



EFFECT OF FRESH FROZEN PLASMA ON INTERNATIONAL NORMALISED RATIO

Pathology

Dr. Sushil Songara Post Graduate Resident, Department of Pathology, Gandhi Medical College, Bhopal.

Dr. Rajni Choudhary Associate Professor, Department of Pathology, Gandhi Medical College, Bhopal.

Dr. Varsha Rampuri* Assistant Professor, Department of Pathology, Gandhi Medical College, Bhopal.
*Corresponding Author

Dr. R.K. Nigam Professor and Head of Department of Pathology, Gandhi Medical College, Bhopal.

ABSTRACT

The use of Fresh Frozen Plasma has significantly increased in the past 2 to 3 decades. It is frequently transfused to patients with mild to moderate elevations in Prothrombin Time (PT) with the assumptions that these tests imply a coagulopathy and that FFP transfusion will correct the coagulopathy. **Aim:** To assess the effect of FFP transfusion on International Normalized Ratio (INR) in patients admitted in Gandhi Medical College and associated hospitals, Bhopal. **Settings And Designs:** An Observational hospital based study. **Materials And Methods:** Total 126 cases attending the tertiary health care center and receiving FFP were studied. **Results:** Mean INR significantly reduced from 2.14 ± 0.92 (range 1.5 – 6.89) to 1.46 ± 0.35 (0.9 – 3.5) after FFP transfusion. Mean FFP transfused was 3.37 per patient. The mean improvement in INR per unit of FFP was 0.20. **Conclusion:** FFP transfusion in most of the cases improves INR but is significant only in 35% cases. There are certain conditions like liver diseases, where it causes significant improvement in INR. Though the amount of FFP required to correct the coagulopathy is high.

KEYWORDS

Fresh Frozen Plasma, International Normalized Ratio, Coagulation Factors

INTRODUCTION

Fresh Frozen Plasma is a Blood product that is extracted from whole blood and frozen to -18°C or below within 6 hours after collection. FFP from a standard donation of whole blood (450ml) usually measures 175-250ml and it contains 70-80 units of factor VIII, IX, VWF and other clotting factors [1]. It contains plasma proteins and all the coagulation factors including the labile factors V and VIII [2]. There are certain situations where FFP is clearly indicated such as coagulation deficiency secondary to liver disease, DIC, dilutional coagulopathy due to massive blood transfusion, in infants with secondary immunodeficiency, antithrombin deficiency and open heart surgery [1].

FFP is frequently transfused to patients with mild to moderate elevations in Prothrombin Time (PT) with the assumptions that these tests imply a coagulopathy and that FFP transfusion will correct the coagulopathy.

Prothrombin Time (PT) measures the clotting time of recalcified plasma in the presence of an optimal concentration of tissue extract (thromboplastin) and indicates the overall efficiency of the extrinsic clotting system. The test also depends on reactions with factor V, VII and X and on the fibrinogen concentration of the plasma [3]. To ensure uniformity of anticoagulation, the result should be reported as an INR (International Normalized Ratio).

MATERIALS AND METHODS

A prospective study was conducted in Department of Pathology, Gandhi Medical College, Bhopal from 1st January 2021 to 30th June 2022 in which 126 patients were analyzed with duly filled consent form along with detailed history and clinical details. The following data was collected: demographic details including age and gender of the patient, provisional clinical diagnosis, indications for FFP, date of transfusion, number of units transfused and coagulation profile of the patient. Blood sample for PT - INR was collected before FFP transfusion, in 3.2% trisodium citrate vial (with anticoagulant and blood ratio of 1:9) and is centrifuged at 3000 rpm for 20 minutes to separate the platelet poor plasma. PT - INR test was done by manual method and the results were noted and compared with pre - transfusion PT - INR value. The data was compiled in MS Excel and was analyzed through IBM SPSS software.

RESULTS

Total 126 patients receiving FFP were included in our study. Out of these, 20 subjects were under the age of 1 year who received FFP less than 1 unit and studied separately. 1 standard unit of FFP was considered 175ml.

6/106 (5.66%) patients were between 1- 14 years comprising the pediatric population while 100/106 (94.33%) were over 14 years of age. Mean age of patients receiving FFP transfusion was 35 years [Table no.1]

Table No. 1 Age Wise Distribution Of Cases

AGE GROUP	COUNT	COLUMN N %
1-14 year	6	5.66 %
>14 year	100	94.33 %
TOTAL	106	100 %

Out of the total subjects, 53/106 (50%) were males and 53/106 (50%) were females. [Table no. 2]

Table No. 2 Gender Wise Distribution Of Cases

SEX	COUNT	COLUMN N %
FEMALE	53	50.00 %
MALE	53	50.00 %
TOTAL	106	100 %

In our study we found that mean INR significantly reduced from 2.14 ± 0.92 (range 1.5 – 6.89) to 1.46 ± 0.35 (0.9 – 3.5) after FFP transfusion. Paired t test was applied, p - value is 0.000 which is less than 0.05 i.e. statistically significant. [Table NO. 3]

Table No. 3 Effect Of FFP On INR

	N	Mean INR	Range	Std. Deviation	P - value (Paired T - test)
Pre – Transfusion INR	106	2.14	5.39	0.92	0.000 (significant)
Post– Transfusion INR	106	1.46	2.60	0.35	

Mean FFP unit transfused was 3.37 per patient. The mean improvement in INR per unit of FFP was 0.20.

According to the formula derived by Holland and Brooks, 37/106 patients (35%) showed significant improvement and 69/106 (65%) did not show significant improvement.

There is positive correlation between pre-transfusion INR and change in INR per unit of FFP (Pearson's correlation coefficient $r = 0.83$). This means that higher the pre - transfusion INR, more is the change in INR per unit of FFP post - transfusion. [Table no. 4]

Table No. 4 Correlations Between Pre - Transfusion INR And

Change In INR Per Unit Of FFP

		Change in INR per unit of FFP
Pre – Transfusion INR	Pearson Correlation test	0.838 Positive correlation
	P - Value	0.000 (significant)
	N	106

DISCUSSION

In our study done on 106 patients we found that the mean INR reduced from 2.14 ± 0.92 (range 1.5 - 6.89) to 1.46 ± 0.35 (0.9 - 3.5) after FFP transfusion (n = 106). this difference was statistically significant (p value < 0.05). However, according to the formula derived by Holland and Brooks (according to this formula, a decrease of 8.9% or more in a pre - transfusion INR per unit of FFP is considered as statistically significant), only 35% (37 / 106) subject showed significant improvement in INR following FFP transfusion. This was 58% (n = 66) in the study done by **Nisha Lekshmy et al (2018)** , in which mean pre - transfusion INR was 3.36 and post - transfusion INR was 1.85. Mean change in INR per unit of FFP transfused was 0.38.

Study done by **Holland and Brooks (2006)** on 103 patients , mean transfusion INR was 2.2 and mean post transfusion INR was 1.5. They found significant improvement in INR after FFP transfusion in 50 % cases. The significant change was observed in 29% cases in study done by **Nagulan et al (2021)** among 251 subjects.

Raturi et al (2018) conducted study over 724 patients and found significant change in INR post FFP transfusion in all cases. Laboratory efficacy post FFP transfusion was seen in 73% cases.

The significant change was seen in 33% in study done by **Kulkarni et al (2012)** in 336 patients.

Our study has closest resemblance with that done by Kulkarni et al (2012) and Nagulan et al (2021) in terms of significance as per formula derived by Holland and Brooks.

CONCLUSION

There is shortage of blood and blood components in most of the developing world. The resources are inadequate in terms of meeting the ever - growing demand of blood components. Appropriate use of blood components is required to ensure their availability for needy patients as well as to avoid the unnecessary risk of transfusion transmitted diseases.

FFP is frequently transfused to patients to with mild to moderate elevations in Prothrombin Time (PT) with the assumptions that these tests imply a coagulopathy and that FFP transfusion will correct the coagulopathy.

FFP transfusion does not correct mild to moderate coagulopathy but has significant impact on severe coagulopathy. Hence , the decision for FFP transfusion must be carefully weighed considering the risks associated with it. Further studies need to be done in this subject so as to make proper guidelines for FFP transfusion.

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