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# GENITOURINARY TUMOURS, PROSTATE



## 844O Docetaxel for hormone-naïve prostate cancer: Results from long-term follow-up of metastatic (M1) patients in the STAMPEDE randomised trial (NCT00268476) and sub-group analysis by metastatic burden

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**Background:** STAMPEDE has previously reported that upfront docetaxel (Doc) improved overall survival (OS) for patients (pts) starting long-term androgen deprivation therapy (ADT). We report the long-term outcomes for M1 pts using OS as the primary outcome measure. We also assessed if benefit of Doc depended on metastatic

burden, as suggested by previous trials, using the CHAARTED definition of high burden (HB) and low burden (LB) baseline disease.

**Methods:** 724 SOC and 362 SOC+Doc pts were recruited with a 2:1 randomised stratified allocation. Analysis used Cox regression models, adjusted for all stratification factors, with emphasis on restricted mean survival time if hazards were non-proportional. Retrospectively-collected imaging data, blinded to trial arm, was used to categorise pts as having LB or HB disease.

**Results:** Median follow-up was ~6.5yr, compared to ~3.5yr when last reported. There were 494 deaths on SOC (41% increase in deaths compared to previous report), with median OS = 43.1 months (m). There was good evidence of benefit of SOC+Doc on OS (median = 59.1m, HR = 0.81, 95% CI 0.69-0.95, P = 0.009). Metastatic burden was assessable for 830/1086 (76%) pts; subgroups were representative of the full M1 cohort in terms of stratification factors. There was no evidence of heterogeneity of Doc effect between the LB and HB subgroups (interaction P = 0.827; LB HR = 0.76, 95%CI 0.54-1.07, P = 0.107; HB HR = 0.81, 95%CI 0.64-1.02, P = 0.064). Analysis of other outcomes also found evidence of benefit of SOC+Doc over SOC in failure-free survival (FFS; HR = 0.66, 95% CI 0.57-0.76, P < 0.001) and progression-free survival (PFS; HR = 0.69, 95% CI 0.59-0.81, P < 0.001), and no evidence of heterogeneity of Doc effect between metastatic burden subgroups for either outcome (FFS: P = 0.792; PFS: P = 0.855). There was no evidence that SOC+Doc resulted in late (after 1yr) G3-5 toxicity compared to SOC (27% vs 28% respectively).

**Conclusions:** The clinically significant benefit in survival for upfront Doc persists after longer follow-up, with no evidence that the benefit differed dependent on disease burden. We advocate that upfront Doc is considered for both LB and HB M1 pts.

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