Effects of Argan Spinosa Oil in the Treatment of Diaper Dermatitis in Infants and Toddlers: A Quasi-Experimental Trial

Study Date:

1- February- 2018 Till 1-June-2019

Results

4.1 Introduction

This study aimed to compare the effect of the traditional medicinal product of Argan Spinosa Oil on the speed up of the healing process and alleviation of the symptoms with that of topical hydrocortisone ointment on cases of DD among Jordanian infants and toddlers younger than two years old. This chapter provides study findings including mother-child sociodemographic, the rate of improvement between treatment groups during the trial and potential associated risk factors with diaper dermatitis.

4.2 Study Sample Characteristics at Baseline

As reported previously, the main eligibility criteria for children in this study was that children having symptoms of DD in both genders, aged younger than two years. They were hospitalized at the time of data collection in pediatric floors at the selected hospitals, outpatient children who were attended to their pediatric clinics and children who attended affiliated health care centers of JMOH.

Therefore, the number of children who met the eligibility criteria and agreed to participate in the study was 140 (87.5%) out of 160 children. Children were divided equally and randomly into two groups (70 children received hydrocortisone ointment and 70 received the Argan Spinosa Oil).

The overall loss in home follow-up visits was 20 (12.5%); 9 children from the Argan Oil group and 11 children from the hydrocortisone group. There are many reasons for non-participation of these caregivers of children such as poor compliance to the treatment protocol, they did not answer their phone to complete the scheduled visits and loss the

follow-up procedure, and their unwillingness to participate in the study after the initial assessment.

4.2.1 Socio-Demographic Characteristics of Mothers

Median used in description of the continuous variables which is much more representative for skewed distributions to derive at central tendency of the sample set. Proportions and percentage used in description of categorical variables.

A total of 140 mothers with a median age at the time of the study was 28 years (IQR, 23-33 years) were involved. Among all mothers, 133 (95%) were Jordanians. Majority of mothers 98 (70%) were resident in urban areas. Almost two thirds of mothers 102 (72.9%) had nuclear family. Most of the mothers 90 (64.3%) had educational qualification of high school or higher. About one-fifth of mothers 28 (20%) were primipara mothers. Most of the mothers 117 (83.6%) had previous experience of caring of children with diaper dermatitis.

One-fifth of mothers 31 (22.1%) were employed and earn money. In regard to the mothers' spouse/partners occupation, the mothers were requested to indicate the total household monthly income and the percentage was 62 (44.3%), 47 (33.6%) and 22.1 (22.1%) had ≤ 300, 301-500, and ≥ 501 Jordan Dinars respectively.

However, 62 (44.3%) of mothers have received information regarding prevention & management of DD mainly from the family member, 54 (38.6%) from health professionals, 11 (7.9%) from media, and 13 (9.3%) from their experience.

Moreover, mothers' demographic baseline characteristics were similar in both study groups at the baseline day of the study as reflected in (Table 1). The study findings retain the null hypothesis (no difference) for the assumption of homogeneity of variance and conclude that there is not a significant difference between the three group's variances with the exception of employment status, which was higher in the Argan Oil group ($p < .025$),

and previous experience of mothers with DD which was higher in the hydrocortisone group ($p < .040$).

4.2.2 Socio-Demographic Characteristics of Children

As mentioned earlier in Table 1, one hundred forty infants and toddlers were participated in the study with approximately 31 (44.3%) males in Argan Oil group and 39 (55.7%) males in hydrocortisone group. They were aged 14 months of median age (IQR, 6-18 months). Median weight of them was 10 kilograms (IQR, 7.3-12 kilograms). Fifty-eight (41.4%) were breastfeed at time of data collection.

In specific, DD was reported among 138 (98.6%) children using disposable diapers exclusively. Median Days of recent DD episode were 3 days (IQR, 2-4 days).

However, a median of stool frequency was reported 2 times per day (IQR, 1-3 times). The water-soaked wipe was used to clean the diaper area was in 51 (36.4 %) of children, whereas 49 (35%) used Alcohol wipes and 40 (28.6%) had never used any type of wipes. Also, half of the mothers (55%) used soap to clean the diaper area. In addition, most of the mothers 113 (80.7%) reported changing diapers < 6 times per day. Also, 88 (62.9%) of mothers did bath ≤ 1 times per week.

Furthermore, about 63 (45%) children who were exposed for air every day developed DD. Aeration was done by leaving the child without diaper at home for at least 10 minutes.

A total of 46 (32.9%) parents applied cream barriers to prevent diaper dermatitis occurrence 29 (41.4%) of mothers in the Argan Oil group and 17 (24.3%) in the hydrocortisone group). Moreover, no infants and toddlers has diarrhea or receiving antibiotics at the time of the data collection.

Infants' demographic baseline characteristics were similar in both study groups at the baseline day of the study (Table 1). The study findings retain the null hypothesis (no difference) for the assumption of homogeneity of variance and conclude that there is not a

significant difference between the three group's variances. with the exception of using barrier cream, which was more frequently used in the Argan oil group ($p < .031$).

Table 1: Demographic characteristics of the study child mother pairs participants by study groups at baseline day

Characteristics	Total (N=140) %	Intervention (n=70) %	Control (n=70) %	p-Value*
Sociodemographic Mother Child Pairs				
Mother				
**Mother Age, years, median (IQR)	28 (23,33)	28.5 (23.8,33)	27 (23,32)	.137
Nationality, Jordanian, (n) %	(133) 95%	(67) 95.7%	(66) 94.3%	1.0
Residence, Urban, (n) %	(98) 70%	(54) 77%	(44) 62.9%	.065
Type of family, Nuclear family, (n) %	(102) 72.9%	(54) 77.1%	(48) 68.6%	.254
Educational Status, High school or higher, (n) %	(90) 64.3%	(49) 70%	(41) 58.6%	.158
Employment, yes, (n) %	(31) 22.1%	(21) 30%	(10) 14.3%	.025
Income, Jordanian Dinar, (n) %				
≤ 300	(62) 44.3%	(26) 37.1%	(36) 51.4%	.229
301-500	(47) 33.6%	(26) 37.1%	(21) 30%	
≥ 501	(31) 22.1%	(18) 25.7%	(13) 18.6%	
Parity, primi-parous, (n) %	(28) 20%	(18) 25.7%	(10) 14.3%	.091
Child				
Child Sex, male, (n) %	(70) 50%	(31) 44.3%	(39) 55.7%	0.176
**Child age, months,median (IQR)	14 (6,18)	14 (5,18)	14 (7.8,19)	.242
**Child weight, kilograms, median (IQR)	10 (7.3,12)	10 (7.2,12)	10 (7.4,12)	.967
Associated factors of incidence DD				
Breastfeeding, yes, (n) %	(58) 41.4%	(28) 40%	(30) 42.9%	.731
Type of Diaper, Disposable diapers, (n) %	(138) 98.6%	(69) 98.6%	(69) 98.6%	1.0

Characteristics	Total (N=140) %	Intervention (n=70) %	Control (n=70) %	p-Value*
Type of wipes, (n) %				
Wet wipes	(51) 36.4%	(31) 44.3%	(20) 28.6%	.152
Alcohol wipes	(49) 35%	(21) 30%	(28) 40%	
Never used	(40) 28.6%	(18) 25.7%	(22) 31.4%	
Previous experience, yes, (n) %	(117) 83.6%	(54) 77.1%	(63) 90%	.040
Frequency of diaper changing, (n) %				
< 6 times per day	(113) 80.7%	(56) 80%	(57) 81.4%	.83
≥6 times per day	(27) 19.4%	(14) 20.3%	(13) 18.6%	
Barrier cream, yes, (n) %	(46) 32.9%	(29) 41.4%	(17) 24.3%	.031
Soap, multiple times per day, (n) %	(77) 55%	(39) 55.7%	(38) 54.3%	.865
Exposure to air, yes, (n) %	(63) 45%	(36) 51.4%	(27) 38.6%	.126
**Stool frequency, times per day, median (IQR)	2 (1,3)	2 (1,3)	2 (1,3)	.844
Bathing, (n) %				
≤ 1 times per week	(88) 62.9%	(40) 57.1%	(48) 68.6%	.162
> 1 times per week	(52) 37.1%	(30) 42.9%	(22) 31.4%	
**Days of DD episode, days, median (IQR)	3 (2,4)	3 (2,4.3)	3 (2,4)	.95
Source of information, (n) %				
Family member	(62) 44.3%	(34) 48.6%	(28) 40%	.466
Health professional	38.6 (54)	32.9 (23)	(31) 44.3%	
Media	(11) 7.9%	(5) 7.1%	(6) 8.6%	
Others	(13) 9.3%	(8) 11.4%	(5) 7.1%	

* Comparisons have been made using Fisher's exact test or Person Chi-square test for categorical variables.

** Comparisons have been made using Mann–Whitney U test for continuous variables.

4.3 Rate of Improvement in Both Groups

1- What is the effect of the traditional medicinal product of Argan Spinosa Oil among infants and children with diaper dermatitis on speed up the healing process and alleviation the symptoms of DD, compared to conventional topical steroid ointment?

Table 2 shows number, score of DD and improvement rates in both study groups according to Davis et al., a five-point scale measuring rash severity. Treatment effects (total scores) were improved markedly in total scores during first, third and seventh day of trial for both study groups. Medication was applied four times per day for both study groups. Caregivers were instructed not to apply any on the affected area such as wet wipes, essence contained soaps, barrier cream or other medications during days of the trail.

The assessment of DD scores for each study group at the baseline day were similar in DD scores as in the used scale, In the Argan Oil group, 32.9% of children had dermatitis with mild irritation compared to 30% in the hydrocortisone group; 31.4% of children had dermatitis with moderate irritation compared to 22.9% in the hydrocortisone group; 12.9% of children had dermatitis with moderate to severe irritation compared to 15.7% in the hydrocortisone group and 22.9% of children had dermatitis with extreme irritation compared to 31.4% in the hydrocortisone group.

The assessment of DD scores for each study group at the first day of treatment have shown less DD scores in the Argan Oil group than hydrocortisone group in DD scores as in the used scale. In particular, in the Argan Oil group, 8.6% of children had non irritation compared to 2.9% in the hydrocortisone group; 52.9% of children had dermatitis with mild irritation compared to 45.7% in the hydrocortisone group; 24.3% of children had dermatitis with moderate irritation compared to 20% in the hydrocortisone group; 11.4% of children had dermatitis with moderate to severe irritation compared to 24.3% in the hydrocortisone group and 2.9% of children had dermatitis with extreme irritation compared to 7.1% in the hydrocortisone group.

The assessment of DD scores for each study group at the third day of treatment have shown less DD scores in the Argan Oil group than the hydrocortisone group in DD scores as in the used scale. In the Argan Oil group, 67.1% of children had non irritation compared to 45.7% in the hydrocortisone group; 21.4% of children had dermatitis with mild irritation compared to 40% in the hydrocortisone group; 7.1% of children had dermatitis with moderate irritation compared to 12.9% in the hydrocortisone group; 1.4% of children had dermatitis with moderate to severe irritation compared to 1.4% in the hydrocortisone group and 2.9% of children had dermatitis with extreme irritation compared to 0% in the hydrocortisone group.

The assessment of DD scores for each study group at the seventh day of treatment was approximately similar in DD scores as in the used scale. In the Argan Oil group, 95.7% had non irritation compared to 98.6% in the hydrocortisone group; 1.4% had dermatitis with mild irritation compared to 1.4% in the hydrocortisone group; 0% had dermatitis with moderate irritation compared to 0% in the hydrocortisone group; 0% had dermatitis with moderate to severe irritation compared to 0% in the hydrocortisone group and 2.9% had dermatitis with extreme irritation compared to 0% in the hydrocortisone group.

Table 2: Rate of Improvement Between Groups on the Baseline, First, Third, and Seventh Day of treatment

Rate of healing	Baseline Day		First Day		Third day		Seventh day	
	Argan Oil (n = 70)	Cortisone* (n = 70)	Argan Oil (n = 70)	Cortisone* (n = 70)	Argan Oil (n = 70)	Cortisone* (n = 70)	Argan Oil (n = 70)	Cortisone* (n = 70)
Normal skin	0 (0)	0 (0)	6 (8.6)	2 (2.9)	47 (67.1)	32 (45.7)	67 (95.7)	69 (98.6)
Mild irritation	23 (32.9)	21 (30)	37 (52.9)	32 (45.7)	15 (21.4)	28 (40)	1 (1.4)	1 (1.4)
Moderate irritation	22 (31.4)	16 (22.9)	17 (24.3)	14 (20)	5 (7.1)	9 (12.9)	0 (0)	0 (0)
Moderate- severe irritation	9 (12.9)	11 (15.7)	8 (11.4)	17 (24.3)	1 (1.4)	1 (1.4)	0 (0)	0 (0)
Extreme irritation	16 (22.9)	22 (31.4)	2 (2.9)	5 (7.1)	2 (2.9)	0 (0)	2 (2.9)	0 (0)
****P Value**	.026		0.000		0.000		0.000	

a Values are expressed as No. (%).

b No significant side effects were observed in both study groups.

*Cortisone, hydrocortisone 1% group.

** Person Chi-square test

As shown in the ordinal logistic regression analysis using Generalized Estimating Equations (GEE) models revealed a significant overall the potential confounders effect: the factors of time, use barrier care, maternal employment status and previous experience of DD. However, infants and toddlers in Argan Oil group about .25 times less likely to have higher grade (score intensity) of DD compared to infants and toddlers in the hydrocortisone group with ($P< .025$).

4.4 Rate of Diaper Dermatitis Intensity Scores in Both Groups

1- What is the effect of the traditional medicinal product of Argan Spinosa Oil among infants and children with diaper dermatitis on speed up the healing process and alleviation the symptoms of DD, compared to conventional topical steroid ointment?

In the Argan Oil group, the DD severity score has decreased in the first day of treatment by 8.6% of children have been none irritation compare to 2.9% in the hydrocortisone group. In the Argan Oil group, the DD severity score has decreased in the third day of treatment by 67.1% of children have been none irritation compared to 45.7% in the hydrocortisone group. In the Argan Oil group, the DD severity score has decreased in the seventh day of treatment by 95.7% of children have been none irritation compared to 98.6% in the control group (see Figure 1).

Mann–Whitney U test indicated that the mean days of disappearing symptoms of infants and toddlers were higher in the hydrocortisone group (Median= 3.34) compared to the Argan Oil group (Median= 2.75), $U= 1810.50$, $p = .006$. A Chi-square test indicated in the Argan Oil group had faster onset of recovery in the first 12 hours compared to the hydrocortisone group, $\chi2 (1, n = 140) = .00$, $p = .000$. No side effects were observed and well tolerated in both study groups.

Table 3: Rate of DD Intensity over time in both study groups

	Number of cases	Intensity of DD in base line	Intensity of DD in Day 1	Intensity of DD in Day 3	Intensity of DD in Day 7
Argan oil	70	100%	64 (91.4%)	23 (32.9%)	3 (4.3%)
Hydrocortisone	70	100%	68 (97.1%)	38 (54.3%)	1 (1.4%)

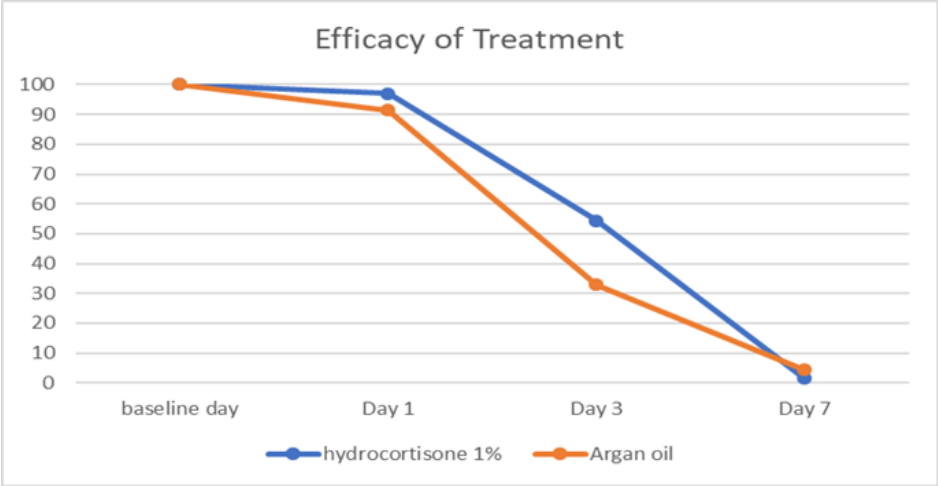

Figure 1: Rate of Diaper Dermatitis Intensity over time in the Study Groups (higher scores indicate severe Diaper Dermatitis)

4.5 Predictors of Diaper Dermatitis

2- What are factors associated with occurrence of DD on infants and children?

In order to determine possible factors that may contribute to the development of diaper dermatitis among Jordanian infants and toddlers, multiple ordinal logistic regression analysis was applied on the total sample (140).

In the multiple ordinal logistic regression models, DD grade in the assessment day served as the dependent variable. The independent variables entered in the model as potential predictors

based on the mother's answers on specific questions in the child history checklist were: Mother Age, Nationality, Educational Status, Residence, Type of family, Employment, Income, Parity, Child Sex, Child age, type of feeding (Breastfeeding), Type of wipes, Previous experience, use Barrier cream, use soap, Exposure the area to air, and frequency of bathing.

As reflected in table 2, the Univariate analysis showed that DD was significantly associated with two of the 17 factors considered: use the barrier cream and frequency of bathing/showering ≤ 1 times per week ($P < 0.05$ for all comparisons; Table 2).

The use of the barrier cream (OR=.52; 95% CI = .27-.99; p=.047) is a protective factor against the development of DD. Therefore, children of mother's use barrier cream about .52 times less likely risk to develop DD compared to children of mothers who did not use the barrier cream. In other words, children who were applied barrier cream were less likely to develop DD.

On the other hand, the effect of frequency of bathing/showering ≤ 1 times per week (OR=2.01; 95% CI = 1.07-3.75; p=.029) was associated with a higher risk of developing of DD. Therefore, children of mothers were of bathing/showering ≤ 1 times per week about 2.01 times more likely risk to develop DD compared to children of mothers were of bathing/showering ≥ 1 times per week.

However, upon fitting these factors using multiple ordinal logistic regression and by specifying 'backward conditional' method with removal at correlated $p < 0.05$. Two (2) factors including use the barrier cream and frequency of bathing/showering ≤ 1 times per week tested.

However, use the barrier cream (OR=.35; 95% CI = .18-.72; p=.004) and frequency of bathing/showering ≤ 1 times per week (OR=1.15; 95% CI = .65-2.10; p=.002) remained significantly associated with diaper dermatitis (Table 2).

Table 4: Summary of the factors that were found on univariate and multivariate logistic regression analysis to be significantly associated with diaper dermatitis

Characteristics	Univariate			Multivariate		
	OR	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Sociodemographic mother child pairs						
Mother						
Mother Age (years)	1.01	.97-1.07	.58			
Nationality, Jordanian	1.09	.28-4.29	.90			
Educational Status, High school or higher	.60	.32-1.12	**.**11			
Residence, Urban	.72	.38-1.39	.33			
Type of family, Nuclear family	.68	.32-1.43	.31			
Employment, employed	1.01	.49-2.07	.98			
Income, Jordan Dinar						
≤ 300	1.12	.51-2.43	.78			
301-500	.75	.33-1.69	.49			
≥ 501						
Parity, Primiparuos	.63	.30-1.34	**.**23			
Child						
Child Sex, male	1.18	.65-2.15	.58			
Child age						
≤ one year age						
Associated Factors of Incidence DD						
Breastfeeding, yes	1.62	.88-2.98	.12			
Type of wipes						
Wet wipes	.60	.28-1.27	**.**18			
Alcohol wipes	1.08	.51-2.28	.85			

Characteristics	Univariate			Multivariate		
	OR	95% CI	p-value	OR	95% CI	p-value
Never used						
Previous experience, yes	.78	.35-1.75	.55			
Frequency of diaper changing						
< 6 times per day	.81	.38-1.73	.59			
Barrier cream, yes	.52	.27-.99	**.047**	.35	.18-.72	**.004**
Soap, multiple times per day	1.24	.68-2.25	.49			
Exposure to air, yes	1.01	.56-1.85	.97			
Bathing						
≤ 1 times per week	2.01	1.07-3.75	**.029**	1.15	.18-.69	**.002**

Dependent Variable: diaper dermatitis score in the assessment day. OR, odds ratio; CI, confidence interval.

4.6 Summary

This chapter provides study findings including mother-child sociodemographic, the rate of improvement between treatment groups during the trial and potential associated risk factors with diaper dermatitis. Ordinal logistic regression analysis using Generalized Estimating Equations (GEE) models was used to describe the changes over the time during trial period and the results showed a statistical significant difference ($p < 0.05$). Infants and toddlers in Argan Oil group about .25 times less likely to have higher grade (score intensity) of DD compared to infants and toddlers in the hydrocortisone 1% group with (P< .025). Univariate and multivariate ordinal logistic regression model was conducted to identify the main predictors that may contribute to the development of DD among Jordanian infants and toddlers after controlling the confounders. use the barrier cream (OR=.35; 95% CI = .18-.72; p=.004) and frequency of bathing/showering ≤ 1 times per week (OR= 1.15; 95% CI = .65-2.10; p=.002) was significantly associated with DD.