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# **A Randomized, Double-Blind, Controlled Trial of Monolaurin Ointment versus Mupirocin Ointment of Bacterial Skin Infections among Pediatric Patients Ages 5 to 18 Years Old in a Community-Based Setting**

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# BACKGROUND

- Skin infection remains one of the leading causes of pediatric consults especially in developing countries like the Philippines
- Mupirocin ointment/cream is commonly and the first line choice with regards to topical antibacterial treatment of bacterial skin infections
- there was an alarming concern about the emergence of resistance

- more researchers and investigators direct their attention to antimicrobial of plant origin which is found to be less in adverse reactions
- limited clinical trials were reported on the use of monolaurin against skin infection specifically in the pediatric population

## OBJECTIVE

The objective of this study is to determine the clinical efficacy of Monolaurin ointment versus Mupirocin ointment in skin infections of children in community-based settings.

# METHODOLOGY

## STUDY DESIGN

Experimental,  
double-blind,  
controlled trial

## SETTING

Community-Based

## SAMPLE

Size: 40  
Confidence interval: 95%  
Power of study: 80%

## INTERVENTION

Subjects were  
randomly assigned to  
monolaurin ointment  
and mupirocin  
ointment (twice daily)  
for 7 days

# RESULTS

**Table 1. Demographic and Clinical Characteristics of Subjects**

	Monolaurin (n=20)	Mupirocin (n=20)
Age in years		
5 (Preschool)	0	0
6-12 (School age)	17	16
13-18 (Adolescent)	3	4
Mean	10.9	10.95
Sex		
Male	11	12
Female	9	8
BMI		
Obese	0	0
Overweight	7	5
Risk for overweight	4	2
Normal	9	11
Wasted	0	2
Severely wasted	0	0
Dermatological findings		
Impetigo	4	5
Infected insect/arthropod bite	10	9
Infected wound	6	6
Localization		
Head	1	0
Trunk	0	1
Limbs	19	19
Number of lesions		
Multiple	13	9
Single	7	11

# RESULTS

## SKIN INFECTION RATING SCALE (SIRS)

**Table 3.1 Skin Infection Rating Scale (SIRS) Baseline, Day 4, and Day 7**

		Monolaurin (n=20)			Mupirocin (n=20)		
		Baseline	Day 4	Day 7	Baseline	Day 4	Day 7
Blistering	Absent	17	18	20	19	20	20
	Mild	2	2	0	1	0	0
	Moderate	1	0	0	0	0	0
	Severe	0	0	0	0	0	0
Exudate	Absent	10	17	20	14	19	20
	Mild	7	2	0	5	1	0
	Moderate	2	1	0	1	0	0
	Severe	1	0	0	0	0	0
Crusting	Absent	2	5	15	0	4	19
	Mild	3	10	5	5	11	1
	Moderate	10	5	0	10	5	0
	Severe	5	0	0	5	0	0
Erythema or Inflammation	Absent	1	1	17	0	6	19
	Mild	2	13	3	5	9	1
	Moderate	11	6	0	10	5	0
	Severe	6	0	0	5	0	0
Itching or Pain	Absent	0	5	18	0	7	19
	Mild	5	9	2	4	21	1
	Moderate	9	6	0	13	1	0
	Severe	6	0	0	3	0	0

Sign/symptom	Score	Definition
Blistering	0=Absent	No evidence of blisters
	1=Mild	Few raised vesicles present on close evaluation
	2=Moderate	Fluid filled vesicles are obvious and are bothersome to the patient
	3=Severe	Extensive area covered with many vesicles which may include large bullous vesicles
Exudate/pus	0=Absent	No evidence of exudate or pus
	1=Mild	Small amounts of fluid/pus coming from the lesions
	2=Moderate	Exudate/pus infected area is moderate
	3=Severe	Extensive areas infected and there is draining exudate
Crusting	0=Absent	No evidence of crusting
	1=Mild	A few areas have some evidence of crusting lesions
	2=Moderate	Crusting is present throughout the infected area
	3=Severe	Thick crusting appears over the entire impetiginous area
Erythema/ inflammation	0=Absent	Skin tone and color are normal; no signs of erythema or inflammation
	1=Mild	Skin is pink with minimal signs of inflammation
	2=Moderate	Skin is red with definite signs of inflammation
	3=Severe	Skin is red and severe inflammation is present
Itching/pain	0=Absent	No signs of itching or indication of pain
	1=Mild	Some evidence of scratching or rubbing the area is evident and patient reports minor discomfort
	2=Moderate	Evidence of scratching and patient reports bothersome, painful lesions
	3=Severe	Evidence of extensive scratching and patient reports pain that interferes with daily activities or sleep.

# RESULTS

**Table 2. Wound size Pre-treatment and Post-treatment**

	Wound size Pre-treatment (mm)	Wound size <u>Post-treatment</u> (mm)	p-value
Monolaurin	13.445	5.545	< 0.00001
Mupirocin	11.66	3.665	0.0002
p-value Monolaurin vs Mupirocin	0.58134	0.42945	

\*p-values >0.05 Not significant; p-values ≤0.05 Significant (T-test)

**Table 3.2 Test of difference based on Skin Infection Rating Scale (Baseline vs Day 4 and Baseline vs Day 7)**

	Monolaurin		Mupirocin	
	Baseline vs Day 4	Baseline vs Day 7	Baseline vs Day 4	Baseline vs Day 7
Blistering	0.38974	0.21186	0.39743	0.39743
Exudate	0.03005	0.00357	0.08851	0.0537
Crust	0.00154	< 0.00001	0.00048	< 0.00001
Erythema	0.00048	< 0.00001	0.00029	< 0.00001
Pain/Itch	0.00048	< 0.00001	0.00029	< 0.00001

\*p-values >0.05 Not significant; p-values ≤0.05 Significant (Mann-Whitney U Test)

**Table 3.3 Test of difference between Monolaurin and Mupirocin based on SIRS**

	Blistering	Exudate	Crust	Erythema	Pain/Itch
Baseline	0.2946	0.11702	0.45224	0.29806	0.3409
Day 4	0.29806	0.2946	0.42465	0.11702	0.08379
Day 7	0.49601	0.49601	0.14231	0.29806	0.39743

\*p-values >0.05 Not significant; p-values ≤0.05 Significant (Mann-Whitney U Test)

# RESULTS

Figure 2. Gram Stain

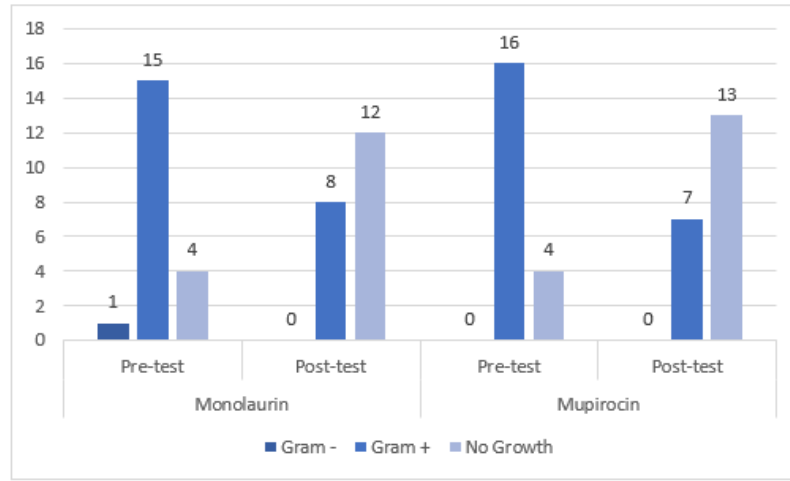


Figure 3. Antibiotic Resistance



Table 4. Test of Difference for Gram Stain

	Monolaurin Pre-test vs Post-test	Mupirocin Pre-test vs Post-test
p-value	0.01345	0.000544
p-value Monolaurin vs Mupirocin	0.882553	

\*p-values >0.05 Not significant; p-values ≤0.05 Significant (Chi-square)



# RESULTS

**Table 5. Bacteriologic Findings**

Isolate	Pre-Treatment		Post-treatment	
	Monolaurin	Mupirocin	Monolaurin	Mupirocin
No growth	4	4	12	13
<i>Corynebacterium jeikeium</i>	1	0	0	0
<i>Pasteurella multocida</i>	1	0	0	0
<i>Staphylococcus saprophyticus</i>	3	1	0	0
<i>Staphylococcus epidermidis</i>	2	4	3	2
<i>Staphylococcus aureus</i>	7	6	2	0
<i>Staphylococcus haemolyticus</i>	0	2	1	0
<i>Staphylococcus hominis</i>	0	1	0	0
<i>Staphylococcus intermedius</i>	0	1	0	0
<i>Staphylococcus lentus</i>	1	0	1	0
<i>Staphylococcus warneri</i>	0	0	1	1
<i>Streptococcus pyogenes</i>	1	0	0	0
<i>Bacillus megaterium</i>	0	0	0	1
Unidentified	0	1	0	3

## CONCLUSION

Similar cure rates occurred in the two groups based on Skin Infection Rating Scale, Gram stain and culture, and wound size. These findings suggest that the monolaurin ointment may be used as a substitute for mupirocin ointment in terms of efficacy, safety, and cost.

## RECOMMENDATION

The investigators recommend an equivalence trial comparing the efficacy of monolaurin ointment vs mupirocin ointment in a hospital setting using a larger sample size.