
Presented Monday, June 4, 2018

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Abstract Disclosures

Background: Cancer-related fatigue (CRF) is one of the most frequent and debilitating symptoms in 60% to 90% of patients with advanced cancer. The fatigue experienced by cancer patients can not only deteriorate patient quality of life, but also affect treatment efficacy and survival rate. PG2 injection developed by PhytoHealth Co., Taiwan with Astragulus Polysaccharides as API is the only drug approved by Taiwan Food and Drug Administration (TFDA) for relieving CRF in patients with advanced cancer. To further explore the effect of PG2 injection at lower dose, we recruited more patients in the current study and observe the effect of PG2 injection in 2 doses. Methods: Patients with advanced cancer receiving standard palliative care (SPC) with moderate to severe CRF (Score of the Brief Fatigue Inventory-Taiwan (BFI-T)≥4) were enrolled. Patients were randomized at a 1:1 ratio into two arms of PG2 injection treatment: 500mg dose or 250mg dose (both were prepared in 500ml saline and injected 3 times per week for 4 weeks) for two cycles. Fatigue improvement response rates (FIRR) were analyzed at the end of the first cycle to determine the efficacy of the two PG2 doses. Improvement of BFI-T score for more than 10% is considered as effective for relieving CRF. Results: Three hundred and ten patients were enrolled in this study. Two hundred and fourteen patients were included in the ITT population, including 111 subjects in high dose group and 103 subjects in low dose group. Results showed that improvement in fatigue scores by at least 10%, 20%, 30%, and 40% was observed in 65.07%, 46.60%, 34.95%, and 26.61% of subjects receiving 250 mg PG2 injection after one treatment cycle when...
compared to the baseline; in 500 mg group, fatigue score improvement by at least 10%, 20%, 30%, and 40% was observed in 65.77%, 51.35%, 34.23%, and 18.92% of subjects after one PG2 treatment cycle when compared to the baseline. **Conclusions:** This study demonstrates that more than 60% of subjects showed at least 10% improvement in fatigue score when compared to baseline after both 250mg and 500mg PG2 treatments. Clinical trial information: NCT01720550. Clinical trial information: NCT01720550

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Abstract Disclosures

Background: Many patients with upper-abdominal malignancies suffer from severe lower back pain radiating to the epigastrium, caused by infiltration of the celiac plexus. The celiac plexus is a network of nociceptive nerves, located along the aorta. Contemporary approaches (opioids, celiac plexus chemical neurolysis, systemic chemotherapy) are often inadequate. The celiac plexus has not previously been targeted using radiation. We hypothesized that ablative radiation targeted to the celiac plexus would alleviate pain.

Methods: We conducted a single arm prospective clinical trial. Eligible patients had celiac-pain > 4/10 on Numerical Rating Scale (NRS), ECOG ≤ 3, no previous abdominal RT, and were evaluable if they completed treatment per protocol with at least one post-treatment visit. The celiac plexus was irradiated from D12 to L2. Radiation was given as either five fractions of 9 Gy or a single-fraction 25 Gy. The primary endpoint was NRS pain 3 weeks post-treatment. Secondary endpoints were toxicity, pain at 6w, analgesic use, and pain interference with daily activities as evaluated by ‘Brief Pain Inventory’ before and after radiation.

Results: 21 patients were evaluable: 2 received fractionated treatment, 19 received 25Gy single fraction. The median age of the study population was 63 yr with a median ECOG of 1, 86% had pancreatic cancer. Patients were a median of 8 months out from diagnosis, and had received a median of one systemic treatment. Toxicity was limited to grade 1-2. All patients reported decreased celiac pain: median baseline pain was 6/10 (IQR 5-7.7), was reduced to 2.3/10 (IQR 0.9-3.9) (p < 0.0005) at 3w, and to 1.8/10 (IQR 0-3.2) (p < 0.0005) at 6w post-treatment. Seven patients reported their celiac pain had been eliminated entirely. Median morphine consumption decreased (NS). Improvement was seen in multiple quality of life measures, includ. total wellbeing (p = 0.0001), daily activity (p = 0.005) and sleep quality (p = 0.002).

Conclusions: Celiac plexus radiosurgery alleviates pain, and improves quality of life
among patients with advanced upper-GI cancer. An international multi-center phase II trial is accruing. Clinical trial information: NCT02356406
Survival of patients treated by a Precision Oncology approach is determined by performance status and lines of therapy.

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Abstract Disclosures

Background: Academic Medical Centers (AMC) and community practices are implementing Molecular Tumor Boards (MTB) to interpret next-generation sequencing (NGS) results and develop clinical guidelines for utilizing NGS results. Reports of MTB experiences from cancer centers nationally vary in their abilities to translate molecular test results to actionable recommendations for their patients. In these efforts, there is not yet a definition for parameters of patients who would benefit most from a Precision Oncology approach. **Methods:** Defining Platforms for Individualized Cancer Treatment (DePICT) is an IRB approved registry trial designed to monitor outcomes of Broward County, FL residents with late-stage refractory cancer (ECOG ≤2) who undergo NGS. After consent, the MTB used NGS results to match patients to targeted clinical trials and therapies. The patients are followed at 12 week intervals. DePICT has consented 141 patients, out of which 111 have had at least one follow up. We analyzed these cases to identify key characteristics of patients that benefit most from NGS testing and MTB review. Groups were defined as those who pursued targeted therapies versus those who pursued standard of care or palliative regimens. Kaplan Meier survival analyses were done in R 3.4.3. **Results:** Patients with ≤3 previous lines of therapy were more likely to pursue targeted therapy than patients with ≥4 lines of therapy (32% vs. 17%, p = 0.045). Only patients with an ECOG score 0 or 1 pursued targeted therapy. An analysis of this population (ECOG < 2, ≤3 lines of therapy) revealed that patients on targeted therapy performed better than their palliative care counterparts. Median overall survival (mOS) for patients who received targeted therapy is 84 weeks (95% CI 36-Not Reached (NR)) and the mOS for patients who did not undergo targeted therapies was 36 weeks (95% CI 36-NR). **Conclusions:** This analysis identifies patients who may benefit most from NGS testing. Patients with ECOG scores of 0 or 1 and 3 or fewer lines of therapy were more likely to go on targeted therapy, and have better outcomes. Patients should be evaluated by precision oncology approaches earlier in their cancer care continuum.
Treating anorexia in people with advanced cancer. a randomised, double blind, controlled trial of megestrol acetate, dexamethasone or placebo.

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Abstract Disclosures

**Background:** This multi-site, double blind, parallel arm, fixed dose phase III study compared megestrol acetate 480 mg/day, dexamethasone 4 mg/day and placebo for their net short-term effect on appetite and quality of life (QoL) in people with advanced cancer. **Methods:** Inpatients or outpatients seeing a palliative care team with anorexia for ≥2 weeks with a score ≤4 on a 0-10 numeric rating scale (NRS; 0 = no appetite, 10 = best possible appetite) were recruited. Participants were randomised to receive megestrol 480 mg, dexamethasone 4 mg or placebo daily for up to 4 weeks. Primary response assessment occurred at day 7, and responders were defined as having more than a 25% improvement in NRS compared to baseline. **Results:** There were 190 people randomised (megestrol acetate n = 61; dexamethasone n = 67, placebo n = 62). At week 1 (primary endpoint), 79.3% of participants in the megestrol group, 65.5% in the dexamethasone group and 58.5% in the placebo group (p = 0.067) were responders. No differences in weight, performance status or quality of life were reported. Treatment emergent adverse events occurred in the majority of participants (90.4%), and included altered mood and insomnia. Hyperglycemia was more frequent in people on dexamethasone. **Conclusions:** Although there was little difference between treatment groups for the primary or secondary effectiveness endpoints, there was a consistent trend in secondary end-points favouring megestrol acetate than dexamethasone or placebo. Sub-group analyses indicate megestrol acetate may be more effective in maintaining body weight for subjects whose appetite responded. Clinical trial information: ACTRN12608000405314.