

# Use of a protease containing antifungal\* to treat damaged and contaminated perineal skin

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\*Trivase (Swiss-American Products, Inc., Dallas, TX)

# Disclosure

- AM Brinton is a private practice, Clinical Nurse Specialist, as well as an employee of SAPI. At the time of this case series, SAPI was not aware of the subjects and no product was initially provided.
- LKS Parnell is a scientific consultant for Precision Consulting and SAPI is a client of Precision Consulting.

# Risk Factors for Perineal Skin Damage

- **Moisture** increases stratum corneum permeability  
encourages microbial growth
- **Urine** alters the protective pH of the skin  
adds moisture and irritants
- **Feces** alters the protective pH of the skin  
adds moisture, irritants, and microbes
- **Skin pH** frequent cleansing and moisture can alter pH
- **Irritants** (i.e. ammonia)  
intensity and duration impact the severity
- **Microbes** can impair healing  
permeate the stratum corneum → secondary infections
- **Friction/shear** diapers, pads, moisture, and frequent cleansing

# Incontinence induced perineal skin damage is prevalent!

Incontinence defined as  $\geq 2$  episodes of incontinence/week

Long-term care: incontinence prevalence

46.4% for urinary

29.5% for fecal

25.6% for urofecal

Perineal skin damage occurs in:

33% hospitalized adults

41% long-term care adults

# Incontinence is a recognized risk factor for pressure ulcers

## Pressure ulcer development

- 22 times greater in hospitalized adults with fecal incontinence than hospitalized adults without incontinence
- Occurring within 2 days of hospitalization strongly associated with incontinence
- In LTC significantly associated with fecal and urinary incontinence (P=0.000)
- AHRQ (AHCRP), JCAHO, and CMS recognize the incontinence-pressure ulcer link

Maklebust Advance 1994;  
Baumgarten JGerBioSciMed 2006;  
Thompson Advance 2005

# Microbial growth can exacerbate skin damage

Microbial growth can increase symptoms of:

- Edema
- Erythema
- Maceration
- Pain
- Pruritus
- Burning

Microbial infection\* risk factors include:

- Any incontinence
- Antibiotics
- Corticosteroids
- Compromised immune system
- Elderly

\*organisms such as *Clostridium difficile* and *Candida albicans*

# Clinical Case Series

- Seven ICU and medical/surgical patients with urofecal incontinence
  - Failed fecal containment
  - All receiving barrier products
  - Severe perineal skin damage
- Polymicrobial cultures of *Candida albicans* AND *Clostridium difficile*, VRE, or MRSA were documented in each
- Patients required various potent analgesics prior to cleaning
- New treatment instituted
  - Foam cleanser^ after each incontinence episode
  - Followed by an application of protease enhanced antifungal\*

^ Elta Foaming Cleanser, \*Trivase

# Clinical Example #1 – JL

- 81 y/o male s/p Full Arrest
- ORIF hip complicated hospital stay  
SIADH; UTI;  $\uparrow K^+$ ;  $\downarrow BP$
- Hx of malignant melanoma w/mets to scalp, sacrum & iliac fossa; CAD; AAAR; BCE
- *C. Albicans*, Stool + C-Diff
- MS for pain
- Severely inflamed, painful, partially denuded buttocks, perineum, scrotum, groin, thighs
- Prior Tx: Sween Perineal Cleanser, Sween Cream, CriticAide, Silvadene<sup>®</sup>, Comfort Wipes
- New Tx: Elta Foam Cleanser, Trivase



## JL (continued)

- 22 hours later
- Decrease in erythema
- States “less painful”
- Airflow mattress overlay placed but using Geri-pads
- Slight decrease in quantity of stooling –no control, oozes nearly constantly
- Bedrest except PT
- Staff comments



## JL (continued)



**Day 4\*:** Open areas are differentiating, intense erythema less.  
More comfortable, rarely requiring MS before cleansing.

**Day 5:** Stopped using any pain med prior to cleansing.

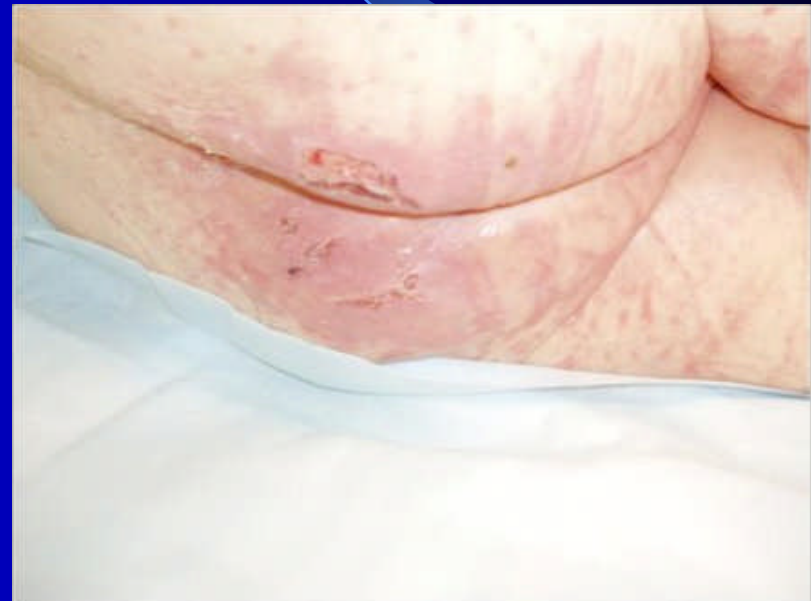
**Day 6\*:** Frequently incontinent of small amounts of stool.

# JL (continued)

**Day 9\*:** Erythema clearing. Now in CHF with pneumonia. ABT changed, increased stooling. On CBR

**Day 12:** Stools firmer but mucoid; wounds closing

**Day 16:** Wounds  $>.5$ cm still on ABT. F/C out, diapered when working with PT. Stool firmer, better control. Antifungal d'cd, switch to barrier.



\*Trivase, ^Elta Seal

# JL (continued)

**Day 19:** Wounds are closed.  
Infrequent incontinent  
stooling.

**Day 23\*:** Now in SNF. Off all  
ABT & Overlay

**Day 29:** On SNF; PEG  
inserted. Remains healed.  
EHOB<sup>®</sup> overlay

**Day 43:** Acute Rehab; walking  
w/assistance; PEG  
supplemental. Remains  
healed, using Foam<sup>^</sup> &  
Barrier<sup>\*</sup>



<sup>^</sup>Elta Cleansing Foam, <sup>\*</sup>Elta Seal

# Clinical Example #2 – JS

- 75 yo female, D/M, legally blind, on BR, (Airflow overlay); Surgical G/T
- *C. Albicans*, Stool + for C-Diff & VRE
- Copious liquid stool from waist to knees
- Severe pain when cleaned Pre-med Dilaudid – screams
- Previous Rx: Sween cream & Sween Microguard Antifungal, CriticAide, Lotrimin, Calmoseptine, Silvadene®
- New Tx: Elta Cleansing Foam; Trivase



# JS (continued)

**Day 2:** More comfortable, less erythema, frequent copious stools. Pt & Staff comment on products

**Day 4\*:** Abdominal & groin folds returned to WNL.  
Erythema markedly ↓  
↑ Epithelialization. Coccyx wound well protected.  
G/T problems; stool quantity & frequency less. Tylenol #3 for pain. Grateful for products.



# JS (continued)

**Day 7:** All skin intact except left buttock & coccygeal – 80% slough. ↓incontinent stooling. Remains on ABT; no pain meds

**Day 11\*:** Marked periwound improvement, pigmentation returning; Coccygeal wound 25% slough. Continue using Foam<sup>^</sup> & antifungal every shift



<sup>^</sup>Elta Foaming Cleanser, Trivase

## JS (continued)

**Day 18:** Periwound skin intact. Coccygeal wound ~ 5% slough, healing rim 100%. To D/C with home health. Adhesive waterproof dressing may be possible. Infrequent incontinent stooling.



# Conclusions from Case Series

Protease enhanced antifungal use resulted in:

- Dramatic improvement in symptoms of:
  - Inflammation
  - Erythema
  - Edema
  - Pain
- Analgesic use quickly decreased
- Patient cooperation increased
- Unexpected and unprecedented improvement of inflammation within 12-24 hrs

# Inflammation can be destructive

- Excess inflammation can cause an imbalance in the tissue environment resulting in:
  - Cyclical tissue damage
  - Delayed or impaired healing
  - Excessive pro-inflammatory components increasing the inflammation and symptoms
  - Increased bacterial load
  - Can lead to a chronic wound and other complications

# Clinical Differences

- Like other antifungal barriers
  - Trivase contains 2% Miconazole
- Unlike other antifungal barriers applied to denuded, inflamed tissue
  - Adheres to denuded tissue
  - Reduced drag
  - Rapid decrease in:
    - Pain
    - Redness
    - Tenderness
- Noted by patients AND nursing staff

# Protease Benefits

- Trivase antifungal contains proteases
- Proteases degrade many inflammatory mediators (MMP9 , TNF $\alpha$ )
- Does not degrade most beneficial components (PDGF, TIMPs)
- Restores environmental tissue balance
  - Resolution of inflammation, pain and itching
  - Improved healing outcomes and skin quality

# Antifungal with proteases provides:

- Protective barrier from moisture, urine, feces, irritants, & microbes
- Protects the stratum corneum
  - By reducing permeability
  - Improving pH
- Aids in resolution of inflammation and symptoms of
  - Erythema
  - Pain
  - Itching
- Results in increased compliance and cooperation
- Degrades pro-inflammatory cytokines (e.g. TNF $\alpha$  and IL-6)
- Results in improved skin integrity

# Future Research

- Compare protease enhanced antifungal versus antifungal without proteases
- Document the clinical differences including:
  - Time to resolution of inflammation and pain
  - Time to healing
  - Progression to ulceration or improvement
  - Analgesic type and usage

# Thank You!!

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