Outpatient Palliative Care: Oxymoron or Innovation?

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Objectives

• To discuss the relevance of palliative care to contemporary oncology practice
• To present preliminary baseline data from an RCT of early vs. usual palliative care involvement
• To discuss socio-demographic determinants of health-related quality of life (HRQL) in patients with advanced cancer

WHO definition of palliative care

• “an approach that improves the quality of life of patients and their families…”

• by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual” (WHO, 2003)

CCO Palliative Care Program Goals

1. Seamless integration of palliative care into the overall patient care system of the Regional Cancer Programs (RCP)

2. Coordination of RCP palliative services with the regional EOL Care Networks

3. Ensure RCP palliative services are of consistently high quality
Principles of palliative care

• Pain and symptom management as central
• Holistic care
• Multidisciplinary team
• Family as the unit of care
• Emphasis on community linkages and home care

UHN Palliative Care Program organizational structure

• Consultation service
  – Inpatient consultations (TGH, TWH, PMH)
    • Inpatient wards, emergency room
  – Outpatient consultations (PMH)
    • Scheduled appointments to palliative medicine clinic
    • Urgent on-site referrals to outpatient clinics
• Palliative Care Unit
  – Admissions from home, hospitals, emergency

Referrals to UHN palliative care service
Palliative care clinics

- 15 half-day clinics weekly
- Staffed by physician, RN Case manager, social worker
- Referrals to other disciplines as necessary
- Completion at every visit:
  - Edmonton symptom assessment scale
  - Assessment of performance status
  - Referral check-list (CCAC, PCU back-up papers, specialists, home palliative care physician.)

Randomized Controlled trial of early palliative care

Targeted Interventions
- Mirtazapine for cancer cachexia
- Fentanyl for breakthrough pain

Cross-sectional studies
- Complementary therapy use
- Pain acceptance

Outpatient palliative care clinic

Research
- Pilot trial of palliative care team intervention
- Pain acceptance
- Pain interventions
- Mirtazapine for cancer cachexia
- Fentanyl for breakthrough pain

RCT of early vs. routine palliative care involvement

Quality Improvement (CCO)
- Symptom scoring
- Functional status
- Symptom clusters
- Collaborative care plans
- Referral check-list
- Prompt sheets for referral to home palliative care

Symptom correlation with time to death
- Symptom clusters
- Referral patterns
- Drug interactions

Costantini et al, J Pain Sympt M, 1999; Cristakis and Escarce, NEJM, 1996; Lamont and Cristakis, Cancer, 2002

Timing of palliative care involvement

- Palliative care team involvement for patients with advanced cancer and their families
  - Generally begins in the last 2 months of life
  - Patients usually have stopped chemotherapy

Timing of palliative care at PMH

- Approximately 30% of cancer deaths referred to UHN palliative care service
- Only 7% (11/151 deaths; 11/110 GI, 0/41 lung) were referred >6 months before death
Reasons for lack of early involvement of palliative care

- Territoriality, both on part of palliative care physicians and oncologists
  - (McGorty and Bornstein, J Eval Clin Pract, 2003)
- Discomfort discussing terminality
- Perception of defeatism
- No sound evidence that early referral results in better care for patients

Studies so far

- Few RCTs and those that have been done have been criticized for methodological reasons
- No completed Canadian RCT
- No trial examining early palliative care versus conventional care

Research Hypotheses

- Compared to conventional care, early intervention by a palliative care team in patients with metastatic cancer will be associated with:
  - (i) better patient health related quality of life (HRQL) (primary outcome measure)
  - (ii) greater patient and caregiver satisfaction with care; (iii) better symptom control; (iv) improved communication with health care providers; and (v) improved caregiver quality of life (ii-v are secondary outcomes)

Current study

- Design:
  - Stratified, cluster-randomized, controlled clinical trial
  - Unit of randomization: medical oncology clinic
  - Unit of inference: Patient/caregiver
- Population:
  - PMH patients with metastatic cancer;
  - prognosis > 6 months-2 years; ECOG ≤ 2
- Recruitment:
  - from 5 tumour sites: Lung, GI, GU, Breast, Gynecology

Intervention:

- Consultation and ongoing follow-up by the palliative care team
- Process evaluation measures: Palliative Care Assessment Checklist (for physicians); Log of telephone calls (palliative care nurse)

Control:

- Conventional care

Primary outcome:

- Health-related quality of life (FACT-G; FACIT-Sp; QUAL-E)

Secondary outcomes:

- Patient and family: Satisfaction with care (FAMCARE)
- Patient only (i) Symptom control (ESAS)
  (ii) Communication with health care providers (CARES: Medical Interaction Subscale)
- Family member only (i) Caregiver quality of life (Caregiver QOL Index-Cancer)
  (ii) Caregiver health and functioning (Medical Outcomes Study Short Form (SF-36))
Baseline Data Analysis

**Objective:** To examine the influence of demographic and disease-related characteristics on health-related quality of life (HRQL)

**Sample:** 172 patients participating in the cluster-randomized trial of early versus routine palliative care

Background: demographic determinants of HRQL

- Normative data for FACT-G and EORTC-QLQ-C30 shows older age and female gender is associated with worse HRQL
- Most other literature on cancer survivors
  - Younger survivors more likely to report ongoing symptoms than older survivors
  - 
Hjermstad et al, JCO, 1998; Fossa et al, Acta Oncol., 2007;

HQRL in advanced cancer patients

- Norwegian cluster-randomized trial (n = 395) using EORTC-QLQ-C30
- Older age associated with less sleeping disturbance, less pain and better emotional functioning
- Female sex associated with worse physical functioning
- No positive impact of living with a partner

Jordhoy et al, British Journal of Cancer, 2001

Baseline Data Analysis - Methods

- Baseline measures for HRQL (FACT-G, QUAL-E) and symptom burden (ESAS)
  - Mean comparisons: age, gender, living situation, education, family income, performance status (PS), and diagnosis
  - T-test and ANOVA with Tukey correction
  - Exploratory analysis using multivariate linear regression
HQRL scales

- FACT-G
  - Physical
  - Social
  - Emotional
  - Functional
- QUAL-E
  - Impact
  - Relationship
  - Preparation
  - Life completion

Baseline Data Analysis: N = 172

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>103 (59.9)</td>
</tr>
<tr>
<td>Mean Age yrs (min-max)</td>
<td>59.7 (23-88)</td>
</tr>
<tr>
<td>Median ECOG (min-max)</td>
<td>1 (0-2)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married/Common law</td>
<td>129 (75.0)</td>
</tr>
<tr>
<td>Single</td>
<td>21 (12.2)</td>
</tr>
<tr>
<td>Separated/Divorced</td>
<td>15 (8.7)</td>
</tr>
<tr>
<td>Widowed</td>
<td>7 (4.1)</td>
</tr>
<tr>
<td>Living alone</td>
<td>33 (19.2)</td>
</tr>
<tr>
<td>College/University education</td>
<td>124 (72.5)</td>
</tr>
</tbody>
</table>

Participants by Site n=172

- Lung 9%
- Breast 20%
- GYNE 19%
- GU 23%
- GI 29%

FACT-G: age differences

<table>
<thead>
<tr>
<th>FACT-G subscales (range)</th>
<th>Mean (SD)</th>
<th>General pop'n¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≤ 60 n = 86</td>
<td>Age ≥ 60 n = 86</td>
<td>Age ≤ 60 n = 662</td>
</tr>
<tr>
<td>Physical (0-28)</td>
<td>18.1 (5.8)**</td>
<td>21.0 (5.2)</td>
</tr>
<tr>
<td>Social (0-28)</td>
<td>22.7 (3.9)</td>
<td>22.3 (4.6)</td>
</tr>
<tr>
<td>Emotional (0-28)</td>
<td>16.4 (4.7)*</td>
<td>18.3 (4.5)</td>
</tr>
<tr>
<td>Functional (0-24)</td>
<td>16.7 (5.9)*</td>
<td>18.8 (5.4)</td>
</tr>
<tr>
<td>Total score (0-108)</td>
<td>73.8 (14.6)*</td>
<td>80.4 (14.5)</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>24 (14.0)</td>
</tr>
<tr>
<td>On disability</td>
<td>36 (20.9)</td>
</tr>
<tr>
<td>Employed</td>
<td>43 (25.0)</td>
</tr>
<tr>
<td>Retired</td>
<td>69 (40.1)</td>
</tr>
<tr>
<td>Household Income</td>
<td></td>
</tr>
<tr>
<td>&lt; $14,999</td>
<td>4 (2.3)</td>
</tr>
<tr>
<td>$15,000 – 29,999</td>
<td>10 (5.8)</td>
</tr>
<tr>
<td>$30,000 – 59,999</td>
<td>28 (16.3)</td>
</tr>
<tr>
<td>&gt; $60,000</td>
<td>62 (36.0)</td>
</tr>
<tr>
<td>Not answered</td>
<td>68 (39.5)</td>
</tr>
</tbody>
</table>

FACT-G: gender differences

<table>
<thead>
<tr>
<th>FACT-G subscales (range)</th>
<th>Mean (SD)</th>
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<tbody>
<tr>
<td>Age ≤ 60 n = 103</td>
<td>Age ≥ 60 n = 69</td>
<td>Age ≤ 60 n = 447</td>
</tr>
<tr>
<td>Physical (0-28)</td>
<td>18.5 (6.0)*</td>
<td>21.0 (4.8)</td>
</tr>
<tr>
<td>Social (0-28)</td>
<td>23.0 (4.0)</td>
<td>21.8 (4.5)</td>
</tr>
<tr>
<td>Emotional (0-28)</td>
<td>16.2 (5.1)**</td>
<td>19.1 (3.5)</td>
</tr>
<tr>
<td>Functional (0-24)</td>
<td>17.1 (6.0)</td>
<td>18.6 (5.4)</td>
</tr>
<tr>
<td>Total score (0-108)</td>
<td>74.8 (15.6)*</td>
<td>80.5 (13.0)</td>
</tr>
</tbody>
</table>

* p<0.05   ** p<0.0005  ¹Holzner et al, Acta Oncol, 2004
FACT-G: performance status

<table>
<thead>
<tr>
<th>FACT-G subscales (range)</th>
<th>ECOG 0 n=76</th>
<th>ECOG 1 n=91</th>
<th>ECOG 2 n=5</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical (0-28)</td>
<td>20.9 (0.6)</td>
<td>19.0 (4.8)</td>
<td>8.3 (2.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Social (0-28)</td>
<td>22.7 (0.5)</td>
<td>22.4 (0.5)</td>
<td>21.1 (1.9)</td>
<td>0.703</td>
</tr>
<tr>
<td>Emotional (0-28)</td>
<td>17.8 (0.5)</td>
<td>17.2 (0.5)</td>
<td>12.8 (2.1)</td>
<td>0.066</td>
</tr>
<tr>
<td>Functional (0-24)</td>
<td>18.8 (0.6)</td>
<td>17.3 (0.6)</td>
<td>9.4 (2.5)</td>
<td>0.001</td>
</tr>
<tr>
<td>Total score (0-108)</td>
<td>80.2 (1.6)</td>
<td>75.8 (1.5)</td>
<td>51.6 (6.3)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

ESAS: gender and age differences

<table>
<thead>
<tr>
<th>Symptom (0-10)</th>
<th>Women n=103</th>
<th>Men n=69</th>
<th>Age &lt; 60 n=86</th>
<th>Age ≥ 60 n=86</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>2.5 (2.9)</td>
<td>2.2 (3.8)</td>
<td>2.9 (2.9)</td>
<td>1.9 (2.6)</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>1.7 (2.5)</td>
<td>2.1 (1.9)</td>
<td>1.8 (2.5)</td>
<td>1.9 (2.5)</td>
</tr>
<tr>
<td>Appetite</td>
<td>3.3 (0.0)</td>
<td>2.1 (1.9)</td>
<td>2.7 (2.7)</td>
<td>2.9 (2.9)</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.2 (2.1)</td>
<td>0.8 (1.7)</td>
<td>1.5 (2.3)</td>
<td>0.7 (1.5)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4.1 (2.5)</td>
<td>3.4 (2.5)</td>
<td>4.2 (2.4)</td>
<td>3.4 (2.6)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>2.3 (2.6)</td>
<td>2.4 (2.4)</td>
<td>2.8 (2.8)</td>
<td>1.9 (2.2)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>3.1 (2.8)</td>
<td>2.9 (3.0)</td>
<td>3.7 (3.0)</td>
<td>2.4 (2.6)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>2.4 (2.8)</td>
<td>1.5 (2.0)</td>
<td>2.6 (2.7)</td>
<td>2.5 (2.0)</td>
</tr>
<tr>
<td>Depression</td>
<td>2.1 (2.6)</td>
<td>1.3 (2.1)</td>
<td>2.2 (2.4)</td>
<td>1.4 (2.3)</td>
</tr>
<tr>
<td>Wellbeing</td>
<td>4.0 (2.6)</td>
<td>2.8 (1.9)</td>
<td>3.6 (2.4)</td>
<td>3.5 (2.5)</td>
</tr>
</tbody>
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ESAS: performance status

<table>
<thead>
<tr>
<th>Symptom (0-10)</th>
<th>ECOG 0 n=76</th>
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<th>ECOG 2 n=5</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.9 (0.3)</td>
<td>2.6 (0.3)</td>
<td>7.2 (1.2)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>1.5 (0.3)</td>
<td>2.1 (0.3)</td>
<td>4.0 (1.1)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Appetite</td>
<td>1.9 (0.3)</td>
<td>3.4 (0.3)</td>
<td>4.6 (1.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nausea</td>
<td>0.8 (0.2)</td>
<td>1.2 (0.2)</td>
<td>4.0 (0.9)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Fatigue</td>
<td>3.2 (0.3)</td>
<td>4.2 (0.3)</td>
<td>6.4 (1.1)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>1.8 (0.3)</td>
<td>2.5 (0.3)</td>
<td>5.8 (1.1)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Insomnia</td>
<td>2.7 (0.3)</td>
<td>3.2 (0.3)</td>
<td>3.6 (1.3)</td>
<td>0.432</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.8 (0.3)</td>
<td>2.1 (0.3)</td>
<td>5.4 (1.1)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Depression</td>
<td>1.4 (0.1)</td>
<td>1.9 (0.2)</td>
<td>5.2 (1.0)</td>
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<td>Wellbeing</td>
<td>3.0 (0.3)</td>
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<td>6.0 (1.1)</td>
<td>&lt;0.005</td>
</tr>
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</table>

Multivariate regression analyses

Poor performance status was associated with:
- worse HRQL (FACT-G, p < 0.0001)
- higher symptom burden (ESAS, p < 0.0001)
- more concern about death preparation (QUAL-E, p = 0.02)

Young age (< 60 yrs) was associated with:
- worse HRQL (FACT-G, p < 0.0001)
  - physical and emotional well-being p<0.001
- higher symptom burden
  ESAS: pain, nausea, depression, anxiety, drowsiness, p<0.005
- more concern about death preparation (QUAL-E, p = 0.0000001)

Female gender was associated with:
- worse emotional well-being (FACT-G, p=0.001)
- worse appetite and general well-being (ESAS, p<0.005)
Lower family income (< $30,000) was associated with:
  • worse social well-being
    (FACT-G, \( p=0.01 \))

Being on disability was associated with:
  • worse functional well-being
    (FACT-G, \( p=0.01 \))

• Living with others was associated with:
  • a higher sense of life completion (QUAL-E, \( p=0.001 \))
  • better social well-being (FACT-G, \( p=0.05 \))

• Being married was associated with:
  • better functional well-being \( (p<0.01) \)

• No differences between cancer sites for HRQL or symptom burden

Baseline Data Analysis - Conclusions

Socio-demographic characteristics are important determinants of HRQL in patients with metastatic cancer

Certain groups of patients may benefit more from early palliative care referral

Research is necessary to determine whether early referral can prevent/alleviate deterioration of HRQL as performance status declines

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