Why Stage at All?

Laura E Edsberg, PhD

You Can See It - What Do You Do About It?

• Do you treat each of these the same?

• How do you decide how to treat them?
How Do We Relate This Information?

• Bedside communication among care providers

• Treatment decisions

Full vs Partial Discussion

• Are all pressure injuries full thickness?

• Are they visually?
Clinical Reasons to Stage

• Bedside communication among caregivers

• Is prevention part of staging?

Progression

• I-IV
• 1-4
• A-D
• Etc.
• Depth = linear measurement
Staging is not unique to pressure injuries

- Cancer is staged

- Describes the severity of an individual's cancer based on the magnitude of the primary tumor as well as on the extent cancer has spread in the body

- Understanding the stage of the cancer helps doctors to develop a prognosis and design a treatment plan for individual patients

  • American Joint Committee on Cancer

Acute Kidney Injury

- Formerly acute renal failure

- Staging system –
  - RIFLE Class
    - risk, injury, failure

- AKIN Stage
  - 1, 2, 3
Spinal Cord Injury

- International standards for neurological classification of spinal cord injury

- Clinician-administered scale used to classify the severity (completeness) of injury in individuals with SCI.
  - American Spinal Injury Association

Progression?

- Is prevention part of staging?
- Or is staging part of prevention?
- Or just a “heralding sign”
Staging is not the end

• Staging is the start

• Stage and now what?

• Call to action – CMS
• Action item based on staging

• What will we do – treat / prevent / study?

Clinical Argument vs. Research

• Why stage?

• Apples to oranges?
Precision

• How will we compare treatments?

• Efficacy?

• All pressure injuries are the same? – Full
  • How do we try to assess details for analysis for that broad term?

Apples to Apples

• Without some way to describe pressure injuries that is universally agreed upon – how do we assess studies?

• Histological work?
Staging isn’t new

• Shea 1975

• Many others

• NPUAP
  – Visual and directly palpable

• Other ways to stage?

If Not Visual Staging System – Then What?

• How do we assess what is in the wound bed or beneath the skin?
Before vs. After

Can we evaluate and predict - intact skin or wound bed

Predictors

- Wound Development
  - Oxygen
  - Temperature
  - Sweat
  - Urine
  - Blood
  - Microstructure
Non-Invasive Tissue Analysis

- Tissue Impedance
- Ultrasound
- Laser Doppler
- MRI
- Others

What and When Do We Evaluate?

- Does timing matter?
- Does location matter?
- Does cost matter?
Fluids

- Urine
- Sweat
- Blood/Plasma/Serum
- Wound fluid

Urine

- Skin collagen metabolism SCI
  - Urinary excretion of Metabolite glucosyl-galactosyl hydroxylysine (glu-gal Hyl)
- Sustained increases in excretion were detected at least 2 months and as much as 5 months in advance of ulcer development
- Increased excretion of glu-gal Hyl was significantly associated (p < 0.05) with the development of a pressure ulcer

Rodriguez & Claus-Walker 1988 Paraplegia
Rodriguez G & Garber S 1994 Paraplegia
Sweat

- Easy specimen collection
- Non-invasive
- Stable marker
- Simple analysis
- Good Sensitivity and Specificity

Bader 2005

Skin Biomarkers

- Sebutape – tape adsorption method
- Diaper, heat, chemical or heat treated
- Measured targets (ELISA) released from the epidermis: IL-1a, IL-1RA, IL-8, TNF-a, MCP-1, GRO-a

Perkins MA et al. Skin Res Technol 2001
Sweat Experiment

- Sensor applied pressure and measured TCpO2 and TCpCO2
- Sweat – lactate and urea measured
- Loaded and unloaded tissue
  - Increases in concentrations of both sweat lactate and urea at the loaded site compared with the unloaded
  - Loaded threshold value TCpO2
- Establishing predictive indicators for the status of loaded soft tissues


Sub-Epidermal Moisture (SEM)

- Possible relationship between SEM and skin damage
- Greatest SEM with erythema
- SEM differed with anatomical location
  - Sacrum vs. Buttocks
- Need more data
- Clinical trail enrolling

Guihan M, Bates-Jensen B 2102 JSCM
Plasma

- Plasma variations of biomarkers for muscle damage
  - Male able-bodied and SCI subjects
- Measured creatine kinase (CK), myoglobin (Mb), heart fatty acid binding protein (H-FABP), C-reactive protein (CRP)
- CRP greatest in SCI and greatest in SCI with Pressure injury
- Further studied in Rat model
  - Mb elevated with compression

Loerakker et al. 2012 J Rehab Res Dev

Impedance Spectroscopy

- Impedance = Opposition to current
- Flexible and stretchable electronic device
  - multiplexed electrode array
- Non-invasive ‘smart bandage’ for early diagnosis
- Map pressure-induced tissue changes

SL Swisher et al. Nature Communications 2015
Impedance Spectroscopy

• Rat model
  – Magnet induced damage
  – 1 or 3 hour

• Ischemic event
• Reactive hyperemia
• Tracked for 3 days post injury

SL Swisher et al. Nature Communications 2015

Impedance Spectroscopy

• Impedance correlated with tissue health
• Histological cross-sections
  – Alteration of cell membranes and tissue structure cause the observed impedance changes
• Tissue Tolerance relationship to impedance
• Data needed to build parameters for humans

SL Swisher et al. Nature Communications 2015
Impedance Spectroscopy

- Detected early damage
- Location
  - Specific sites
  - Full body
- Cost
- Validity

SL Swisher et al. Nature Communications 2015

Non-Invasive Tissue Imaging

- Ultrasound
- Temperature/Infrared
- Laser Doppler
- MRI
- others
Tissue Visibility

• What are we looking for?

• EARLY
  Microstructural changes

• Early US work looks like a hole and kind of late to the party
Histologic Sections

- Epidermis
- Dermis
- Subcutaneous
- Muscle

Collagen

- Major mechanical fiber in skin
- Alignment
- Dimensions
Collagen Remodeling

- Response to forces
  - Normal
  - Pathologic Condition
  - Wound Healing

Tissue Imaging

- Does the imaging match the histology?
- What are we looking for or at?
- Depth of injury?
- Dermal, epidermal?
- What about DTPI?

Ultrasound Studies

- Hard to read if novice, research limitations – evolution of injury
- Limitations of research
- Ethical considerations
- Cost?
- Speed?
- How Often?
US of Pressure Injury

- **Phase 1:** pockets of edema in the tissue between the bone and the dermis, such as in the subdermal tissue
- **Phase 2:** the spread of the edema by direct extension into the dermis
- **Phase 3:** increased subdermal edema with frank dermal edema and subepidermal edema or pooling of fluid.

Quintavalle PR, Lyder CH et al. Ad Skin Wound Care 2006

Deep Tissue Ultrasound

- Intermediate-frequency (10-MHz)
- 12 subjects
- Abnormal US findings in deep tissue of individuals with pressure injuries
- 1,2, Unstageable pressure injuries present

Deep Tissue Ultrasound

- Followed injury progression
- IV, Healed, Unstageable
- No DTPI developed or were tracked
- Discontinuous fascia may predict progression of pressure injury


Ultrasound and Thermography

21 patients with 28 pressure injuries

- Stage 1 or 2 initially
- Tracked for 1 week

Nakagamo G et al. Wounds 2011
Ultrasound and Thermography

- Deep tissue
  - High on thermographic assessment
  - Heterogeneous hypoechoic area findings

- Injury with an unclear layered structure and increased temperature
  - Risk of delayed wound healing or wound deterioration was 6.85 times higher

  Nakagamo G et al. Wounds 2011

US vs MRI

- MRI Gold Standard
- Is it realistic?
- When would we do?
- Transport
- Cost
US vs MRI

- 6 subjects
  - 2 w/o SCI, 2 w/ recent SCI, 2 with long-term SCI
- Confirm ultrasound as an imaging modality for acquiring measurements of internal anatomical features associated with DTPI risk
- Ultrasound imaging is a viable methodology for measuring the unique bone and soft tissue features that affect the risk of deep tissue injury

Akins JS. Med Eng and Physics 2016

Dilemma

- If we don’t know what we are looking for, how do we know when or how to measure it?
Need more research

- Ongoing work
- Technology developing may make visual assessment obsolete or enhance it

Staging is not the end

- Staging is the start
- Call to action – CMS
- Action item based on staging
- What will we do –
- How will it impact how we treat / prevent / study?
International Support for Revised Staging System

- Survey
- Canada and Some Latin America Countries
- Overall 80% consensus from respondents

The National Law Review

- January 9, 2017

Recommend providers of pressure injury treatment take note of these recent changes and incorporate the new terminology and staging system into their diagnoses and treatment moving forward.
- Integrate these changes into their patient charts and any facility specific wound documentation
- Proper wound classification contained within the patient's chart will permit a party to use the patient's treatment records as evidence of the severity of the patient's wounds over time. This evidence coupled with documented proof of the administering of the recommended wound care treatment will permit any party to present a high-quality defense to any pressure injury lawsuits that may arise.
Thank You!!

Questions?