



Original Research

Systematic versus on-demand early palliative care: results from a multicentre, randomised clinical trial



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KEYWORDS

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Abstract Background: Early palliative care (EPC) in oncology has been shown to have a positive impact on clinical outcome, quality-of-care outcomes, and costs. However, the optimal way for activating EPC has yet to be defined.

Methods: This prospective, multicentre, randomised study was conducted on 207 outpatients with metastatic or locally advanced inoperable pancreatic cancer. Patients were randomised to receive 'standard cancer care plus on-demand EPC' (n = 100) or 'standard cancer care plus systematic EPC' (n = 107). Primary outcome was change in quality of life (QoL) evaluated through the Functional Assessment of Cancer Therapy – Hepatobiliary questionnaire between baseline (T0) and after 12 weeks (T1), in particular the integration of physical, functional, and Hepatic Cancer Subscale (HCS) combined in the Trial Outcome Index (TOI).

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Patient mood, survival, relatives' satisfaction with care, and indicators of aggressiveness of care were also evaluated.

Findings: The mean changes in TOI score and HCS score between T0 and T1 were -4.47 and -0.63 , with a difference between groups of 3.83 (95% confidence interval [CI] $0.10-7.57$) ($p = 0.041$), and -2.23 and 0.28 (difference between groups of 2.51 , 95% CI $0.40-4.61$, $p = 0.013$), in favour of interventional group. QoL scores at T1 of TOI scale and HCS were 84.4 versus 78.1 ($p = 0.022$) and 52.0 versus 48.2 ($p = 0.008$), respectively, for interventional and standard arm. Until February 2016, 143 (76.9%) of the 186 evaluable patients had died. There was no difference in overall survival between treatment arms.

Interpretations: Systematic EPC in advanced pancreatic cancer patients significantly improved QoL with respect to on-demand EPC.

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1. Introduction

Over the years, the palliative care (PC) professional community has attempted to change how PC is conceived, offering an interpretation that is not limited to hospice or end-of-life care. Although there is, in fact, more than one 'definition' for PC [1], it is acknowledged that it can be subdivided in two major areas: 'early' palliative care (EPC) and 'end-of-life' palliative care (EoL PC). EPC is mainly delivered through PC clinics for outpatients or through PC consultations for patients in inpatient units. EoL PC is more often performed in inpatient hospice and PC units. Although some regard 'home care hospice programmes' as a form of EPC [1], this is open to debate. For the purposes of this study, the concept of home care hospice programmes is considered a part of EoL PC.

Different outcomes have been studied for EPC, e.g. improved quality of life (QoL), better healthcare, and lower costs [2]. Results from several original studies and systematic reviews showed evidence in favour of EPC together with best anticancer treatment compared to the latter alone, although data were not uniformly positive [1,3–6]. When this study began, the presence of EPC in the management of advanced cancer patients was generally accepted [7] and it would have been anachronistic to consider a 'best anticancer treatment only' arm as the standard arm.

In clinical practice, however, oncologists tend to request the intervention of EPC professionals only when they feel that a situation is too complex to manage alone. One could say that the standard arm in oncology for EPC has become the 'best anticancer treatment plus on-demand EPC'. We considered the interventional arm as the best anticancer treatment plus systematic EPC, defined as planned, systematic EPC together with standard cancer care starting from the diagnosis of metastatic disease. PC, although in different ways, is so performed in both arms, as it was in the previous studies from other authors [4,5]. Reasonably, the first on-demand PC intervention is almost never an isolated event, with EPC subsequently performed on a continuous basis

to manage the needs of the patient also in the 'on-demand' approach.

We chose to evaluate patients with a highly lethal tumour such as pancreatic cancer. The 2008 global cancer incidence estimates ranked pancreatic cancer as 13th of the 20 most commonly diagnosed cancers worldwide (2%, about 250,000) [8]. In 2014, pancreatic cancer had the lowest 5-year relative survival (6%) of 30 classified tumours in the United States of America [9]. In 2008, pancreatic cancer was the eighth cause of death worldwide, accounting for 4% of all cancer deaths (304,000) [10]. In Europe, pancreatic cancer is currently the fifth (5.4%) cause of death from cancer in males and the fourth (6.7%) in females [11].

The aim of the present study was to compare the impact of 'standard cancer care + systematic EPC' with that of 'standard cancer care + on-demand EPC' on patient-reported outcomes, use of health services and quality of end-of-life care in patients with advanced gastric or pancreatic cancer who were candidates for antitumour treatment. This paper presents the clinical results from the pancreatic study population.

2. Materials and methods

2.1. Study design

From October 2012 to February 2015, we randomly enrolled patients with newly diagnosed metastatic pancreatic cancer to a multicentre, randomised study to receive either 'standard cancer care plus on-demand EPC' (standard arm) or 'standard cancer care plus systematic EPC' (interventional arm). The study was approved by the Ethics Committee of the participating centres and all patients provided written informed consent (ClinicalTrials.gov NCT01996540).

2.2. Patient selection

Eligibility criteria were as follows: diagnosis of inoperable locally advanced and/or metastatic pancreatic

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