PROpatient: a registry-based randomised controlled trial of symptom monitoring and care coordination to improve quality of life for patients with upper gastrointestinal cancer

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BACKGROUND

Patients with pancreatic (PC) and oesophagogastric (OGC) cancer have a dismal prognosis, with five-year survival of only 9.8 to just over 30%, even when detected early and treated aggressively (1). These cancers are characterised by high symptom burden, even in the early stage (2). It is critical that people with these cancers receive the best possible symptom control, while the search continues for treatments to improve survival.

AIMS

To determine if symptom monitoring, using patient-reported outcomes (PROs), integrated into clinical practice in real-time, via care coordination, improves health outcomes for patients with PC and OGC in high-volume hospitals in Victoria.

PRIMARY OBJECTIVE

To assess whether the PROpatient intervention improves health-related quality of life, as measured by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire core 30 (EORTC-QLQ-C30).

SECONDARY OBJECTIVES

To assess whether, compared to usual practice, the PROpatient intervention reduces health service use, emergency department visits, information needs, support needs, psychological distress and anxiety, and depression. These outcomes will be evaluated at baseline, 3-, 6- and 12-months. Due to the poor life expectancy of PC and OGC cancers, the primary endpoint will be 6-months.

METHODOLOGY

Patients participating in the upper gastrointestinal cancer registry (UGICR) who were diagnosed with PC or OGC at any of the n=12 participating health services in Victoria (including Cabrini Health) were eligible to participate.

Participants randomly allocated to the **control arm** receive usual, decentralised care as determined by individual health services.

Participants randomly allocated to the **intervention arm** receive frequent symptom monitoring and centralised nurse care coordination in addition to the usual care from their health service.

RECRUITMENT

1. Patients identified via the UGICR.
2. Patients contacted via telephone and screened for trial eligibility:
   - Participating in UGICR.
   - New diagnosis of PC or OGC.
   - Diagnosed/managed/treated at participating site.
3. Patients sent a PICF and followed up to obtain verbal consent.
4. Patients sent a *Personify Care* link, complete baseline questions, and are randomly allocated to the intervention or control.

198

Total participants recruited to the trial.

Intervention = 99

Control = 99

74

Participants with **pancreatic cancer**.

Intervention = 37

Control = 37

124

Participants with **oesophagogastric cancer**.

Intervention = 62

Control = 62

RESULTS

We anticipate that the PROpatient intervention will result in: improved quality of life, reduced anxiety and depression, reduced health service use and emergency department visits; lower level of information needs; and increased median survival.

Results of the trial will be disseminated in peer-reviewed publications and conference presentations.

SIGNIFICANCE

By using the UGICR as a platform for our randomised controlled trial (RCT), we hope to highlight the potential for clinical registries to assist with rapid participant recruitment, and effectively reducing associated effort and costs of RCTs.

The definitive role of integrating real-time PROs into clinical care and ongoing centralised care coordination in reducing unmet needs (in an Australian context for patients with PC and OGC) is unknown and, in the presence of such substantial needs, must be tested as a priority.

ETHICS

Ethics approval has been received from Monash Health under the National Mutual Acceptance scheme. Research governance approval has been received from all participating sites.

ACKNOWLEDGEMENTS

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REFERENCES

1. Australian Institute of Health and Welfare. Cancer in Australia 2019.
2. Beesley VL, et al. Psycho-Oncology; 2015, 19(5): 508-516.