favour of Esc. At 10 yr, bPFS was 42% (95% CI = 37−47%) Std and 54% (95% CI = 49−60%) Esc. Long-term HT was reported for 220 with fewer men starting HT and later on Esc: HR = 0.77 (95% CI = 0.59–1.00; p = 0.05). Further data, including prostate-cancer specific survival and metastases-free survival will be presented; a blinded death review is ongoing.

Conclusions: Escalated dose radiotherapy with neo-adjuvant HT showed an advantage in early efficacy outcome measures but this did not translate into an improvement in overall survival. Five extra fractions of RT may have led to less exposure to long-term HT. Survival rates in both arms were much higher than originally expected.

Support: The trial is supported by the UK Medical Research Council

Gynaecological Cancer

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22LBA LATE BREAKING ABSTRACT

Quality of Life in the ICON7 GCIG Phase III Randomised Clinical Trial

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Background: ICON7 (ISRCTN 91273375) evaluated the addition of bevacizumab (bev) to standard chemotherapy (CT) in the first line treatment of ovarian cancer. Bev was scheduled concurrently with CT (18 weeks) and as maintenance (54 weeks). 1,528 patients were recruited. MRC sponsored the trial, and Roche provided bev for all patients.

The primary endpoint, progression free survival, showed a 15% improvement at 12 months and an overall 1.5 month improvement with bev (restricted mean). This quality of life (QL) sub-study addresses short-term QL of patients during the period on and immediately after trial treatment.

Materials and Methods: QL was collected using the EORTC QLQ-C30 questionnaire at regular intervals until disease progression. The primary QL outcome was Global QL at 54 weeks. Three QL hypotheses were prospectively generated for the addition of bev

1. gastro-intestinal symptoms resolve more rapidly during chemotherapy
2. problems associated with wound healing (pain, body image, social and physical function) are greater at the midpoint of chemotherapy and
3. improvement in fatigue and social functioning is less during continuation of bev.

Other subscales were explored including subgroups from initial survival analyses.

Comparisons were by analysis of variance, controlling for baseline scores. A benefit for bev is indicated by a positive difference in global QL.

Results: Those receiving bev had a clinically small but statistically significant detriment in global quality of life at 54 weeks (table).

None of the hypothesised differences between the treatment arms were supported (all p > 0.05).

Bev was associated with clinically small but statistically significant detriments in exploratory analyses of role and emotional function, appetite, financial worries and chemotherapy side effects (all p < 0.01).

Missing data were present. Sensitivity analyses indicate caution is required in interpreting these observations.

Parameter	N	Comparison	Difference (Bev −CT)	P-value
Global QL	777	Difference in mean QL at 54 weeks	−6.38	<0.0001

Conclusions: Results suggest clinically small deficits in global quality of life and several other patient-reported outcomes associated with the addition of bev to standard CT in ovarian cancer. This should be considered in determining the optimal treatment.

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23LBA LATE BREAKING ABSTRACT

Quality of Life Outcomes of a Randomized, Placebo-Controlled Trial of Bevacizumab in the Front-Line Treatment of Ovarian Cancer: a Gynecologic Oncology Group Study

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Background: Results of a randomized, double-blind, placebo-controlled phase 3 trial indicate that the addition of bevacizumab to concurrent carboplatin and paclitaxel chemotherapy followed by maintenance bevacizumab (R3) prolongs progression-free survival in the front-line treatment of advanced epithelial ovarian cancer compared to chemotherapy alone (R1) or chemotherapy concurrent with bevacizumab in cycles 2−6 only (R2). Quality of Life (QOL) was compared among groups.

Methods: The Trial Outcome Index of the Functional Assessment of Cancer Therapy-Ovary (FACT-O TOI) was used to assess QOL before cycles 1, 4, 7, 13, and 21; and 6 months after completing study therapy. Differences in QOL scores between groups were assessed using a linear mixed model, adjusting for baseline score and age. Treatment effect size was calculated as the ratio of the treatment difference to the baseline standard deviation in the control group (R1). The significance level is set at 0.0167 to account for multiple comparisons.

Results: A total of 1,693 patients (566 in R1, 554 in R2, and 573 in R3) comprised the sample for the QOL comparisons. At cycle 4, the patients in R2 (p < 0.001) and R3 (p < 0.001) reported QOL scores that were 2.7 points (98.3% CI: 0.88–4.57; p < 0.001; effect size = 0.18) and 3.0 points (98.3% CI: 1.13–4.78; p < 0.001; effect size = 2.0) lower respectively, than those in R1. While the observed differences in QOL were statistically significant, they were not considered clinically significant. The difference in QOL scores between R1 and R3 remained statistically significant up to cycle 7, 2.3 points lower (98.3% CI: 0.33–4.14; p = 0.005; effect size = 0.15) in group R3. These scores were not statistically different between patients in R2 and R3. A similar trend was evident in subscale analyses, in which the patients in R2 and R3 reported statistically (not clinically) lower functioning than those in R1. The percentage of patients who reported abdominal discomfort (AD score >0) dropped over time, without significant differences between study arms.

Conclusion: The addition of bevacizumab compromised QOL to a mild extent during chemotherapy, but had no prolonged effect on QOL after chemotherapy completion. Quality of life improved from baseline to cycle 13 for each treatment group, as did abdominal discomfort.

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24LBA LATE BREAKING ABSTRACT

Mutation and Protein Expression Biomarkers Correlate with Response to AKT Inhibition in a Phase I Trial of the Oral Pan AKT Inhibitor GSK2141795 (GSK795) in Patients (pts) with Platinum Resistant Ovarian Cancer

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Background: AKT pathway activation is central to clinical platinum resistance. Molecular analysis of paired tumour biopsies (PTB) was undertaken in a GSK sponsored phase I trial of GSK795, PCS113124, with investigator led translational component in platinum resistant ovarian cancer pts.

Methods: 11 pts received GSK795 in 3 cohorts of 25–50–75 mg for 2 or 4 weeks, escalating to 75 mg following pharmacodynamics (PD) assessment. SUV, Ki and MRglu PET PD parameters were derived by 3 sequential FDG-PET scans. Response assessment was by RECISTv1.1