OPINION

Gemcitabine improves survival and clinical benefits for patients with advanced pancreatic cancer

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ABSTRACT

Only very lately has the idea of a chemotherapy-induced, palliative effect on disease-related symptoms in patients with pancreatic cancer been discussed in the literature. When attempting to evaluate whether treatment with various 5-FU-containing regimens led in an improvement in performance status, a weight gain, or an improvement in tumor-related symptoms in patients with gastric or pancreatic cancer, suggested that these criteria may be used to gauge the clinical effectiveness of a given therapy. Using that earlier work as a foundation and the aim to quantify any improvement in disease-related symptoms, we created the clinical benefit concept as a way to evaluate the impact of cancer chemotherapy.

Key Words: *Pancreatic cancer; Haemoglobin; Karnofsky's performance; Analgesic*

INTRODUCTION

The Clinical benefit is defined by us as a composite evaluation of pain, performance status, and weight. When these measures continue to improve over time, a patient is considered a clinical benefit responder. In the current trial, the major end point is the clinical benefit, which is measured prospectively. Since no quality-of-life instrument had been prospectively validated in patients with advanced, symptomatic pancreatic cancer at the time of study's design, an assessment of quality of life was not used. However, there has also been no prospective validation of the idea of a clinical benefit responder.

A randomised trial was conducted on individuals with pancreatic cancer because gemcitabine looked to have some anticancer effects and may even have a stronger impact on the clinical benefit measures. In patients with advanced pancreatic cancer, a comparison of gemcitabine versus the conventional drug 5-FU was carried out. This trial was conducted to see if gemcitabine was superior than 5-FU monotherapy in terms of clinical benefit, objective response (full or partial response), time to progressive disease, or survival. Since 5-FU is simple to administer and well tolerated, it was chosen as the control since no other drug or combination of agents has been shown to be more effective than 5-FU for treating patients with advanced pancreatic cancer.

Patients having a pathologic diagnosis of pancreatic cancer that was locally progressed or metastatic and untreatable by curative surgical resection were enrolled in this randomized study. Previous chemotherapy recipients were not permitted to participate. If the area that had been irradiated wasn't the only source of quantifiable or assessable disease, patients who had previously undergone radiation therapy could be included. Patients had to have a minimum baseline Karnofsky performance level of 50 and a minimum expected life span of 12 weeks. The minimum requirements for an appropriate baseline bone marrow reserve were a WBC count of 3,500/pL, a platelet count of 100,000/gL, and a hemoglobin level of 9.5 gm/dL. AST and ALT levels that are three times the upper limits of normal, a total bilirubin level of 2.0 mg/dL, and adequate baseline hepatic function Both good renal function (defined as serum creatinine concentration: 1.5 mg/dL) and transaminase levels below the upper limits of normal (unless the tumour affected the liver, in which case the levels might be up to five times the upper limits of normal) were also necessary. The trial's main goal was to determine whether certain disease-related signs and symptoms had improved (clinical benefit).

In order to qualify, patients had to meet at least one of the following criteria:

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(1) baseline Karnofsky performance status of less than 80

(2) baseline analgesic consumption of less than 10 morphine equivalent mg/d

(3) baseline pain intensity score of greater than 20 mm (of a possible 100 mm on the Memorial Pain Assessment Card [MPAC]). Each patient had to give their signed, witnessed, and informed consent in order to participate in the study. All patients experienced a pain stabilisation period that lasted for 2 to 7 days prior to the start of treatment. Patients were given morphine sulphate or hydromorphone in a fixed regimen that intended to provide appropriate pain management with no more than four additional doses of analgesics per day to control breakthrough pain. Analgesics were adjusted to achieve this goal. Patients did not move on to the therapy portion of the trial if they could not tolerate these analgesics or if their pain could not be stabilised. Prior to beginning study drug treatment, participants with stable pain were randomly assigned to receive either gemcitabine or 5-FU at a central site. The procedure was single-blind. The research. Because a rash was a potential side effect of treatment with both 5-FU and gemcitabine, the study medication was not blinded to the investigator. Due to its toxicity, a rash subsequent to 5-FU would suggest that the drug's dosage may need to be adjusted, in contrast to a rash secondary to gemcitabine, which would not. The patients filled out their MPAC card and an analgesic usage diary without being informed of their treatment allocation, however the treating physician was aware of whether the patient was getting gemcitabine or 5-FU. In addition, two impartial observers evaluated the performance status.

The primary effectiveness end goal in this study was clinical benefit, which was determined by measuring three typical debilitating signs or symptoms, including pain, functional impairment, and weight loss, that are present in the majority of patients with advanced pancreatic cancer. The main indicators of clinical benefit were functional impairment (measured by Karnofsky performance status) and pain (measured by pain intensity and analgesic usage). Body weight was used to measure weight change, which was regarded as a secondary indicator. To establish baseline measurements, patients engaged in a pain stabilization lead-in period. Following this, patients completed an MPAC card and an analgesic intake diary to track their daily pain levels. The remaining factors were evaluated on a weekly basis. The status of Karnofsky's performance was evaluated by two impartial observers. patients' medical conditions. Every 4 weeks, the health status of the patients in both trial groups was evaluated.

Each patient's response to the key clinical benefit measures (pain or performance status) was categorized as either positive, stable, or negative (Table 1). Both the subjective assessment of pain intensity and analgesic use were included in the categorization for pain. Positive results in every instance showed a long-lasting (by 4 weeks) improvement over the baseline. If the patient's pain and performance status were both stable, the secondary clinical benefit measure of weight was used to determine whether or not the patient had had a clinical benefit. Patients required to be positive for at least one criteria (pain, performance status, or weight) without being negative for any of the others in order to receive an overall clinical benefit response rating of positive at least four weeks have to pass after this improvement.

The primary assessments of pain and performance status were assessed first; only if weight was positive could a patient who was only stable on these primary measures be considered to have experienced an overall clinical benefit response. The classification of the other patients was "without having obtained clinical beneficial response other ways to gauge effectiveness. Objective tumour response, survival, and time to disease progression were evaluated prospectively in addition to the clinical benefit measures. Pain painful degree (measured daily on the MPAC 0-100 visual analogue scale). Positive: A 50% decrease from baseline sustained during 4 weeks, assuming a pain score of at least 20. For patients with a performance status of 50, 60, or 70, a sustained improvement of 20 points from baseline over the course of 4 weeks. A 50% drop from baseline, maintained for 4 weeks, assuming a minimum of 10 analgesics.

Negative: Any deterioration from baseline that lasts for four weeks.

Stable: A different outcome consumption of analgesics (measured weekly in milligrammes of morphine equivalent). Any deterioration from baseline that lasts for four weeks

Stable: A different outcome Karnofsky's status as a performer (measured weekly). Any decline of 20 points or more from the baseline that lasts for more than four weeks. A different outcome secondary action secondary action (measured weekly). Positive weight gain of 7% from baseline that lasted for 4 weeks (excluding third-space fluid).

Non positive: Any other trial result. The removal of all clinical signs of the tumour for at least 4 weeks, during which the patient was free of all cancer-related symptoms, was considered a complete tumour response. A partial response was deemed to exist when all measurable lesions showed a 50% decrease in the sum of the products of 2 perpendicular diameters for a minimum of 4 weeks. No single lesion's size must have increased by more than 25% over this time, and no new lesions may have appeared. A rise in the total of the products was considered a sign of progressive illness. A deterioration in clinical state that was compatible with disease progression, the development of any new lesions, or an increase in the sum of the products of the diameters of measured lesions by > 25% were all considered signs of progressive disease. Patients who failed to exhibit a complete, partial, or progressive response while participating in the trial for at least 8 weeks were labelled as having stable illness. The period of time between the administration of the study drug's first dose until the patient was diagnosed with a progressive condition or had their treatment stopped, whichever came first, was referred to as the "time to progressive disease."

Complete blood counts, chemical profiles, urinalyses, and weekly history and physical exams were used to assess patients. any and all symptoms, or lab abnormalities were evaluated utilizing the WHO's toxicity criterion.