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Research Article

TO STUDY THE CLINICAL PROFILE OF CIRRHOTIC PATIENTS BEFORE AND AFTER FFP TRANSFUSION ESPECIALLY WITH REGARDS TO BLEEDING TENDENCIES

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Abstract:

Background: Inappropriate use not only leads to a wastage of limited resources depriving more needy patients, but also leads to an increased healthcare cost and increased risk of transfusion related complications.

Objective: To study the clinical profile of cirrhotic patients before and after FFP transfusion especially with regards to bleeding tendencies.

Methods: The present prospective observational study was carried out in the Guru Nanak Dev Hospital/ Govt. Medical College, Amritsar. The patients presenting to medical emergency, medical outdoor and indoor with liver cirrhosis on ultrasound abdomen were selected for the purpose. A total 100 patients with written informed consent were included in the study. Clinical efficacy of fresh frozen plasma transfusion on clinical symptoms like hematemesis, melaena, ecchymosis and petechiae in liver cirrhosis patients was recorded and compared before and after transfusion of FFP.

Results: While comparing the clinical efficacy of 10ml, 15ml and 20ml/kg body weight of FFP transfusion in cirrhotic patients with clinical symptoms like hematemesis, melaena, ecchymosis and petechiae, we obtained statistically significant improvement in all three doses of FFP transfusion, but the percentage of improvement in clinical symptoms is more in 20ml/kg body weight of FFP transfusion than 15 and 10 ml/kg body weight of FFP transfusion.

Conclusion: Liver cirrhosis associated with mild coagulation abnormalities, bleeding in cirrhosis patients may be due to variceal and non-variceal cause, but variceal originis most common cause. Liver cirrhosisisalso associated with defect in coagulation factor synthesis so most patients also present as non-variceal bleed..

Keywords: Clinical Profile, Cirrhotic Patients, FFP Transfusion, Bleeding Tendencies.

INTRODUCTION

The etiology of cirrhosis can usually be identified by the patients history combined with serologic and histologic evaluation. Alcoholicliver disease and hepatitis C are

the most common cause in the western world, while hepatitis B prevails in most parts of Asia and sub-Saharan Africa. After identification of the hepatitis C virus in 1989 and of non-alcoholic steatohepatits (NASH) in obese and diabetic subjects, the diagnosis of cirrhosis without an apparent cause is rarely made.[1,2]

Complications of cirrhosis are portal hypertension which leads to gastro esophageal varices, portal hypertensive gastropathy, ascites and spontaneous bacterial peritonitis and other complications are hepato renal syndrome, hepatic encephalopathy, hepato pulmonary syndrome and coagulopathy.[3,4,]

Ultrasonography is most commonly used diagnostic investigation of cirrhosis. It provides important information on hepatic architecture, is cheap andis widely available. Nodularity and increased echogenicity of the liver are often found in cirrhosis but are also present in steatosis.[5,6] There is typically atrophy of the right lobe and hypertrophy of the left and especially caudate lobes. However, the width of the caudate relative to the right lobe is a poor predictor of cirrhosis.[7] Ultrasonography and Doppler ultrasonography of portal and central vein diameters and velocities are useful screening tests for portal hypertension and vessel patency. Contrast ultrasonography examines the appearance of echogenic micro bubbles in the hepatic vein. Their appearance after antecubital injection is correlated inversely with fibrosis.[8,9] Ultrasonography is the first imaging modality for suspected hepatocellular carcinoma (HCC), but its sensitivity and specificity to detect HCC is below that of CT or MRI.[10]

Fresh frozen plasma is indicated for the deficiency ofcoagulation factors with abnormal coagulation tests in the presence of active bleeding. FFP is also indicated for a planned surgery or invasive procedure in the presence of abnormal coagulation tests, reversal of warfarin in the presence of active bleeding or planned procedure when vitamin K is inadequate to reverse the warfarin effect, thrombotic thrombocytopenic purpura, and congenital or acquired factor deficiency with no alternative therapy. Other more specific recommendations for FFP based on systematic review include trauma patients requiring massive transfusion and warfarin-related intracranial hemorrhage. Other situations where the administration of FFP cannot be recommended for or against based on systematic review include FFP transfusion at a plasma-to-RBC ratio of 1:3 or more in trauma patients with massive transfusion. Conditions that cause the deficiency of multiple coagulation factors and may require the administration of FFP include liver disease and disseminated intravascular coagulation.[11,12,13]

FFP can only be administered intravenously. FFP must be ABO compatible with the recipient's red cells. The FFP container and fluid upon visual inspection should have no leakage, clots, or abnormal color.FFP is stored at -30°C. Prior to administration, FFP is thawed in a water bath at 30 to 37°C over 20 to 30 minutes or in an FDA-cleared device as quickly as 2 to 3 minutes. FFP should be administered immediately after thawing. If FFP is not given immediately after thawing, it should be stored at 1 to 6ºC.If the thawed FFP is not used in 24 hours, it should be discarded. Once thawed, the activity of clotting factors, particularly factor V (FV) and factor VIII (FVIII),

decline gradually. After initial dosage, re-administration may be needed every 6 to 8 hours if there is continued bleeding due to the short half-life of factor VII(FVII). Factor VII has a half-life of 2 to 6 hours.

The therapy of FFP is monitored clinically with signs of bleeding and chemically with coagulation studies and fibrinogen levels. Eachunit of FFP contains approximately 200 to 250 ml. Apheresis-derived units contain as much as 400 to 600 ml. Administration of one 250 ml unit should raise the fibrinogen level by 5to10mg/dl. The goal of therapy is the cessation of bleeding. The laboratory value goal is to correct the prothrombin time/activated partial thromboplastin time to less than 1.5 times normal.[14,15,16]

MATERIAL AND METHODS

The present prospective observational study was carried out in the Guru Nanak Dev Hospital/ Govt. Medical College, Amritsar. The patients presenting to medical emergency, medical outdoor and indoor with liver cirrhosis on ultrasound abdomen were selected for the purpose. A total 100 patients with written informed consent were included in the study. Clinical examination and USG abdomen was done in every patient. PTI was done in patients before and aftertherapy of fresh frozen plasma. The approval of institutional ethics committee of Govt. Medical College, Amritsar was taken before the start of the study.

INCLUSION CRITERIA:

All liver cirrhotic patients with low PTI with bleeding complications.

EXCLUSION CRITERIA

Patients with other known bleeding disorders

Patients thus selected was transfused 10-20 ml/kg body weight of fresh frozen plasma (FFP) and therapeutic effect of FFP on the patients was noted.

Fresh frozen plasma was arranged from blood bank of Guru Nanak Dev Hospital, Amritsar. PTI was done at the time of enrolment and after transfusion of FFP.

PTI was done within the complex of Guru Nanak Dev Hospital, Amritsar.

PTI less than 100% was taken as low PTI.

PTI procedure was done by manual method.

Test procedure of PTI/INR:

- Sample was collected by vein puncture with aseptic precaution. Sample was put in a PTI vial which contains trisodium citrate (mix exactly 9 parts of freshly collected blood with one part of trisodium citrate).
- Reagent vial was brought to room temperature (20-30ºC). Contents of the vial was mixed to homogeneous suspension completely.
- Aspirated from the reagent vial enough reagent for immediate testing requirements in a thoroughly clean and dry test tube (plastic test tubes are preferred).
- Reagent was prewarmed (reagent used is thromboplastin) and brought to 37ºC before use in test procedure (5-10 minutes may be required depending on the reagent volume to attain 37ºC before testing).
- Reagentvialwasrecappedandreplaceimmediatelyto2-8ºC.
- 0.1 ml of plasma (PPP) was added to a 12 x 75 mm tube and place the tube in a water bath for 3 to 5 minutes at 37ºC.
- 0.2 ml of thromboplastin reagent (prewarmed at 37ºC for atleast3 minutes) was added to the tube forcefully and simultaneously starting a stopwatch. Shaking the tube gently to mix contents.

- Gently tube was tilted back and forth and stopwatch was stopped as soon Possible the first fibrin strand was visible and the gel/clot formation begins. Time in seconds was recorded.
- Step 4-6 were repeated for duplicate test on the same sample.

- Prothrombin time (PT) was calculated by findings the average of duplicate test value.
- INR was calculated from PT ratio using a thromboplastin with a known ISI.
  INR was calculated as

$$INR = \frac{\text{Patient PT}}{\text{Mean normal PT}}$$

- Mean normal PT = mean of normal range that is specifically determined by each user laboratory for each lot of thromboplastin reagent with specific instrument and techniques routinely used for patient testing.
  PTIwascalculatedbypercentageofPTratio.

The PT was assessed and INR calculated on a single *test,* the pre and post transfusion PTI/ INR will be calculated in order to studythe effect of FFP on PTI/INR.

Post transfusion PTI/INR was done within 1 hour of completion of transfusion.

All observations were noted on proforma after filling the consent form.

STATISTICAL TOOLS

The data was tabulated and analyzed with spss17.0 statistical software. Mean ±SD, p value by chi square test, range and percentages were calculated. One way Anova, Posthoc and student's t test for data and chi square test for consolidation of tables were used.A p value of <0.05 was taken as significant relationship.

RESULTS

Out of 100 cirrhotic patients, maximum 31(31%) patients age was between 41-50years. Out of 100 cirrhotic patients, 87(87%) were males and 13(13%) were females.

TABLE1: DISTRIBUTION OF SUBJECTS ACCORDING TO GENDER

Sex	No.ofcases	% age
Male	87	87.0
Female	13	13.0
Total	100	100.0

TABLE 2: AVERAGE IMPROVEMENT OF PTI AFTER FFP TRANSFUSION

	Average Improvement in PTI

PTI groups (FFP(ml/kgbody weight)	80-99%	60-79%	40-59%	20-39%	<20%
10ml	1.87%	1.54%	1.83%	-	-
15ml	4.13%	3.26%	3.20%	-	-
20ml	2.76%	1.69%	7.13%	3.6%	-

Average improvement in PTI after transfusion of FFP. Cirrhotic patients having PTI between 80-99%, 60-79% and 40-59% showed average improvement in PTI of 1.87%, 1.54% and 1.83% after transfusion of FFP at 10ml/kg body weight respectively.After transfusion of FFP at 15ml/kg body weight, patients having PTI between 80-99%, 60-79% and 40-59% showed average improvement in PTI of 4.13%, 3.26% and 3.2% respectively. After transfusion of FFP at 20ml/kg body weight, patients having PTI between 80-99%, 60-79%, 40-59% and 20-39% showed average improvement in PTI of 2.76%, 1.69%, 7.13% and 3.6%respectively. On an average 20 ml/kg body weight dose of FFP was able to increase the PTI maximally in all the groups especially in patients who were having lower pretransfusion PTI i.e. especially <60% of PTI

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TABLE 3: DISTRIBUTION IN CLINICAL SYMPTOMS AFTER TRANSFUSION OF FFP

FF P (ml/ kg)	Hematemesis		Melaena		Ecchymosis		Petechiae	
	Pre transf usion	Post transf usion	Pre Transf usion	Post Transf usion	Pre Transf usion	Post transf usion	Pre transf usion	Post transf usion
10	4	2	26	3	3	1	4	1
15	-	-	12	1	7	1	7	1
20	15	1	34	4	10	0	10	0

After transfusion of FFP at 10 ml/kg body weight, 2 out of 4 patients who had hematemesis, 23 out of 26 patients who had melaena, 2 out of 3 patients who had petechiae and 3 out of 4 patients who had ecchymosis, showed improvement in symptoms. After transfusion of FFP at 15 ml/kg body weight, 11out of 12 patients who had melaena and 6 out of 7 patients who had petechiae and ecchymosis, showed improvement in symptoms.13 out of 15 patients who had hematemesis and 30 out of 34 patients who had melaena and 10 patients who had petechiae and ecchymosis showed improvement in symptoms after transfusion of FFP at 20ml/kg body weight.

TABLE 4: DISTRIBUTION OF SUBJECTS ACCORDING TO IMPROVEMENT IN CLINICAL SYMPTOMS AFTER FFP TRANSFUSION

Symptoms	Present		Resolved		Non resolved	
	No.	%	No.	%	No.	%
Hematemesis	19	19.0	16	16.0	3	3.0
Melaena	72	72.0	64	64.0	8	8.0
Ecchymosis	20	20.0	18	18.0	2	2.0
Petechiae	21	21.0	19	19.0	2	2.0

Out of 100 cirrhotic patients with bleeding manifestation,19(19%) patients had hematemesis, in that 16(16%) patients were improved after FFP transfusion,72(72%) patients had melaena in that 64 (64%) patients were improved, 20(20%) patients had ecchymosis in that 18 (18%) patients were improved and 21(21%) patients had petechiae in that 19 (19%) were improved after FFP transfusion.

TABLE 5: IMPROVEMENT OF CLINICAL SYMPTOMS AFTER FFP TRANSFUSION (ml/kg BODY WEIGHT)

FFP ml/kg	Total Symptoms	Symptoms improved	Symptoms not improved	Percentage Improvement ofsymptoms	p value
	No.	No.	No.	%	
10	37	30	7	81%	0.01
15	26	23	3	88%	0.01
20	69	64	5	93%	0.01

Out of 37 patients who were clinically symptomatic, 30 patients showed improvement in clinical symptoms after transfusion of FFP at 10 ml/kg body weight. 23 out of 26 patients who were clinically symptomatic showed improvement in clinical symptoms after transfusion of FFP at 15ml/kg body weight. And 63 out of 69 patients who were clinically symptomatic, showed improvement in clinical symptoms after transfusion of FFP at 20ml/kg bodyweight. These improvement in clinicalsymptoms were statistically significant (pvalue <0.05) in all 3 categories of FFP transfusion, but percentage of improvement in clinical symptoms after transfusion at 20 ml/kg body weight is more as compared to 15ml/kg and 10ml/kg body weight.

DISCUSSION

Various guidelines for appropriate FFP use have been proposed.[17] However many of these are mainly expert consensus rather than recommendations derived from meticulous scientific studies. Moreover, the threshold for PT and aPPT prolongation of >1-1.5 times was based on outdated retrospective studies. PT and aPPT are poor predictors of perioperative bleeding especially in patients with negative bleeding history. Therefore theutility of routine preoperative coagulation testing has been questioned.

According to British committee for standards in hematology guidelines, bleeding history including family history, details of prior surgeries and anticoagulant treatment should be taken prior to surgery. Patients with negative bleeding history do not require routine preoperative coagulation testing. However, some recent papers still recommend routinely performing PT, aPPT and platelets count prior to surgery and invasive procedure and liver cirrhosis in adults and children. FFP usage has been increasing in our institute since few years. Hence we took up a study on the institutes FFP usage with the specific aims of auditing our FFP usage according to the age of patient, indications for FFP administration, appropriate and inappropriate usage of FFP and improvement in PTI/INR with FFP transfusion in liver cirrhosis patients.

Cirrhosis of liver is a growing cause of significant morbidity and mortality of modernization. Cirrhosis patients have a disturbed balance between procoagulant and anti-coagulant factors and a very poor reserve of these factors leads to increased bleeding risk as well as increased thrombotic risk. This coagulation imbalance is not reflected by conventional coagulation test. Although variceal bleeding remains being the most prevalent coagulopathy associated exacerbation, thrombotic complications are not un-common in the cirrhotic patients.

We also studied the improvement of clinical symptoms like hematemesis, melaena, ecchymosis, petechiae in cirrhosis patients after transfusion of FFP.30 out of37 patients showed improvement in clinical symptoms after transfusion of FFP at 10ml/kg body weight, 23 out of 27 patients showed improvement in clinical symptoms after transfusion of FFP at 15ml/kg body weight, 63 out 69 patients showed improvement in clinical symptoms after transfusion of FFP at 20ml/kg body weight.Theseimprovement in clinical symptoms were statistically significant in all 3 categories of FFP transfusion patients, but percentage of improvement in clinical symptoms after transfusion of FFP at 20 ml/kg body weight is more as compared to FFP transfusion at 10ml and 15ml/kg body weight. So higher doses of FFP transfusion at 20ml/kg body weight is more efficacious in correction of coagulopathy thisresultisin concordance with the dual study by Youssef etal.Role of fresh frozen plasma infusion in correction of coagulopathy of chronic liver disease suggested fresh frozen plasma infusions using thenumber of units commonly employed in clinical practice infrequently correct the coagulopathy of patients with chronic liver disease. Higher volumes (6 or more units) may be more effective.

One more study conducted by Baxi et al, a retrospective chart review was used to identify patients with cirrhosis, admitted with upper gastrointestinal bleed.169 patients were included in the study, out of which 111 patients received no FFP, 34 received 1-2 units of FFP and 24 received more than 3 units of FFP. Compared to those whoreceived no FFP, patients who received 1-2 units (OR 0.02, p=0.3) or more than 3 units of FFP(0.01,p=0.16) wereless likely or no moreto have evidence of active bleeding at endoscopy respectively. So higher dose of FFP is required for correction of coagulopathy in liver cirrhosis.

This study highlights the facts that alcohol is the most common cause of liver cirrhosis, liver cirrhosis is associated with mild coagulation abnormalities, prothrombin index/ international normalized ratio test can be used as marker for correction of coagulopathy in cirrhosis. Commonly recommended dose of FFP (10-15 ml/kg body weight) in clinical practice infrequently correct the coagulopathy, so higher dose (≥20ml/kg body weight) may be more effective incorrection of coagulopathy. Further large scale studies are needed to be conducted to substantiate the findings depicted in our study.

CONCLUSION

For correction of coagulation factors we can use fresh frozen plasma as it contain all coagulation factors, common recommended dose used in clinical practice is 10-15ml/kg body weight but studies shows that this dose is ineffective in correction of coagulopathy in liver cirrhosis so larger doses ≥ 20 ml/kg body weight may berequired to correct the coagulopathy in cirrhosis, currently limited studies are available on this topic, thus further large scale studies are needed to standardize the dose of FFP in liver cirrhosis.

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