Cost-Effectiveness Evaluation of a New Alcohol Free Film-Forming Incontinence Product Protectant

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Abstract:
This study was conducted to help optimize napraplication schedules for a new alcohol free, film-forming incontinence skin protectant. Additionally, cost-efficiency of the new skin protectant was compared to a commonly used perineal ointment and zinc oxide cream. Forty patients with existing skin breakdown due to incontinence were enrolled into this study and randomly assigned into five groups. Groups 1, 2, and 3 received the new film-forming skin protectant every 8, 48, and 72 hours, respectively. Groups 4 and 5 received the cream or ointment or perianal cream per current protocol (2X per day and once at night). Results show significant improvement in skin condition for each of the five groups over the 12-day study period and no significant differences between the groups. These results indicate that, for the film-forming skin protectant, barrier efficacy can last even 72 hours after product application. Weight of the perineal ointment used per day varied, adjusted 1.5 grams, giving a daily cost of $0.62 to $0.68 ($1.00 depending on volume of product from a major national medical supplier). Similarly, weight of the zinc oxide cream increased 1.6 grams giving a daily cost of $0.19 to $1.44. Costs per day of treatment for the new barrier film protectant were $0.29, $0.61, $0.83, $1.30, and $2.09 for 24, 48, 72, 48, and 24-hour treatments, respectively. These costs do not include nursing time and subject products which will additionally offset costs of the treatment protocol.

13Mo No Sting Barrier Film
"Swabs" Per Care
"Swabs" Baza

Introduction:
It is estimated that over 50% of the 1.5 million nursing home residents in America are incontinent. The total annual cost to treat incontinence is in excess of the nearly 8 billion dollars annually spent in treating this disorder. Incontinence adversely affects individuals to promote physical and social wellbeing and has a considerable psychological impact on both the patient and caregiver. Despite its considerable economic, physical, and psychological impact, incontinence is still a largely neglected problem. Treatment traditionally involves the use of pads in combination with perineal or zinctal ointments and creams. Perineal creams, however, easily transfer from the skin of the perineum to the hand and are not intended for use with high absorbency. Zinc oxide creams, in addition to being more costly than perineal creams, are money to use and interfere with patient care.

Background:
Recent advances in incontinence skin protection technology have been introduced to the market. The new technology is designed to form a liquid film by a variety of incontinent patients. The film appears to act as a barrier, decrease the number of subject products which are subject to the patient and caregiver. This study is designed to determine the optimal napraplication schedule for these products. The study was conducted in two phases. In Phase I, patients were randomly assigned to receive one of two treatment products: Swabs Per Care or Swabs Baza (a common perineal ointment containing zinc acetate crystals). These products were applied three times a day for a period of 12 consecutive days. In Phase II, patients were randomly assigned to receive the 3M No Sting Barrier Film with applications every 24, 48, 72, and 72 hours. In both phases of the study, patients participated in the study for 12 consecutive days.

Methods:
The study was conducted in two phases. In Phase I, patients were randomly assigned to receive one of two treatment products: Swabs Per Care or Swabs Baza (a common perineal ointment containing zinc acetate crystals). These products were applied three times a day for a period of 12 consecutive days. In Phase II, patients were randomly assigned to receive the 3M No Sting Barrier Film with applications every 24, 48, 72, and 72 hours. In both phases of the study, patients participated in the study for 12 consecutive days.

Subjects:
Forty patients who had prior history of incontinence (nurse, stool, or both) and who exhibited at least moderate skin breakdown resulting in the moisture score of 2.0-4.0 or 0-10 each were included in this study. There were eight patients enrolled into each of the five treatment groups.

Assessments:
1. Upon enrollment into the study, all subjects were assessed for risk of pressure ulcer formation using the Braden Scale Assessment Tool.
2. Frequency and type of incontinence episodes for each patient were recorded by the caregivers.
3. Urinary tract infections were monitored for each patient throughout the 12 days of study.
4. Cost of product per day of treatment was assessed for the five treatment groups. The costs of the Per Care and Baza products were adjusted to specific sites and were used daily to provide an assessment of amount of product used per day of treatment. Each application of the 3M No Sting Barrier Film was recorded to provide a similar record of amount of product used per day of treatment. A readiness-to-use product cost depending on volume of product obtained will be determined from a major national medical supplier.

Statistical Methods:
The statistical significance of the study was assessed using Analysis of Variance. The study included repeated measures within a patient over time. The model included an interaction product (treatment), patient nested within subject, product plus time and product by time interaction. The effect of product was evaluated by the mean difference in each patient. The overall F-test was conducted at p = 0.05 (2df).

Discussion:
1. Results: Assessment: The standard Braden assessment technique published in the ACFTR Clinical Practice Guideline 1995 was used to assess patients upon enrollment into this study. The tool assesses risk (0-24) for prediction of pressure ulcer formation. The technique assigns empirical scores for each factor and individual risk factors scores are then added together. The total possible score is 24 with the average in this study being 16.8 indicating that these patients were at some risk to further skin breakdown. There were no significant differences among the treatment groups.

2. Frequency of Incontinence Episodes: Caregivers were asked to record on a data collection form every time the patient was found to be incontinent. Patients enrolled into this study were assessed at least 3 times (0.9 to 1.3 SEM) times per day, 75% of the incontinence episodes involved urine only, 9.6% involved stool only, and 12.5% involved both urine and stool. There were no significant differences among the treatment groups.

3. Skin Condition Assessment: Skin condition was assessed using an assessment tool designed specifically for this study. The tool incorporates individual measures of "severity of Redness" (0 to 5), "Degree of Erosion" (0 to 4), and "Intensity of Roughness" (0 to 3). The individual scores are added to one of a 10-point scale. Measurement of "Skin Condition" (0 = healthy intact skin; 10 = severely damaged). The score "Skin Condition" score for patients enrolled into this study. The average "Skin Condition" score for patients enrolled into this study was 4.0 (1.7 SEM) indicating that these patients exhibited moderate skin breakdown after use of the product. At the end of the 12 days of study participation, all five treatment groups showed significant improvement in skin condition compared to the pretreatment scores. There were no significant differences in skin condition among the five treatment groups at any time during the study.

4. Cost of Product per Day of Treatment: Amount of product used per day of treatment was assessed for each patient during the 12 days of treatment. For the Per Care and Baza products, tubes of product were assigned to each patient group. The tubes were used by weight and each tube was weighed at the beginning of each day. This data was then averaged for each treatment group. For the 3M No Sting Barrier Film, each application and total number of applications of the product was recorded on a data collection form.

Knowing the average gram weights of Per Care and Baza used per day of treatment, and knowing the average and range of product cost (depending on volume of product from a major national medical supplier), we were able to calculate average and range of product cost per day of treatment. Likewise, for the 3M No Sting Barrier Film, the average number of applications used per day of treatment, and knowing the average range of product cost (depending on volume of product from the same major national medical supplier), we were able to calculate average and range of product cost per day of treatment. The average amount of Per Care used per day of treatment was 13.6 ± 1.9 SEM grams, giving an average daily cost of $0.75 and a range of $0.63 to $0.88. Similarly, weight of Baza used per day averaged 16.1 ± 2.2 SEM grams giving an average daily cost of $1.21 and a range of $0.07 to $1.04. For the 3M No Sting Barrier Film, average and range of product costs $0.78 ($0.63 to $0.91), $0.83 ($0.67 to $0.97), and $1.17 ($0.83 to $1.48) for 24, 48, and 24-hour treatment groups, respectively. These costs do not include nursing time and subject products which will additionally offset costs of the treatment protocol.

Conclusions:
These clinical data contributes findings by the manufacturer that barrier products of the 3M No Sting Barrier Film may be much longer than the currently indicated 2.5 hours. These data additionally indicate that given a 24-hour application schedule, the 3M No Sting Barrier Film costs approximately the same per day of use as a commonly used perineal ointment (Swabs Per Care) and costs less per day of treatment than a commonly used zinc oxide cream (Baza).