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Professional paper

Evaluation of Fresh Frozen Plasma Usage at the University Hospital Center Rijeka

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ABSTRACT

The aim of this investigation was to assess the rate and appropriate use of fresh frozen plasma (FFP) at the Clinical Hospital Center Rijeka in two six-month periods, at an interval of 5 years, before and after introducing clinical standards for transfusion practice and hemovigilance, and to evaluate the results of applied measures. We studied 315 patients transfused with 1341 doses of FFP in two six-month periods from September to February of 1999/2000 and 2004/2005. The first period (1999/00) of the study was retrospective and 226 patients were transfused with 928 FFP units. The second period (2004/05) was prospective and we studied 89 patients transfused with 413 units. In the first period blood bank records were retrospectively reviewed and in the second period all FFP requests, performed coagulation tests and transfusion episodes were prospectively analyzed. The number of inappropriate transfusions decreased from 39.8% to 23.6%. In most patients (85.1%), coagulation tests were made prior to FFP transfusion. The number of patients transfused with one and two FFP doses decreased, while those transfused with three or more doses increased. Most of the appropriately transfused patients were those with active bleeding due to coagulation factor deficiency and massive transfusions. The least were those requiring reversal of warfarin effect. Our results demonstrated a decrease in the number of patients treated with FFP in the second period. The introduction of clinical standards of good transfusion practice and hemovigilance showed positive effects. Considering that there was a number of inappropriately transfused patients continued education of all health personnel engaged in transfusion treatment is evidently necessary.

Key words: *clinical transfusion practice, fresh frozen plasma, guidelines, hemovigilance*

Introduction

Transfusion of components derived from human blood underpins modern medicine. However, transfusion is not without risks. Furthermore, there is a lack of consensus among clinicians on the criteria of the appropriate use.

Fresh frozen plasma (FFP) is a blood product produced from human plasma, separated from donated whole blood after centrifugation and frozen rapidly to –30°C or bellow within six hours after collection[1], or from plasmaphaeresis. Therefore, FFP is a good source of coagulation factors including labile factors V and VIII. In Croatia, FFP is not pathogen reduced. The production and distribution of drugs and consequently of blood products is regulated by laws, rules and recommendations[2–8].

A high rate of inappropriate use of FFP is a significant problem worldwide, both in the developed and developing countries[9–13]. Inappropriate use not only leads to a wastage of limited resources thus depriving more needy patients of their use, it also leads to increased healthcare costs and risk of transfusion related complications such as viral transmission, which could cause significant morbidity and mortality. The relative risk of death within 10 years increases by 7.3% *per* unit of FFP[14]. Therefore, the expected benefits of FFP therapy should exceed the possible risk.

Indications for transfusing FFP are very limited[5–8,15–22]. The current national guidelines fulfill all conditions for

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the appropriate use of FFP, i.e. the presence of bleeding or invasive procedure with coagulopathy or multiple factor-deficiencies due to conditions such as disseminated intravascular coagulation (DIC), liver failure, massive transfusion, emergency reversal of warfarin effect, over--anticoagulation with warfarin, prolongation of prothrombin time (PT) or activated partial thromboplastin time (APTT) to 1.5 times that of normal control and as the replacement fluid in plasma exchange for thrombotic thrombocytopenic purpura (TTP) or the hemolytic-uremic syndrome (HUS). The primary method for documenting a coagulation factor deficiency is by measuring PT and APTT.

FFP is absolutely contraindicated in patients with IgA deficiency or in patients with hypersensitivity to plasma proteins. FFP is not indicated in DIC or anticoagulant reversal without bleeding. There are some situations in which FFP is inappropriately used such as volume resuscitation expander, nutritional support in protein losing states like burns and in plasma exchange procedures for conditions other than TTP and HUS.

Each unit of FFP raises the factor level in an adult by 3%–5%. As a result, 1–2 units are an insufficient dose in adult patients with significant coagulopathy. The recommended dosage is 10–20 mL of plasma per kg of body weight corresponding to 4–6 units in a 70 kg adult, but it could be exceeded in massive bleeding.

Response to FFP transfusion should be monitored through the measurement of coagulation activities by traditional laboratory techniques (PT, APTT and the level of coagulation factors) and the clinical state of patients[15]. Therefore, the coagulation parameters should be measured before and after FFP transfusion to record the degree of correction. If FFP is given to a bleeding patient, the clinical response may be the best indication of transfusion effectiveness.

Transfusion reactions appear in 3%–5% of transfused patients[16]. The largest avoidable risk to patients from transfusion is probably due to the transfusion of FFP for inappropriate or unproven clinical indications. Allergic reactions and anaphylaxis, transfusion related acute lung--injury (TRALI), hemolysis from transfused antibodies to blood group antigen, especially ABO antibodies, transfusion associated circulatory overload (TACO) and infections (freezing does not remove free viruses such as hepatitis A, B, C, human immunodeficiency virus and parvovirus B19)[23] are of particular concern.

Various strategies are used worldwide to reduce inappropriate use of blood products. These include administrative interventions, such as the screening of requests by hematologists or transfusion specialists, by using the request forms that incorporate appropriate indications as reminders for clinicians, clinical audit cycles and education for health care staff.

The aim of this study was to compare the appropriateness of FFP transfusion at the Clinical Hospital Center Rijeka, a tertiary care teaching hospital with 1191 beds, in two different six-months periods: from September 1999 to February 2000, and in the same period 5 years later, after the implementation of clinical transfusion practice, education and hemovigilance.

Materials and Methods

All patients (n=315) transfused with FFP, with the exception of pediatric, from September 1999 to February 2000 and from September 2004 to February 2005 were enrolled into this study. The first period (1999/00) of the study was retrospective and 226 patients were transfused with 928 FFP units. The second period (2004/05) was prospective and 89 patients transfused with 413 units were studied. In the first period blood bank records were retrospectively reviewed and in the second period all FFP requests and transfusion episodes were prospectively analyzed. The recorded data included department requests for FFP, patient's presenting problems, reasons for FFP request, date of transfusion, number of units transfused and coagulation profile of patient (before and after FFP use) if available.

Assessment of the appropriateness of FFP use was made conforming to the national guidelines that are consistent with the European Guidelines[5]. The judgment of appropriate usage was mainly based on the patient's diagnosis, clinical indications, (e.g., active bleeding, emergency surgery or invasive procedure) and pretransfusion coagulation results as well as adequate dosage.

Transfusions were assigned into three categories: appropriate, inappropriate or possibly appropriate. The latter included cases for which there was insufficient information to fully asses the episode, and those situations in which the indication for the use of blood components was controversial. When reasons for transfusion were unclear (missing laboratory parameters or clinical data), transfusion was considered inappropriate.

All data were assembled into a database created by the MS Excel program and statistically analyzed on a PC using the Statistical Data Analysis Software System, Version 7.1 StatSoft Inc.2005. Categorical outcome variables were compared between two groups based on the χ^2-test or Fisher's exact test (where the p value <0.05 was considered statistically significant).

Results

During the first study period a total of 928 units of FFP and 4549 units of PRBC were issued (ratio 0.2:1). Five years later a total of 413 FFP units and 4383 PRBC were transfused (0.09 FFP per 1 PRBC). The ratio of FFP and PRBC use was an indicator of the quality of transfusion therapy when comparing the two different periods.

We studied 315 patients transfused with 1341 doses of FFP in two six-month periods. In the first period 226 patients were transfused with 928 FFP units and 89 patients with 413 units in the second period. There was no

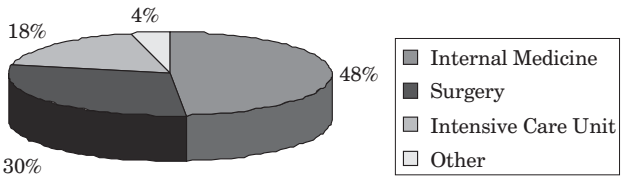

Fig. 1. Distribution by departments of patients treated with fresh frozen plasma.

change of hospital regimen and diagnosis pattern in the two periods.

The distribution of patients who received FFP by operating service is shown in Figure 1. Internal medicine patients accounted for most of the cases (48%) with surgery patients representing the second largest percentage (30%). The third major user was the Intensive Care Units (18%).

An analysis of appropriateness of FFP usage in two different periods, according to national guidelines, is shown in Table 1. In the first period appropriate usage of FFP was found in 51.8% of patients, probably appropriate in 8.4% and inappropriate usage in 39.8%. Five years later FFP transfusions were judged appropriate for 67.4% of patients, probably appropriate for 9.0% and inappropriate for 23.6%. If we compare the appropriateness of FFP usage in both periods, the difference is statistically significant (χ^2=7.62, df=4; p=0.022), the number of patients appropriately transfused increased from 51.8% to 67.4%, and consequently, those treated inadequately decreased from 39.8% to 23.6%.

The laboratory assessment before FFP transfusion is shown in Table 2. There is no significant difference between both periods (p=0.806). The majority of patients had coagulation tests before FFP usage (85.4% in the first and 84.3% in the second period).

Analysis of post-FFP treatment coagulation tests done in patients in different periods are shown in Table 3. Laboratory assessment of post FFP transfusion was performed in 32.1% of patients in the first period and in 33.3% of patients five years later, so the difference is insignificant (p=0.839).

Evaluation of FFP usage according to the number of transfused units in different periods is shown in Table 4. The total number of treated patients with respect to the number of transfused FFP units was statistically different by periods (χ^2=11.248; df=2; p=0.004). In the first period 4.9% of patients received one FFP unit, 47.3% received two units while 47.8% received three or more units. Five years later only 2.3% patients were transfused with a single unit, 29.2% with two and 68.5% with three or more units of FFP.

An analysis of the patients transfused with FFP for appropriate indications such as hemorrhagic diathesis, massive transfusion and warfarin reversal are listed in Table 5. The transfusion of FFP did not differ significantly in the two different periods regarding the reasons for FFP use (χ^2=2.37; df=2; p=0.306). The most common reason for FFP usage in both periods was hemorrhagic diathesis (61.5% and 70.0% of patients respectively), followed by massive transfusion (32.5% and 21.7% of patients) and warfarin reversal (6.0% and 8.3% of patients).

Discussion

Clinical practice is characterized by great variations in the use of FFP. Findings from a 1991 retrospective audit showed that FFP was used inappropriately in 60%

TABLE 1
APPROPRIATENESS OF FFP USAGE

			Appropriateness of FFP usage (Number and % of the patients)			Total
			Appropriate	Probably appropriate	Inappropriate	
Period	1999/00	Count	117	19	90	226
		Expected count	127	19.4	79.6	226.0
		Row %	51.8%	8.4%	39.8%	100.0%
		Column%	66.1%	70.4%	81.1%	71.7%
	2004/05	Count	60	8	21	89
		Expected count	50.0	7.6	31.4	89.0
		Row %	67.4%	9.0%	23.6%	100.0%
		Column%	33.9%	29.6%	18.9%	28.3%
Total		Count	177	27	111	315
		Expected count	177.0	27.0	111.0	315.0
		Row %	56.2%	8.6%	35.2%	100.0%
		Column%	100.0%	100.0%	100.0%	100.0%

p=0.022, FFP – fresh frozen plasma

TABLE 2
PRE-FFP TREATMENT COAGULATION TESTS

			Pre-FFP treatment coagulation tests (Number and % of the patients)		Total
			Not available	Available	
Period	1999/00	Count	33	193	226
		Expected Count	33.7	192.3	226.0
		Row%	14.6%	85.4%	100.0%
		Column%	70.2%	72.0%	71.8%
	2004/05	Count	14	75	89
		Expected Count	13.3	75.7	89
		Row%	15.7%	84.3%	100.0%
		Column%	29.8%	28.0%	28.2%
Total		Count	47	268	315
		Expected Count	47.0	268.0	315.0
		Row%	14.9%	85.1%	100.0%
		Column%	100.0%	100.0%	100.0%

p=0.806, FFP – fresh frozen plasma

of cases. In Croatia in 1992 even 50% to 80% of FFP was not used in compliance with the approved indications[24].

Recent studies often show unjustifiable use of FFP but published data differs considerably. Belgian University Hospital records demonstrated that the use of FFP was not indicated in 67% of the patients[25] and in New Zealand in 33%[26].

The appearance of the variant Creutzfeldt-Jacobs disease and other viruses like the West Nile virus, and rising concerns regarding their transmission through blood transfusion are crucial to evaluate and optimize blood component usage and reduce wastage, especially FFP[27]. Inappropriate transfusion of FFP represents the largest risk for transfused patients that could be avoided by respecting the indications for use[28].

In many countries, including Europe and the United States, the use of blood products continued to rise in the last two decades, especially the use of FFP relative to packed red blood cells (PRBC)[29,30]. Soutar has reported that the use of FFP has increased 2% annually for the past 5 years[31].

TABLE 3
POST-FFP TREATMENT COAGULATION TESTS

			Post-FFP treatment coagulation tests (Number and % of the patients)		Total
			Not available	Available	
Period	1999/00	Count	131	62	193
		Expected count	130.3	62.7	193.0
		Row %	67.9%	32.1%	100.0%
		Column%	72.4%	71.3%	72.0%
	2004/05	Count	50	25	75
		Expected count	50.7	24.3	75.0
		Row %	66.7%	33.3%	100.0%
		Column%	27.6%	28.7%	28.0%
Total		Count	181	87	268
		Expected count	181.0	87.0	268.0
		Row %	67.5%	32.5%	100.0%
		Column%	100.0%	100.0%	100.0%

p=0.839, FFP – fresh frozen plasma

TABLE 4
THE USAGE OF FFP ACCORDING TO THE NUMBER OF TRANSFUSED UNITS

			Number and % of the patients transfused with			Total
			1 FFP unit	2 FFP units	3<FFP units	
Period	1999/00	Count	11	107	108	226
		Expected Count	9.3	95.4	121.3	226.0
		Row %	4.9%	47.3%	47.8%	100.0%
		Column %	84.6%	80.4%	63.9%	71.8%
	2004/05	Count	2	26	61	89
		Expected Count	3.7	37.6	47.7	89.0
		Row %	2.3%	29.2%	68.5%	100.0%
		Column %	15.4%	19.6%	36.1%	28.2%
Total		Count	13	133	169	315
		Expected Count	13.0	133.0	169.0	315.0
		Row %	4.1%	42.%	53.7%	100.0%
		Column %	100.0%	100.0%	100.0%	100.0%

p=0.004, FFP – fresh frozen plasma

The diversity of available data induced us to investigate the FFP consumption in our hospital and whether there was an increase during the studied five-year period. We were also interested in finding out whether the introduction of clinical transfusion practice, education and the control of transfusion therapy affected the use of FFP.

During the first study period from September 1999 to February 2000 a total of 928 units of FFP (approximately 215 liters) and 4549 units of PRBC were issued. The volume of red cell units transfused was used as denominator to allow comparison of FFP use between the two studied periods in our hospital and interhospital comparison, as well as comparison with other references. In the first period this FFP/PRBC ratio was 0.2:1, which corresponds to Soutar's data[31]. Five years later a total of 413 FFP units were transfused (approximately 100 liters) and 4383 PRBC, consequently 0.09 FFP per 1 PRBC indicating a tendency of decrease of FFP use. Similar results were obtained in Spain[32].

Tuckfield et al. showed that rates of inappropriate FFP transfusion episodes fell significantly from 31% to 15% after blood product request forms were modified to incorporate indications for transfusion and relevant clin-

TABLE 5
REASONS FOR APPROPRIATE USE OF FFP

			Reasons for use of FFP (Number and % of the patients)			Total
			Hemorrhagic diathesis	Massive transfusion	Warfarin reversal	
Period	1999/00	Count	72	38	7	117
		Expected Count	75.4	33.7	7.9	117.0
		Row %	61.5%	32.5%	6.0%	100.0%
		Column %	63.2%	74.5%	58.3%	66.1%
	2004/05	Count	42	13	5	60
		Expected Count	38.6	17.3	4.1	60.0
		Row %	70.0%	21.7%	8.3%	100.0%
		Column %	36.8%	25.5%	41.7%	33.9%
Total		Count	114	51	12	177
		Expected Count	114.0	51.0	12.0	177.0
		Row %	64.4%	28.8%	6.8%	100.0%
		Column %	100.0%	100.0%	100.0%	100.0%

p=0.306, FFP – fresh frozen plasma

ical and laboratory data, and monitored for confirmation with applicable transfusion guidelines[33]. Similar results were obtained by Hawkins et al. who found that 33% of transfused units were given inappropriately[26]. After a five year implementation of clinical transfusion practice at our hospital, which included screening of requests by transfusion specialists, using the request forms that incorporate laboratory data and clinical diagnosis, consultations with the prescribers, clinical audit cycles and education for health care staff, there was a significant decrease of unjustified FFP treatment from the 39.8% in the first period to 23.6%.

The standard dose of FFP is 10–20 mL/kg. However, some evidence showed that this recommended dose has not been efficient in correcting deficiencies of individual coagulation factors whereas 30 mL/kg has been[34].

Consequently, it is considered that transfusion of 1–2 FFP doses is absolutely inadequate (if not for pediatric patients) and that a minimal therapeutic dose is 3 FFP units or more (depending on body weight and on coagulation deficit requiring correction). Our results have also indicated that there was a statistically significant reduction of the total number of patients receiving 1 or 2 FFP units, and a rise of those treated with 3 or more units in the second period, thus improving the quality of transfusion therapy.

In a study of Hui et al. a major indication for FFP transfusion was the reversal of warfarin required to correct prolonged international normalized ratio. The second reason for the use of FFP was massive transfusion[35]. Recommendations given by some authors[17] do not support the use of FFP in a massive transfusion unless it is guided by a coagulation test. In our study, the largest part of FFP went properly to patients with abnormal coagulation test results associated with bleeding, 61.5% in the first period and 70% five years later, followed by massive transfusions 32.5% or 21.7% respectively, and the least due to warfarin reversal only 6% or 8.3% respectively. One of the possible reasons for such differences is that the ambulatory for anticoagulation therapy is within the Clinical Institute for Transfusion Medicine where such patients are regularly checked and in case of overdose without signs of hemorrhagic diathesis they are treated with vitamin K, and warfarin is discontinued in compliance with the recommendations. It is interesting to notice that the reasons for appropriate use of FFP have not changed significantly throughout the examined periods.

There are great discrepancies between the data of performed laboratory coagulation tests (complete coagulogram) before FFP transfusion. Marti-Carvajal et al. reported in 1999 that at the Venezuelan general university hospital the prevalence of appropriate use of FFP was only 26%, and in no case was a prior determination of the patient's coagulation deficiency made in order to decide on the use of FFP[12]. Jones et al. has found that 88% of the FFP issued showed reasons for treatment and pre- and post-treatment coagulation results were available for all patients[36], while in other publication only 65.9% had coagulation tests before FFP transfusion[37]. In our study we found that most of the patients, 85.1% had pretransfusion coagulation tests but in only 32.5% of patients were coagulation variables measured after transfusion. The findings were similar in both studied periods.

The number of inappropriately treated patients was reduced from 39.8% to 23.6%. Most of the patients (85.1%) had coagulation tests done before FFP transfusion. The number of patients transfused with 1 or 2 doses of FFP decreased, while those treated with 3 or more increased. The most frequent justified FFP transfusions were due to coagulation disorders with bleeding, followed by massive transfusion and warfarin reversal.

We believe that these results are the consequence of the introduction of clinical transfusion practice, education, hemovigilance and good cooperation with other specialists who applied transfusion therapy in compliance with the applicable guidelines and recommendations. Numerous authors demonstrated that inappropriate FFP transfusion was thus reduced[38–40], which was also confirmed by our five-year experience.

High quality, efficient and safe transfusion therapy is just a part of the entire health care. Therefore, an improved quality of transfusion therapy has an impact on health care in general and on the whole community, since blood and drugs produced from blood are the national treasure of each country.

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PROCJENA UPORABE SVJEŽE SMRZNUTE PLAZME U KLINIČKOM BOLNIČKOM CENTRU RIJEKA

S A Ž E T A K

Cilj rada bio je ispitati primjenu svježe smrznute plazme (SSP) i kvalitetu transfuzijskog liječenja bolesnika u dva šestomjesečna razdoblja, u razmaku od 5 godina, prije i poslije uvođenja standarda kliničke transfuzijske prakse i sustavnog nadzora transfuzijskog liječenja (hemovigilance-a), te ocijeniti učestalost i opravdanost primjene SSP u Kliničkom bolničkom centru Rijeka i učinke poduzetih mjera. Ispitano je 315 bolesnika liječenih s 1341 dozom SSP, u razdoblju od rujna do veljače 1999/2000. i 2004/05. godine. U prvom razdoblju retrospektivnom analizom transfuzijske dokumentacije o izdavanju krvnih pripravaka ispitano je 226 bolesnika liječenih s 928 doza SSP. U drugom razdoblju prospektivno su praćeni svi zahtjevi za transfuzijom SSP, opravdanost indikacija i izvršeni koagulacijski testovi i analizirano je 89 bolesnika transfundiranih s 413 doza SSP. Broj neopravdano liječenih bolesnika smanjio se s 39,8% na 23,6%. Većina bolesnika (85,1%) imala je učinjene testove zgrušavanja prije transfuzije SSP. Smanjio se broj bolesnika transfundiranih jednom i dvije doze SSP, a povećao broj liječenih s tri ili više. Najviše adekvatno liječenih bolesnika bilo je zbog krvarenja uslijed koagulacijskog poremećaja, zatim zbog masivnih transfuzija, a najmanje zbog poništavanja djelovanja varfarina. Naši rezultati ukazuju na smanjen broj bolesnika transfundiranih SSP u drugom razdoblju. Uočen je povoljan učinak uvođenja standarda dobre kliničke transfuzijske prakse i hemovigilance-a. Kako određeni broj bolesnika nije trebao biti liječen krvnim pripravcima, potrebno je nastaviti s započetim, posebno s edukacijom svih zdravstvenih djelatnika uključenih u transfuzijsko liječenje.