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Enteral Albumin Supplementation in Postoperative Cardiac Surgical Infants: A First

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Abstract—*Hypoalbuminemia following cardiac surgery with cardio pulmonary bypass (CPB) is unavoidable and mediated by hemodilution, inflammation, increased vascular permeability and fluid seepage (3rd spacing) into the interstitial compartment due to low plasma oncotic pressure. Intravenous albumin is being used since long to treat hypoalbuminemia. In this pilot study albumin supplemented expressed breast milk (EBM) was given to the infants, to evaluate the tolerance and benefits of albumin supplementation after cardiac repair. Methods: Ten cyanotic congenital heart disease infants < 6 months of age, weighing ≥ 2.5 kg at birth were randomized into control and study groups after obtaining institute ethics committee approval. Both the groups were fed as per their randomization code with EBM or supplemented EBM. This feed composition provided 11.15 % protein, 40.5% fat and 44% carbohydrate which was higher than that of EBM (contains 5% protein, 47% fat and 40% carbohydrate). Result: The study group consumed more energy, protein and carbohydrate as compared to the control group114.56±18.07 v/s 103.85±78.49, 3.19±0.50 v/s 1.39±1.05, 12.83±2.0 v/s 10.37±7.8 respectively on POD 5th. Serum albumin level showed a positive trend in study group 2.8±0.38, 2.85±0.44 and decreasing trend in control group 3.3±0.50, 3.2±0.45 from POD 1st to 3rd respectively. Ventilation duration and ICU stay were longer in control group than study group 120.75±84.5 v/s 109±92.88 and 8.5±4.5 v/s 8±5.29 respectively. Conclusion: As a first, EBM was supplemented with oral albumin in cardiac surgical infants. This feed is tolerable, without any side effects. It augments protein and calorie with restricted volume, helps in convalescence of these infants postoperatively.*

Introduction

Infants with congenital heart disease (CHD), irrespective of the nature of their cardiac defects [1] are malnourished in preoperative [2–5] as well as in post-operative period [6,7]. Hypoalbuminemia is considered as a predictor of morbidity and mortality in intensive care unit (ICU) patients and it frequently occurs in children undergoing cardiac surgery with cardiopulmonary bypass (CPB) [8]. Hypoalbuminemia cause several physiological derangements including reduction in plasma oncotic pressure, peripheral and intestinal edema and decreased gastrointestinal motility with intolerance to enteral nutrition [9]. These factors may result in prolonged ventilation, longer ICU and hospital stays and ultimately the higher expenses [10, 11]. Intravenous albumin supplementation has been on use since long and improves the serum albumin concentration, organ function and calorie intake [12]. Albumin supplementation is considered as safe [13] because albumin preserves oncotic pressure, prevents interstitial edema, maintain vascular barrier competency and keep microcirculation intact [14]. But if this albumin can be supplemented enterally/orally to these post-cardiac surgical children, will have multiple advantages including, gastrointestinal tract functioning, hormonal secretion and reduced chances of I/V induced infections. This randomized controlled trial (pilot study) was conducted to assess the tolerance and effect of oral albumin supplementation in infants below six months of age after their congenital cardiac repair.

Methods

Study design

This study was an open label randomized controlled trial (pilot study), conducted in the ICU of cardiothoracic vascular surgery (CTVS) of a tertiary care teaching hospital in north India. The study was approved by institute's ethics committee.

Subject

Ten infants less than 6 months old, ≥ 2.5 kg birth weight with cyanotic congenital heart disease (CCHD), consuming mother's milk only were recruited for this pilot study. They were admitted in the CTVS ICU post cardiac surgery from March 2018 to May 2018. The infants undergoing emergency and closed heart surgery, prior hospital admission with severe infection, on higher antibiotics, ventilator and consuming formula feed were excluded. The infants who had longer feeding interruption (FI) i.e. more than 24 hours, required parenteral nutrition, peritoneal dialysis, extracorporeal membrane oxygenation (ECMO) support were also excluded.

Randomization and allocation concealment:

The children were randomized into two groups - control (C) and study (S) by using computer generated variable block size randomization. Opaque, sealed envelopes containing group code "C" and "S" were serially arranged with the sequential number. These envelopes were kept under the supervision of nursing in-charge (not involved in the trial). The envelopes were opened after confirmation of the eligibility of the infant and respective treatment was given to them.

The control group was fed with expressed breast milk i.e. standard protocol of our ICU and study group received supplemented EBM. The enteral feeding was initiated in both the groups after around six hours of surgery when they became hemodynamically stable without significant mediastinal bleeding.

Dietary intervention

There is lack of recommendation of nutritional requirements for these infants with congenital cardiac ailments. Revised Recommended Dietary Allowances (RDA) 2010, available for normal healthy infants was utilized for these infants too as a standard. But existing literature has shown that these postoperative catabolically stressed infants are unable to consume that much calories even.

The isocaloric (1kcal/ml) feed was planned to meet the target 90 kcal/kg/day after hemodynamic stability. The composition of feed was prepared by adding albumin RRT (Venky's nutrition, India), crystal sugar (Balram sugar, India) and simyl MCT (medium chain triglyceride) oil (FDC limited, India) in EBM. The albumin RRT and sugar were minutely measured by a digital weighing scale (Note book series digital scale) by maintaining strict hand hygiene. This feed composition provided 11.15 % protein, 40.5% fat and 44% carbohydrate which was higher than that of EBM (contains 5% protein, 47% fat and 40% carbohydrate) [15]. Fresh feed was prepared for each patient every time. The feed was started with 5 ml test dose and gradually increased as per the tolerance of the patient. The respective feed was given to both groups till 15 days of ICU stay or their discharge from the ICU, whichever was earlier. The patients were monitored for any adverse effect.

Assessment and parameters:

Preoperative, intraoperative and postoperative parameters were collected through a preformed proforma.

Preoperative information comprising socio-demographic, complete cardiac diagnosis, birth weight , gestational age, biochemical parameters like - total protein, albumin, bilirubin, AST, ALT, urea, creatinine, C-reactive protein (CRP), phosphate, hemoglobin, total leukocyte count. This information was recorded from the patient's hospital records and through mother's interview.

Intraoperative information cardiopulmonary bypass (CPB) and aortic cross clamp (ACC) time was recorded from patient's surgical records.

Postoperative information comprising of same biochemical parameters as in preoperative period was recorded on alternate days from patient's hospital record.

The daily consumption of nutrients including energy, protein, fat, carbohydrate was calculated by using dietcal software (Profound tech solution, India). Volume of feeding and any FI (feed interruption) or problems were recorded every day in both the groups.

Anthropometric measurements (weight and length) were taken when the patient was extubated or before shifting from the ICU. It was difficult to measure the weight in the immediate postoperative period as these children would be with many invasive devices with multi inotropes and little scary from safety point of view to weigh outside the basinet , and we don't have the weighing machine working in basinet and also weighing was not possible with lines and other devices. The weight was measured by portable weighing scale and length of the patient was measured by non-stretchable measuring tape.

The microbiological isolation of any infective pathogen from different body fluids i.e. respiratory secretions, blood and wound discharge was carried on the 3rd postoperative day and thereafter when indicated.

Statistical analysis

Numerical variables were expressed as mean ± standard deviation (SD). For the baseline characteristics, comparisons of numerical data were performed using Man whitney test and comparisons of categorical data were performed using Fisher's exact test. Differences with $P < 0.05$ were considered statistically significant. All calculations were conducted using STATA 14.0(IBM, Chicago, USA).

Results

8 out of 10 patients were followed till their discharge from the ICU, one patient had long FI and another had unavailability of mother's milk after 2 days of surgery so both were withdrawn from the study. Statistical analysis was performed for 5 ICU stay days for these 8 infants. Enteral/oral albumin was tolerated by these infants, supplemented with the mother's

milk, we didn't notice any side effects except in one child who manifested minor facial rash, but resolved spontaneously within next 48 hours. Mother's milk remains the integral part of all the feeds and at the same time we could increase the calorie, protein content of the feed, and were able to supplement more calories with lesser volume of milk during the early postoperative period when fluid restriction is usually a standard practice.

The comparison of the various variables between the two groups is given in the following tables.

Table1 represents baseline characteristics in terms of their age and intraoperative parameters comprising ACC and CPB time, which were comparable in both the groups.

Table 1: Baseline and intra-operative characteristics

Variables	Control (Mean±SD)	Study (Mean±SD)	p value
Age (months)	4.62±1.79	3.75±1.70	0.55
ACC(min)	52.75± 24.11	75± 55.28	0.56
CPB(min)	96.5± 14.79	140.75 ± 64.47	0.38

*Values are expressed as Mean

Table 2 shows that study group consumed more calorie, protein, fat and carbohydrates as compared to the control group and protein consumption was statistically significant between the groups. The feeding was started as early as 6 hours after surgery in both the groups. This data shows that the actual calorie consumption was substantially below what was recommended for healthy children of same age group 90kcal/kg/day (RDA 2010). However, no hypoglycemic episode was recorded in either group on routine monitoring as per the institute protocol. Oral supplementation of albumin in study group was well tolerated by the cardiac surgical infants without any side effects.. There was insignificant increase in trend of fat and carbohydrate consumption in study group. Cultures obtained on 3rd POD did not yield any microorganism and none of these eight children manifest severe infection/sepsis.

Table 2: Macronutrient consumption

Energy (kcal/day)				Protein (gm/day)			Fat (gm/day)			Carbohydrate (gm/day)		
Days	Control	Study	p value	Control	Study	p value	Control	Study	p value	Control	Study	p value
1	67.83±64.16	91.15±31.10	0.24	0.91±0.86	2.53 ±0.86	0.04	3.74±3.54	4.11±1.40	0.56	6.78±6.41	10.22±3.47	0.24
2	87.93±48.88	125±30.69	0.14	1.17±0.65	3.48 ±0.85	0.02	4.85±2.70	5.64±1.38	0.24	8.79±4.89	14±3.45	0.14
3	87.1±50.36	127.6±44.50	0.14	1.16 ±0.67	3.55±1.23	0.04	4.80±2.78	5.75 ±2.00	0.56	8.70 ±5.03	14.27 ±4.96	0.08
4	77.05±61.10	145.83 ±36.08	0.15	1.03±.82	4.06±1.62	0.03	4.25 ±3.37	6.58±1.00	0.47	7.70 ±6.11	16.33±4.04	0.15
5	103.85±78.49	114.56 ±18.07	0.50	1.39 ±1.05	3.19±0.50	0.07	5.73±4.33	5.17 ±0.81	0.50	10.37±7.83	12.83±2.02	0.50

*Values are expressed as Mean±SD

*Values are expressed as Mean

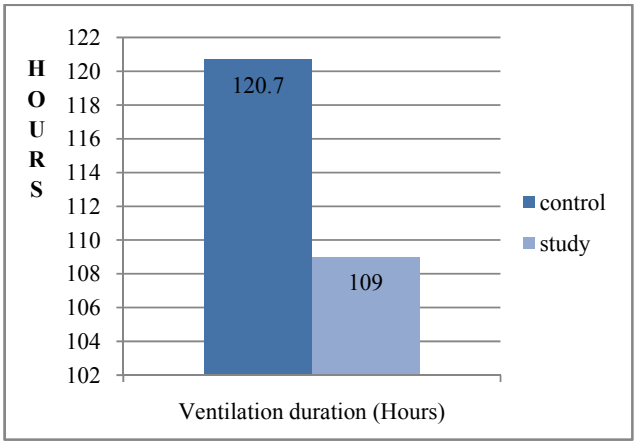
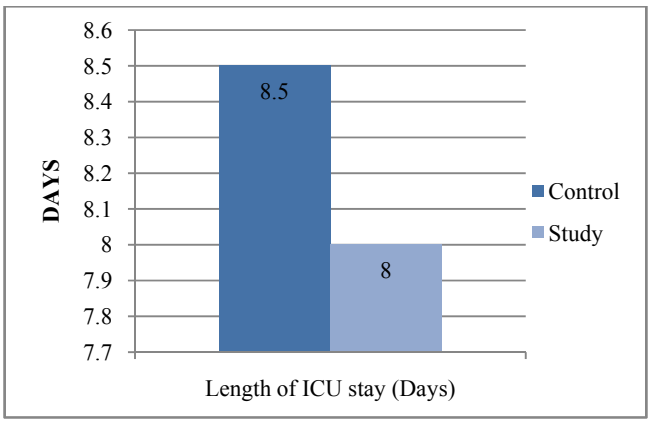


Figure 1 Ventilation duration (Hours)

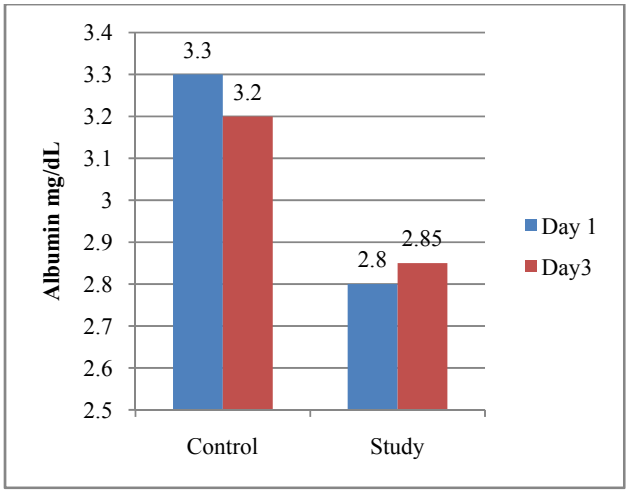
Figure 1 shows that patients in control group required ventilator support for longer hours as compared to the study group120.75±84.5 v/s 109±92.88 respectively. But it was not statistically significant.



*Values are expressed as Mean.

Figure 2: Depicts the length of ICU stay (Days)

Figure 2 shows that the control group spent more days in ICU as compared to the study group8.5±4.5 v/s 8±5.29 respectively.



*Values are expressed as Mean

Figure 3: Serum Albumin levels postoperatively

Figure 3 shows an increasing trend of serum albumin level in study group and a decreasing trend in control group during the 5 postoperative days in the ICU. The serum albumin trend were 2.8±0.38, 2.85±0.44 and 3.3±0.50, 3.2±0.45 in the groups C & S from POD 1st to 3rd respectively.

Discussion

Children with CHD are malnourished as per their weight for age z score in pre and postoperative period and it has always been a part of concern among them. In addition to the poor nutritional status, postoperative hypoalbuminemia is very common after cardiac surgery with CPB, leading to increases morbidity and mortality risks [16], [11]. Malnutrition cachexia and preoperative hypoalbuminemia increases the risk of nosocominal infection (NI) after CPB and they require longer postoperative ventilation support [17].

A prospective observational study has reported that serum albumin levels decrease in response to CPB [18] which may adversely affect the clinical outcomes postoperatively. We do supplement intravenous albumin to almost all infants post cardiac surgery to increase the plasma oncotic pressure, better hemodynamics and renal function. A prospective study has reported that lower serum albumin level (< 3.0 g/dL) after cardiac surgery was associated with longer hospital stay [8]. We found similar results (increased length of ICU stay), but were not statistically significant probably due to small pilot project. Like other parenteral injections I/V albumin carries chances of allergy, anaphylaxis, blood borne infections and also it is expensive [19], whereas oral/enteral albumin supplementation is devoid of all these complications. We supplement this albumin in exact calculated amounts as per kg body weight (avoiding excess albumin affecting its osmolality) in mother's milk. Advantage is twofold i.e. the children are not deprived of their mother's milk (the best valued nutrition with stronger immunity boost), early enteral feeding postsurgery preserves and maintains GI function. A combined balanced nutritional update is prepared to make the feed isocaloric with calculated amount per kg body weight protein, fat and CHO while avoiding side effects like diarrhea, feed intolerance and interruptions etc. Albumin supplementation was tolerable by the infants but we observed abdominal distension in 2 cases that were resolved within 24 hours and feeding was resumed after stabilization.

We started enteral nutrition around 6 hours after surgery to preserve the gut motility, to prevent translocation of gut microbiota and to avoid I/V supplementation related side effects. The enteral feeding composition was planned and implemented to minimize the feeding complications and to fulfill the caloric goal. Though we could not achieve the expected calorie goal (as per RDA recommendation 2010, India) but the overall nutrient consumption was higher in the study group as compared to the control group and the increased protein uptake was found to be statistically significant in the study group without causing any harm.

Enteral use of Albumin RRT in infants was a first and was not reported in the past. We from this pilot study found that oral albumin supplementation with mother's milk was possible, and tolerable by the infants.

We verified that the addition of albumin RRT in mothers milk for feeding the babies (infants) enterally soon after cardiac surgery is a first of its kind and we found that this is well accepted and tolerated by the infants provided given in right proportions with few very early good observations like shorter length of ICU stay and overall better convalescence postoperatively. We did not interfere with the treatment protocol of the ICU team for managing patients postoperatively for low cardiac output, FI, ventilation etc. As such early enteral feeding with mother's milk is a standard protocol for our ICU patients. The number of study population in this pilot project was very less; we could not study all the recruited (10) patients for full 15 postoperative days due to various reasons already discussed in the methods.

Limitations

We specifically did not compare between intravenous albumin and oral albumin supplementation, their difference. But we need to study this in larger number of patients to strengthen our early observations into evidence.

Conclusion

As a first, EBM was supplemented with oral albumin in cardiac surgical infants. This feed is tolerable, without any side effects. It augments protein and calorie with restricted volume, helps in convalescence of these infants postoperatively.

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