presentations. Diagnosis of advanced pancreatic cancer is associated earlier opioid commencement. People with pancreatic cancer may benefit from routine early referral to palliative care services to coordinate complex pain management needs due to earlier pain presentations and shorter prognosis.

OP-8 A FEASIBILITY RANDOMIZED CONTROLLED TRIAL COMPARING OPIOID DOSE ESCALATION VS. METHADONE ADDITION FOR REFRACTORY CANCER PAIN

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10.1136/spcare-2024-ANZSPM.8

Background Cancer pain affects 38–85% of cancer patients, with higher incidence in advanced stages.[1] Poorly controlled cancer pain, often with neuropathic elements, presents a significant unmet medical need. Despite various opioid formulations, 47% of physicians report difficulties in managing opioid-refractory pain.[2] Methadone has shown superior efficacy to other opioids, such as morphine, especially for neuropathic pain poorly controlled by other opioids.[3] Currently, opioid escalation is the standard, but is often inadequate, and although the methadone add-on (AO) method has been reported to be safe and effective for refractory cancer pain, no randomized controlled trials (RCTs) have been conducted.

Aims This study aims to explore the feasibility of conducting a double-blind RCT to assess the efficacy and safety of the methadone AO method for opioid escalation in patients with cancer pain.

Methods This study is a single-facility, double-blind, parallel-arm RCT. A total of 22 patients will be enrolled between July 2024 and September 2025. Eligible participants are adults with unresectable advanced cancer experiencing refractory cancer pain on an appropriate dose of opioid analgesia (60–300 mg oral morphine equivalent daily dose, OMEDD) and a Karnofsky Performance Status (KPS) >50. Participants will be randomized (1:1) to the methadone AO arm or the standard treatment arm. Evaluations will be conducted at baseline (randomization), day 1, 8, and 15. In the methadone AO arm, patients will receive over-capsulated methadone 5 mg or 10 mg, and in the 5 mg group, placebo will be used to unify the twice-daily dosing of the study drug. In the standard treatment arm, patients will receive over-capsulated oxycodone 10 mg or 20 mg. The primary endpoint is the completion rate of the two-week study treatment, defined as 70% or more. Secondary endpoints include changes in BPI scores before and after the study treatment and adverse events.

Discussion Several considerations influenced the study design. First, the methadone dosage required careful determination. Previous studies suggest equivalence ratios of OMEDD 30–90 = 4:1, 90–300 = 6:1, and over 300 = 8:1. For this study, we set the morphine-to-methadone ratio at 6:1, which is safer than the 3:1 and 5:1 reported in other studies but less conservative than NCCN recommended 10:1. Second, the primary endpoint was defined as achieving a study completion rate of at least 70%. Although no prospective clinical trials exist, a Canadian cohort study (N=146) reported a continuation rate of 78.1% at Day 15 with a mean methadone dose of 6 mg. This data and discussions within our study group, led us to set a 70% completion rate. Finally, we chose a 2-week study period based on previous research: Mercadante et al. (n=108) found stable methadone doses over 4 weeks, and Bruera et al. (n=103) reported over 20% pain relief by Day 8 with no dose change between Days 14 and 28. Thus, 2 weeks is sufficient for efficacy and safety assessment. Based on the results of our study, we plan to conduct a larger-scale RCT of the methadone to establish a treatment for refractory cancer pain.

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OP-9 SHOULD WE GIVE UP ON LIDOCAINE TRIALS? IMPLICATIONS OF PRELIMINARY RESULTS OF THE LIDOCAINE FOR NEUROPATHIC CANCER PAIN FEASIBILITY STUDY (LICPAIN)

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10.1136/spcare-2024-ANZSPM.9

Background Lidocaine infusions are used variably around Australia to treat people with neuropathic cancer pain. The LiCPAIN trial aimed to determine the feasibility of conducting a double-blind randomised controlled trial of continuous subcutaneous lidocaine for neuropathic cancer pain. The primary objective was

Methods Palliative care inpatients at 5 metropolitan NSW sites were randomised to a 72-hour continuous infusion of subcutaneous lidocaine or placebo at 1–2mg/kg/hr, capped at 120mg/

kg/hr. Participants had cancer pain with neuropathic features, with a worst pain score of four out of ten or higher in the past 24 hours despite adequate trial of opioid and adjuvant analgesics. Exclusion criteria included increased risk of cardiac or neurological toxicity due to pre-existing conditions, altered metabolism and drug interactions. Efficacy and toxicity assessment informed infusion titration daily.

Results Seventeen participants were randomised out of 124 screened. The mean age was 64.1 years (SD=11.2) and 77% were female. The mean weight was 70.8kg (SD=23.3). The mean worst pain score at baseline was 7.8 (SD=1.2) with a mean daily oral morphine-equivalent regular opioid use was 189.2mg (SD=160.6).

The completion rate of study medication and procedures was 93% (95% confidence interval 5%) and 88% completed 72 hours of study medication. Four participants were randomised in the first eighteen months and it took 54 months to reach sample size.

There was no significant difference between the number of intervention and placebo participants who had a reduction of 1 or more points for worst pain on the BPI-SF (50% vs 57% p=0.77). The mean change in worst pain on the BPI-SF was –0.7 (SD=XX) in the intervention group and –2.0 (SD=XX) in the placebo group (p=0.23).

Discussion This study met the primary outcome demonstrating that it is feasible for randomised participants to complete the study medication and procedures. The high placebo response rate and wide confidence interval informs us that a large sample size would be required to power a definitive phase III study. This data suggests that while the study design is feasible once participants are recruited, the slow recruitment rate would necessitate a large number of sites and resources to determine the benefit of continuous subcutaneous infusion of lidocaine using this methodology. These results inform future clinical trials of lidocaine and other analgesics which may need to consider how to optimise recruitment through study design and processes.

This feasibility study is not powered for efficacy, limiting the significance of findings for pain reduction. The placebo response rate in this study was very high compared to other pain studies which commonly find a reduction of about 20% in pain intensity.

The evidence base in palliative care has grown rapidly in the past 30 years transforming the way we practice medicine. This study provides important insights into design and feasibility of clinical trials of lidocaine for people with neuropathic cancer pain.

OP-10 DEVELOPING CLINICAL GUIDANCE TO SUPPORT ACCESS TO INTERVENTIONAL PAIN MANAGEMENT FOR PEOPLE WITH PAIN DUE TO PANCREATIC CANCER

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10.1136/spcare-2024-ANZSPM.10

Background Pancreatic cancer can have a high burden of pain, and, for many people, management of this pain is complex. Interventional approaches to pain management are well established, but timely identification of those who may benefit and access these pain interventions is variable. The National Pancreatic Cancer Roadmap was developed by Cancer Australia to support improved outcomes for people affected by pancreatic cancer and includes the development of pathways for timely access to pain management and early referral to palliative care. Alongside these pathways was the need to develop guidance for clinicians to support patient access to interventional pain management when required. The aim of this project was to develop clinical guidance to support referral for interventional pain management in the setting of pain due to pancreatic cancer.

Methods Throughout the development of the pathways, literature reviews were conducted alongside extensive stakeholder and expert consultation with individuals across all states and territories in Australia. A wide variety wide range of groups were represented including clinicians, consumers, peak body organisations, culturally and linguistically diverse groups and Aboriginal and Torres Strait Islander communities. The development of clinical guidance was informed by the National Clinical Effectiveness Committee Standards for Clinical Practice Guidance, with specific attention was given to: a) Ensuring multidisciplinary input in the development of guidance.

b) Considering geography and coverage.

c) Understanding implementation implications.

Draft Clinical Guidance documents were iteratively re-presented to the stakeholders with feedback incorporated into subsequent refined drafts.

Results Clinical Guidance which has levels of evidence and practical information for clinicians were established to be linked to the pathways to pain management and palliative care. A set of overarching principles to inform the Clinical Guidance were developed including the importance of patient-centred care and supported decision-making; care coordination; timely access to pain management and palliative care, and cultural factors that may influence the expression and assessment of pain.

The Clinical Guidance recommends that for people with refractory pain (defined as pain not adequately controlled with pharmacological management or intolerable side effects after 2–4 weeks), coeliac plexus or splanchnic plexus neurolysis should be considered, with evidence of effect, outcomes and other considerations for clinicians outlined. Early identification of those who may benefit from coeliac plexus or splanchnic plexus neurolysis should be considered including discussion of those with refractory pain at multidisciplinary cancer meetings. Evidence and guidance on the role of radiotherapy and intrathecal analgesia are also presented.

Conclusion The National Pancreatic Cancer Roadmap developed by Cancer Australia set out the need to establish pathways to timely pain management, including interventional pain management and palliative care, with supporting Clinical Guidance linked to key points in these pathways. Implementation into national systems of care is the next step towards these pathways and accompanying Guidance improving outcomes for people with pancreatic cancer and their families.

This project is funded by Cancer Australia, National Pancreatic Cancer Roadmap – Delivery of early implementation priorities.