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ABSTRACTS SELECTED FOR POSTER PRESENTATIONS

Gastrointestinal Malignancies—General

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Evaluation of Anti-Cancer Drugs in Advanced and Metastatic Non-Colorectal Gastrointestinal Cancers

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Background: We previously described quantitative methodology to evaluate anti-cancer drugs in colorectal cancer, based on survival, adverse effects, cost (C), and administration.

Objectives: Evaluate and compare anti-cancer drugs and combinations used in the treatment of patients with non-colorectal gastrointestinal cancers.

Methodology: Previously reported data on median overall survival (mOS) and adverse events (AEs) of the various drugs and combinations were used. The cost (in US dollars) of an entire treatment course for one patient weighing 70 kg, or 1.7 m^2, was calculated; this was divided by the survival gain (in days) over control (C/S). Point (P) values were assigned for three parameters: C/S, AEs, and A. For C/S, P value ranged from 1.0 (C/S < 25) to 0 (C/S > 700). For administration (A), P value ranged from 2.5 (oral) to 0 (daily injections or prolonged infusion). The P value for AEs ranged from 0 (placebo) to 5.0 (fatalities) using Common Terminology Criteria (CTC) v 3.0. Changes in patients' performance status (Karnofsky and WHO scales), as an indirect measure of quality of life, were integrated into AEs grading. The assigned AE P value for chemotherapy (CT) was 2.5-3.0; for tyrosine kinase inhibitors (TKIs), and trastuzumab/CT, 3.0; and for TKIs/CT 3.5. P values of AEs and A of combinations were based on all drugs in the combination. Corrected C/S (cor-C/S) was sum of point values of [C/S + A - AEs], reference drug being 10 + 2.5 – 0 and respectively 100%. Each drug/combination was evaluated by S, C/S and cor-C/S. Rating of "A" was assigned to OS > 360 days or C/S < 25 and "F" for OS of < 10 days and C/S > 700.

Results: In advanced/metastatic (a/m) gastroesophageal junction (GEJ) cancer, trastuzumab (Tr) combined with CT (ToGA) resulted in relatively low C/S of 81, which increased with increasing number

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of Tr cycles. In biliary tract cancer, cisplatin/ gemcitabine (Gem) scored low C/S and high cor-C/S secondary to low cost of Gem. In a/m pancreatic cancer, there was no clear winner among all combinations tested; however, erlotinib/gemcitabine (Moore et al, 2007) scored the highest C/S (684) and lowest cor-C/S, (0%). In inoperable hepatocellular carcinoma, sorafenib (Llovet et al, 2008) showed C/S of 216 and cor-C/S 60%.

Discussion: C/S in days could serve as a rapid tool to evaluate and compare anti-cancer drugs. Association of C/S with AEs and A was a more integrated and realistic methodology for drug evaluation and seemed to penalize drugs with higher AEs grade and cumbersome A. Assessment of P values, however, was investigator-dependent.