**1579** POSTER

**Overall treatment utility: A novel outcome measure reflecting the**

**balance of benefits and harms from cancer therapy**

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**Introduction:** Established clinical trial endpoints fail to individually capture

the balance of benefits and harms from cancer treatments. ‘Overall

Treatment Utility’ (OTU) is a novel composite outcome measure that

was developed within the FOCUS2 trial in elderly patients treated

with chemotherapy for advanced colorectal cancer. It combines clinical

and radiological response, toxicity, adverse events and patient-reported

acceptability of treatment. OTU needs further development and validation.

This study aimed to test the feasibility and value of measuring OTU in an

alternative frail/elderly population with advanced gastric or oesophageal

(GO) cancer.

**Methods:** Patients were randomised between three treatment arms

containing triplet, doublet or single agent chemotherapy. Details of the

trial and conventional outcomes are reported elsewhere. OTU was scored

according to the algorithm used in the FOCUS2 trial which categorises

outcome into a three-point ordered categorical scale (good/intermediate/

poor). Data return and compliance with the patient-reported component

was recorded. Survival analysis was used to correlate OTU with overall

survival (OS) and progression free survival (PFS).

**Results:** The study included 55 patients with a median age of 75 (range

50−87). OTU provided useful information enabling discrimination between

treatment arms. OTU was prognostic for OS in patients alive at Week 12

(logrank test for trend p = 0.0001), PFS in patients alive and progression

free at week 12 (logrank test for trend p = 0.0003). Radiological response

(RECIST) was less prognostic for OS (logrank test for trend p = 0.40).

Alternative formulations of OTU were also investigated. The distribution

between good, intermediate and poor OTU varied depending on the cutpoint

in patient question responses.

**Conclusion:** OTU is a feasible and useful outcome measure that combines

objective and subjective information regarding the balance of benefit

and harm of treatment in a frail/elderly population with GO cancer. It

correlates more strongly with overall survival than radiological response.

Further research should focus on establishing the optimal definition and

combination of patient reported outcomes.

***No conflict of interest.***