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Quality of life measurements and reporting in randomized controlled trials of pancreatic cancer: a systematic review

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120058

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 December 2023 and was last updated on 13 December 2023.

INTRODUCTION

Review question / Objective To assess differences measurements and reporting of randomized controlled trials measuring quality-of-life in pancreatic cancer.

Rationale The rationale for this study is to standardize and improve the measurement of health-related quality-of-life (HRQoL) in pancreatic ductal adenocarcinoma (PDAC) clinical trials, ensuring that patient-centered outcomes are consistently and accurately assessed across different studies. This is crucial for understanding the real-world impact of treatments on patients' well-being and for guiding more informed clinical decisions.

Condition being studied Pancreatic cancer (PDAC).

METHODS

Search strategy We conducted a systematic review of phase 3 RCTs in PDAC that measured HRQoL following PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (24). This study was deemed exempt by the IRB due to use of publicly available data. We focused on assessing randomized phase III clinical trials in the first-line setting, as HRQoL data in the second line setting for PDAC is understandably scarce. We chose to focus on RCTs to provide an assessment of different interventions on HRQoL. The databases PubMed.gov and ClinicalTrials.gov were searched using the keywords “Phase 3 clinical trial” and “pancreatic cancer”, which yielded 269 initial results (Figure 1). We included all studies from the inception of the databases, until March 21st, 2023. The earliest date of inclusion

was in 2002.The review methods were established prior to the conduct of the review.

Participant or population Patients enrolled in phase III randomized controlled trials with pancreatic cancer.

Intervention NA.

Comparator NA.

Study designs to be included Phase III randomized controlled trials.

Eligibility criteria We selected phase 3 RCTs in the first line setting of PDAC in accordance with PRISMA guidelines. Two independent reviewers (A.C. and C.O.) screened the titles and abstracts of articles to assess their relevance in duplicate. The eligibility criteria included phase 3 clinical trials involving patients with pancreatic cancer, studies that measured quality-of-life outcomes as a primary or secondary endpoint, and trials with sufficient data for synthesis and analysis. Studies were excluded if they were phase 1 or 2 trials, involved non-human subjects, lacked data on quality-of-life outcomes, or were in the second-line setting. Any reviewer disagreements regarding study eligibility were resolved through discussion and consulting a third reviewer (G.T.). Individual studies were not assessed for quality, as our main focus was to evaluate differences in methodologies.

Information sources PubMed.gov and ClinicalTrials.gov.

Main outcome(s) Differences in HRQoL instruments, frequency, as well as survey completion rates in metastatic, locally advanced/metastatic, and localized pancreatic cancer.

Quality assessment / Risk of bias analysis Quality of the studies was not assessed as the main focus of the study was to understand methodological differences in how PDAC RCTs measure HRQoL.

Strategy of data synthesis The extracted data, HRQoL measurements, were qualitatively analyzed and presented in a descriptive manner. The instrument utilized, frequency applied, duration of study, patient demographics, disease progression of patient cohort, number of patients, survey completion rates, and reported results were identified from each trial and tabulated. SCRs for HRQoL assessments were aggregated by disease progression, and treatment arm, when available, per the reporting of the trial (metastatic, locally advanced/metastatic, or localized/resectable). SCR was calculated using the number of surveys completed at a specific timepoint, divided by the total number of patients enrolled. If a trial divided SCR by treatment arm, the arms were combined to get an aggregate SCR for each trial. A simple linear regression model was used to calculate 50% SCRs in, metastatic only, locally advanced/metastatic, and localized/resectable disease only trials. We considered the time point at which a 50% SCR as a reference point to base survey frequency to maximize SCR and capture the experience of more patients. The choice of a 50% SCR as a reference point was guided by a pragmatic understanding of the challenges of measuring quality-of-life longitudinally in PDAC: loss of data due to attrition, disease progression, treatment side effects, or death. Fifteen of 23 trials measuring HRQoL reported SCRs and were included in our analysis. Reported SCRs were averaged, when possible, at each time point between trials to find the time point at which a 50% SCR was reached for each patient cohort (Supplementary Table 1). Data was qualitatively syntesized. Survey complete.

Subgroup analysis No subgroup analyses were conducted.

Sensitivity analysis Sensitivity analyses were not conducted.

Language restriction English.

Country(ies) involved United States.

Keywords Quality of life methods; health-related quality-of-life; patient-reported outcomes; survey methods; pancreatic cancer.

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