Reliability, validity & clinical use of Functional Pain Scale-hospital version (FPS-hv) for inpatients with chronic pain

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Conflict of Interest Disclosure

- A. Arnstein, No Conflict of Interest
- B. Gentile, No Conflict of Interest
- C. Wilson, No Conflict of Interest


“...the unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right.” (p.47)

1.1. To achieve vital improvements in the assessment and treatment of pain will require a cultural transformation.
Chronic Pain, the Public Health Crisis

- 126 Million Americans afflicted with recurrent pain > 3 mo.
  - 25 Million daily chronic pain
  - 23 Million pain strong enough to interfere with health & functioning
  - 11 Million high impact chronic pain
    - Category 4 has (mean) 6 comorbidities vs. Category 1 ≤ 1 comorbidity
- Leading burden of disease (WHO)
  - Lower back & neck pain #1 x 35 years
  - Afflicts 900 million people worldwide, at a toll of 95 Million YLD
- Cost in 2008 estimated at $35 Billion / year
  - Healthcare & disability
- What percentage of hospital patients have chronic pain?

Background and Significance

- Inadequate assessment contributes to poor pain control
  - Under-treatment, overtreatment or failure to treat
- Focusing only on intensity is inadequate
  - Ignores its impact on biopsychosocial functioning
- Important to use of reliable, valid biopsychosocial pain tools
  - Focus reassessment on how pain impairs physical function

Challenges & limitations of 1-dimensional pain assessment tools in hospitals

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<th>Numerical Pain Scale</th>
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<th>Verbal Descriptive Pain Scale</th>
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Challenges & limitations of assessing chronic pain patients in hospitals

- Pain intensity not a sensitive measure
- 30% pain reduction possible for only 1/3 of patients
  - May not be sustainable
  - 1 point difference on 0-10 scale considered “clinically meaningful”
- Pain-related functional impairment is problematic
- Disuse, deconditioning & complications of immobility
- Inability to participate in rehabilitation efforts
- Delayed discharge, disposition to institution, readmission
- Psychosocial effect of functional impairment
- Can’t “fix” a chronic disease with Acute Care Hospitalization

Prevention Approach to Chronic Pain (NPS, 2016)

- Primary Prevention
  - Prevent painful illness, injury, painful procedures without pre-treatment
  - Screen for past exposure to pain, SUD, & treatment response (tailor therapy)
  - Expedient, effective resolution of acute pain using multimodal methods
- Secondary Prevention
  - If signs/symptoms of chronic pain syndromes emerge
    - Initiate evidence-based pharmacologic & non-drug therapies
    - Consider referral to an appropriate specialist
    - Refine treatment plan based on patient responses, preferences, culture & risks
  - Evaluate SUD risks, S/Sx of SUD before Opioid Rx/refill
- Tertiary Prevention
  - Provide education & counseling to lower risk of disability & depression
    - Engage in self-management strategies that promote ability to function & cope
    - Use medications as prescribed; abstain from self-medicating with alcohol/drugs
  - Recognize/treat chronic pain as a chronic disease requiring specialty services, social support and use of self-management strategies

Preventing “High Impact Chronic Pain”

- High Impact Chronic Pain has a substantial impact on ability to perform work, social & self-care activities for ≥ 6 months
- Nurse-led actions improve biopsychosocial functioning
  - 20-30% improvement in pain, disability, depression
  - 40% improvement in pain self-efficacy
  - Outcomes (except self-efficacy) sustained at 1 year

Past use of the Functional Pain Scale

• Validated in elderly with permission to use clinically 1-3
  • New scoring option (0-10) available
    • Odd scores to accommodate MDS 0, 1, 3, 5, 7, 10.
    • Discussed MGH revised scoring with Dr. Gloth

• Clinical use in hospitalized adults
  • Nurses, patients & family find it easy and meaningful
  • Nurses particularly like for patients they question validity of NPS
  • Responsive to improvements in chronic pain patients.


Need to validate Functional Pain Scale as revised for hospital use

• Scope and Standard of all nurses’ practice
  • Reduce pain, alleviate suffering, maximize functional capacity
  • Functional Pain Scale listed as a validated tool for teens & adults
  • Intensity dimension alone inadequate to guide therapy
  • Standard elements of reassessment
  • Analgesia, Activity, Adverse Effects (including aberrant behaviors)
  • 2018 TJC Pain standard includes improved functioning as a standard measure of treatment success

1. ANA/ASPNNCP (2016). Pain Management Nursing: Scope and Standards of Practice (2nd Ed.). Silver Spring, MD

Purpose of the Study

• Primary Aim:
  • Test psychometrics of FPS in hospitalized chronic pain patients
  • Test-retest reliability
  • Validity compared to other standard pain measures

• Secondary Aim:
  • Evaluate utility, ease of use by nurses (email survey)
  • Identify advantages and disadvantages of FPS in current state
Methods

- A prospective IRB-approved pilot study
- 93 hospitalized adults with chronic pain.
- Initially patients were included only during first 24 hours
  - Due to low enrollment, this requirement was dropped
- Data were collected from validated pain scales:
  - Functional (FPS), Numeric (NPS), Biopsychosocial measure (PEG), and Quality of Pain Care (APS-POQ-r) scales.
  - Test-retest reliability & construct validity were tested using standard correlation methods
  - Descriptive statistics examined, reported where applicable

Methods at Aurora Health Care

- Methods
  - Population studied and Research Methods (MGH & Aurora Health Care)
- Instruments
- Statistical Analysis

Instrument validity

How valid is the measurement?

- **Face validity:**
  - Does it appear to professionals as a valid way to measure pain?

- **Criterion related validity ("instrument validity"):**
  - How does it compare to other measurements of pain intensity?
    - Convergent = high associations with other measures of pain intensity
    - Divergent = low associations with measures different from pain intensity

- **Content validity:**
  - Did it measure what it was supposed to (pain intensity)?

- **Construct validity:**
  - Does it concur with the theoretical concept measured?
  - Are high ratings associated with interference with biopsychosocial functioning?
Reliability:
Have the same results on repeated measures?
Consistency or repeatability of your measures

- **Test-retest** Measures stability.
  - Are pain scores at start & end of a 15 minutes interview stable?
- **Inter-rater**: Extent to which 2 raters agree, how consistent are different raters in obtaining the same score?
  - MGH 2 data collectors
    - 90% agreement on 10 patients

Validity & Reliability of NPS

- **Numeric Pain Scale** (Standard for comparison in many studies)
  - Standard clinically used pain scale
  - Strongly correlated with VAS, the gold-standard research tool
    \( r = 0.85 - .95, p < 0.001 \)
  - Strongly correlated with VDS and FPS-R; other widely used measures of pain intensity
  - Validity, reliability & sensitivity well studied in many populations
### Functional Pain Scale (FPS) Validation

- Development and Psychometrics (0-5 scale)
  - Validity, reliability & responsiveness established (100 elders)
    - Test Retest and interrater reliability excellent \( r = 0.97 \)
    - Numeric Pain Scale least reliable in population studied \( r = 0.18 \)
    - Concurrent Validity with PPI \( r = 0.9 \) and NPS \( r = 0.85 \)
    - FPS was more responsive to change than VAS, PPI, MPS-SF, & PPI

\( VAS = \) Visual Analog Scale; \( PPI = \) Present Pain Intensity; \( MPS-SF = \) McGill Pain Scale Short Form; \( NPS = 0-10 \) Scale


### Validity & Reliability of PEG

- **PEG Scale** (recommended in CDC Guidelines for chronic pain measurement)
  - Derived from BPI, used around the world for >30 years
  - Measures Pain, Activity and Affect domains (5-10 minutes to administer)
  - PEG uses 3 BPI-SF questions
  - Reliability \( a = 0.73 - 0.89 \) in different studies
  - Construct validity: \( r = 0.60 - 0.95 \) in 2 studies
  - Sensitive to change over 6 month period
  - ASKS: “On a scale of 0-10” ...
    1. What number best describes your pain on average in the past week?
    2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?
    3. What number best describes how, during the past week, pain has interfered with your general activity?


### Validity & Reliability of APS-POQ-r

- **American Pain Society Patient Outcomes Questionnaire–R**
  - Reliability \( a = .85 \)
    - Subscales: Affective/Activity interference/Pain \( a = .82 - .83 \)
    - Construct validity: per principal component factor analyses, contrasting groups and prediction modeling
    - Sensitivity to change not tested
  - Dimension of Pain tested
    - Pain severity and relief;
    - Impact of pain on activity, sleep & negative emotions;
    - Side effects of treatment;
    - Helpfulness of information about pain treatment;
    - Ability to participate in pain treatment decisions;
    - Use of non-pharmacological strategies.

APS-POQ-r Dimensions of Pain Quality

- Pain severity and relief;
- Impact of pain on activity, sleep & negative emotions;
- Side effects of treatment;
- Helpfulness of information about pain treatment;
- Ability to participate in pain treatment decisions;
- Use of non-pharmacological strategies.

MGH Tools Use by Nurses

- First-line tool is 0-10 NPS
- Among second-line tools:
  - 48% used the Functional Pain Scale
  - 32% used Simple Descriptive
  - 14% used Faces Pain Scale – revised
  - 5% PAINAD (Advanced Dementia)
  - 1% Nociceptive Pain Scale (comatose of MCS)

MGH Participant Recruitment

- First inquired about chronic pain admits past 24Hrs
- Created an Epic-based Severe Pain Report
  - Identified patients with severe pain
  - Reached out to CNS or other nurse-leader for inclusion criteria
  - Permission from RN to approach patient
  - Describe study and waiver of consent
  - With assent, interviewed patient
  - Initial plan to follow up with subset in 24 hours dropped
Study Subjects (N=93)

- Subject mean age was 50.6 (range 21-81), half were female
  - Half were female; & 73% were Caucasian
  - Education: 35% High School; 28% some college; 37% BS-PhD
  - 46% were hospitalized for pain control.
    - Back pain = 11; Infection ? IVDU = 9; Alcohol/SUD = 6
  - Pain intensity was moderately severe NPS = 6.6 (SD 2.4)
  - Mean FPS-hv scores = 5.7 (SD 1.8)
    - Intolerable & interferes with activities that required exertion

Test-Retest Reliability

- Numeric Pain Scale
  - Excellent (r = .91; p < .01)
- Functional Pain Scale-hospital version (FPS-hv)
  - Good (r = .84; p < .01)

Correlation interpretation (Pearson r)
- 0.8 – 1 = Very Strong
- 0.6 - 0.79 = Strong
- 0.4 – 0.59 = Moderate
- 0.2 – 0.39 = Weak

Convergent Validity of the Functional Pain Scale-hospital version (FPS-hv)

- Correlations between FPS-hv scores and ...
  - Pain intensity
    - NPS – FPS-hv r=.75 (p<.01) - strong correlation (Pearson r)
    - PEG – FPS-hv r=.34 (p<.01) - weak correlation (Spearman’s rho)
  - Functional Status (FPS-hv to items on APS-POQ-r)
    - In-bed activities r=.30 (p=.003) weak correlation (Spearman’s rho)
    - Out of bed activities r=.52 (p<.001) moderate correlation (Spearman’s rho)
Discriminant Validity of FPS-hv to affective dimension of chronic pain

- Weak correlations between FPS-hv and ....
  - Pain-related anxiety: $r=.27$ ($p<.01$)
  - Pain-related depression: $r=.23$ ($p=.02$)
  - Pain-related fear: $r=.26$ ($p=.02$)
  - Pain-related helplessness: $r=.34$ ($p<.01$)

- FPS item #2 (Tolerability)
  - Not correlated with fear, or depression
  - Weakly correlated to:
    - Anxiety $r=.22$ ($p=.03$)
    - Helplessness $r=.29$ ($p<.01$)

Results at Aurora Health Care

- Methods
- Population studied and Research Methods (MGH & Aurora Health Care)
- Instruments
- Statistical Analysis

Secondary Analysis of APS-POQ-r items

- Non-drug methods
  - 26% never encouraged to use
  - 46% sometimes encouraged to use
  - 28% often encouraged to use
  - 82% used at least 1 non-drug method

- Participation in treatment planning
  - 26% did not participate in treatment planning
  - 40% participated to varying degrees in treatment planning
  - 34% participated in treatment planning as much as desired

- Satisfaction with Pain Relief (Median Satisfaction = 6/10)
  - 0 = Extremely dissatisfied (15%)
  - 10 = Extremely satisfied with relief (23%)
    - Participation in treatment accounted for 49% of the variance in patient satisfaction
Discussion

• Tool Performance as used
• Clinical Examples
  o Older adult surgical patient
  o Renal failure patient with suspected SUD
• Challenges encountered with PEG and APS-POQ-r scales
  o Challenges encountered with clinical application
    ➢ Training nurses in its use
    ➢ Clinical utility
    ➢ Documenting discrepancies between FPS-hv and NPS

General conclusions about the FPS-hv

• Good reliability and validity as a pain intensity measure for adults with chronic pain
• Strongly correlates with pain intensity & the extent pain interferes with functioning
• Weakly correlates to emotions commonly linked to chronic pain
• Nurses generally like & use the FPS-hv tool
  o 60% indicated it guides discussions about goal-directed therapy
  o 40% not as easy or accurate as NPS
• Scoring between 4-6 difficult to quantify
  o Suggest re-wording of score = 5

Original FPS-hv Scoring

0 = no pain
2 = tolerable pain: able to perform activities of daily living
4 = able to tolerate some activities: pain prevents some “active” activities, such as walking, ADLs, etc
5 = intolerable: able to perform some, but not all “active” (usual) activities
6 = intolerable: Interferes with most “active” but not passive activities, such as reading, watching TV
8 = intolerable: Interferes with all “active” and most passive activities such speaking about pain
10 = intolerable: patient is unable to do anything or even speak due to their pain
Suggested Refined FPS-hv Scoring

0  = No pain
2  = Tolerable pain: able to perform all activities permitted
4  = Tolerate pain: able to perform some permitted activities: pain prevents full engagement in rehabilitative activities
5  = Tolerable pain that becomes intolerable and interferes with physically demanding activities (e.g. Physical Therapy)
6  = Intolerable: interferes with most activities requiring physical exertion, but not passive activities, such as reading, watching TV, talking
8  = Intolerable: Interferes with all "active" and most passive activities such speaking about pain
10 = intolerable: patient is unable to do anything or even speak due to their pain

Further Study Needed

• Different populations of hospitalized patients
  o Nature & severity of illness / injury
  o Comorbidities, including SUD
  o Acute (e.g. post-operative) pain
  o Patients who are frail or disabled at baseline
• Comparisons to other standard measures of functioning
  o Standardized Patient-reported Outcome measures
  o Standardized objective clinical measures (mobility, strength, endurance)
  o Independence in ADL, progress toward healing/rehabilitative goals
• Can it improve patient experience with pain relief?
  o Engagement/participation in treatment planning
  o Satisfaction with relief and care provided
  o Improved self-management efforts

Intra-agency collaboration challenges
MGH - Aurora Health Care
Thank you Collaborators

- Deb Gentile, PhD, RN-BC; Senior Research Scientist
  - Aurora Health Care
  - ? Inclusion of Cindy Anderson MSN, Christian Cottingham, RN, Kirsten MacGrath, RN, Nicole Mroczynski, RN, and other RN collaborators?

- Marian Wilson, PhD, MPH, RN-BC | Assistant Professor
  - Washington State University College of Nursing
  - ? Inclusion of Psychometrician

- Maggie Florence RN; Research Assistant Massachusetts General Hospital (MGH)
- Elaine Mandell RN; Jack Miles RN; study staff MGH