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Effect of Virgin Coconut Oil Application on the Skin of Preterm Newborns: A Randomized Controlled Trial

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ABSTRACT

Background: Preterm constitutes a major part of neonatal mortality, particularly in India. Due to dermal immaturity, preterm neonates are susceptible to various complications like infection, hypothermia, etc. Emollient application is a traditional practice in our subcontinent.
Aims: To find out the efficacy of coconut oil application for skin maturity, prevention of sepsis, hypothermia and apnea, its effect on long-term neurodevelopment and adverse effect of it, if any.
Material and methods: A randomized controlled trial was conducted in the rural field practice area of Department of Community Medicine, Burdwan Medical College from March 2014 to August 2018. Preterm born in the study period was divided into Group A (received virgin coconut oil application) and Group B (received body massage without any application). Neonatal skin condition was assessed on 7th, 14th, 21st and 28th day of life. Neurodevelopmental status was assessed on 3rd, 6th and 12th months.
Results: A total of 2294 preterm were included in the study. Groups A and B consisted of 1146 and 1148 preterm infants, consecutively. Mean gestational age of the study population was 31.9 ± 3.4 weeks and 50.4% were male. Mean weight loss in first few days was less in group A but mean weight gain per day was higher in group B. Lesser incidences of hypothermia and apnea, and better skin maturity and neurodevelopmental outcome were noted in group A. No significant adverse effect was noted with coconut oil application.
Conclusion: Use of coconut oil helps in dermal maturity and better neurodevelopmental outcome. Further studies are warranted for universal recommendation.

KEYWORDS: preterm, coconut oil, skin maturity, neurodevelopmental outcome

INTRODUCTION

Newborn mortality is an important indicator of socioeconomic status and an important contributor to infant mortality and under-5 mortality [1]. The incidence of preterm birth in Africa and south-east Asian Region (SEAR) is nearly 15 million per year and a large proportion of preterm babies died due to complications of prematurity [2]. The mortality rate of preterm babies has crossed 50% in some developing countries [3, 4]. Difference in the genetics of women of SEAR countries and interplay of different cytokines leads to a large number of preterm births in

this region [5]. Neonatal sepsis is the major cause of fatalities in preterm. Skin of preterm newborns is immature partially due to the absence of vernix and partial development of stratum corneum without proper architecture [6, 7]. High environmental load of pathogenic organisms and malnutrition are two important contributors of mortality of preterm in developing countries. Oil massage is a traditional practice in Indian subcontinent for centuries. It acts by augmentation of the skin barrier, supplementation of essential fatty acids, reduced water loss and hypothermia and thereby reduces infections and newborn mortality [8, 9]. It is also helpful in promoting growth. Different studies found contradictory evidence of topical application of emollients in preventing infections. Different authors also used different types of emollient in different parts of the world including sunflower oil, mustard oil, vegetable oil, etc. [2, 10, 11]. They are also helpful in promoting weight gain. This variation may be due to use of emollients of different nature. Due to this discrepancy in different studies, there is still no evidence-based recommendation of emollient application in newborn infants. Some frequently used preparation especially mustard oil and olive oil are found to be deleterious to newborn skin [12, 13]. There is scarcity of studies regarding emollient application in Indian settings. However, this can be useful in reducing neonatal mortality, especially in developing countries like India. Cost of coconut oil application is also low. Apart from this, coconut oil also has documented microbicidal effect [14].

Hence, this study was undertaken to find out the efficacy of coconut oil application on skin maturity, prevention of sepsis, apnea and hypothermia, long-term adverse neurodevelopmental outcome, and adverse effects associated with coconut oil application, if any.

MATERIALS AND METHODS

A randomized controlled trial was conducted in the rural field practice area of Department of Community Medicine, Burdwan Medical College in between March 2014 and August 2018 after taking necessary ethical permission from Institutional Ethics Committee (BMC/PG/2726 dated 20 January 2014). It consisted of 24 villages in the Memari II block of Purba Bardhaman District, West Bengal. All the newborns born in the mentioned time period and gestational age <37 weeks (estimated by modified Ballard Scoring) were included in the study after taking informed consent from the mother/parent. Newborns with major congenital anomaly, congenital malformations of skin, with signs of existing skin infection/rash, critically ill and whose parents denied consent were excluded from the study. Preterm newborns born during the study period were divided into two groups (A and B) using computer-generated randomization with sealed opaque envelope. Newborns included in Group A received virgin coconut oil, 5 ml four times daily. Coconut oil was applied all over body excluding face and scalp after proper hand-washing by gentle massaging by on-duty staff nurse (during period of hospitalization) and by mother/relatives (after discharge). Newborns who belonged to group B receives gentle massaging by the on-duty nurse (during hospitalization) or by the primary care-givers (after discharge) without any application over skin. All of them (staff nurses, mothers and care-givers) were trained regarding the proper method of application of oil and/or method of gentle body massage. This study cannot be blinded due to the specific fragrance of coconut oil. Though we followed complete enumeration method in our study, the sample size was adequate to assure 80% power and 95% confidence to the study. Data were collected by especially trained personnel, using a pretested, predesigned schedule. Skin condition was assessed by using Neonatal Skin Condition Score (NSCS) [7] on 7th, 14th, 21st and 28th day which is widely used in different parts of the world. Condition of skin was scored based on three parameters-dryness, erythema and breakdown. Three scores are collected to get the NSCS. For estimation of weight portable weighing machine with an accuracy of 5 g was used [HITES, Class III]. Serum vitamin D3 level was estimated at 30th day of life by an automatic immunoassay analyzer (bench-top/chemiluminescence/human Maglumi 600). Neurodevelopmental outcome was measured by trained personnel using DASII scale at 3rd, 6th and 12th month. Late-onset neonatal sepsis was defined as clinical signs of sepsis (onset after 72 h of life) and positive sepsis screen with or without positive blood culture.

Collected data were entered into MS excel worksheet after double-checking (Microsoft, Redwoods, USA). Kolmogorov–Smirnov test revealed that all

the continuous data were normally distributed. Categorical data were expressed in proportion, whereas mean and standard deviation were used for normally distributed data. Chi-square test was used to check the association between variables in contingency tables. Student's *t*-test was used for checking the significance of difference between two means. Pearson's product moment correlation coefficient was used for calculating the degree and direction of relationship between two variables. Finally, a binary logistic regression model was used for calculating the adjusted odds ratio taking use of coconut oil as an independent variable. The value $p < 0.01$ was taken as statistically significant. Data were analyzed using SPSS software version 19.0 (Statistical Packages for the Social Sciences Inc., Chicago, USA).

RESULTS

A total of 2294 preterm newborns were included in our study. Group A constituted 1146, and Group B consisted of 1148 preterm neonates (Fig. 1) having a mean gestational age of 31.9 ± 3.4 weeks and 50.4% (1156) of them were male. Majority of the mothers belonged to lower socioeconomic status (60.6%, $n = 1390$). About 75.5% (1732) of the newborns included in this study were born by normal vaginal delivery. And 4.4% (101) of the newborns were born out of twin/multiple pregnancy. There was no significant difference noted among group A and group B in terms of gestational age, sex, socioeconomic status, type of pregnancy, mode of delivery and presence of risk factors for sepsis ($p > 0.01$) (Table 1).

Mean weight loss in the first few days of life was significantly less in group A (4.71% ± 0.39% vs. 7.82% ± 0.55%, $p < 0.01$) whereas mean weight gain was significantly more in group A (1.21% ± 0.17% vs. 0.89% ± 0.12%, $p < 0.01$). Incidence of hypothermia (1.9% vs. 5.8%, $p < 0.01$) and apnea (1.2% vs. 5.1%, $p < 0.01$) were significantly lesser in group A than group B. Mean serum vitamin D3 level on day 30 was more among newborns of group A than group B. (32.3 ± 1.2 vs. 24.6 ± 0.8 ng/ml, $p < 0.01$). There was no significant difference in mean NSCS between two groups

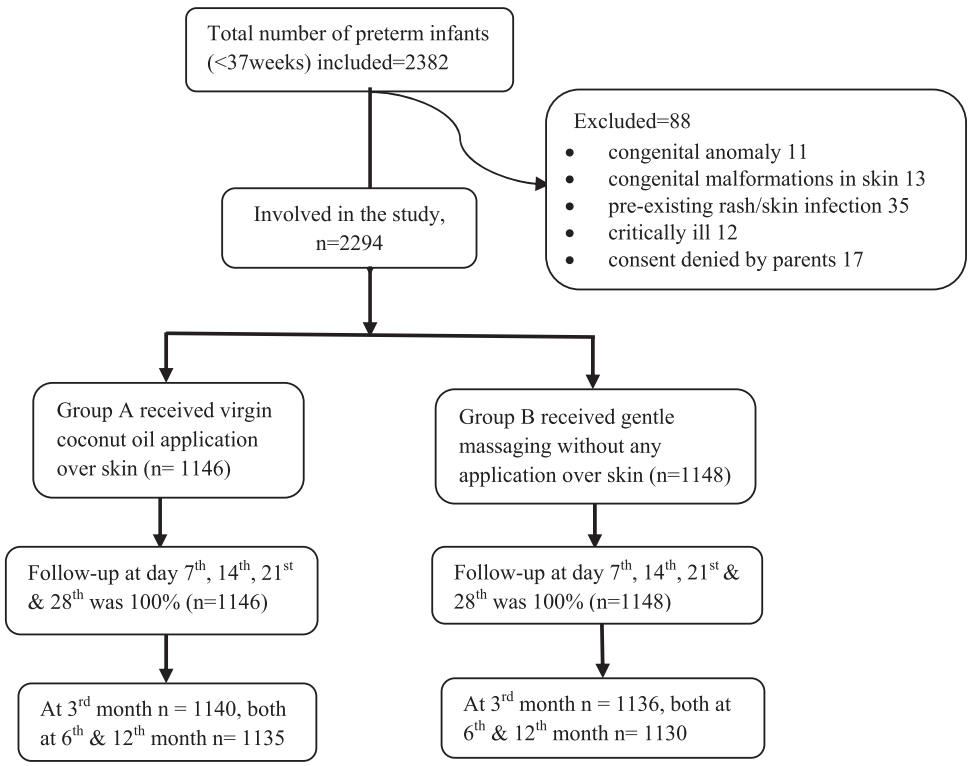

Fig. 1. Flow-diagram representing the progression of the study.

Table 1. Baseline characteristics of group A ($n = 1146$) and group B ($n = 1148$)

Variables	Group A ($n = 1146$), n (%)	Group B ($n = 1148$), n (%)	Significance
Gestational age			
34–37 weeks	794 (69.3)	801 (69.8)	$\chi^2 = 0.06$
<34 weeks	352 (30.7)	347 (30.2)	$p = 0.79$
Sex			
Male	584 (51.0)	572 (49.8)	$\chi^2 = 0.30$
Female	562 (49.0)	576 (50.2)	$p = 0.58$
Socioeconomic status			
Upper	74 (6.5)	72 (6.3)	
Middle	379 (33.1)	378 (32.9)	$\chi^2 = 0.04$
Lower	693 (60.4)	698 (60.8)	$p = 0.97$
Type of pregnancy			
Single	1094 (95.5)	1099 (95.7)	$\chi^2 = 0.10$
Multiple	52 (4.5)	49 (4.3)	$p = 0.75$
Mode of delivery			
NVD	856 (74.7)	875 (76.2)	
AVD	7 (0.6)	9 (0.8)	$\chi^2 = 1.11$
CS	283 (24.7)	264 (23.0)	$p = 0.57$
Risk factors of sepsis			
Absent	1075 (93.8)	1076 (93.7)	$\chi^2 = 0.01$
Present	71 (6.2)	72 (6.3)	$p = 0.93$

NVD, normal vaginal delivery; AVD, assisted vaginal delivery; CS, cesarean section.

at the time of entering study (4.9 ± 1.1 vs. 5.0 ± 1.0, $p > 0.01$). But later, it was observed that the score was significantly better in group A than group B on multiple occasions on day 7, 14, 21 and 28 ($p < 0.01$). It was also noticed that skin of newborns of group A matured early. Both motor and mental developmental quotients were significantly higher among newborns of group A than Group B at 3rd, 6th and 12th months (Table 2).

Babies of group A lost less weight in early part of life, gained more weight and had a higher mean level of vitamin D3 (on day 30) than group B. There was also lesser incidences of hypothermia and apnea in group A than group B. Newborns of group A were 0.31 (95% CI: 0.24–0.39) and 0.59 (95% CI: 0.45–0.74) times less likely to suffer from decreased skin maturity and adverse neurodevelopmental outcome, respectively. They were also 0.45 (95% CI: 0.39–0.53) and 0.62 (95% CI: 0.58–0.67) times less likely to develop hypothermia and apnea, respectively. All these observations were found to be significant statistically ($p < 0.01$).

There was no significant difference between group A and group B in the incidence of late-onset sepsis (2.7% vs. 3.2%, $p > 0.01$), rash (1.8% vs. 2.0%, $p > 0.01$), and accidental slippage of the baby (0.3% vs. 0.1%, $p > 0.01$). Significantly more proportion of mothers complained that the method of applying coconut oil was cumbersome (2.0% vs. 0.3%, $p < 0.01$) (Table 3).

DISCUSSION

The putative benefits of oil application as well as the massage induced tactile kinesthetic stimulation to the newborn skin in the form of improved skin barrier function, thermoregulation and also possible positive effect on growth have been documented in various previous literature [12, 15–18]. One recent systemic review concluded that emollient application is a potentially promising intervention in low resource settings as it facilitates better weight gain, and decreases risk of infection and associated newborn mortality in preterm neonates [19]. They have

Table 2. Distribution of different study variables in group A ($n = 1146$) and group B ($n = 1148$).

Variables	Group A ($n = 1146$)	Group B ($n = 1148$)	Significance
Weight loss[a] (% of body weight)	4.71 ± 0.39	7.82 ± 0.55	$t = 156.2$, $p<0.01$
Weight gain/day[a] (% of body weight)	1.21 ± 0.17	0.89 ± 0.12	$t = 52.1$, $p<0.01$
Hypothermia[b]	22 (1.9%)	67 (5.8%)	$\chi^2 = 23.6$, $p<0.01$
Apnea[b]	14 (1.2%)	58 (5.1%)	$\chi^2 = 27.7$, $p<0.01$
Serum Vitamin D3[a] (ng/ml)	32.3 ± 1.2	24.6 ± 0.8	$t = 180.8$, $p<0.01$
NSCS			
At the time of entering study	4.9 ± 1.1	5.0 ± 1.0	$t = 2.27$,
Day 7[a]	4.3 ± 0.9	5.1 ± 1.1	$t = 19.1$, $p<0.01$
Day 14[a]	4.4 ± 0.9	5.4 ± 1.2	$t = 22.6$, $p<0.01$
Day 21[a]	4.2 ± 0.8	5.5 ± 1.2	$t = 30.5$, $p<0.01$
Day 28[a]	3.9 ± 0.7	4.8 ± 1.0	$t = 24.9$, $p<0.01$
Neurodevelopmental score (motor)			
3rd month[a]	0.86 ± 0.08	0.72 ± 0.07	$t = 44.6$, $p<0.01$
6th month[a]	0.90 ± 0.07	0.84 ± 0.08	$t = 19.1$, $p<0.01$
12th month[a]	0.96 ± 0.08	0.92 ± 0.07	$t = 12.7$, $p<0.01$
Neurodevelopmental outcome (mental)			
3rd month[a]	0.85 ± 0.07	0.73 ± 0.06	$t = 44.1$, $p<0.01$
6th month[a]	0.89 ± 0.07	0.83 ± 0.08	$t = 19.1$, $p<0.01$
12th month[a]	0.97 ± 0.09	0.93 ± 0.06	$t = 12.5$, $p<0.01$

[a]Mean ± SD.
[b]Number (proportion), NSCS, Neonatal skin condition score.

Table 3. Distribution of different complications in group A ($n = 1146$) and group B ($n = 1148$).

Variables	Group A ($n = 1146$), *n* (%)	Group B ($n = 1148$), *n* (%)	Significance
Late-onset sepsis	31 (2.7)	37 (3.2)	$\chi^2 = 0.51$, $p = 0.47$
Rash	21 (1.8)	23 (2.0)	$\chi^2 = 0.09$, $p = 0.76$
Accidental slippage	3 (0.3)	1 (0.1)	$\chi^2 = 1.00$, $p = 0.31$
Cumbersome method	23 (2.0)	4 (0.3)	$\chi^2 = 13.5$, $p < 0.01$

also mentioned the further requirement of large-scale effectiveness trials for better assessment. Neither of the previous studies had involved larger participant, nor had they thoroughly assessed the effects of coconut oil application on skin maturity of preterm newborn as well as other morbidity profile like ours.

In our study, we found that use of coconut oil in newborn skin helped in skin maturity and prevented hypothermia and apnea in newborn. It was also associated with a higher level of serum vitamin D3 and a better neurodevelopmental outcome. Supplementation of essential fatty acid by the emollient (helps in skin maturity), prevention of insensible water loss (less latent heat and hence, less hypothermia) and stimulation during application (better neurodevelopment and prevention of apnea) may be responsible for these findings [8, 9]. Strunk, *et al.* [20] also similarly noted that application of coconut oil was helpful in improving skin maturity and a better barrier function leading to a decrease in the incidence of neonatal sepsis of late-onset type. We also noticed a decrease in the incidence of late-onset sepsis after application of coconut oil but failed to achieve statistical significance. In another trial

by Edward, *et al.* [21] found that there was an improvement of neonatal skin maturity after application of coconut oil but there was also a simultaneous increase in sepsis. However, this study was conducted in an intensive care unit and the increase in the incidence of sepsis may not be solely due to the emollient application. They also did not use coconut oil but used another emollient named Aquaphor. Different studies from developing countries revealed that there was an alteration of pathological flora of skin after application of coconut oil and it was responsible for the decrease in the incidence of late-onset sepsis [2, 22]. This finding may be attributed to the microbicidal properties of coconut oil [14, 23]. Similar to that of various previous studies, our study also revealed that the weight gain was better after emollient application [16–18]. But Strunk, *et al.* [20] did not observe any such difference between the study and control group.

Though we used the complete enumeration method for recruitment of study subjects, we achieved a sample size enough to give adequate power to the study. The main constraint was that the trial could not be blinded due to the specific fragrance of coconut oil. Severely ill infants were excluded from the study. Hence, the finding of this study should not be generalized. Before generalization of the findings, further research (preferably multicentric) should be undertaken.

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