**Section:** Transfusion Medicine

**Original Research Article**

# EVALUATION OF THE LEVEL OF COAGULATION FACTORS V AND VIII ON STORING FRESH FROZEN PLASMA AT DIFFERENT TEMPERATURES - A STUDY AT REGIONAL BLOOD BANK AND CEmONC CENTRE

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## Abstract

**Background:** Fresh frozen plasma has a wide range of applications in day to day clinical practice.[1] It is used to treat coagulation factor deficiencies, actively bleeding patients on long term anticoagulation and to treat the coagulopathy that occurs with massive bleeding.[2,3] Other uses are as an adjuvant therapy in disseminated intravascular coagulation, decompensated liver disease, cardiopulmonary bypass and massive transfusion. The objective is to compare the stability of coagulation factors in plasma, frozen and stored at -30°C or -70°C for a period of 3 months. **Materials and Methods:** This prospective study was done among twenty fresh frozen plasma units from healthy donors collected in the Department of Transfusion Medicine, The Tamilnadu Dr. MGR Medical University (Regional Blood Bank), Guindy, Chennai and Twenty fresh frozen plasma units from healthy donors collected in the Department of Transfusion Medicine, Government Kilpauk Medical College and Hospital (CEmONC-Comprehensive Emergency Obstetric and Newborn Care centre), Kilpauk, Chennai, were randomly selected. **Result:** 40 units were separated in to 2 aliquots and stored at -30°C and -70°C. At the end of 3 months, these samples were thawed and evaluated for factor V, VIII, fibrinogen, PT and APTT on day 0. Then, the thawed plasma samples were stored at 2°C to 6°C, which were evaluated for the above parameters on day 1, 3 & 5. The values for the above parameters were also noted on the day of collection. **Conclusion:** The coagulation factors V, VIII and fibrinogen values were essentially within accepted therapeutic range on day 5 of thawed plasma stored at 2 to 6°C, even though there was a statistically significant difference observed.

## INTRODUCTION

The freezing and storage of FFP is done over a wide range of temperatures. As per the AABB guidelines, freezing and storage settings vary from less than -18ºC up to -65ºC.[1] The guidelines have further stated that attaining a lower temperature for storage may retain the stability of the coagulation factors over a longer duration than standard temperature.[2]

In Tamilnadu, blood bank units have different plasma freezers for storage purposes. Commonly used are -30ºC and -70ºC plasma freezers for FFP preparation and storage. Tertiary care units in the state are equipped with -70ºC freezers whereas majority of the peripheral centers still utilize the -20ºC to -30ºC freezers. This variability is a point of concern with respect to the stability of the coagulation factors.

Transfusion guidelines also add that FFP should be used within a short time after thawing at 30°C to 37°C (6 hrs if stored at room temperature, 24 hrs if stored at 1°C to 6°C).[3]

Once thawed, FFP may not always be transfused immediately and is kept for a period of time at room temperature, many units of such may go unutilized.[4]

The short storage time of the thawed plasma is a definite hindrance in its utilization. This is further

challenged when the expected demands in situations needing FFP transfusions do not comply with the actual supply.

For emergency situations like massive haemorrhage and DIC the immediate availability of FFP may get delayed because of the time required for the thawing procedure. FFP thawed and kept in large amounts in anticipation of an emergency may be wasted if the event does not happen.

If the level of coagulation factors remains in the therapeutic range after a significant duration of storage of thawed plasma, it can be safely used for patients. This will reduce plasma wastage and provide adequate units during emergency situations.

Therefore we have designed this study to compare the stability of coagulation factors in plasma, frozen and stored at -30°C or -70°C for a period of 3 months.

## MATERIALS AND METHODS

This prospective study was done among twenty fresh frozen plasma units from healthy donors collected in the Department of Transfusion Medicine, The Tamilnadu Dr.M.G.R Medical University (Regional Blood Bank), Guindy, Chennai and Twenty fresh frozen plasma units from healthy donors collected in the Department of Transfusion Medicine, Government Kilpauk Medical College and Hospital(CEmONC-Comprehensive Emergency Obstetric and Newborn Care centre), Kilpauk, Chennai, were randomly selected. Period of study was October 2017 –September 2018

**Sample Size:** 40 (calculation done using the formula)

**Inclusion Criteria**

- Blood units collected by proper aseptic methods with in appropriate time (6- 8 minutes)
- Plasma components prepared within 6-8 hrs of collection, frozen at different temperatures (-30ºC and at -70ºC) were taken for study.

**Exclusion Criteria**

- Low volume collections.
- Lipemic collections.
- Plasma units with RBC contamination.

**Procedure**

- Donor units collected in Quadruple bags were randomly selected for study purpose.
- As per NACO guidelines 1% of the collection units or maximum of 4 units/month have been taken for our study purpose after ethical clearance obtained from the Institutional Ethics Committee
- The selected whole blood units were subjected to component separation within 6-8 hrs of collection and the separated plasma gets collected in secondary bag.
- Twenty fresh frozen plasma units from healthy donors collected in the Department of Transfusion Medicine, The Tamilnadu Dr.M.G.R Medical University (Regional Blood Bank), Guindy, Chennai and Twenty fresh frozen plasma units from healthy donors collected in the Department of Transfusion Medicine, Government Kilpauk Medical College and Hospital( CEmONC-Comprehensive Emergency Obstetric and Newborn Care centre), Kilpauk, Chennai, were randomly selected.
- The selected whole blood units were subjected to component separation within 6 to 8 hours of collection and the separated plasma gets collected in secondary bag.
- Initial baseline values of factor V, VIII and fibrinogen levels in the selected units were measured
- PT and APTT values also were measured in the plasma units
- The plasma units were stored at -30°C and at -70°C in plasma freezer
- After 3 months of storage, the selected FFP units were thawed at +30°C to+37°C FV, FVIII, fibrinogen levels and PT, APTT values were measured in the thawed plasma on day 0,day 1,day 3 and day 5 of storage at 2°C to 6°C.
- Sampling of plasma for measurement of factor levels on every occasions were done by stripping followed by mixing the bag contents
- Clotting factor V, VIII, Fibrinogen levels and PT, APTT values were measured using Coagulometer (Erba ECL 412, TransAsia Bio Medicals).
- Results were statistically analyzed using SPSS version 17 software.

Sample Collection for the evaluation of Coagulation Factor Activities in FFP

Initial level of coagulation factor activities in the selected plasma units before kept in the freezer was noted. Then the plasma units were aliquoted in to 2 bags and kept at -30°C and at -70°C. Those units were kept in that particular storage temperatures for up to 3 months duration. After that those FFP units were taken andthawed at + 37°C in a thawing bath. Coagulation factor activities in the thawed FFP units were tested immediately after thawing and noted as day 0 values (0 hrs value). Further, the same reading were taken after 24 hrs and noted as day 1(24 hrs value). After the 24 hour expiration time, thawed fresh frozen plasma were kept at 2°C to 6°C for 4 more days. Samples were taken at day 3 (72 hrs value) and day 5 (120 hrs value) of storage at 2°C to 6°C for study purpose.

**Statistical analysis**

- All statistical analysis was performed using Statistical Package for Social Science (SPSS, version 17) for Microsoft windows.
- The data were normally distributed and therefore parametric tests were performed.
- The data were expressed as Mean and SD.
- Independent sample student t test were used to compare continuous variables between two groups. Paired sample test were used for within groups. A two sided p value $< 0.05$ was considered statistically significant.


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## RESULTS

In both the groups, even the coagulation values measured immediately after thawing (day 0) showed a statistically significant difference compared to baseline. This significance extended up to day 5. However, all the values of observed parameters were within the physiological limits. This shows that the process of storage of Fresh Frozen Plasma does cause a decrease in the coagulation factors immaterial of the storage temperature, though within therapeutic range.

Between the groups, the -70°C group performed better in retaining the stability of coagulation factors. This was evident in the statistically significant difference observed between the groups at 72 hours and 120 hours after thawing and storage at 2 to 6°C. The values observed in the -30°C group was however in the hemostatic range.

Among the factors, fibrinogen was found to be the most stable with lesser fluctuations from the baseline values. Factor VIII was observed to be the most labile among the observed parameters, decreasing by 28% from the baseline value. Yet, the therapeutic measure of atleast 0.5 units/ml as suggested by the European Pharmacopoeia was not breached.

There is statistical significant difference between Sample at -30°C and Sample at -70°C at 72 Hours and 120 Hours in Factor V levels, fibrinogen levels, and F VIII levels. [Table 1]

There is no statistical significant difference between Sample -30°C and Sample -70°C in PT, APTT at p> 0.05. [Table 2]

There is statistical significant difference between baseline and 0, 24, 72 and 120 hours in Sample -30°C and in Sample -70°C in fibrinogen. [Table 3]

There is statistical significant difference between baseline and 0, 24, 72 and 120 hours in Sample -30°C and -70°C in F V. [Table 4]

There is statistical significant difference between baseline and 0, 24,72 and 120 hours in Sample -30°C and --70°C in in F VIII. [Table 5]

There is statistical significant difference between baseline and 0, 24,72 and 120 hours in Sample -30°C and --70°C in PT. [Table 6]

There is statistical significant difference between baseline and 0, 24, 72 and 120 hours in Sample -30°C and --70°C in APTT.

From Day 0 to Day 5 the plasma clotting factors- Fibrinogen, Factor V and Factor VIII levels are decreasing gradually on storing at 2°C to 6°C. Simultaneously PT and APTT values are increasing as we mentioned in the above table. It showed the correlation between plasma clotting factor Fibrinogen and PT value, factor VIII and APTT value, Factor V and PT, APTT values. [Table 7]

**Table 1: Comparison of Factor V levels at -30°C and -70°C.**

| | Group | N | Mean | Std.Deviation | Sig |
|---|---|---|---|---|---|
| F V IU/ml - Baseline | -30°C | 40 | .9957 | .11953 | 1.00 |
| | -70°C | 40 | .9957 | .11953 | |
| F V IU/ml - 0 hour | -30°C | 40 | .9175 | .09111 | 0.181 |
| | -70°C | 40 | .9475 | .10703 | |
| F V IU/ml - 24 hours | -30°C | 40 | .8525 | .08602 | 0.071 |
| | -70°C | 40 | .8895 | .09484 | |
| F V IU/ml - 72 hours | -30°C | 40 | .7763 | .07427 | 0.009** |
| | -70°C | 40 | .8238 | .08307 | |
| FV IU/ml - 120 hours | -30°C | 40 | .6948 | .06421 | 0.000*** |
| | -70°C | 40 | .7573 | .07961 | |

**P<0.01, *** p<0.001

**Table 2: Comparison of Prothrombin time at -30°C and -70°C**

| | Group | N | Mean | Std.Deviation | Sig |
|---|---|---|---|---|---|
| PT secs - baseline | -30°C | 40 | 13.473 | .9457 | 1.00 |
| | -70°C | 40 | 13.473 | .9457 | |
| PT secs – 0 hour | -30°C | 40 | 13.980 | .9595 | 0.297 |
| | -70°C | 40 | 13.755 | .9565 | |
| PT secs - 24 hours | -30°C | 40 | 14.468 | .9638 | 0.221 |
| | -70°C | 40 | 14.198 | 9940 | |
| PT secs – 72 hours | -30°C | 40 | 15.03 | .949 | 0.567 |
| | -70°C | 40 | 14.90 | .959 | |
| PT secs – 120 hours | -30°C | 40 | 15.95 | .955 | 0.695 |
| | -70°C | 40 | 15.87 | .922 | |

**Table 3: Comparison between baseline and follow up in fibrinogen at -70° C**

| | | Mean | N | Std. Deviation | Sig |
|---|---|---|---|---|---|
| Pair 1 | FIB mg/dl - baseline | 289.1625 | 40 | 10.72169 | |
| | FIB mg/dl - 0 hour | 284.8400 | 40 | 10.27908 | 0.000*** |
| Pair 2 | FIB mg/dl - baseline | 289.1625 | 40 | 10.72169 | |
| | FIB mg/dl - 24 hours | 280.5975 | 40 | 10.18930 | 0.000*** |
| Pair 3 | FIB mg/dl - baseline | 289.1625 | 40 | 10.72169 | |
| | FIB mg/ml - 72 hours | 275.8600 | 40 | 9.84117 | 0.000*** |
| Pair 4 | FIB mg/dl - baseline | 289.1625 | 40 | 10.72169 | |
| | FIB mg/dl - 120 hours | 270.8350 | 40 | 10.06554 | 0.000*** |


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*** p < 0.001

**Table 4: Comparison between baseline and follow up in F V at -30°C**

| | | Mean | N | Std.Deviation | Sig |
|---|---|---|---|---|---|
| Pair 1 | FV IU/ml - baseline | .9957 | 40 | .11953 | |
| | FV IU/ml - 0 hour | .9175 | 40 | .09111 | 0.000*** |
| Pair 2 | FV IU/ml - baseline | .9957 | 40 | .11953 | |
| | FV IU/ml - 24 hours | .8525 | 40 | .08602 | 0.000*** |
| Pair 3 | FV IU/ml - baseline | .9957 | 40 | .11953 | |
| | FV IU/ml - 72 hours | .7763 | 40 | .07427 | 0.000*** |
| Pair 4 | FV IU/ml - baseline | .9957 | 40 | .11953 | |
| | FV IU/ml - 120 hours | .6948 | 40 | .06421 | 0.000*** |

*** p < 0.001

**Table 5: Comparison between baseline and follow up in F VIII at -30°C**

| | | Mean | N | Std.Deviation | Sig |
|---|---|---|---|---|---|
| Pair 1 | FVIII IU/ml - baseline | .9348 | 40 | .07524 | |
| | FVIII IU/ml - 0 hour | .8507 | 40 | .06738 | 0.000*** |
| Pair 2 | FVIII IU/ml - baseline | .9348 | 40 | .07524 | |
| | FVIII IU/ml - 24 hours | .7675 | 40 | .06905 | 0.000*** |
| Pair 3 | FVIII IU/ml - baseline | .9348 | 40 | .07524 | |
| | FVIII IU/ml - 72 hours | .6793 | 40 | .06154 | 0.000*** |
| Pair 4 | FVIII IU/ml - baseline | .9348 | 40 | .07524 | |
| | FVIII IU/ml - 120 hours | .5822 | 40 | .05299 | 0.000*** |

*** p < 0.001

**Table 6: Comparison between baseline and follow up in PT at -30°C**

| | | Mean | N | Std. Deviation | Sig |
|---|---|---|---|---|---|
| Pair 1 | PT - baseline | 13.473 | 40 | .9457 | 0.000*** |
| | PT - 0 hours | 13.980 | 40 | .9595 | |
| Pair 2 | PT - baseline | 13.473 | 40 | .9457 | 0.000*** |
| | PT - 24 hours | 14.468 | 40 | .9638 | |
| Pair 3 | PT - baseline | 13.473 | 40 | .9457 | 0.000*** |
| | PT - 72 hours | 15.03 | 40 | .949 | |
| Pair 4 | PT - baseline | 13.473 | 40 | .9457 | 0.000*** |
| | PT - 120 hours | 15.95 | 40 | .955 | |

*** p < 0.001

**Table 7: Comparison between baseline and follow up in APTT at -30°C**

| | | Mean | N | Std. Deviation | Sig |
|---|---|---|---|---|---|
| Pair 1 | APTT - baseline | 29.148 | 40 | 1.3204 | 0.000*** |
| | APTT - 0 hours | 29.750 | 40 | 1.3044 | |
| Pair 2 | APTT - baseline | 29.148 | 40 | 1.3204 | 0.000*** |
| | APTT - 24 hours | 30.99 | 40 | 1.306 | |
| Pair 3 | APTT - baseline | 29.148 | 40 | 1.3204 | 0.000*** |
| | APTT - 72 hours | 33.023 | 40 | 1.2589 | |
| Pair 4 | APTT - baseline | 29.148 | 40 | 1.3204 | 0.000*** |
| | APTT - 120 hours | 34.073 | 40 | 1.2876 | |

*** p < 0.001

## DISCUSSION

FFP is an important derivative of either whole blood or apheresed blood. It finds a multitude of applications in routine critical care and intra-operative settings. A prolonged shelf life of thawed plasma implies greater utility and decreased wastage. This should however be accomplished with retention of the functional properties of FFP. A number of studies and audits have been done worldwide to analyse this requirement.[5]

In a country like ours with limited resources, optimal usage of available facilities and materials should be done. These available resources for storage of FFP vary from centre to centre. This prompted us to perform this study. Through this study we aimed to compare the stability of coagulation factors in FFP that was stored previously at -30°C and at -70°C.

Blood samples were collected from the department of Transfusion Medicine and from Government Kilpauk Medical College which is a CEmONC (Comprehensive Emergency Obstetrics and Newborn Care) centre. The baseline values of the observed parameters were measured immediately after separation of FFP. These FFP were divided into two groups. One set was frozen at -70°C and another set was frozen at -30°C.

In our study, Prothrombin time (PT) values were prolonged by 0.28 seconds immediately after thawing and by 2.4 seconds at 120 hours in -70°C group compared to baseline values. Similarly, the -30$^{o}$ group also showed an increase of 0.51 seconds


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after thawing and 2.48 seconds over the period of 5 days. The changes were statistically significant even as early as 0 hours of thawing in both the groups. However, the values were within the therapeutic range in both the groups over the period of analysis and the difference between the groups was not statistically significant.

Nagadeh HT performed a similar study except that the freezing process of plasma was to a single temperature by blast freezer.[6] They observed that the average lengthening of Prothrombin time was statistically significant from day 1 to day 5 but was within the physiological limits. Their results correlate with our findings. A similar observation has been made by Yazer MH and associates.[7] They found that the percentage increase in PT from day 0 to day 5 was 22% which is identical to the increase observed by us. Both the above mentioned authors demonstrated that though there is a modest increase in PT values on storage of thawed plasma, it does not exceed the permissible limits and our study too complies with theirs.

Activated Partial Thromboplastin Time (aPTT) values too showed a trend similar to the PT values in our study. There was an increase of 15.47% from baseline at day 5 in -70°C group and 16.91% in -30°C group. Though the increase was statistically significant within the group, the inter group variations were not statistically significant. The increase was also not pathological.

An increase in APTT values by 12.2% from day 1 to day 5 has been observed by Nagadeh HT and colleagues.[6] We too met with a similar trend in our study. The -70°C group showed an increase by 13.95% from day 1 to day 5 and the -30°C group, by 14.52% over the duration of storage. Yazer MH and colleagues27 too showed a similar result wherein the increase in APTT values was 10.3%. They had opined that APTT values are in the therapeutic range at the end of 5 days of thawed plasma storage at 1°C to 6°C.

Fibrinogen levels showed a decrease on storage of thawed plasma at 2°C to 6°C over 120 hours. The degree of fall was by 6.33% in -70°C group and 8.58% in -30°C group. Both the groups showed statistical significant difference at 72 hours and 120 hours of storage with respect to the change in fibrinogen levels between them.

Noordin SS and friends published a study in Indian Journal Of Haematology and Blood Transfusion in the year 2017 and they observed a fall in fibrinogen levels by 8.01% at the end of day 5 when compared to the baseline value and this is identical to our findings.[8] Further, a statistically significant change even on day 0 compared to baseline values was recorded by them as well as by us.

In contrast, Sidhu RS and associates,[9] in 2006 have demonstrated a non- significant change of 1.9% in fibrinogen levels from day 1 to day 5 in the research article in Journal of Clinical Apheresis, whereas we recorded a significant change of 6.66% and 4.91% in -30º and -70°C groups respectively from day 1 to day 5.

Gosselin RC and colleagues,[10] in 2015 have found that fibrinogen values are the least affected by vial types, freezing and thawing conditions and temperatures. Earlier, Alesci S and others have also demonstrated that freezing and storage methods have minimal or no effect on fibrinogen assays in their publication in Thrombosis Research in 2009.

Downes KA also found no decrease in fibrinogen levels on storage of thawed and stored plasma over a period of 5 days.[11]

The degree of fall in Factor V levels on storage was statistically significant within the individual groups (24.24% in -70°C group vs 30.30% in -3°C group). In comparison to the baseline values, the levels in the samples immediately after thawing (0 hour) also showed a statistically significant fall in both the groups and it continued till 120 hours. When the changes were compared between the groups, it was observed that the -30°C group had a more significant fall in F V levels than -70°C group from 72 hours onwards. The clinical outcome of the fall however was not of significance because the coagulation tests were within permissible limits.

Buchta C,[12] and others in the year 2004 published their findings in Vox Sanguinis and they observed a fall in F V levels to 78% of baseline values on day 5 of storage of thawed plasma at 4°C. This is similar to the 24% fall reported in our study.

Smak Gregoor PJ et al,[13] way back in 1993 have analysed the coagulation factor levels of FFP and cryoprecipitate free plasma. They observed that the levels of F V decreased by up to 36% in FFP group and by 42% in the cryoprecipitate free plasma group at the end of 28 days of storage at 4°C. They further added that such stored plasma over 28 days retained the properties to achieve adequate hemostasis.

Lamboo M and colleagues,[14] performed an identical study in Netherlands and published their recordings in Transfusion Medicine in 2007. Their results showed that the F V level decreased by 35% at the end of 2 weeks of storage of thawed plasma and this fall was gradual from the baseline values. They reported that once thawed, FFP can be stored in room temperature for 6 hours and up to 2 weeks at 4°C. Nagadeh HT and others62 too observed a fall of 20% in day 5 of storage from day 1.

A still higher fall of 33.5% from day 1 was reported by Yazer MH and friends in their study published in Transfusion in 2008.[7] Both the above authors however said that the values were within therapeutic range. Our findings correlate with the above mentioned authors.

In contrast, Downes KA et al,[11] observed an insignificant fall of 16% in F V levels on day 5 relative to day 1. Their study also opined that the fall does not affect the clinical outcome of the analysed samples and the stored plasma can be safely administered to patients in need.


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Sidhu RS and colleagues reported a lesser degree of fall of 8.8% of F V levels over the study duration but the change was statistically significant.[9]

Factor VIII was found to be the most labile factor in our study. Both the groups showed a significant reduction in the values of F VIII as early as immediately after thawing in comparison to the baseline values over the study period. The inter group difference was also statistically significant. Though the fall at the end of day 5 was by 37% in -30°C group, the absolute value of 0.5822 was above minimal requirement of 0.5 units/ml recommended by the European Pharmacopoeia.3 Yet, the clinical results in the form of APTT did not reflect any deviation from the physiological limits.

Buchta C,[12] and colleagues obtained a reduction of 22% in F VIII values on storage and the end values were within the treatment requisites. This is similar to the 28% observed by us in the -70°C group. However, the -30°C group had a more pronounced fall in F VIII levels by 31.58% in our study.

Downes KA,[11]had reported in their study that the fall in F VIII levels over the period of storage represents a true decline in the coagulation factors. They observed a 41% fall in groups A and O and 35% fall in group B. Their findings correlate with our observations. However they have summarized that thawed and stored plasma can be used to treat patients with coagulopathy and not for patients with isolated F VIII deficiencies.

Sidhu RS,[9] and others observed a fall of 14.3% in F VIII levels over the 5 day period. This was lesser than the recordings seen in our study. However the end point values were within the recommended therapeutic requisites.

In contrast, Noordin SS et al8 reported a greater fall (>50%) in F VIII levels on storage of thawed plasma. Their values decreased from 71.6 to 35.9 at the end of 5 days. They have opined that the greater degree of fall could be because of the lower initial values at the start of the analysis.

According to DGHS,[15] once thawed the FFP should be administered at the earliest and maximum within 24 hours if stored at 2°C to 6°C.

According to AABB,[16] FFP on thawing has a shelf life of 24 hours at 1°C to 6°C. FFP which is thawed and stored longer than 24 hours must be relabeled as Thawed Plasma, and it can be stored for an additional 4 days at 1°C to 6°C. In our study as mentioned above we have studied the extended shelf life of plasma after thawing and storing at 2°C to 6°C for 5 days.

Numerous studies have been done to analyse the probable storage time of thawed plasma frozen at various temperatures and stored over various duration. We have compared the results of those studies with ours.

## CONCLUSION

In our study, the coagulation factors V, VIII and fibrinogen values were essentially within accepted therapeutic range on day 5 of thawed plasma stored at 2 to 6°C, even though there was a statistically significant difference observed. This enables reduced wastage of unused thawed plasma with qualitatively acceptable factor levels. In emergency situations, these units can be issued and utilized immediately as a life saving measures.

Further, our study showed acceptable correlation between PT, APTT values and coagulation factor levels, which approximately evaluates the quality of plasma in centres lacking facilities to do factor assay.

This study reiterates the extended shelf-life of thawed plasma, which can be utilized in emergency situations in CEmONC and tertiary care hospitals.

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