Clinical trial comparing the effectiveness of two skin protectants for the treatment of Incontinence Associated Dermatitis

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BACKGROUND

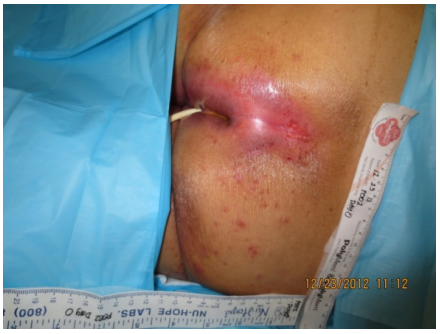
Incontinence Associated Dermatitis (IAD) can occur as a consequence of repeated exposure to urine or fecal matter. Untreated, IAD can result in extensive skin destruction, infections, itching and pain. For prevention and treatment of Incontinence Associated Dermatitis (IAD), structured skin care regimens including gentle cleansing and a skin protectant are recommended.

AIM

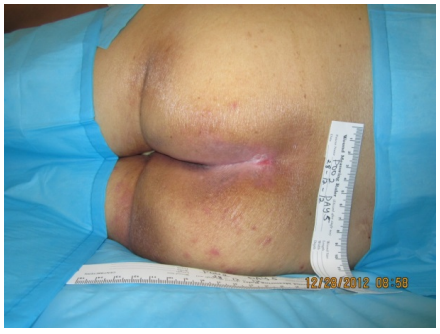
To compare the effectiveness of two topical zinc oxide based diaper rash products in a structured care regimen for the treatment of IAD in adults and older children.

METHOD

Two-arm, randomized controlled trial with blinded outcome assessment. Population: children >12 years and adults with urinary and/or fecal incontinence and Kennedy IAD Severity Score of 3.0 or greater. The Kennedy IAD Severity Score is a cumulative severity score ranging from zero (no IAD) to 9: assessors attribute scores of 0-3 for three domains: skin redness or inflammation, area of skin breakdown, and erosion. Patients were randomized to receive a structured skin care regimen of gentle cleansing and either of two zinc oxide based topical ointments: Calmoseptine Ointment or Desitin Maximum Strength Diaper Rash Paste. Primary outcome: percentage of participants completely healed (IAD Severity Score of zero). Secondary outcomes included: IAD Severity Score at baseline and each study day; size of area affected by IAD at baseline and each study day. Required sample size was calculated to be 118, increased by 20% to 142 to allow for withdrawals due to discharge, participant choice or other reasons.



Day 0: Perianal IAD (moderate redness & severe dermal erosion) extending to the sacrum with GII pressure ulcer within the affected area (IAD Severity score = 6)



Day 5: Healed perianal IAD as evidenced by new and pinkish epithelium, leaving only the GII sacral pressure ulcer (IAD Severity score = 0)

Calmoseptine® Ointment

The trial was funded by Calmoseptine Inc.

RESULTS

Numbers completely healed & total IAD area (cm^2) for each follow up day by treatment group					
	Calmoseptine		Desitin		p value
	n (%) completely healed	N	n (%) completely healed	N	
Day 1	1 (1.4)	69	0	73	.302 [c]
Day 2	2 (2.9)	68	1 (1.4)	73	.518 [c]
Day 3	2 (3.0)	66	3 (4.3)	69	.685 [c]
Day 4	4 (6.6)	61	4 (5.9)	68	.874 [c]
Day 5	6 (10.2)	59	4 (6.2)	65	.412 [c]
Day 6	14 (25.0)	56	5 (7.7)	65	.009 [c]
Ever healed during study	15 (21.7)	69	7 (9.6)	73	.046 [c]
Ever (complete follow up)	14 (25.0)	56	7 (10.8)	65	.039 [c]
	Mean (SD) total IAD area	N	Mean (SD) total IAD area	N	
Day 0	227.8 (160.1)	69	202.7 (186.9)	73	.393 [t]
Day 1	183.9 (134.1)	69	219.1 (195.6)	73	.216 [t]
Day 2	154.8 (120.1)	68	188.6 (188.9)	73	.210 [t]
Day 3	127.2 (115.8)	66	203.2 (200.8)	69	.008 [t]
Day 4	109.1 (129.0)	61	199.0 (189.9)	68	.002 [t]
Day 5	96.8 (126.8)	59	174.2 (147.2)	65	.002 [t]
Day 6	82.1 (111.9)	56	163.7 (144.5)	65	.001 [t]

SD Standard deviation [c] Chi-square test [t] t test

Between December 2012 and March 2014, 142 patients were enrolled, of which 118 completed the seven day study with data for six days' daily follow up. Mean age at baseline was 59.0 (SD 17.5) and a majority (73.9%) was female. 97.2% of the participants were bedbound and all were in diapers on all study days. No statistically significant differences were identified between the two treatment groups in terms of age, gender, body mass index, use of antibiotics, albumin, IAD severity or size of area affected. No significant differences were observed in incidence of urinary or fecal incontinence or stool consistency over the study period.

Percentages of patients completely healed and mean total areas affected by IAD are presented in the table. By end of follow up, significantly higher numbers of participants were completely healed in the Calmoseptine group. Treatment with Calmoseptine was associated with statistically significantly smaller affected areas from Day 3 onwards. Analyses of covariance, adjusting for baseline area affected, indicated that Calmoseptine was associated with significantly greater reductions in area affected on all follow up days.

CONCLUSIONS

The care regimen conferred healing benefits in both groups, illustrating the importance of structured approaches in treating IAD.

In this trial, used as part of such a regimen, Calmoseptine Ointment was significantly more effective in healing IAD than Desitin: 25% in the Calmoseptine group were completely healed at 6 days compared with 7.7% in the Desitin group.

Full report: Razor BR, Buckley BS, Quiambao P, Dofitas R, Baltazar W. Incontinence-associated dermatitis (IAD) study: Blinded assessment and treatment with zinc oxide-based ointment. World Council of Enterostomal Therapists Journal 2014; 34 (4): 13-23 For additional information contact: Dr Rodney Dofitas rdofitas@yahoo.com