

A Cross Sectional Comparative Non Randomized Interventional Cohort Study to Assess the Weight and Sepsis Rate among Pre Term Babies Receiving TPN and Not Receiving TPN at Selected Hospitals of Indore in the Year 2015-2016

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Abstract: Parental nutrition is an essential component in the management of many newborn infants, particularly in premature low birth weight infants admitted to newborn intensive care units⁴. The present study was a cross sectional comparative non randomized interventional cohort study design adopted to assess the net cumulative weight loss and weight gain as well as sepsis rate among pre term babies admitted in neonatal intensive care unit of Choithram Hospital and Research Centre, Indore. The study was conducted among 30 pre term babies selected through multi stage sampling technique, i.e. pre term babies were selected using purposive sampling technique and then convenient sampling technique was used to put pre term babies 15 in experimental and 15 in control group. The pre term babies receiving Total parenteral nutrition had more weight gain compared to preterm babies not receiving Total parenteral nutrition assessed on Day1,3,5 & 7 as well as the percentage of weight loss was decreased in preterm babies receiving total parenteral nutrition. There was significant change in the biochemical parameters CBC (Hb, MCV, Platelets) sodium, potassium, chloride, calcium, CRP and blood culture in both the groups. There were 7(47%) of babies who had sepsis in control group who were not receiving total parenteral nutrition compared to 3(20%) of preterm babies had sepsis in experimental group who were receiving total parenteral nutrition

Keywords: Total parenteral nutrition, Biochemical parameters and sepsis rate

1. Background

Premature infants, known as preemies, come into the world earlier than full-term babies. Prematurity occurs when a pregnancy lasts less than 37 weeks. Those who weigh more than 500 grams have a more than 60% chance of survival, although their chances of complications are greater. Premature babies have special nutritional needs because they grow at a faster rate than full-term babies and their digestive systems are immature. Pre mature babies who are very small or very sick cannot use their digestive systems to process food. These babies require intravenous (IV) feedings — called TPN, or total parenteral nutrition — made up of fats, proteins, sugars, and nutrients. TPN is given through a small tube inserted into a large vein through the baby's skin or umbilical stump. Infection is a big threat to pre mature babies because they're less able than full-term infants to fight germs that can cause serious illness¹.

Parenteral nutrition is an essential component in the management of many newborn infants, particularly in premature low birth weight infants admitted to newborn intensive care units². Postnatal growth of very low birth weight (VLBW) neonates has always remained a challenge in NICU³.

Evidenced based recommendations have been given by AIIMS and NNF in 2011 on initiating total parenteral nutrition starting from the first day of life, especially to very

low birth weight (VLBW) infants in the achievement of postnatal growth at a rate that approximates the intrauterine growth of a normal fetus at the same post conception age. But it is not been implemented with a fear to develop sepsis leading to decreased administration on TPN affecting 60% of term births after foetal growth restriction⁴.

2. Need of the Study & Literature Review

The incidence of pre term babies, in 2015 is nearly 22 million newborns—an estimated 16% of all babies born globally that year had pre term babies⁴. Every year, an estimated 15 million babies are born preterm (before 37 completed weeks of gestation), and this number is rising. Preterm birth complications are the leading cause of death among children under 5 years of age, responsible for nearly 1 million deaths in 2013. India (3 519 100) ranks first among 10 countries with the greatest number of preterm births⁵.

A study reported in the medical journal **INVENTI IMPACT NEONATAL AND PEDIATRIC NURSING, 2015** a research was conducted to evaluate the efficacy and safety profile of new consensus formulations in preterm infants born less than 32weeks of gestation, a before and after study conducted at a tertiary neonatal intensive care unit and came out with the conclusion that new consensus parenteral nutrition solution provided better protein intake in the first seven days and were associated with greater weight gain in the first four weeks⁶.

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Skouroliaiou Maria, Koutri Katerina, Stathopoulou Maria et al⁷ conducted a study on two groups of 30 preterm infants (28–36 weeks) with respiratory failure to know the results of utilization of standardized computerized parenteral nutrition protocols and regimens for neonates compared to the results of protocols and regimens prescribed by individual neonatologists on neonatal outcome (weight changes, adequacy of parenteral nutrition, days of hospitalization, clinical outcome) in 2009. Standardized, computer based protocols were applied for the prescription of parenteral nutrition formulations in the first group, while on the other, regimens prescribed by neonatologists were used. Body weight was measured; blood count and biochemical profile were performed at the beginning and at the end of parenteral nutrition support. Findings of the study revealed that standardized protocols provided more energy, protein and micronutrients than the non-standardised. Neonates that receive standardized total parenteral nutrition gained weight and had better blood count and biochemical values during total parenteral nutrition support compared to the other group that lost weight during total parenteral nutrition support. These differences were also statistically significant. Regarding the total days of hospitalization, no differences were found between the two groups.⁷

Investigators personal experience during clinical posting was that there was weight loss in babies who were not receiving TPN which further led to increased weight loss during their later days of life. Many hospitals in India are still lagging behind for implementation of TPN from first day of life because of risk for developing sepsis in future days due to lack of skilled professionals. Hence, it is required to evaluate the effect of TPN on low birth weight babies starting from first day of life.

3. Problem Statement

A cross sectional comparative non randomized interventional cohort study to assess the weight and sepsis rate among preterm babies receiving total parenteral nutrition and not receiving total parenteral nutrition at selected hospitals of Indore during the year 2015-2016.

3.1 Objectives

- To assess the baseline details about the preterm babies.
- To compare the net cumulative weight loss and weight gain of the preterm babies of experimental group and control group.
- To compare the biochemical profile of preterm babies of experimental group and control group.
- To compare the sepsis rate among preterm babies of experimental group and control group

3.2 Hypothesis

- **H1.** There is a significant difference in weight of babies in experimental group and control group at the level $p \leq 0.05$
- **H2.** There is a significant difference in biochemical profile of experimental group and control group at the level $p \leq 0.05$

- **H3.** There is a significant difference in sepsis rate of babies in experimental group and control group at the level $p \leq 0.05$

3.3 Research Methodology

- **Research design:** -cross sectional non randomized interventional cohort group design was adopted in the study.
- **Setting:** The study was conducted at Choithram Hospital and Research Centre.
- **Population:** It included preterm babies admitted in neonatal intensive care unit (NICU) at choithram hospital and research centre.
- **Sample and sample size:** In the study the sample size comprises of 30 preterm babies admitted in NICU of choithram hospital and research centre.¹⁵ in each experimental and control group.
- **Sampling Technique:** The samples were selected through multistage sampling technique and hospitals were selected through convenient sampling technique.

Tool: The tool used for data collection in the research study was organized as follows:

Section A (i): Maternal Baseline Data

Section A (ii): Neonatal Baseline Data

Section B: Physiological Parameters

Section C: Biochemical Parameters

3.4 Validity and Reliability

The prepared tool along with the statement, objectives, hypothesis, operational definitions & criteria checklist were given to 7 experts from the field of child health 1 (Neonatologist), 2 (Pediatric Consultant), 4 (Pediatric Professor) 1 (Statistician). Reliability of the digital weighing machine used to record the parameter (Weight) was calculated using test retest method which was computed using Karl Pearson correlation formula and reliability was $r=0.95$. Laboratory is participating in the external quality assurance programme of internal and external validation agencies. Lab is also practicing inter lab comparison programme.

3.5 Procedure for Data Collection

Written permission was obtained from the concerned authority of Choithram Hospital & Research Centre prior to data collection. A total of 30 samples were selected for the study. The data collection period was from 18th April 2016 to 20th June 2016.

Consent was taken from the consultants under whom the samples were admitted as well as from the parents and confidentiality was assured. The purpose of the study was explained to the parents and informed consent was obtained from them. Multistage sampling technique was used in which purposive sampling was done for the selection of preterm babies and convenient sampling to put the samples in the experimental group and control group respectively.

Preterm babies in the experimental group received TPN through PICC line and the fluids were kept under laminar

flow for nearly 1 hour before administration and in the control group preterm babies received intravenous fluids through I/V access which was not kept under laminar flow. Hospital was selected which provided TPN for pre term and investigated for biochemical parameters on Day 1 and Day 7. Staff nurses of both the labour ward and NICU informed the researcher about the pre term births through telephonic conversation. The preterm babies who fulfilled the inclusion criteria were included in the study.

Weight was assessed on day 1, 3, 5, & 7 along with the biochemical factors on day 1 & day 7. The investigator faced much difficulty in collecting the data as admission of preterm babies decreased during the data collection period but assessment of the parameters required invasive procedures but it was as per the hospital protocol & thus no changes in the hospital routines were brought about in the study. The parents were co-cooperative and willing to participate in the study. The investigator terminated the data collection process by thanking the consultants, staff and parents for their co-operation & participation in the study.

4. Major Findings of the Study

The data analyzed according to the objectives of the study using descriptive and inferential statistics.

I. Socio demographic data: Maternal baseline data:

Data reveals that majority 8(53%) of the mothers in experimental and control group were in the age group of 20-25 Years. In both group most of the mothers 9(60%) were primigravida and 6(40%) were multigravida. Majority of the mothers of both the groups had no history of medical complications in previous pregnancy experimental group 10(67%) control group 11 (73%) respectively. Regarding mode of delivery more than half 8(53%) of the mothers in the experimental group had normal vaginal delivery, whereas in control group majority of the mothers 10 (67%) had Lower section caesarean section, majority of the mothers used antenatal steroids in both groups experimental group 9(60%), control group 13(87%) respectively. With respect to history of pre-eclampsia most of the mothers of both the groups did not had history of pre eclampsia, experimental group 9(60%), control group, 11(73%) respectively.

II. Socio demographic data: Neonatal baseline data

Result revealed that in the experimental group majority of the pre terms babies 8(53%) were with the birth weight of 1100-1500gm, whereas in the control group, majority 7(47%) were with the birth weight of $\geq 1500-2500$ gm. Most preterm babies 9(60%) of experimental group and control group had gestational age of 29-32 weeks. With respect to gender of the baby most of 10 (67%) pre term babies were female in the experimental group whereas in the control group, majority 11(73%) were male. Data reveals that majority of the mothers used antenatal steroids in both groups experimental group 9(60%), control group 13(87%) respectively.

With respect to history of pre-eclampsia most of the mothers of both the groups did not had history of pre eclampsia, experimental group 9(60%), control group, 11(73%) respectively.

III. Comparison of weight loss among experimental group & control group

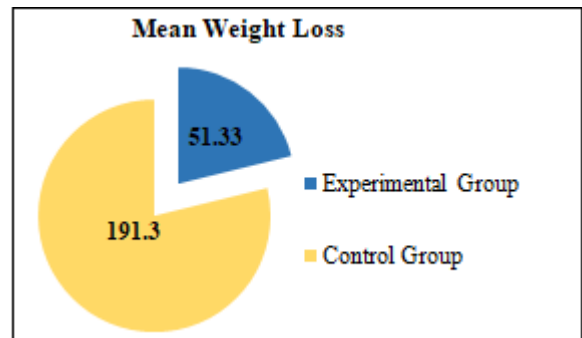


Figure 1: Pie diagram showing weight among Experimental group & Control group

Preterm babies in the experimental group had mean weight loss of 51.3gms and percentage of weight loss in the range of 0%-11% whereas preterm babies in the control group had mean weight loss of 191.3gm and percentage of weight loss in the range of 2.3%-21% with the mean difference of 145.3gm. The computed t-value was 3.87 at degree of freedom 14. The researcher found that statistically there was significant difference in the weight loss between experimental group and control group at $p \leq 0.05$. Thus, it can be inferred that there was increase in weight loss in the control group compared to experimental group.

IV. Comparison of weight gain among experimental group & control group

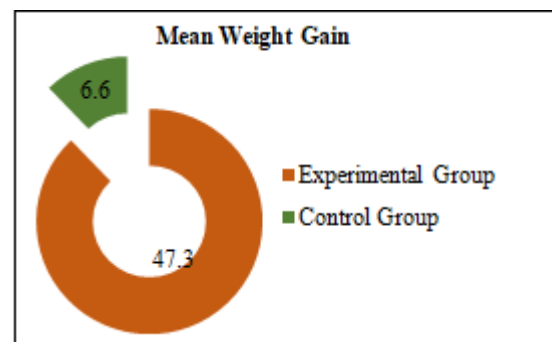


Figure 2: Doughnut diagram showing weight among Experimental group & Control Group

Preterm babies in the experimental group had mean weight gain of 47.3gm, whereas in the control group pre term babies had mean weight gain of 6.6 gm with the mean difference of 40.7gm and standard deviation of 8.37. The computed t-value was 3.86 at degree of freedom 14, which shows that there is statistical significant difference in the weight gain between experimental group and control group at $p \leq 0.05$. There was weight loss in pre term babies of control group till day 7 and weight gain in pre term babies of experimental group from day 5.

V. Comparison of Haemoglobin among experimental group and control group

Data depicts that the mean hemoglobin level in experimental group was 2.85gm% & that in control group was 1.30gm% with the standard deviation of 2.25. The computed t-value was 2.67 at degree of freedom 14 indicates that there is

significant difference in the level of hemoglobin among experimental and control group at $p \leq 0.05$. Thus, there is a significant difference in the level of hemoglobin between experimental and control groups.

vi. Comparison of TLC among experimental group and control group

Data depicts that the mean total leucocyte count in experimental group was 4639.8 per cumm & that in control group was 2214.0 per cumm with the standard deviation of 1640.7. The standard error was 423.9. The computed t -value was 5.7 at degree of freedom 14. The researcher found that statistically there was significant difference in the level of total leucocyte count between experimental group and control group at $p \leq 0.05$.

vii. Comparison of platelets among experimental group and control group

Data depicts that the mean platelet in the experimental group was 94609/lacs/cumm and in the control group was 31203/lacs/cumm. The computed t -value was 7.3 at degree of freedom 14 with the standard deviation of 33801.3 indicates that there is a significant difference in the level of platelets between experimental and control group at $p \leq 0.05$.

viii. Comparison of MCV among experimental group and control group

Data depicts that the mean MCV in experimental group was 10.7 fl & that in control group was 5.06 fl with the standard deviation of 4.50. The computed t -value was 4.86 at degree of freedom 14. Thus, there is a significant difference in the level of MCV between experimental and control groups at $p \leq 0.05$.

ix. Comparison of sodium among experimental group and control group

Data depicts that the mean total sodium in experimental group was 7.07 mEq/L & that in Control group was 4.6 mEq/L with the standard deviation of 2.60. The standard error was 0.67. The computed t -value was 4.56 at degree of freedom 14. The researcher found that statistically there was significant difference in the level of sodium between experimental group and control group at $p \leq 0.05$.

x. Comparison of potassium among experimental group and control group

Data depicts that the mean total potassium in experimental group was 2.94 mEq/L & that in control group was 1.80 mEq/L with the standard deviation of 0.94. The computed t -value was 4.75 at degree of freedom 14. Thus, there is a significant difference in the level of potassium between experimental group and control group at $p \leq 0.05$.

xi. Comparison of chloride among experimental group and control group

Data depicts that the mean chloride in experimental group was 10.8 mEq/L & that in control group was 4.4 mEq/L with the standard deviation of 4.64. The computed t -value was 5.37 at degree of freedom 14. The researcher found that statistically there was significant difference in the level of chloride between experimental group and control group at $p \leq 0.05$.

xii. Comparison of calcium among experimental group and control group

Data depicts that the mean calcium in experimental group was 1.93 mEq/L & that in control group was 1.01 mEq/L with the standard deviation of 0.724. The standard error was 0.18. The computed t -value was 4.91 at degree of freedom 14. The researcher found that statistically there was significant difference in the level of calcium between both experimental group and control group at $p \leq 0.05$.

xiii. Comparison of sepsis rate among experimental group and control group

Table 1: Chi Square value showing difference in sepsis rate among Experimental Group and Control Group, $N=30$ ($n_1 = 15, n_2 = 15$)

Groups	Not Detected	Detected	df	χ^2	Table value
Experimental Group	12	3	1	3.6	3.84 NS
Control Group	7	8			

$P \leq 0.05^*$ $p \leq 0.01^{}$ $p \leq 0.001^{***}$ S-Significant NS- Non Significant df-degree of freedom**

Data in the Table No.1 shows the sepsis rate among experimental group and control group, among 15 preterm babies in experimental group only 20% (3) of the pre term babies had CRP level >6 and blood culture positive, whereas in the control group nearly half of the preterm babies 47% (7) had CRP >6 and blood culture positive. There is no significant statistical difference in the level of sepsis at $p \leq 0.05$. But difference in the sepsis rate can be seen in both the experimental and control groups shows clinical significance.

5. Discussion

Discussion on comparison of net cumulative weight loss and weight gain among experimental group and control group

Data depicts that the preterm babies in the experimental group had mean weight loss of 51.3gms and percentage of weight loss in the range of 0%-11% whereas preterm babies in the control group had mean weight loss of 191.3gm and percentage of weight loss in the range of 2.3%-21% with computed t-value 3.87.

With respect to net weight gain data reveals that the preterm babies in the experimental group had mean weight gain of 47.3gms, whereas in the control group pre term babies had mean weight gain of 6.6 gms, t_{14} 3.86 at the level $p \leq 0.05$

Findings revealed that there was increased weight loss in pre term babies of control group who did not received TPN till day 5 of life when compared to weight loss of pre term babies in the experimental group who received TPN on the other hand when both the groups were compared on weight gain, pre term babies of experimental group had more weight gain from day 5 to day 7. This shows that administration of TPN to pre term babies helps in improving weight as well as helps in reducing the postnatal weight loss. So, TPN should be given to preterm babies in order to reduce their length of stay in NICU. **Hence, HYPOTHESIS (H₁) is accepted.**

Discussion on comparison of biochemical parameters among experimental group and control group

S.No	Parameters	Experimental Group Mean Difference (D7-D1)	Control Group Mean Difference (D7-D1)	t-value
1.	Hemoglobin	2.85gm%	1.30gm%	2.67
2.	TLC	4639.8Per cumm	2214.0Per cumm	5.7
3.	Platelet	94609lacs/cumm	31203lacss/cumm	7.3
4.	MCV	10.7fl	5.06fl	4.86
5.	Sodium	7.07mEq/L	4.6mEq/L	4.56
6.	Potassium	2.94mEq/L	1.80mEq/L	4.75
7.	Chloride	10.8mEq/L	4.4mEq/L	5.37
8.	Calcium	1.93mEq/L	1.01mEq/L	4.91

Findings of the study revealed that in experimental group mean hemoglobin level was more i.e 2.85gm% & that in control group was 1.30gm% ,with t_{14} -2.67, similarly for the the mean total leucocyte count it was more in the experimental group 4639.8per cumm & that in control group was 2214.0 per cumm, t_{14} - 5.7, when both the groups were compared for the mean platelet level the experimental group had 94609lacs/cumm and in the control group had 31203lacs/cumm, t_{14} -7.3, this shows that experimental group had more platelet level than control group. However the mean MCV level was more in experimental group than in control group i.e 10.7fl & 5.06fl respectively, t_{14} - 4.86. All the electrolytes were compared between experimental and control group and the result showed that mean sodium level of the experimental group was 7.07mEq/L whereas in the control group was 4.6mEq/L with t_{14} -4.56 whereas for the mean total potassium level experimental group had 2.94mEq/L and in control group was 1.80mEq/L with t_{14} - 4.75, for the mean chloride in experimental group was 10.8mEq/L whereas in control group was 4.4mEq/L, t_{14} - 5.37 however the mean calcium in the experimental group was 1.93mEq/L & that in control group was 1.01mEq/L, t_{14} - 4.91 at $p \leq 0.05$.

This shows that the electrolyte level in the pre terms receiving TPN was more when compared to pre terms who only received intravenous fluids. So, it can be inferred that that administration of TPN along with intravenous fluid is more effective for preterm babies which would further help in maintaining the electrolyte balance in them.

Hence, HYPOTHESIS(H₂) is accepted.

The findings of the study were supported with the study conducted K Krohn, J Babl, K Reiteret all⁸ conducted a study in 2005 to evaluate the use of standard solutions on the paediatric intensive care unit. PN solutions were either prescribed individually or as standard solutions. They evaluated the frequency of standard solution prescriptions and their modification, compared nutrient intakes with standard vs. individual PN solutions as well as the occurrence of laboratory anomalies. Standard PN solutions were prescribed in 68% of cases, individual PN solutions in 32%. Modifications of standard PN solutions were performed in 54%. Findings revealed that the intake of a number of macronutrients and electrolytes was similar with individual and standard PN, but calcium and phosphate intakes were lower with individual total PN. Electrolyte imbalances occurred slightly more often with individual PN than with standard .Standard PN solutions were used in the

majority of patients on a paediatric intensive care unit. Thus, it can be concluded that electrolyte imbalances can be maintained by administering standardised parental nutrition to pre term babies.

Discussion on difference on sepsis rate among experimental group & control group

It was observed that among the 15 pre term babies of the experimental group who were receiving total parental nutrition had less sepsis rate i.e the sepsis rate 20%(3) whereas pre term babies of the control group who received only intra venous fluid had more sepsis rate 47%(7) But there was no significant difference in the sepsis rate among experimental group & control group at the level $p \leq 0.05$ though there was difference in the sepsis rate among both the groups.

Hence, Hypothesis H₃ is rejected. The researcher highly regrets to say that there is no relevant study to support the above findings.

So, it can be concluded that administration of TPN under all aseptic precautions as well as with the use of laminar flow system could reduce the sepsis rate and it can be also concluded that administration of TPN is an independent risk factor for sepsis occurring in preterm babies admitted in NICU.

6. Conclusion

In very low birth weight pre term infants, due to the immaturity of the gastrointestinal systems, enteral feeding cannot be established in the first few days of life. The goal of nutritional support in pre term infants is to achieve a postnatal growth similar to that of a normal fetus at the same post conceptual age. Based on the present study the following conclusions were drawn total parental nutrition has effect on reducing the net cumulative weight loss and significantly improves the weight gain of the low birth weight babies, sepsis rate was also comparatively decreased in pre term who received TPN.

Researchers suggest that early initiation of TPN in pre terms babies could improve the weight gain as well as prevent from other complications such as necrotising enterocolitis. Dedicated health care staff and nursing staff can play a significant role in improving the knowledge and practice toward administration of TPN by using strict aseptic techniques.

It was a great experience of doing this research study. All the mothers, Doctors and Staff were very cooperative in collecting the data. The constant help of guide and co-guide provided a positive reinforcement for the successful completion of the study. On the whole, the researcher experienced immeasurable excitement and zeal along with exploring new areas and in improving the knowledge while conducting the research study.

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