Chapter 4

Result

During the study period from April 1995 to February 1996, 4233 neonates were screened by umbilical cord blood hematocrit, 83 neonates met the inclusion critria and were entered into the study. All the neonates were stratified into 5 strata according to the predisposing factors clinically. The blocked randomization was used to allocate the patients in each strata to one of the two treatment groups. There was no significant difference in distribution of stratification between each treatment group (table1).

Table 1 stratification and blocked randomization between study groups

Predisposing factors	Control goup (FFP)	Treatment group (NSS)	P* Value
Small for gestational age	17	16	NS
Appropriate for gestational age	14	14	NS
Large for gestational age	8	7	NS
Dysmaturity / Postterm	1	2	NS
Increased placental transfusion	2	2	NS
Total	42	41	

* Fisher exact test
NS = non significant

The control group, consisted of 42 infants, was subjected for partial exchange transfusion using fresh frozen plasma and the treatment group,

consisted of 41 infants, was subjected for partial exchange transfusion using normal saline solution.

There was no significant difference in baseline characteristics of the study population among the control and treatment groups (Table2).

Table 2 Characteristics of the study population.

Characteristics	Control group	Treatment group	p Value
Sex (M : F)	20:22	19 : 22	0.91*
Gestational age (weeks)	38.512 ± 0.214	38.707 ± 0.204^	0.68 °
Apgar score at 1 min	7.930 ± 0.183	7.951 ± 0.164	0.88 °
Apgar score at 5 min	8.738 ± 0.077	8.902 ± 0.047	0.07 °
Birthweight (gms)	2932 ± 102	2883 ± 113	0.75 °
Types of delivery (normal : others)	36 : 6	27 : 14	0.07*
Hypoglycemia (+ : -)	21 : 21	14 : 27	0.31*

* Chi - square, ^ mean ± standard error of the mean (sem), ° Student t - test.

The infants who developed hypoglycemia were treated, therefore, the level of blood sugar prior to partial exchange transfusion was not different among the study groups ($t = 0.17$, $p = 0.86$).

Because the blood banking process in preparing for type and cross matching for plasma took 3 hours, the AB plasma (non - typing necessary) was kept available for partial exchange transfusion to avoid delay. Time at diagnosis and time at treatment which included time for waiting the procedure to get started were compared. There was no statistically significant difference between them (Table 3).

Table 3 Comparison of processing timing (minutes)

Time	Control group	Treatment group	p* Value
Time from birth to diagnosis	135 ± 10	141 ± 10^	0.87
Time from birth to treatment	233 ± 9	221 ± 10	0.41
Duration from diagnosis to treatment	96 ± 7	81 ± 7	0.15
Duration of procedure	27 ± 10	27 ± 3	0.95

* Student t - test, ^ mean ± sem

The amount of blood taken out was equal to the amount of fluid used for partial exchange transfusion. There was no statistically significant difference when the amount of fluid used between two study groups were compared (Control group 47.7 ± 11.1, treatment group 47.3 ± 11.5 p = 0.87).

Main outcomes were failure rates at immediate, 4 hours and 24 hours post exchange, defined as Hct post exchange ≥ 65%, it was discovered that there was no failure in both control and treatment groups. All post exchange Hct were below 65%. But when the mean Hct post exchange were compared, it was demonstrated that immediate post exchange Hct in the control group was significantly lower than the treatment group (Table 4).

Table 4. Hematocrit (%)

Hct	Control group	Treatment group	p* Value
Pre-exchange	72.05 ± 0.29	72.59 ± 0.32^	0.22
Immediate post exchange	56.45 ± 0.72	60.34 ± 0.44	0.000087
4 hours post exchange	57.31 ± 0.73	58.81 ± 0.68	0.13
24 hours post exchange	56.45 ± 0.65	57.76 ± 0.62	0.14

* Student t -test, ^ mean ± sem

When magnitudes of decreasing Hct from base line were compared at immediate, 4 hours and 24 hours post exchange transfusion, there was significant difference between magnitude of decreasing of Hct at immediate post exchange between study groups, implying that fresh frozen plasma was able to bring down Hct (at 95% confidence interval 13.876 and 17.144) at greater magnitude than normal saline was (at 95% confidence interval 11.142 and 13.338) (Table 5).

Table 5 Comparison of magnitude of decreasing Hct from base line (%)

Magnitude of Hct difference	Control group	Treatment group	p* Value
Pre-exchange -post exchange Hct (immediate)	15.51 ± 0.81	12.24 ± 0.54^	0.001
Pre-exchange-4 hours post exchange Hct	15.02 ± 0.94	13.78 ± 0.72	0.30
Pre-exchange -24 hours post exchange Hct.	15.67 ± 0.78	14.83 ± 0.62	0.40

* Student t -test, ^ mean ± sem

For blood chemistry derangement, there were 29 episodes in the control group when compared to 31 episodes in the treatment group.Though

hypoalbuminemia of 13-episodes in treatment group was far more than the control group of 7 episodes, there was no statistically significant difference (table 6). The degree of derangement in each episode was so minimal and closed to physiologic level of each blood chemistry of the newborn infants.

Table 6 Blood chemistry derangement

Categories	Control group	Treatment group	p* value
Hypernatremia	-	1	
Hypokalemia	5	4	
Hyperchloremia	7	8	
High bicarbonate	4	2	
Low bicarbonate	-	1	
Low creatinine	1	-	
Hypocalcemia	4	1	
Hypoproteinemia	1	-	
Hypoalbuminemia	7	13	0.23
Total	29	31	

* Fisher exact test

The twenty four hours weight change was compared, there was no statistically significant difference in weight gain or loss among the two groups.

For economic study, our results have shown that both alternatives achieved the target of lowering the hematocrit to less than 65% after the first transfusion. No case had acute complications. Therefore total cost items have real data from the study (Table7). Not all the costs below are described in detail.

Table 7. Data of Total Cost-items

Item	Content	Alternative A (FFP)	Alternative B (NSS)
1	Screen and diagnoses	40.00	40.00
2	Partial exchange transfusion	1218.00	95.00
3	Physician	2414.00	2396.96
4	Nurse	1279.42	1270.39
5	Re-test of Hct.	80.00	80.00
6	Serum lab tests	200.00	200.00
7	Re- transfusion	(Re-A)	(Re-B)
8	Managing complications	(Com-A)	(Com-B)
9	Other part of hospitalization	(H-A)	(H-B) *
	Subtotal of item 1,2,3,4,5,6	5231.42	4082.35

Re = Re-transfusion, Com = Complication, H = hospitalization.

* not include in the final analysis

Item 1,5 and 6 are the cost for lab tests.

Item 2 "partial exchange transfusion", alternative A excludes the cost of blood cross-matching because plasma AB was used, only the cost of plasma, special blood set, syringes, transportation and carrier (the hospital clerk went back and forth to get the plasma) and other necessities (ice bucket, electric thermos to warm water for thawing the frozen plasma, etc) are included. In alternative B only the cost of normal saline, common I.V. set and syringes are included (Table 8). The fee of the clerk is calculated based on her salary not including fringe benefit per hour times the length of time spent in transporting the plasma.

Table 8. Cost of Partial Exchange Transfusion

Alternative A (FFP)		Alternative B (NSS)	
Plasma	650.00	Normal saline	25.00
Special blood iv set	240.00	Common iv set	30.00
Syringes	40.00	Syringes	40.00
Transportation	100.00		
Carrier (clerk)	180.00		
Other necessities	8.00		
Total	1218.00	Total	95.00

Item 3 "cost of physician" , the cost is the sum of three parts : from the time of birth to the start of treatment (observation,preparation and waiting for the plasma and normal saline, etc.), the first transfusion and 24 hour observation after transfusion. The cost of each part is calculated as the time period multiplied by the salary per minute of the physician. The cost of the nurse (suppose only one duty nurse for this case and only one physician was counted) is calculated the same way as that of the physician (table 9).

Table 9. Cost of the Physician and Nurse

Content (of physician)	Alternative A (FFP) Duration (min)	Cost (Baht)	Alternative B(NSS) Duration (min)	Cost (Baht)
Pre-transfusion observation	233	330.86	221	313.82
Transfusion	27	38.34	27	38.34
Post-transfusion observation	1440	2044.80	1440	2044.80
Total	1700	2414.00	1688	2396.96

Note : 1) The monthly salary of the physician is 15,000 Baht/month not include fringe benefit when divided by 22 days, 8 hours and 60 minutes, is equal to 1.42 Baht/min.

2) The nurse's salary is about 53% less (8000 Baht/month) than that of the physician, thus the cost of the two alternatives is 1279.42 and 1270.39 Baht respectively.

3) Attention to the almost equal of pre-transfusion duration of the two alternatives due to controlled processing timings.

The cost of re-transfusion in item 7 is the result of the re-transfusion rate multiplying the summation of the cost of items 2,3,4,5 and 6 in alternative A only. The re-transfusion rate, according to our study is zero in both alternatives.

The cost of managing the complication in item 8 is also the result of the complication rate multiplying the cost of complication which is equal to zero.

The last cost - item is the routine cost of hospitalization which is not different in both alternatives.

From our study we find that the largest difference between the two alternatives is the total cost of the transfusion treatment. Thus, a one -way sensitivity analysis can be conducted.

$$TA = 5231.42 + (Re\text{-}A) + (Com\text{-}A) + (H\text{-}A)$$

$$TB = 4082.35 + (Re\text{-}B) + (Com\text{-}B) + (H\text{-}A)$$

Where Re = re - transfusion cost

Com = complication cost

H = hospitalization cost

TA - TB = Delta = 1149.07 (Fig 1)

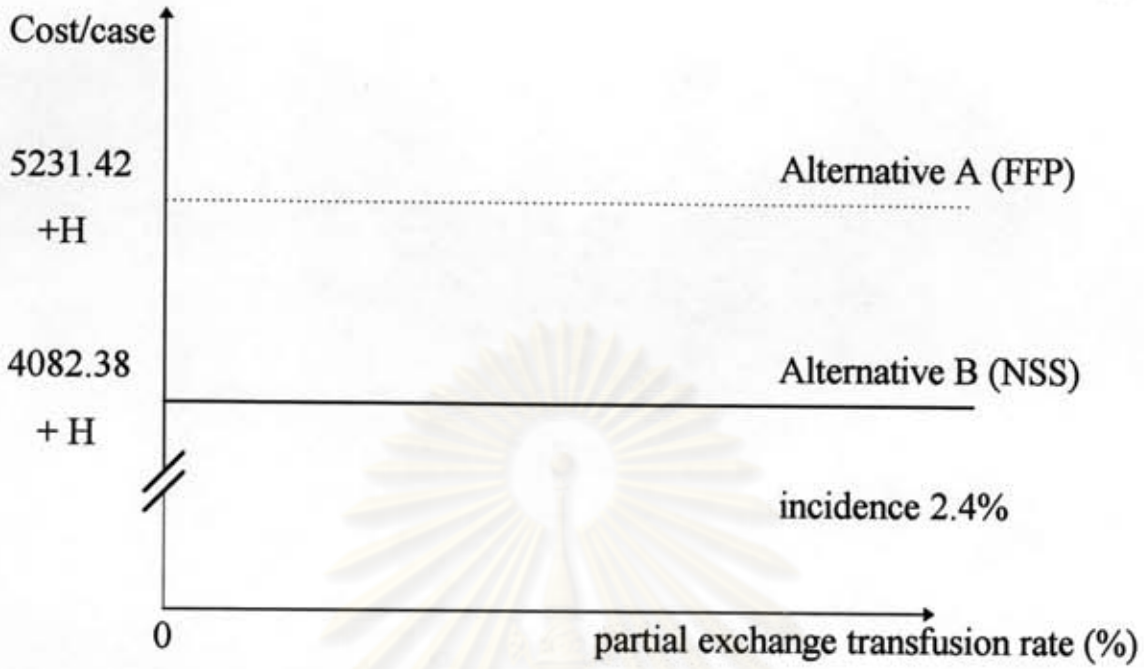

Fig 1. Sensitivity analysis

It is shown that, according to this study, the cost of normal saline is 1149.07 Baht cheaper than that of fresh frozen plasma for partial exchange transfusion in the presence of no re-transfusion rate, no complication, equal cost of hospitalization in both alternatives in polycythemic neonates that have hematocrit between 70-78%.