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Double Volume Exchange Transfusion in Newborn—Peripheral Vessel (PVET) Vs Umbilical Venous Catheterization (UVET)--- A Randomized Trial

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Abstract:
Background: *Double volume exchange transfusion is a cornerstone to prevent permanent brain damage in case of neonatal jaundice.. Several adverse effects have been reported in DVET done by conventional pull-push technique through umbilical vein (UVET) which do not occur when done by peripheral vessel (PVET).*
Aims: *To compare the efficacy in decreasing serum bilirubin between UVET and PVET and to compare the adverse effects and relative safety between the two methods.*
Methodology: *A randomizedcontrolled trial with 50 cases in each limb was carried out in Neonatology unit of Department of Paediatrics of a tertiary level referral unit in North east India.*
Results: *PVET was successfully done in 40 neonates. Seven cannulations failed (14%, n=7/50) in PVET group and were done via umbilical route .Three cannulations got disloged. So umbilical artery route was done in 57 neonates.Most of the exchanges were donewith TSB value in the range of 20-25mg/dl (n= 41, 42.27%). The mean duration of exchange transfusion procedure time was 100.18±24.86 mins in UVET group Vs 100.23±25.68 mins in PVET group(p=0.29). The mean TSB after 12 hours of exchange was 17.32 mg/dl in UVET compared to 17.91mg/dl with PVET. There was 30.72% reduction from pre exchange TSB in UVET vs 38.4% reduction in PVET (p=0.13) . This study showed a higher percentage of decrease in bilirubin level if DVET is done via peripheral route. Complications were more common in UVET group.*
Conclusion : *PVET technique can be safely done in neonates and can be used routinely in neonates requiring DVET.*
Keywords: *Exchange transfusion, Neonatal jaundice, Peripheral vessel, serum bilirubin, efficacy.*

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I. Introduction

Double volume exchange transfusion (DVET) is the accepted modality of treatment of neonates with hyperbilirubinemia at risk for development of kernicterus. Conventionally the 'pull push' technique of DVET through the umbilical vein(UVET) is still in practice. Problems with DVET through UV are faced when babies have omphalitis, abdominal distension, necrotizing enterocolitis and in older neonates with a healed umbilicus. Along with these problems, several studies have also reported many adverse events including death in DVET done by this method[1,2]. Few studies have reported that peripheral vessel exchange transfusion(PVET) is simple and safe with few complications[3,4,5]. Still very few centres have adopted this as routine procedure for DVET, There are no recommendation till date regarding the method of choice for DVET. Peripheral arterial catheterization needs expertise and may be possible only in Tertiary level care unit. However adequate exposure to the procedure and experience can make it possible even in level II Units.

Hence this study was undertaken to compare the efficacy in decreasing serum bilirubin between UVET and PVET and to compare the adverse effects and relative safety between the two methods & also to know the causes of hyperbilirubinemia in these children.

II. Aims And Objectives

AIM: To find out the efficacy of PVET in reducing serum bilirubin.

Objectives:
Primary:
1. To compare the efficacy between UVET and PVET in decreasing serum bilirubin level.
2. To compare the adverse effects and relative safety between the two methods.

Secondary:

1. To find out the causes of hyperbilirubinemia in these babies.

III. Materials & method

The study was carried out in Neonatology unit of Department of Paediatrics of a tertiary level referral unit in North-east India from May 2015 to September 2016. Permission from Instituitional Ethics Committee (IEC) was taken.It was a Randomized Controlled Trial (RCT) with 50 cases in each limb. All term stable neonates (both inborn and outborn) presenting with hyperbilirubinemia and requiring DVET as per neonatal hyperbilirubinemia practice guidelines of American Academy of Pediatrics(AAP) 2004 were included in this study.Term neonates means gestational age (GA)>37 completed weeks and<42Weeks were included. Neonates with stable vitals (Heart rate 100-160/min, Respiratory rate 40-60/min, Capillary Refill Time <3sec. O_2 saturation 90-100% and Skin Temperature 36.5-37.5^{0}C were defined as stable. Preterm neonates, jaundiced neonates with unstable vitals, indication of exchange transfusionfor causes other thanhyperbilirubinemiasuch as polycythemia,sepsis etcwere excluded from this study.

Once clinically significant jaundice was detected, total serum bilirubin level was estimated and if it came to be in exchange range DVET was planned. Until the procedure was performed babies were placed under phototherapy. Those decided for DVET were randomized. Randomization was done according to computer generated randomization number. The sheetof paper with the randomization numbers was folded and put in opaque sealed envelope which was opened once eligibility was determined and DVET was decided for a patient. Detailed maternal history, physical examination of the neonate and various pre and post exchange investigations were recorded in a predesigned proforma. Hemoglobin(Hb) %, PCV, mother's blood group, baby's blood group and Rh type, Peripheral blood smear for red cell morphology, reticulocyte count and glucose 6 phosphate dehydrogenase level were investigated in neonates decided for DVET. Pre exchange Serum bilirubin, random blood sugar (RBS), serum sodium, potassium, calcium level and platelet count were done. Serum bilirubin was done post exchange at 12 hours, 6 hours and 12 hours and then 12 hourly until baby was off phototherapy.These investigations were done in the Pathology & Biochemistry Department. RBS was checked by glucometer.

III.1 DVET Procedure

Procedure was done by Post Graduate trainee under supervision of Medical Officers and Faculties of Neonatology Unit. Phototherapywas initiated once it was indicated in these neonates as per AAP guidelines based on total serum bilirubin level and continued during and after procedure. Prewarmed blood in citrate – phosphate dextrose ≤ 3 days old was used for all exchange transfusions. All the exchanges were performed under radiant warmer. Two operators carried out the procedure using aliquot volume size of 3-5% of the neonates total blood volume depending on the weight of the baby. Pull and push method was used in UVET while in cases of PVET blood was let out through an artery usually the radial artery and blood was transfused in aliquots through a peripheral vein.

The general condition of the neonate, heart rate, respiratory rate, skin temperature, O_2 saturation was monitored in all cases continuously by the attending nurse. Circulation in the catheterized limbs (in case of DVET by PVET) during and at least 24 hours after the procedure was monitored.

Adverse events like apnea, seizure, bradycardia (HR<100/min), cardiac arrest, shock, desaturation (O2 saturation <87% needing oxygen), Hypocalcemia (total serum calcium <7.5 mg/dl), hyperkalemia (serum potassium >5.3mmol/lt), hyponatremia (serum sodium <130mmol/lt), thrombocytopenia (platelet count <100000/cu mm of blood) during or 12 hours after the procedure was noted. All neonates were observed for 48 hours after the procedure for evidence of sepsis and for omphalitis in case of DVET done by umbilical vein, and forhematoma and ischemia of the concerned limb in case of DVET by PVET.

III.2 Procedure of DVET by Peripheral Vessels

Before each cannulation, modified Allen's test[6] was done to confirm adequate collateral circulations of the limb. One of the radial arteries was tried for cannulation for drawing blood. Course of the artery was located by palpation. In each case the artery was aseptically cannulated with a 24 gauze cannula and blood was drawn from the artery and discarded by one person through a 3- way cannula in aliquots. Simultaneously equal volume of blood was replaced through a peripheral vein using a 24 gauze cannula by another person. The arterial line was flushed with 0.5 ml heparinized (5 units/ml) NS after withdrawal of every 50 ml of blood. ET was done by umbilical vein in whomradial artery cannulation failed. Number of aliquots in and out was monitored and recorded simultaneously in a standard chart.

III.3 Procedure of ET by Umbilical Vein

Here an umbilical venous catheter was inserted under aseptic conditions. Site was prepared aseptically using povidone iodine. The abdomen wasdrapped using sterile towels. The umbilical stump was cut with the

scalpel blade about 2 cm from the skin. The umbilical stump was held with a toothed forcep and opening of the vein was identified. The catheter was prefilled with normal saline and was gently pushed into the umbilical vein. The catheter tip was advanced only as far as is necessary (usually 2- 5 cm) to establish good blood flow.Then pull push technique was used. Similar to PVET al details were monitored and recorded in a standard chart.

III.4 Statistical Analysis used:

The data was entered in Statistical Package for the Social Sciences (SPSS) for Windows version 16.0.The Chi-square test was used to examine the association between different variables. P<0.05 was considered as statistically significant.

IV. Results

During the study period, PVET was successfully done in 40 neonates. Seven cannulations failed (14%,n= 7/50) in the PVET group and were done via umbilical route. Three radial artery cannulations got dislodged (6%) after doing few aliquots and later continued by umbilical vein and hence were excluded from this study. So the total number of neonates in umbilical route group was 57.Of the total exchanges, males were 58.76% and females were 41.24% (Fig.1). Seventy nine percent (79%) of DVET were done between day2-day7 of life (n= 77, 79.4%)(Fig 2).Most of the exchanges were donewith TSB value in the range of 20-25mg/dl (n= 41, 42.27%)(Fig 3.). The mean duration of exchange transfusion procedure time was 100.18±24.86 mins in UVET group Vs 100.23±25.68 mins in PVET group, the difference was not statistically different (p=0.29). Commonest cause of hyperbilirubinemia was idiopathic (n= 47, 48.5%) followed by ABO incompatibility (n= 33, 34%)(Table 1). Out of them 6 neonates (6.2%) needed second DVET, in which 5 were done via umbilical route in both the times and one via peripheral route. The mean TSB after 12 hours of exchange was 17.32 mg/dl in UVET compared to 17.91mg/dl with PVET. There was 30.72% reduction from pre exchange TSB in UVET vs 38.4% reduction in PVET [p=0.13] (Table 3). This study showed a higher percentage of decrease in bilirubin level (although not statistically significant) if DVET is done via peripheral route.Complications of hyperkalemia and thrombocytopenia were more commonly seen in UVET, though are not statistically significant. Other complications such as hypocalcemia, hypernatremia were also seen in a few cases where the DVET was done via umbilical route. One baby had apnea during the procedure where the exchange transfusion was being done via umbilical route & the procedure was stopped after that event. No cases of DVET related mortality was observed in both the groups.

V. Figures and Tables

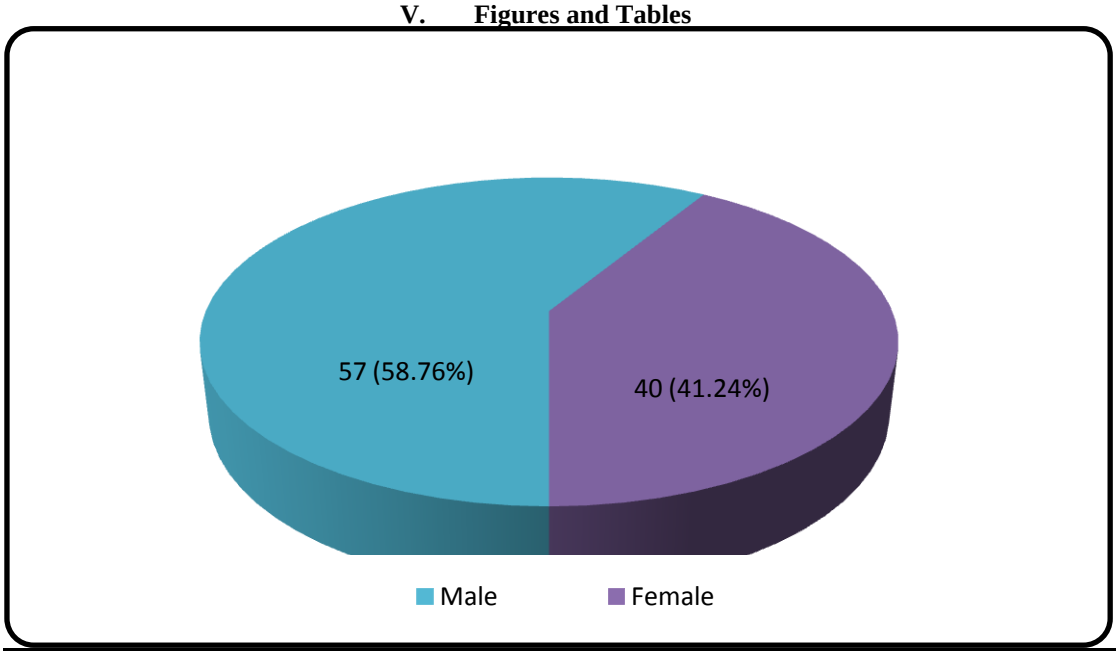

Figure 1. Sex wise distribution

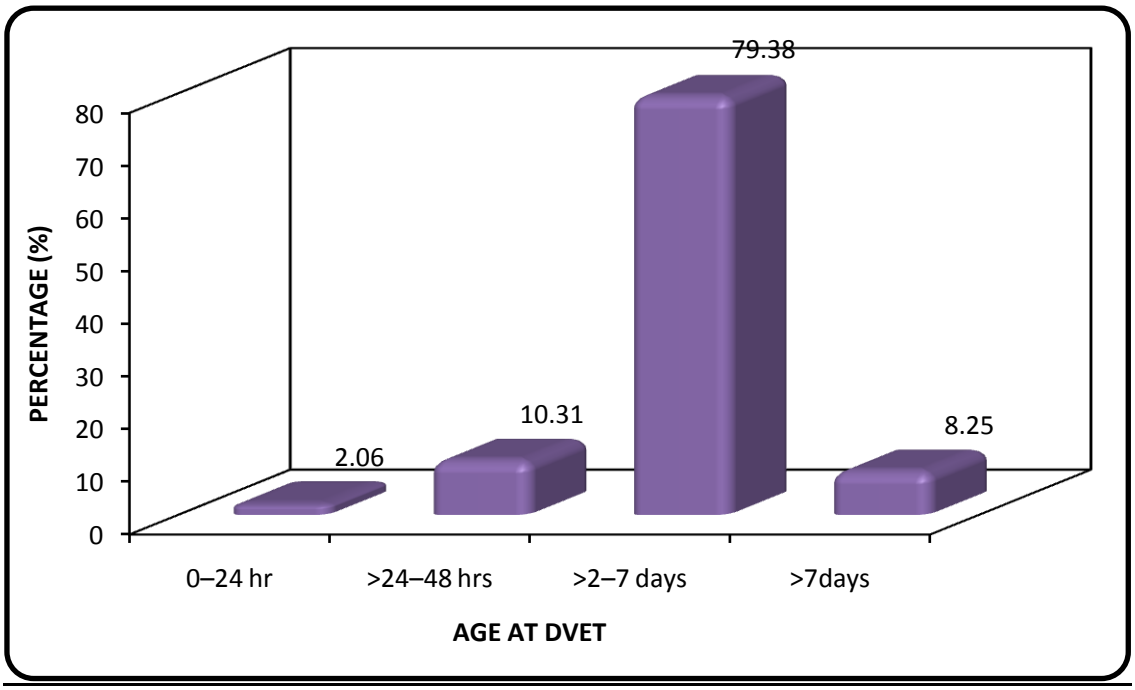

Figure2. DVET Age

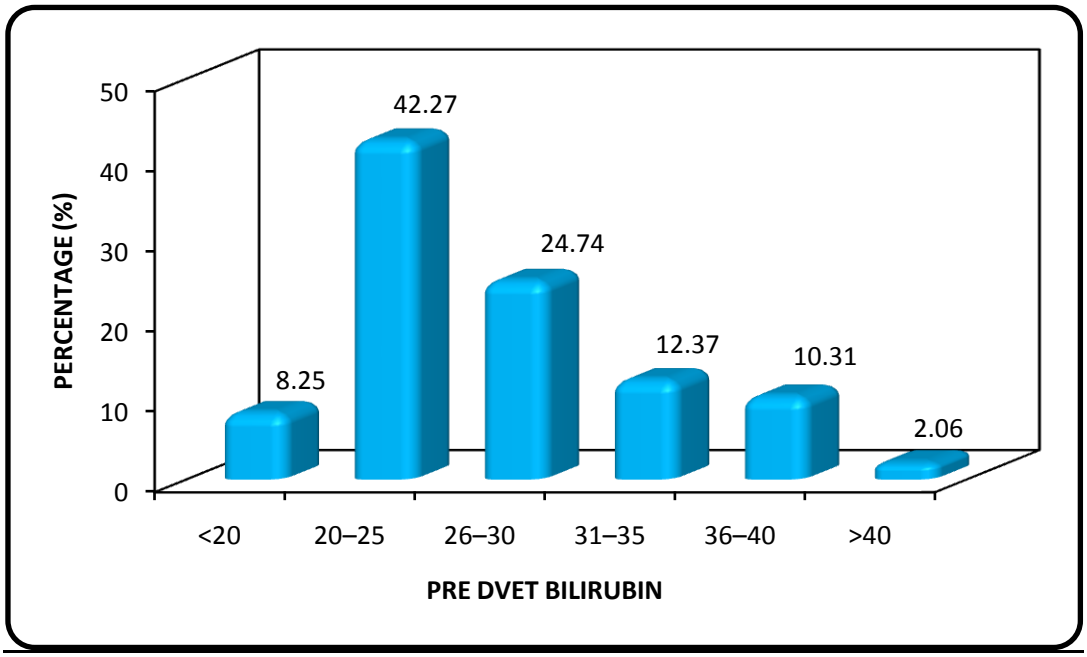

Figure 3. Pre DVET bilirubin level

Table 1. Percentage decrease in bilirubin

Post DVET age	UVET	PVET	P Value
2 hrs	27.6%	38.1%	0.13
6hrs	28.14%	39.4%	
12 hrs	30.72%	38.41%	

Table 2. Causes of hyperbilirubinemia

Cause of hyperbilirubinemia	**UVET (n)**	**PVET (n)**	**TOTAL (n)**	**PERCENTAGE %**
Idiopathic	24	23	47	48.5%
ABO Incompatibility	24	09	33	34%
G6PD deficiency	08	05	13	13.4%
Rh Incompatilibity	01	02	3	3%
Others (cephalhematoma)	00	01	1	1%

Table3. Complications of DVET

COMPLICATIONS	**UVET (n)**	**PVET (n)**	**TOTAL (n)**	**PERCENTAGE (%)**
Thrombocytopenia	6	2	8	8.24%
Hyperkalemia	5	3	8	8.24%
Hypocalcemia	2	3	5	5.15%
Hypercalcemia	1	1	2	2.06%
Hypernatremia	1	0	1	1.03%
Hypokalemia	1	0	1	1.03%
Apnea	1	0	1	1.03%
Total	17 (17.52%)	9 (9.28%)		

VI. Discussion

Almost three decade back Peripheral vessel exchange transfusion (PVET) was carried out by Sagi et al[3] . Use of PVET was proposed to be considered for infants requiring ET (Exchange Transfusion) to avoid the various complications associated with the use of umbilical view for ET[4,5].

The first study to be reported where a comparision of the efficacy and safety of ET using Peripheral Vessel with that of a conventional UVET (Umbilical vein exchange transfusion) was done by Hsiao Nenget al[9] in 2008. In our study mean duration of DVET via peripheral route was found to be 100.23±25.68 min and 100.18±24.86 min in UVET group, with no statistical difference in the duration between the two methods. No difference in duration was also found by Hsiao Nenget al[9]. By peripheral route, Devraj V. Raichuret al[10] did the procedure with a mean duration of 109 min and T. F Fok, L Y So et al[4]completed with a mean duration of 90 min.

Although the efficacy of both the methods in decreasing TSB was statistically comparable (p=0.13), there was a greater percentage of decrease in bilirubin post exchange in PVET group compared to UVET group (38.4% vs 30.21%). Even in the study by Hsiao Nenget al,[9]no statistical difference in the efficacy of eliminating bilirubin from circulation between the two methods were found. Use of PVET has revealed that this method is effective in decreasing the serum bilirubin from circulation (mean drop in severe bilirubin concentration was 45% to 49% with p=0.1) and is associated with fewer adverse events[4,10]. There was significantly fewer adverse effects when using the PVET method (0%) compared with 14.3% when using the UVET[9]. There were no procedural death and only few complications (blockage of arterial catheter in very few babies) when DVET was done by the peripheral route[4,5]. Some studies have shown that DVET via umbilical veins is associated with many complications. Steiner et al[7] reported that the overall ET related adverse event rate including hypocalcemia and thrombocytopenia was upto 73% (33 of 45 patients). Guaranet al[8] reported that 7 (4.3%) of 248 neonates who underwent ET died as a result of complications associated with the procedure. Safety of PVET with better temperature control and decrease chances of sepsis has been documented by Sheikh M A et al[11]. The findings of our study indicate a lesser risk of procedure related complication if PVET is done compared to UVET. We found 17.52% complication rate in UVET group compared to 9.28% in PVET group. There was no ET related death in our study.

In the PVET procedure only one limb need to be exposed. So temperature control becomes less of a problem as the baby's clothing need not be removed. The cardiovascular changes caused by fluctuations in circulatory volume are minimized, as removal and replacement of blood takes place simultaneously.

VII. Conclusion

PVET can be done safely in patients with omphalitis or intra-abdominal complications and with minimal iatrogenic risks. Our experience gives evidence that the PVET technique is safe and can be used routinely in most babies who require DVET. Very few centres have adopted this as the procedure of choice.Successful placement of the arterial catheter is necessary for thesuccess of PVET and it requires some skill, experience and expertise.

Acknowledgement

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