Aim: Malignant Ascites is debilitating for pts. with advanced cancer which negatively impacts the quality of life (QoL). Causative treatment approaches are still limited. It has previously been shown that tumor cell production and/or increases of Vascular Endothelial Growth Factor (VEGF) might be a major cause of the formation of malignant ascites. Intraperitoneal Bev could therefore be an option for symptom control of refractory malignant ascites.

Methods: Pts. with advanced GI cancer and malignant ascites who had received paracentesis at least once within the past 4 weeks were randomly assigned in a 2:1 ratio to intraperitoneal Bev (400mg absolute in 100 ml NaCl 0.9%) or Pl after paracentesis. During the 8-week treatment period, a minimum interval of 14d was kept between the applications of the study drug. First primary endpoint was the paracentesis-free survival (ParFS). Second primary endpoint was best response (BR) defined as the longest paracentesis-free period within the 12-week observation period. Further endpoints were overall survival, QoL, serum and ascites VEGF. ParFS and BR were compared using the logrank test and the Wilcoxon-Mann-Whitney test, respectively.

Results: 53 Patients (median age 63y) were randomized (37 Bev/16 Pl arm) whereas 49 pts. received at least one application of the study drug and qualified for the intention to treat analysis. The median ParFS was 14d (CI:11-17d) in the Bev arm and 10.5d (CI: 7-21d) in the Pl arm (hazard ratio 0.74, CI:0.40-1.37; p = 0.16). The BR was 19d for the Bev arm (range 6-66d) and 17.5d for the Pl arm (range 4-42d) with a p value of 0.85. Median OS was 64d (CI:45-103d) for the Bev arm and only 31.5d (CI:20-117d) for the Pl arm (p = 0.31). The proportion of pts. with at least one CTC grade 3-5 event occurred was similar with 20/33 (61%) in the Bev arm and 11/16 (69%) in the Pl arm. Results on serum and ascites VEGF will be presented at the meeting.

Conclusions: In this unfavorable group of terminally ill pts. intraperitoneal Bev was well tolerated but did not result in a significantly better symptom control of malignant ascites compared to the control.

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