INTRODUCTION

Pancreatic cancer is a leading cause of cancer-related mortality with 22% of patients having distant metastasis at the time of diagnosis. The poor outcomes in this population are associated with late presentation and advanced stage at diagnosis. There is a need for novel treatment options to improve survival outcomes in patients with metastatic pancreatic cancer.

MATERIALS AND METHODS

Methods: Patients with locally advanced or metastatic pancreatic cancer were enrolled in a phase II study at 46 centers in the United States. The primary endpoint was 6-month survival. Secondary endpoints included progression-free survival and safety. No standard chemotherapy regimen was a comparable arm. The study was open-label and non-randomized. The primary endpoint was 6-month overall survival. Safety data were assessed with measures including adverse event (AE) reporting.

RESULTS

RESULTS (continued)

Table 2. Safety and Efficacy Results by Subject

<table>
<thead>
<tr>
<th>Group</th>
<th>Median OS (mo)</th>
<th>95% CI</th>
<th>CR (n)</th>
<th>PR (n)</th>
<th>SD (n)</th>
<th>PD (n)</th>
<th>Objective SR (n)</th>
<th>CR Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMA</td>
<td>11.2</td>
<td>9.3-12.1</td>
<td>0</td>
<td>2</td>
<td>11</td>
<td>0</td>
<td>12</td>
<td>16.7</td>
</tr>
<tr>
<td>GCA</td>
<td>11.5</td>
<td>9.6-12.4</td>
<td>0</td>
<td>2</td>
<td>11</td>
<td>0</td>
<td>12</td>
<td>16.7</td>
</tr>
</tbody>
</table>

SUBJECT DEMOGRAPHICS

The study included 36 patients with metastatic pancreatic cancer who were treated with SMA or GCA. Median age was 65 years (range 42-78) and median PS was 0 (range 0-2). The majority of patients had unresectable disease (89%). The most common prior treatments included chemotherapy (94%), radiation (94%), and hormonal therapy (78%).

OBJECTIVES

Objectives: The primary objective was to evaluate overall survival in patients with metastatic pancreatic cancer treated with SMA vs. GCA. Secondary objectives included progression-free survival, safety, and tolerability. The study was designed to detect a 6-month survival difference with 80% power at a 0.05 significance level.

RESULTS

BROAD IMPROVEMENT IN HEALTH AND QUALITY OF LIFE, INCLUDING:

- Lower pain levels
- Improved physical function
- Increased appetite
- Reduced nausea

CASE STUDIES

Case 1: A 65-year-old male with localized pancreatic cancer was enrolled in the study and received SMA. After 6 months, the patient experienced a 50% reduction in pain levels and an overall increase in appetite. The patient was able to resume normal activities and continue working.

CONCLUSIONS

SMA was well-tolerated and demonstrated a promising safety profile. Further studies are warranted to evaluate the potential benefits of SMA in this patient population.