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TOPICAL ZINC OXIDE BASED CREAMS IN A STRUCTURED CARE REGIMEN FOR THE TREATMENT OF INCONTINENCE ASSOCIATED DERMATITIS IN HOSPITALIZED ADULTS AND OLDER CHILDREN: A RANDOMIZED, CONTROLLED TRIAL.

Hypothesis / aims of study

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 (1). Consensus guidelines recommend skin protectants for patients at risk of developing IAD, and early treatment where IAD occurs (1,2).

There are few published clinical trials of IAD products and treatments, and consensus statements and reviews have called for high quality research evaluating their effectiveness (1,2,3). This trial compared the use of two topical zinc oxide based diaper rash products in a structured care regimen for the treatment of IAD in hospitalized adults and older children.

Study design, materials and methods

Two-arm, randomized controlled trial with blinded outcome assessment of two topical IAD treatments. Population: children >12 years and adults with urinary and/or fecal incontinence and IAD, assessed to score 3 or greater on the Kennedy IAD Severity Score. The Kennedy IAD Severity Score is a cumulative severity score ranging from zero (no IAD) to 9, which requires assessors to attribute scores of 0-3 for three domains: size of area affected, skin redness or inflammation, and erosion. The sum of these scores is the IAD Severity Score[1, 12]. Written, informed consent was obtained from all participants and/or guardians.

Patients were randomized to receive a structured skin care regimen with either of two zinc oxide based topical ointments: Calmoseptine Ointment or Desitin Maximum Strength Diaper Rash Paste. Calmoseptine contains 20% zinc oxide, combined with menthol, chlorothymol (antiseptic and antifungal), glycerin (emollient with water-retaining properties), lanolin (moisturizing skin conditioner), sodium bicarbonate (antipruritic), phenol (antiseptic) and thymol (antiseptic, antifungal and deodorizer). Desitin contains 40% zinc oxide, combined with lanolin, petrolatum (moisturizing ointment base) and cod liver oil (skin moisturizer and protectant).

Following enrolment, all participants received the same structured care regimen for treatment of IAD for six days following study entry. At least twice daily and as required by incontinence episodes, treatment and care was provided by nurses and nursing aids trained in the study regimen to ensure its consistent implementation, using identical cleansing products, methods and diapers. Wet or soiled diapers were removed and the affected area was gently cleansed. Vigorous cleaning was avoided. A thin layer of the study topical ointment was applied prior to putting on a new diaper.

The primary outcome was percentage of participants completely healed, defined as a Kennedy IAD Severity Score of zero. Secondary outcomes included: time to complete healing in days; IAD Severity Score at baseline and each study day; size of area affected by IAD at baseline and each study day; Pain Scores and Itch Scores at baseline and each study day. The 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.

Results

Between December 2012 and March 2014, 142 patients were enrolled, of which 120 completed the seven day study with data for six days' daily follow up. Mean age 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, mean total areas affected by IAD and mean changes in those areas are reported in the table. On Days 5 and 6 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 (ANCOVA), adjusting for baseline area affected, indicated that Calmoseptine was associated with significantly greater reductions in area affected on Days 1 ($F = 26.26$, $p = .000$), 2 ($F = 12.41$, $p = .001$), 3 ($F = 32.95$, $p = .000$), 4 ($F = 39.16$, $p = .000$), 5 ($F = 17.16$, $p = .000$), and 6 ($F = 18.40$, $p = .000$).

	Calmoseptine		Desitin		p value
	n (%) completely healed	N	n (%) completely healed	N	
Day 1	0	70	1 (1.4)	72	.322 [c]
Day 2	1 (1.4)	70	2 (2.8)	72	.576 [c]
Day 3	7 (10.6)	66	3 (4.4)	68	.173 [c]
Day 4	11 (18.0)	61	6 (13.3)	67	.131 [c]
Day 5	14 (23.7)	59	4 (6.2)	64	.006 [c]
Day 6	16 (28.6)	56	5 (7.8)	64	.003 [c]
	Mean (SD) total IAD area	N	Mean (SD) total IAD area	N	
Day 0	226.8 (159.2)	70	199.3 (185.9)	72	.346 [t]

Day 1	184.9 (133.4)	70	215.9 (195.0)	72	.272 [t]
Day 2	159.2 (124.7)	70	184.8 (187.3)	72	.344 [t]
Day 3	127.2 (115.8)	66	199.4 (199.7)	68	.012 [t]
Day 4	109.1 (128.9)	61	195.0 (188.5)	67	.003 [t]
Day 5	96.8 (126.8)	59	169.4 (143.2)	64	.004 [t]
Day 6	82.1 (111.9)	56	157.7 (137.4)	64	.001 [t]

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

Assessments of complete healing presented in the table are investigator-assessed, lead by a principle investigator blinded to allocation. Fully independent blind primary outcome assessments based upon detailed daily photography were not complete before abstract submission. However, analysis of the 96% of participants for whom independent blind assessments were avalilable indicate similar statistically significant results.

Interpretation of results

This single-center study compared two topical IAD treatments in a structured care regimen amongst largely bedbound hospitalized adults and older children, in whom IAD was often severe. The care regimen conferred healing benefits in both groups, illustrating the importance of such structured approaches in treating IAD. Used as part of such a regimen, Calmoseptine ointment appears superior to Desitin, conferring a greater likelihood of complete healing within six days and reduction of area affected by some 50% within four days.

Concluding message

A structured care regimen and use of a zinc-based skin protectant can be used to treat IAD. Used as part of such a regimen, Calmoseptine ointment appears superior to Desitin.

References

1. Gray M, Bliss DZ, Doughty DB, Emer-Seltin J, Kennedy-Evans KL, Palmer MH: Incontinence Associated Dermatitis: A Consensus. J Wound Ostomy Continence Nurs 2007, 34:45-54.
2. Gray M, Beeckman D, Bliss DZ, Fader M, Logan S, Junkin J, Selekof J, Doughty DB, Kurz P: Incontinence Associated Dermatitis: A Comprehensive Review and Update. J Wound Ostomy Continence Nurs 2012, 39:61-74.
3. Beeckman D, Schoonhoven L, Verhaeghe S, Heyneman A, Defloor T: Prevention and treatment of incontinence-associated dermatitis: literature review. J Adv Nursing 2009, 65:1141–1154.

Disclosures

Funding: The research was funded by Calmoseptine Inc, 16602 Burke Lane, Huntingdon Beach, California, U.S.A. **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.Gov registration number NCT02080247 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Research Implementation and Dissemination Office Ethics Committee of the University of the Philippines College of Medicine **Helsinki:** Yes **Informed Consent:** Yes