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Research Article

Normal Saline versus Fresh Frozen Plasma for Partial Exchange Transfusion in Neonatal Polycythemia

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Abstract

Background: *Polycythemia in the newborn is defined as a central venous Hct over 65% or a haemoglobin value above 22g/dl. As the viscosity increases, there is an impairment of tissue oxygenation and perfusion and a tendency to form micro thrombi. Significant damage may occur if these events occur in the cerebral cortex, kidneys and adrenal glands. Hence this condition requires urgent diagnosis and prompt management however the choice of replacement fluid remains controversial.*

Objective: *To assess the hematocrit at 0, 6, 24 hours after partial exchange transfusion with normal saline and fresh frozen plasma and to compare the effects is both the two groups.*

Method: *The study was performed in neonatal care unit, Department of Pediatrics VIMSAR Burla from October 2016-september 2018. 29 Neonates matching the inclusion criteria were enrolled for this randomised controlled trial having two arms NS arm(neonates in whom NS was used as replacement fluid for PET) and FFP arm(neonates in whom FFP was used as replacement fluid). The various parameters were measured at 6 hour and 24 hour of exchange transfusion and compared between the groups.*

Results: *There was overall no significant difference in the hematocrit, hemoglobin values measured at 6 hour,24 hour after PET in both the groups .Similarly in other parameters also there was no significant difference between both the groups. However, the interval between the diagnosis and treatment in NS group was less as compared to FFP group and came out to be significant as p value<0.00. The cost expenses of using FFP was more than that of NS which also was stastistically significant.*

Conclusion: *PET with normal saline is as safe and effective as Fresh Frozen Plasma as there was no clinically or statistically significant difference between them. Normal saline was cheap, readily available and effective substitute for management of neonates with polycythemia as compared to FFP and hence should be considered as an ideal replacement fluid for PET.*

Keywords: *PET-Partial exchange transfusion, NS-Normal saline, FFP-Fresh frozen plasma.*

Introduction

The term polycythemia means an increased cell number. However, it is mostly used to refer specifically to increased circulating red blood cell mass[1]. RBC mass is estimated using hematocrit (Hct) measurement, which is defined as the percentage of RBC is a given volumes of blood. Term newborn usually have a higher HCT compared to older children and adults[2]. This increased Hct is a normal compensatory mechanism in these infants for the relative tissue level hypoxia that is prevalent in the intrauterine

environment and it is exacerbated by the high affinity of fetal hemoglobin for oxygen. The viscosity of blood is directly proportional to the hematocrit and plasma viscosity and inversely proportional to the deformability of red blood cells[3,4]. Symptoms of hypoperfusion correlate better with viscosity as compared to hematocrit. Viscosity is, however, difficult to measure at the bedside.

The effectiveness of FFP/polygelatin as replacement fluid for PET is still not established[5].There is no study regarding the efficacy of various replacement fluid for PET in the management of neonatal polycythemia in our set up. Because our clinical observations indicate that polycythemia continues to be a common diagnosis and both the condition and its treatment carry significant risks of morbidity, we felt it was time to re-explore this condition. Our first step in reopening this topic for close examination was to determine how the research from the 1990s and 2000s affected the clinical practice here in our institute.

Methods

All neonates admitted into the neonatal unit, VIMSAR Burla, during september 2018 to february 2019 were send for routine complete blood count and those fulfilling our inclusion criteria (1) venous haematocrit > 70% (2) venous haematocrit 65–70% with symptoms or signs attributable to polycythaemia—respiratory distress, apnoea, cyanosis, lethargy, irritability, jitteriness, seizures, impaired peripheral circulation (defined as skin capillary refilling time > 3 seconds), and hypoglycaemia were enrolled as subjects. The Exclusion Criteria were (1)dehydration (2)congenital anomalies (3)hemodymically unstable. Total of 29 neonates were enrolled in the study.

Detailed history of the neonate including perinatal and antenatal history relevant to polycythemia were taken from reliable informant (parents) and routine investigations i.e. CBC, serum electrolytes, serum total bilirubin were sent and compared with the normal values. Those having polycythemia were included in the study. The neonates were randomly allocated by computer to receive PET with either isotonic NS (0.9% NaCl) or FFP. This study was registered in CTRI (Clinical Trial Registry of India) and was approved by the same. peripheral vein. The informed consent was obtained from the parents of the infants enrolled. The blood volume for PET was calculated from the initial haematocrit of the patients and the desired haematocrit of 55% as follows:

Volume to be exchanged (ml) = [body weight (kg) × 80 ml/kg × (initial−desired haematocrit)] / initial haematocrit.

During PET, blood was withdrawn from umbilical vein and infusion of replacement fluid was done through a peripheral vein. We measured the various exposure outcomes prior to the study, then conducted PET. After conducting PET, we measured different variables at 6 hours and 24 hours after PET. Patients were followed up to 24 hours to look for any immediate complications. Statistical analysis was performed by using SPSS v 23. Continuous data are expressed is mean, standard deviation. Categorical data are expressed in percentage. Independent T test was done to compare 2 continuous variables. Categorical variables were compared by Pierson's chi-square test.

Observation

The total study consisted of 29 neonates that were followed up for 24 hours after partial exchange transfusion.

The mean and standard deviation for all the variables taken in the study were calculated for both the groups (Normal saline and freshfrozen plasma) and t=statistics, chi square along with the degree of freedom were calculated to find the P value for statistical significance, P value <0.05 is defined to be statistically significant.

The various parameters taken as variables were birth weight, weight on admission, hamatocrit, hemoglobin, total serum bilirubin, serum sodium,

serum calcium, heart rate, respiratory rate, oxygen saturation. Out of the total 29 neonates, males were 58% in NS group and 41% is FFP group respectively. Similarly females were 41% and 59% in NS group and FFP group respectively.

From the total number of neonates mostly were term delivery accounting for 79.3% whereas preterm delivery figured to 20.7%. However the gestational age had no statistical significance as evident from the p value.24.1% neonates were delivered by LSCS and 75.9% by NVD, out of which NS and FFP group had 86% and 64% NVD delivery respectively.

Most of the neonates were AGA as evidenced by the number. They constituted for 79.3% of the total neonates. In NS group 72% were AGA, 7% LGA and 21% SGA whereas in FFP group 87% were AGA and 13% were SGA.

Neonates presenting lethargy were 13.8% only with 7% is NS group and 20% in FFP group.

Jaundice constituted 28% in NS group and 40% in FFP group. Jitteriness was found in 2 patients accounting for 6.9% of total cases and respiratory distress was seen in 3 patients which constituted 10.3% of total patients. Also there was no significant difference between hb values between the two groups as at 0 hr p=0.98,at 6 hr p=0.83 and at 24 hr p=0.79.

On application of independent t test to all other outcome measures there was no significant difference as observed by their p values tabulated below.

Overall there was no significant difference among the groups on comparison of all the outcome measures at three different time intervals. Paired t test was also used to calculate interval between diagnosis of polycythemia and PET taken as d-p interval and it came out to be significant.

In majority of infants, symptoms disappeared within 24 hours. However 1 patient in FFP group developed hypocalcemia. No other adverse clinical events were observed after PET.

Table 1 Comparison of mean between the groups

Outcome measures	NS group Mean [standard deviation]	FFP group Mean [standard deviation]
HR 0 hr	140.21 [7.86]	138.80 [5.33]
HR 6 hr	142.9 [5.64]	133.31[6.67]
HR 24 hr	139.2[10.68]	139.20[9.98]
RR 0 hr	53.2[8.70]	54.06[7.69]
RR 6 hr	55.3[8.76]	53.13[6.68]
RR 24 hr	52.3[10.5]	52.06[5.56]
RBS 0 hr	90.1[21.8]	96.40[14.5]
RBS 6 hr	90.9[17.89]	96.60[13.34]
RBS 24 hr	91.01[17.89]	96.00[11.23]
Bilirubin 0 hr	5.21[2.45]	5.66[3.47]
Bilirubin 6 hr	6.57[5.66]	4.86[1.40]
Bilirubin 24 hr	6.14[5.84]	4.93[1.27]
Hb 0 hr	24.05[.09]	24.09[.98]
Hb 6 hr	18.71[1.08]	18.28[1.39]
Hb 24 hr	17.91[1.31]	17.93[.90]
Hct 0 hr	70.35[2.27]	70.33[2.66]
Hct 6 hr	59.14[3.25]	59.80[3.34]
Hct 24 hr	59.21[3.35]	60.3 [3.03]
Sr Na 0 hr	136.21 [5.35]	137.2[5.61]
Sr Na 6 hr	138.50[5.43]	1.29[2.23]
Sr Na 24 hr	139.07[5.46]	137.5[3.7]
SrCa 0 hr	.97[0.11]	1.00[0.07]
SrCa 6 hr	0.98[0.06]	1.08[0.12]
SrCa 24 hr	0.95[0.09]	1.03[.12]

Table 2 Comparison of outcome measures between the two groups

Outcome measures	t [df]	p-value	95% Confidence Interval of the Difference	
			Lower	Upper
HR [0 hr]	.570 [27]	.573	-3.67478	6.50335
HR [6 hr]	.072 [27]	.943	-.26294	.28199
HR [24 hr]	.078 [27]	.938	-7.57750	8.17750
RR [0 hr]	1.033 [27]	.311	-89.06430	269.64525
RR [6 hr]	-.280 [27]	.782	-7.10098	5.39622
RR [24 hr]	.788 [27]	.438	-3.56629	8.01391
RBS [0 hr]	.095 [27]	.925	-5.98024	6.56119
RBS [6 hr]	-.922 [27]	.365	-20.18379	7.66951
RBS [24 hr]	-.988 [27]	.332	-17.44592	6.10307
SrBil [0 hr]	-.402 [27]	.691	-2.76264	1.85788
SrBil [6 hr]	1.130 [27]	.269	-1.39129	4.80081
SrBil [24 hr]	.783 [27]	.440	-1.96036	4.37941
Hb [0 hr]	-.120 [27]	.906	-.78643	.69976
Hb [6 hr]	.939 [27]	.356	-.51445	1.38302
Hb [24 hr]	-.046 [27]	.964	-.87607	.83798
Hct [0 hr]	.026 [27]	.980	-1.86992	1.91754
Hct [6 hr]	-.536 [27]	.596	-3.17370	1.85942
Hct [24 hr]	-.942 [27]	.354	-3.55551	1.31742
Sr Na [0 hr]	-.516 [27]	.610	-5.23715	3.13239
Sr Na [6 hr]	1.049 [27]	.303	-8.76377	27.09711
Sr Na [24 hr]	.814 [27]	.423	-2.34057	5.41676
SrCa [0 hr]	-2.915 [27]	.007	-.17201	-.02990
SrCa [6 hr]	-1.010 [27]	.136	-1.089	0.3799
SrCa [24 hr]	-1.001 [27]	.331	-1.069	0.3488

Table 3 Comparison of costing and d-p interval

	NSG	FFPG	t[df]	p value
d-p interval	1.28 ± 0.46	2.92 ± 0.99	-0.53[13]	0.00
costing	0	96± 3.4	-3.01[13]	0.00

Fig 1 Change in Hematocrit Values in both groups

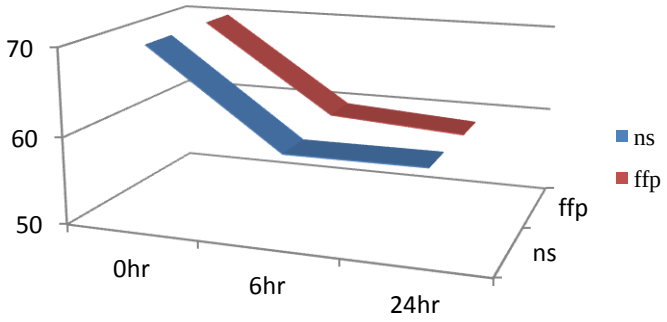
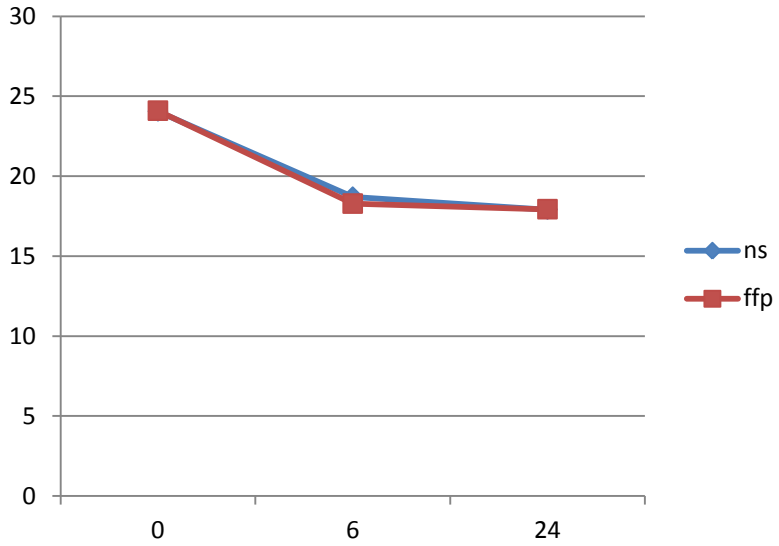


Figure 2 Comparison of Haemoglobin Values in both groups



Discussion

There was overall no significant difference in the hematocrit values measured at 6 hour,24 hour after PET in both the groups as P value =0.98,0.56,0.34 respectively . Haemoglobin values also have shown no significant difference between the groups as evidenced from their p value=0.96,0.36 and0.95 at 0,6 and 24 hours respectively.

Similarly in other parameters also there was no significant difference between both the groups. There was improvement symptomatically in the subjects of both the groups. However 1 patient from FFP group developed asymptomatic hypocalcemia at 6 hours of PET. The interval between diagnosis and treatment in NS group was less as compared to FFP group and came out to be significant as p value<0.00.

Conclusion

There is no apparent benefit of using FFP over normal saline for PET as the costing of FFP which includes the cost of blood bag, testing for HIV, HBV, HCV etc, transportation, storage, temperature maintenance was much more as compared to normal saline.

PET was effective in reducing hct and in relieving clinical symptom related to neonatal polycythemia. It was concluded that PET with normal saline is as safe and effective as Fresh Frozen Plasma as there was no clinically or statistically significant difference between them, Normal saline was cheap, readily available and effective substitute for management of neonates with polycythemia.

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