

A Randomized Controlled Clinical Trial of Olive Oil Added to Human Breast Milk for Weight Gaining in Very Low Birth Weight Infants

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Abstract

Objective: Evaluating the effect of vegetable oil, as a supplement to breast milk in increase the weight gaining of VLBW neonates.

Materials and methods: In this single blind; Randomized clinical trials , in NICU of Vali-asr Hospital, Tehran University of Medical Sciences, 2005–2006; A total of 48 VLBW neonates referred & admitted to NICU, who did not have any major GI (especially NEC), respiratory or cardiac diseases; participated randomly in two groups: intervention & control. Vegetable oil was added to the milk of 25 neonates (0.5 cc per 30cc of milk) and the other 25 neonates with similar conditions that were selected as a control group, did not get any type of supplementary nutrition. Daily feeding volume in both groups was 150–200 cc for each kilogram of body weight.

Results: Weight gaining in interventional groups was considerably more than control group. ($p < 0.04$). There were also significant statistical differences in hospitalization period between the two groups, 28.9 days in interventional and 20.33 days in control group, ($p < 0.03$). However, no significant side effects were observed.

Conclusions: There is no report regarding contraindication linking the use of vegetable oil intended for appropriate weight gaining or reducing hospitalization period to neonatal chronic diseases.

Keywords: Vegetable Oil, VLBW infant, Neonatal weight gain

Introduction

Approximately 1% of all newly born infants suffer from VLBW (<1500 g), nonetheless 50% of all deaths belong to this group (1).

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VLBW infants may experience immature function of GI and renal system, metabolic problems, difficulties in extra uterine adaptation along with severe diseases such as respiratory distress, patent ductus arteriosus (PDA) and hyperbilirubinemia (2).

Meanwhile, there are numerous cases indicating inadequate nutrition during first few days after birth might have disastrous outcome, therefore one of the most important issues is providing suitable

nourishment for neonates that actually may guarantee their future health and wellbeing (3).

On the other hand, long-term hospitalization of neonates may increase the risk of nosocomial infections and consequently their conditions change for worse. For that reason finding an immediate solution for getting these infants to reach discharge conditions will be helpful (1).

It goes without saying that breast milk is the gold standard for feeding neonates in any given condition, but since pre-term neonates have smaller amount of nutritional reserves needing more nourishment and calories per each kilograms of their body weight, and as breast milk cannot supply them with necessary sustenance, adding special nutritional supplements either in form of powder or liquid is highly recommended (4).

Since similar human milk fortifiers are expensive and not easily accessible in our country's market, and based on the worldwide medical experiences, we came to a decision to substitute vegetable oil as a milk fortifier in order to provide additionally needed calories intended for neonatal growth.

This study indicates that adding vegetable oil (olive oil) to preterm infants' diet is exceptionally effective in weight gaining as well as reducing hospitalization period, as a result of improvement of their immune system.

Materials and methods

In NICU of Vali-asr Hospital, Tehran University of Medical Sciences (2005–2006), we planned a single blind; randomized clinical trial; which was a medicine student thesis.

In this pilot study, qualified very low birth weight (< 1500 grams birth weight) neonates were selected randomly (according to block randomization) in two groups; 25 in interventional and 25 neonates in control group. Exclusion criteria were any major GI (especially NEC), respiratory or cardiac disease.

Neonates with less tolerance of liquid ingestion were excluded too. The participants (neonates) and their mothers; and researcher who assessed the outcomes were blind.

The 25 neonates in the control group were merely fed with breast milk, and with Pre Nan formula (Nestle-Switzerland Co.).

The 25 neonates of interventional group were fed with breast milk and Pre Nan formula too and an additional quantity of vegetable oil as supplementary; 0.5 cc/30 cc of milk from olive oil

(Tarem-Iran Co.)

A medicine trained student (owner of thesis) generated the allocation sequence and enrolled neonates and assigned them in these two groups.

We suggest that an additional vegetable oil (available easily in the markets) to breast milk formula increase neonatal weight gain, decrease hospitalization period, without any side effect.

Throughout this study, weight gaining, increase of height and head circumference, hospitalization period, GI and respiratory complications in both groups were compared up to the time of discharge.

GI complications were such as lavage over 1-2 cc/kg, green discharge during lavage, abdominal distention, hematochezia and vomiting.

The infants who were younger than 5 days old and required mechanical ventilation, apnea, and oxygen dependency over 28 days were considered as respiratory complications.

Ethical Remarks

This project was founded on the proposal of a medical student which has been approved by the research board of the Medical School of Tehran University of Medical Sciences

It should be mentioned that the amount of vegetable oil added as supplement was the exact amount recommended in neonatologies references which was used in situations that supplementary fortifying powder (similac. H. M. F) was unavailable.

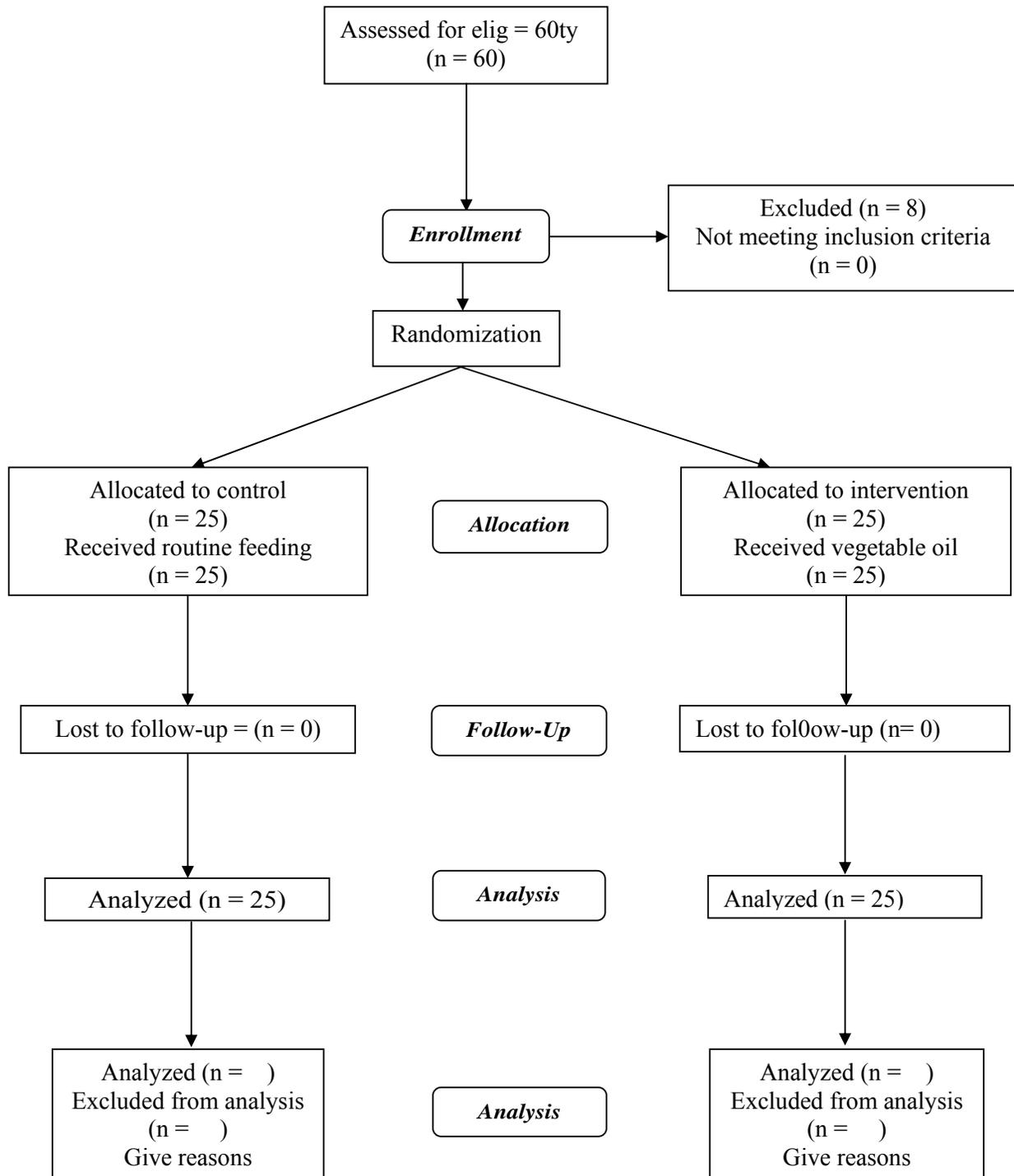
The vegetable oil that was applied for this purpose was cultivated for non-contamination; and after that the mixture of vegetable oil and milk was carefully shaken by one of the staff who has been trained for this project in advance, until the mixture turned into micro lipids.

(In view of the fact that this mixture should be thoroughly shaken and due to the danger of aspiration, this method is not recommended to be used at home, and must be only applied during hospitalization and up to the time of discharge.)

Furthermore parents of the patients were requested to sign the Inform Consent fully aware; so this study was not performed in opposition to medical principals and ethics.

Intervention method

The neonates were fed once the vital signs stabilized; neonates, whose weight were less than



1000 gram and 3 days old, were initially fed 1 cc for each kg every 8 hours and the next day 1 cc for each kilogram every 6 hours and on the third day the amount reached to 1 cc/kg for every 4 hours.

Neonates, whose weights were over 1000g, and 3 days old, were fed 1 to 2cc/kg every 2-3 hours at the beginning. These amounts were increased during several days and finally reached the ideal volume of 200cc/kg of breast milk, and daily amount of 150cc/kg of Pre Nan Formula (Nestle-Switzerland Co.) was used too, (In Iran fortifying powder for adding to mother breast milk is unavailable, therefore for increasing daily calories fed by neonate we have to use formula milk too. So that by increasing the milk the necessary protein was provided) .14 days after birth, vegetable oil was added to milk in micro lipid form (Tarem Iran Co.), and in every other meal 0.5 cc of corn powder and olive oil was added to 30cc of milk. At the end, the control group received 120 to 134 kcal/kg daily and the interventional group received 147.5 to 161.5 kcal/kg taking into account the calories of vegetable oil that was added as supplementary, (which means we increased the daily calorie intake to 27 kcal.)

The collected data, by a medicine trained student (owner of thesis) ,was extracted from information gathered in data base, statistical software SPSS _{v.15} was used in this regard, and based on the goals of the

project; descriptive and analytical statistical tests such as T-Test and Paired T-Test were also applied. We didn't have any loss to follow up and there were not interim analyses.

Results

Out of 48 neonates, 25 were in control group, and 25 were in interventional group.

In interventional group gestational mean age was 30.89 ±3.30 week in interventional group, and 31.30±3.27 in control group. In interventional group height mean was 38.14±3.67 at birth, and increased to 40.22±3.58 at time of discharge.

In interventional group weight mean was 1184±245.08 at birth that increased to 1425.77±203.29gr at discharge time. In control group weight mean was 1293.11±217.88 at birth that increase to 1410±203.79gr at discharge time.

In interventional group head circumference mean was 27.45±1.54 cm at birth and increased to 29.43cm at discharge time.

In control group HC was 27.67±1.77 cm at birth that increased to 28.95±1.98 cm at discharge time.

There was 280.49±27.203gr weight gaining in interventional and 117.63±40.126 in control group.

Hospitalization mean period in interventional group was 20.33 days and 28.29 days in control group (Table 1).

Table 1: Anthropometric values,GA and Hospitalization in two groups

	Mean	Standard Deviation	*P value
gestational age			
Interventional Group	30.89	3.306	NS
control group	31.30	3.279	
Height at birth			
Interventional Group	38.14	3.582	NS
control group	39.72	3.520	
Height at discharge			
Interventional Group	40.22	3.582	NS
control group	41.66	3.091	
weight at birth			
Interventional Group	1184.76	245.084	NS
control group	1293.11	243.424	
weight at discharge			
Interventional Group	1425.25	217.881	NS
control group	1410.74	203.298	
HC at birth			
Interventional Group	27.45	1.548	NS
control group	27.67	1.770	
HC at discharge			
Interventional Group	29.43	1.055	NS
control group	28.95	1.982	
Hospitalization			
Interventional Group	28.29	12.287	0.003
control group	20.33	8.766	
weight gaining			
Interventional Group	280.49	27.203	0.004
control group	117.63	40.126	

* T student test, $\alpha < 0.05$

Table 2: Frequency of Gastrointestinal Complications in two groups

group	Gastrointestinal complications				
	None N(%)	Lavage > 1-2cc/kg N(%)	Abdominal Distention N(%)	Vomiting N(%)	Total N(%)
Interventional	20 (76.2)	3 (14.3)	1 (4.8)	1 (4.8)	25 (100)
Control	16 (66.7)	7 (25.9)	0 (0)	2 (7.4)	25 (100)
TOTAL	36 (70.8)	10 (20.8)	1 (2.1)	3 (6.3)	50 (100)

Table 3: Frequency of Respiratory Complications in two groups

group	Respiratory Complications					Total
	Without complications	Needing respirator 5 days	Apnea	Oxygen dependency after 28 days of Birth	Needing respirator after 5 days	
IG	19 (71.4)	3 (14.3)	2 (9.5)	1 (4.8)	0 (0)	25 (100)
CG	15 (61.5)	7 (26.9)	2 (7.7)	0 (0)	1 (3.8)	25 (100)
Total	34 (66)	10 (21.3)	4 (8.5)	1 (2.1)	1 (2.1)	47 (100)

Table 2 and 3 shows gastrointestinal and respiratory complications that occurred.

Discussion

Milk fat provides 50-60% of necessary energy for neonatal. Also 50-55% of breast milk's fat is unsaturated. 35% of cow milk fat is unsaturated. Vegetable oil contains 70-79% unsaturated fat and great amounts of linoleum acid (3).

Adding vegetable oil to cow milk not only increased its calories but also made it more digestible.

Vegetable oil (not coconut oil which is used in India) has been consumed as a supplementary product in many countries all over the world with favorable results on the issue of neonatal weight gaining as well as acceleration of gaining weight progression (3).

The suitable fat that can be added as supplementary to neonatal nutrition is a combination of MCT and LCT. Although LCT contains a huge amount of essential fatty acid that can be found in nearly all vegetable oils for instance olive oil (3).

However MCT cannot provide essential fatty acids which are mostly found in coconut oil. On the other

hand, essential fatty acids (unsaturated) have positive effects on infants' neuro-development growth (5-8).

This study indicates that adding vegetable oil (olive oil) to preterm infants' diet is exceptionally effective in weight gaining as well as reducing hospitalization period, as a result of improvement of their immune system.

Vaidya and his colleagues have also reached to the same conclusions in 1992 (5).

In the end, it can be concluded that wherever supplementary products are not easily accessible, in order to increase calorie intake in preterm neonates, or in cases that neonates suffer from chronic cardio-respiratory diseases with limitation on liquid and carbohydrates ingestion owing to decrease of generating of carbon dioxide in body metabolism, vegetable oil can be used.

It should be mentioned that so far there has been no success in producing MCT and LCT in Iran.

Acknowledgement

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Authors declare no conflicts.

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