A Research Journey to Improve Outcomes of Patients with Chronic Heart Failure

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CNS, Kaufman Center for Heart Failure
Objectives

• Discuss my experiences in nursing research related to management of heart failure
  — The good, the bad
  — Mistakes and ah-ha moments

Disclosures

• None, related to this presentation
My Research Journey - 2 Paths
• Nurses *knowledge about* heart failure self-care principles
• Nurses *comfort in* educating patients about heart failure self-care principles
• *Frequency in* which hospital nurses educate patients about heart failure self-care principles
Clinical Experiences Shaped New Research

• In 1999… was discussing self-care principles in heart failure with nurse leaders and educators (hospital & home care):
  – Developing a HF handbook
  – Calcium channel blockers
  – Physician failure to respond to home care nurse concerns
Clinical Experiences Shaped New Research

- Clinical influences by *patients*:
  - When delivering education, listened to messages from patients:
    - Rinses canned corn and hotdogs
    - Eating watermelon when on a tight fluid restriction
    - Guessing Na+ intake
    - Does not follow diet plan when eating out
      - Ate out 3-4 days/week
Clinical Experiences Shaped New Nursing Knowledge

- Completed a RoL (1999)
- No reports on nurses knowledge of HF education principles
  - Physicians, administrators and nurses ASSUMED nurses:
    - Know what they are talking about when educating patients
    - Understand guideline-directed medical therapies content on self-care
Program of Research Evolved

• Developed a tool that measured nurses knowledge of heart failure self care principles
  – 20-items; Y/N response set
  – Checkbox if you want more info on topic
  – Content validity testing
  – Heart failure handbook team support; assisted in getting RNs to complete paper survey anonymously
Nurse’s Knowledge - 6 studies

Kalowes P et al. *Heart Lung* 2011;40:362 (A)
Translation: Developed RN Education Program
- Mandatory for CICU, HF-ICU and Tele RNs
Discoveries Lead to New Research

• Unable to determine the depth and breadth of HF self-care knowledge on different themes with only 20 questions and Y/N responses
  —Needed to learn strengths and weak areas for each self-care theme to:
    —Develop focused interventions
    —Spend time and $ on interventions

Knowledge ≠ Action
Discoveries Lead to New Research

Comfort and frequency in delivering education

• **Comfort scale**: 1, *completely uncomfortable* to 7, *completely comfortable* (standardized to 0-100)
• **Frequency scale**: 0, *never*; 10, *always* (0-100%)

  - 8 themes; 44 items:
    - Medications (10 items)
    - Low sodium diet (7 items)
    - Activity/exercise (6 items)
    - Fluid restriction (3 items)
    - S/Ss of worsening condition (4 items)
    - Daily weight monitoring (4 items)
    - S/S of fluid overload (4 items)
    - HF illness beliefs (6 items)
Heart Failure Hospital Nurses Need HELP to Educate Patients

Typical Amount of Time Spent Providing HF Discharge Education

- 43.5%
- Time, minutes; N = 118

# RESULTS

<table>
<thead>
<tr>
<th>Comfort Factor*</th>
<th>n</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>118</td>
<td>81.4 (11.3)</td>
</tr>
<tr>
<td>Weight monitoring</td>
<td>117</td>
<td>90.0 (12.0)</td>
</tr>
<tr>
<td>Signs/Symptoms of worsen condition</td>
<td>117</td>
<td>88.8 (11.8)</td>
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<tr>
<td>Signs/Symptoms of fluid overload</td>
<td>116</td>
<td>88.5 (12.2)</td>
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<tr>
<td>Fluid restriction</td>
<td>117</td>
<td>88.3 (12.7)</td>
</tr>
<tr>
<td>HF beliefs</td>
<td>117</td>
<td>83.2 (14.9)</td>
</tr>
<tr>
<td>Low sodium diet</td>
<td>117</td>
<td>80.0 (14.5)</td>
</tr>
<tr>
<td>Medications</td>
<td>117</td>
<td>78.0 (13.8)</td>
</tr>
<tr>
<td>Activity / exercise</td>
<td>117</td>
<td>73.0 (19.3)</td>
</tr>
</tbody>
</table>

*, responses of comfortable or very comfortable
Medications

## RESULTS

<table>
<thead>
<tr>
<th>Comfort Factor*</th>
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<td>71.5 (29.0)</td>
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<td>88.8 (11.8)</td>
<td>S/S fluid overload</td>
<td>116</td>
<td>70.1 (30.5)</td>
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<tr>
<td>S/S fluid overload</td>
<td>116</td>
<td>88.5 (12.2)</td>
<td>Weight monitoring</td>
<td>117</td>
<td>69.8 (29.8)</td>
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<tr>
<td>Fluid restriction</td>
<td>117</td>
<td>88.3 (12.7)</td>
<td>Fluid restriction</td>
<td>116</td>
<td>68.5 (29.2)</td>
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<tr>
<td>HF Beliefs</td>
<td>117</td>
<td>83.2 (14.9)</td>
<td>HF Beliefs</td>
<td>117</td>
<td>59.9 (29.4)</td>
</tr>
<tr>
<td>Low Na+ Diet</td>
<td>117</td>
<td>80.0 (14.5)</td>
<td>Medications</td>
<td>116</td>
<td>56.8 (25.5)</td>
</tr>
<tr>
<td>Medications</td>
<td>117</td>
<td>78.0 (13.8)</td>
<td>Low Na+ Diet</td>
<td>117</td>
<td>48.0 (29.2)</td>
</tr>
<tr>
<td>Activity/Exercise</td>
<td>117</td>
<td>73.0 (19.3)</td>
<td>Activity/Exercise</td>
<td>117</td>
<td>42.7 (29.4)</td>
</tr>
</tbody>
</table>

Cond., condition; S/S, signs/symptoms; *, responses of comfortable or very comfortable **, completed 70-100% frequency

Many interventions:
- Revised patient “HF handbook”
  - Added “how to” details in self care
- Revised videos; included more self-care content
- PharmD's: 1:1 hospital medication
- 2x workshops/educations
- CNS, PharmD, and dietician
  - Group HF classes 3x/wk
- 1 pg HF “zones” pt. handout w a toll free phone line
- Mandatory RN on-line education module
  - Focus: diet, medication, activity/exercise and weight monitoring
2 of 9 recommendations to clinicians:
- Ensure qualified and trained HF nurse/other providers deliver HF services
- Allot adequate time in hospital and post-discharge to deliver complex interventions and assess patient and caregiver responses
Improving Heart Failure Outcomes

Patients:
• RCT: video education
• Comparative study: Common Sense Model of Illness Beliefs to educate patients pre-discharge
• RCT (pilot): 1000 mL fluid restriction x 6 weeks post discharge
• RCT (pilot): “Code RED” on adherence to 7 day follow-up appointment
• Descriptive research: Factors of activity/exercise non-adherence
• Correlation research: Whole body impedance and PAWP
• RCT: Innovative discharge intervention to ↓ 30-day re-admission
Video Education Discoveries

• Single center, RCT
• Some patients randomized to video education never even took the plastic wrap off the video
• No change in healthcare consumption between groups
• Video patients had:
  — Greater sign/symptom reduction \((P < 0.04)\)
  — Edema \((P < 0.01)\) and fatigue \((P < 0.01)\)
  — Initiated more actions for edema \((P < 0.05)\) and dyspnea (both \(P < 0.01)\)
  — Higher mean self-care behavior score \((P < 0.01)\), reflecting ↑ self-care adherence
Pt Education using the CSM

Comparative study (2 group, pre-post design)
- 244 subjects; 6 month follow-up
- Multivariate results:
  - Hospitalization:
    - Fewer 1st hospitalizations for decompensated HF
      - OR (95% CI): 0.54 (0.31, 0.97), \( p=0.039 \)
      - No differences in all hospitalization, hospitalization for HF or hospital LOS
  - ED care:
    - Fewer ED visits d/t HF decompensation
      - OR (95% CI): 0.29 (0.13, 0.62), \( p=0.001 \)
    - Unplanned office visits for HF care
      - No differences between groups

Fluid Restriction – Is it Independently Meaningful?

• Fluid restriction may be easier to manage than following a strict low sodium diet
  – Can develop easy systems of measuring and monitoring fluid intake
  – Can quench thirst with hard candy & suckers
  – No reading labels and counting sodium content

• Randomized, controlled pilot study
  – Patients followed x 6 weeks post discharge
  – Usual care, n= 26
  – Intervention group, n= 20


Physicians: fluid torture
# SALT-HF RESULTS

<table>
<thead>
<tr>
<th>Change in QoL Scores</th>
<th>1 Liter Group</th>
<th>Usual Care Group</th>
<th>P Value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Limitations</td>
<td>-16.7 (-32.5, -8.8)</td>
<td>-2.1 (-19.3, -14.4)</td>
<td>0.10</td>
</tr>
<tr>
<td>Symptom Frequency</td>
<td>-31.2 (-45.3, -17.2)</td>
<td>-8.3 (-37.5, 2.1)</td>
<td>0.044</td>
</tr>
<tr>
<td>Symptom Burden Sc.</td>
<td>-33.3 (-56.2, -18.7)</td>
<td>0 (-25.0, 8.3)</td>
<td>0.025</td>
</tr>
<tr>
<td>Total Symptom Score</td>
<td>-32.3 (-52.1, -20.3)</td>
<td>-5.2 (-29.2, 4.2)</td>
<td>0.026</td>
</tr>
<tr>
<td>Self-Efficacy Score</td>
<td>0 (-25, 0)</td>
<td>0 (-21.8, 9.4)</td>
<td>0.59</td>
</tr>
<tr>
<td>QoL Score</td>
<td>-25 (-41.7, -10.4)</td>
<td>-16.7 (-45.8, 12.5)</td>
<td>0.28</td>
</tr>
<tr>
<td>Overall Summary Sc.</td>
<td>-24.7 (-34.2, -11.9)</td>
<td>-6.7 (-29.1, 5.1)</td>
<td>0.050</td>
</tr>
<tr>
<td>Clinical Summary Sc.</td>
<td>-25.3 (-29.1, -12.4)</td>
<td>-6.7 (-24.5, 10.3)</td>
<td>0.044</td>
</tr>
</tbody>
</table>

*, Difference 60 D to baseline; **, Wilcoxon rank sum test

Fluid Restriction – Is it Independently Meaningful?

• Results:

Clinical QoL Summary by Fluid Restriction Group

Baseline

60-day Follow-up

UC (n=26) 1-L/D (n=20)  

p = 0.34  

UC (n=23) 1-L/D (n=18)  

p = 0.039

Fluid Restriction – Is it Independently Meaningful?

• Results:
  – Signals of < ED visits and HF rehospitalization

More research is needed.
HF Readmission in 30 Days 2007-2009; N=1,330,157

7 day-post discharge visit adherence rates were (< 50%)

- 13.4% of 30-day readmissions (Day 0 - Day 3)
- 31.7% of 30-day readmissions (Day 0 - Day 7)
- 61.0% of 30-day readmissions (Day 0 - Day 15)

329,308 rehospitalization; 24.8%

APN-Led RED Intervention

• “Code RED Card” pilot intervention
  – 3 education points + card w contact info, picture & visit info
    – **Risk:** early post-discharge vulnerable period
    – **Re-Evaluation:** need to assess if changes made in-hospital remain beneficial
    – **Readmission:** reduce return in 30 days
APN-Led RED Intervention

• “Code RED Card” pilot intervention

↓

• Results: 77% (Intervention) vs. 40% (Usual care) show rates; \( p=0.01 \)
  – Unknowns re important features of RED:
    – Card (contact info; knows who will be providing care)?
    – Belief that the person on the card was “waiting” for them to show?
    – 3 messages?
    – Individual attention to detail?

More research is needed
Activity and Exercise in HF

HF-ACTION: poor intervention adherence

GOALS:
>90 min/wk; [--------- > 120 minutes/week --------]

# Subjects adhering to exercise duration goal

1-3 months 10-12 months 22-24 months 25-36 months

Full adherence Partial adherence

(50% adherence)


Cleveland Clinic
HF-ACTION; N=959 Intervention Pts who were Event Free @ 3 Months

CV Mortality or HF Hospitalization

- Filled circles, adjusted logarithmic analysis, \( p<0.001 \);
- Open circles, unadjusted analysis

Percent of Time Spent in Different Activity Modes Over 6 Days: in Chronic Stable HF

NYHA III
- 72% Passive
- 17% Active
- 9% Walking
- 1% Fast walking

NYHA II
- 64% Passive
- 17% Active
- 14% Walking
- 3% Fast walking

NYHA I
- 61% Passive
- 14% Active
- 16% Walking
- 4% Fast walking

Daily total Wearing Time (min)

Activity and Exercise in HF

• When followed, activity and exercise improved primary outcomes

• Predictors of activity and exercise in HF were unknown

• Conducted a mixed-methods study
  —Qualitative study; 48 subjects, single center
  —Multicenter, international descriptive study; 6 sites
Seven Themes Related to Exercise Adherence (N=48; single site)

• Patients not knowing and physicians not telling
• Scared into doing or not doing it
• Life gets in the way
• Meaningful support versus meaningless talk
• Emotional connections to exercise
• Value did not always equal motivation to move
• Disconnection between self-confidence and actions

Patients not knowing and physicians not telling

What were you told by your doctor about exercising?

• Just very general things, “You should do this.”
• That I should start doing it. Nothing specific but, “Get out and walk.”
• They said, “You do whatever you want to do. If you don’t feel like doing it, don’t do it.”
• I think that on a gradual basis, it might strengthen my heart, but I’m not sure.
• My doctor said not to go overboard ‘cause my heart’s been compromised.
• To do what I felt like I could do and be comfortable.
• He kind of left it up to me to do what I wanted to do.
Since Instructions For Exercise were not Specific, Patients were not Clear on what “Exercise” Meant

- I am stretching my toes, my feet, and my arms and stuff like that.
- I do some degree of isometric and stuff like that.
- I walk to the grocery store and stuff like that. I walk the dogs out and chain them up.
- It’s all stretch, isometric stretching...in my living room or bedroom or kitchen or outside or wherever I feel like doing it.
- Some walking...to the corner store and back... like 10 minutes or longer.
Because patients were not told specifically what to expect, they were sometimes scared to do it.

- I reckon if I exercise too much, I’d have a heart attack.
- You can get short of breath, or you get tired, or like you can get chest pains, something like that.
- I get scared sometimes ’cause of my heart rate.
- I don’t want to bring on a heart attack.
- When you’re short of breath, you stay away from anything that’s going to cause you to breathe fast or even faster.
- I’m afraid that walking will cause my heart to beat fast and I’ll be laying out on the sidewalk.

## Quantitative Component; N=492

<table>
<thead>
<tr>
<th>General Factors</th>
<th>N</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Age, yrs; mean, SD</td>
<td>490</td>
<td>62.8 ± 13.55</td>
</tr>
<tr>
<td>BMI, mg/kg/m²; mean, SD</td>
<td>489</td>
<td>29.34 ± 6.73</td>
</tr>
<tr>
<td>Gender, male; n (%)</td>
<td>492</td>
<td>319 (64.8)</td>
</tr>
<tr>
<td>Lives with someone; n (%)</td>
<td>492</td>
<td>353 (71.7)</td>
</tr>
<tr>
<td>Caucasian; n (%)*</td>
<td>392</td>
<td>299 (76.3)</td>
</tr>
<tr>
<td>Highest education; n (%)</td>
<td>492</td>
<td></td>
</tr>
<tr>
<td>High school or less</td>
<td></td>
<td>232 (47.2)</td>
</tr>
<tr>
<td>Some college-bachelors degree</td>
<td></td>
<td>200 (40.6)</td>
</tr>
<tr>
<td>Masters or doctorate degree</td>
<td></td>
<td>60 (12.2)</td>
</tr>
</tbody>
</table>

*, Not obtained in Swedish sample; n=100
Odds of Moderate-Vigorous Exercise – of 18 Characteristics

<table>
<thead>
<tr>
<th>Factor; Level</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI; Quartiles</td>
<td>0.69</td>
<td>0.53, 0.89</td>
<td>0.005</td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td>0.51</td>
<td>0.34, 0.74</td>
<td>&lt;.001</td>
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<tr>
<td>Live with someone; Y vs. N</td>
<td>0.49</td>
<td>0.26, 0.92</td>
<td>0.029</td>
</tr>
<tr>
<td>HMO Insurance; Y vs. N</td>
<td>0.45</td>
<td>0.23, 0.86</td>
<td>0.018</td>
</tr>
<tr>
<td>CMS Payment; Y vs. N</td>
<td>0.59</td>
<td>0.35, 0.98</td>
<td>0.043</td>
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<tr>
<td>Smoker; Recent-current vs. never-former</td>
<td>0.46</td>
<td>0.25, 0.84</td>
<td>0.014</td>
</tr>
<tr>
<td>Health perception: Very good vs. good, fair &amp; poor</td>
<td>8.57</td>
<td>4.09, 19.18</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*, Wald test

Albert NM ©, 2015 Exercise Adherence
Predictors of Exercise Adherence

N = 492

- Patient characteristics / Exercise factors
- HF status/condition characteristics
- Psychological, social, environmental, economic, and others

Albert NM ©, 2015 Exercise Adherence
Activity-Exercise Discoveries

Translation and translation needs:
• Include better messaging to patients about:
  — Benefits; esp. when health is poor!
  — What to do
  — *HOW to do it*
    — Reinforce / repeat education
    — Increase self-confidence
• Educate RNs about discussing mobility and activity with patients
• Need: RCT of *natural walking* and other physical activities in the hospital & immediate post-discharge period and clinical outcomes
Next Steps

• Need to learn more about why healthcare team members no longer routinely mobilize and ambulate patients

• Need to develop an in-hospital intervention to increase mobility and ambulation among patients with HF
Impedance Monitoring in HF

- *Congestion* is our #1 problem related to hospitalization
- *Objective markers* (JVP, *S3 heart sounds*) have poor sensitivity, but good specificity
- *Subjective markers* are not well understood by patients
  - Cannot tell when symptoms get worse
PCWP & Mortality Post Vasodilator Tx

Total Mortality Risk (%) vs Months

- PCWP >16 mm Hg
  - P = .001
  - 0 months: 0%
  - 6 months: 10%
  - 12 months: 20%
  - 18 months: 30%
  - 24 months: 40%

- PCWP ≤16 mm Hg
  - 0 months: 0%
  - 6 months: 5%
  - 12 months: 10%
  - 18 months: 15%
  - 24 months: 20%

Fonorow G. Reviews CV Med. 2001;257
CI & Mortality HF Post Vasodilator Tx

Cardiac Index >2.6 L/min-M²

Cardiac Index ≤2.6 L/min-M²

Total Mortality Risk (%)

Months

Fonorow GC. Reviews CV Med 2001;257
Hypothesis: If CO/CI measurements by Thoracic Impedance were Accurate, would “Impedance” also be accurate?

Mean discrepancy (bias) between thermodilution & bioimpedance cardiac output was very small: 0.08 L/min (range, -0.18 to 0.35)

Concordance correlation coefficient of all 29 paired measurements was 0.89 (P < .001)
Hypothesis: If CO/CI Measurements by Thoracic Impedance were Accurate, would “Impedance” also be Accurate?

- Thoracic fluid content values and LV diastolic pressures were converted into quartiles
  - Hypovolemic
  - Normal volume
  - Moderate hypervolemic
  - Severe hypervolemic
- Correlation: $r=0.39; p=.02$
  - Statistically significant
  - Clinically, not strong enough to act
## Whole Body vs Thoracic Bio-Impedance

<table>
<thead>
<tr>
<th></th>
<th>Whole body Bio-impedance</th>
<th>Thoracic Bio-impedance</th>
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</thead>
<tbody>
<tr>
<td><strong>Patient Connection</strong></td>
<td><img src="image1.png" alt="Whole body connection" /></td>
<td><img src="image2.png" alt="Thoracic connection" /></td>
</tr>
<tr>
<td><strong>Company/ Devices</strong></td>
<td>NI Medical – NICaS</td>
<td>Cheetah Medical, Osypka, Physioflowflow</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>Meet FDA guidelines for statistical bioequivalence</td>
<td>Does not meet FDA guidelines for statistical bioequivalence</td>
</tr>
<tr>
<td><strong>Reproducibility</strong></td>
<td>Very good, Strong and clean signal detected from the periphery</td>
<td>Compromised due to competing signals in the thorax area from aorta, lungs, atria, vena cava and artifacts due to heart movements</td>
</tr>
<tr>
<td><strong>Disposables cost (per application)</strong></td>
<td>Low (require only 2 sensors)</td>
<td>High (require 4 sensors)</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td>5 min by technician, No need to undress</td>
<td>15 min by technician, Need to take off shirt</td>
</tr>
</tbody>
</table>
Whole Body Impedance

• PAWP and whole body impedance
  – N = 57 patients
  – Bland-Altman mean (SD) difference:
    – Total body water:
      – -29.7 (12.2)%; p < .0001

• Summary:
  – There is no agreement between PAWP measurements of total body water
Informal Caregivers

• Play critical “roles” in effective management of HF
  – Contribute to self care
  – Provide social and emotional support
• But… what does that really mean?
Current “Supporter” Research

*Design:* Longitudinal comparative, 2 cohorts

- **Patients & supporters;** baseline and 90 day follow-up; *multiple research themes:*
  - **Patients:** (1) relationships with partners, (2) actual roles carried out in general and related to HF self-care, (3) thoughts and feelings about roles in HF, (4) health perceptions of self, and (5) characteristics
  - **Care partners:** 1 - 5 + perceptions of the patients’ functional status and services received, support from health care providers, burden, quality of life
Current Intervention Research

• IT person pitched a great idea about a potential way to decrease 30-day rehospitalization
• Involved developing a model and getting buy-in from a corporate partner
  – Found corporate partner who created a prototype and had 1000 samples made
• RCT in progress; need 1000 patients to observe meaningful differences in 30 day rehospitalization
  – Will complete an interim analysis after 500 enrolled to assess statistical trends
Thoughts About the Journey

• Collaborate with colleagues
• Develop partnerships
• Be willing to take a rocky or slippery road
• Make lemonade from lemons
• Use clinical practice and current/new knowledge to develop research ideas
  —Get input from others
My Research Journey

Collaboration ⇔ Make Friends … Engaging Experiences ⇔ Improve lives of patients
FUN