Conclusion:

It is concluded that treatment with large volume paracentesis with intra-venous polygeline is a safe and effective and it is also less expensive than paracentesis with albumin infusion for treating tense ascites in patients with hepatic cirrhosis.

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