Recruitment and Retention in a Pilot Study of Pharmacogenomics and Pain Control in Palliative Care

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BACKGROUND

- Increasingly, research is aimed at identifying hereditary basis for inter-individual differences in opioid effects to explain altered efficacy and side effects in cancer pain management
- To date, a limited number of studies have examined relationship of genetic variants and pain relief to cancer pain control in palliative care settings

Study Aim

- To determine rates of recruitment and retention in a pilot study investigating genetic variants and their relationship to pain relief over time in cancer patients receiving palliative care

METHODS

Eligibility Criteria

- 18 years of age or older
- Able to speak and read English
- Newly referred to an outpatient palliative care clinic for pain management
- Had not undergone surgery within last three months and not scheduled to undergo surgery in next three months

Procedures

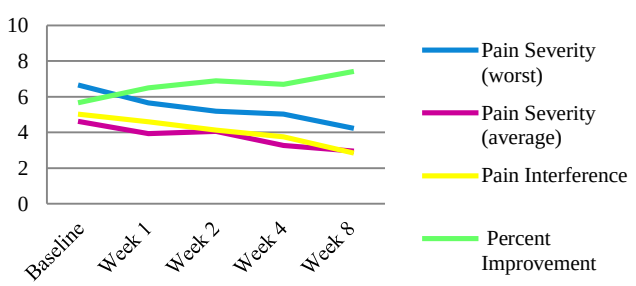
- Patients referred to clinic were screened for eligibility and approached during initial clinic visit
- Blood sample for genetic analysis was collected or scheduled and participants completed baseline assessment
- Participants were reassessed for pain and opioid side effects 1, 2, 4 and 8 weeks later

Measures

- Brief Pain Inventory-Short Form (BPI-SF)
- Pain Catastrophizing Scale (PCS) - *baseline only*
- M. D. Anderson Symptom Inventory (MDASI)
  - Modified to include additional opioid related side effects
- Demographic characteristics were obtained using standardized self-report questionnaire

RESULTS

Pain Ratings from Baseline to 8 Week Follow-up



Pain scores (0-10,10 = worst pain imaginable, e.g.) and pain relief (0-10, 10 = 100% relief) trended in the expected direction over study period

RESULTS

Recruitment & Retention

- In 18 months, 459 eligible patients were screened, 229 approached.
- Nearly half cancelled or no-showed for their initial clinic visit.
- One hundred twenty patients (M age = 55 years, female = 52.5%) were enrolled
- Baseline assessments were completed by 95%; 67.5% completed at least two follow-up assessments
- Pain catastrophizing marginally (p = .09) related to retention; higher catastrophizing – fewer assessments completed
- Blood samples were provided by 75% while on-study
- Approximately 26% were lost to follow-up, withdrew consent, or were discharged to hospice or died

Participant Characteristics

Demographic Characteristics		Medical Characteristics	
Mean age = 55 years		Stage III	17%
Range = 22 - 80 years		Stage IV	66%
Non-Hispanic	88%	Lung	16%
White/Caucasian	93%	Breast	12%
Married	54%	Sarcoma	7.5%
High School Graduate	93%	Ovarian	7%
Income ≥ 40K	57%	Leukemia	7%
Serving as a caregiver	8%	Other	50.5%

CONCLUSIONS

- High rates of no-shows/cancellations in outpatient palliative care clinic adversely affect recruitment
- Retention over eight weeks was moderately successful in this population
- Findings demonstrate feasibility and acceptability of examining genetic variants and their relationship to pain control in a palliative care setting
- Results have informed design of a prospective randomized trial examining genotype-guided versus usual care pain management in a palliative care outpatient clinic

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