themes emerged: Impact on the person, adjustment, external support and tailored individualised information. Participants explored how these factors assisted or hindered their recovery and what affected recovery. Participants not on a surgical pathway, those with shorter hospital stay, or outpatient care only, had less understanding of the need for, or availability of, rehabilitation services. Those who had longer hospital stays, i.e. the UGI patients, had better contact with rehabilitation professionals, especially physiotherapists and dietitians. Participants without Allied Health Professional (AHP) support reported a "drop-off" in professional support following treatment. Those with AHP support did not. Participants with GYN cancers accessed fewer rehabilitation services, expressed more psychosocial impacts and concerns regarding returning to work. Their younger median age and genders may explain some of those differences. It was often unclear to participants with unmet needs where to get guidance and help. Service inequalities were also identified; those treated as private patients received less inpatient and outpatient rehabilitation. Many participants felt that there were less services and support readily available than for others with more common cancer types. Most participants wanted individualised guidance to self-manage consequences of cancer and treatment rather than return to hospital for treatment.
Conclusions: Participants in this study reported seeking a new normality. Those who had contact with AHPs during treatment were more likely to feel supported and less likely to report unmet needs. These results will inform a future intervention study exploring the provision of individualised guidance at the end of treatment.

6638 POSTER

Medical Utilization and Cost of Liver Cancer in Taiwan

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Background: Taiwan implemented a comprehensive and universal National Health Insurance (NHI) program to cover all inhabitants. This study aimed to assess the medical utilization and cost of liver cancer patients under NHI in Taiwan.
Methods: This retrospective cross-sectional study used a sampled NHI research database containing one million beneficiaries. Claims of liver cancer patients in 2009 were analyzed.
Results: Among 2335 liver cancer patients identified, 2178 (93.3%) patients used outpatient services and 1193 (51.1%) patients used inpatient services. Liver cancer accounted 1.8% of the total cost of NHI. The cost per visit was $59.3 for outpatient and $2070.3 for inpatient. The annual cost per patient was $4746.6, with $1951.0 for outpatient and $2795.6 for inpatient. Patients who were female, age at 60's, lower income, living in Southern Taiwan, had higher cost per patient ($p < 0.0001$). Fees for consultation, treatment and medical supply (57.3%) accounted for the highest portion of outpatient cost, followed by drug fees (30.0%), and diagnosis fees (11.2%). Ward fees (19.0%) accounted for the highest portion of inpatient cost, followed by drug fees (18.7%), X-ray fees (14.9%). Private hospitals were visited most frequently.
Conclusions: The cost of liver cancer care is substantial and varied by sex, age, income, and geographic distribution. It is critical to identify cost-effective treatment strategies.

6639 POSTER

Polymorphisms Associated With the Clinical Outcome of Biliary Tract Cancer (BTC) Patients Treated With the Epirubicin, Cisplatin and Capecitabine (ECX) Regimen

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Background: Biliary tract cancers (BTC) are rare but highly fatal malignancies, and most chemotherapeutic agents have disappointing efficacy against these tumours. Our previous phase II study showed that combined locoregional and systemic chemotherapeutic regimen was active and safe, with results similar to the gemcitabine-platinum regimen (Cantore et al., Cancer 2005; Valle et al., N Engl J Med. 2010), but predictive factors for maximizing therapeutic efficacy are warranted. Therefore, this study was aimed at evaluating the association of polymorphisms in key genes with outcome of BTC patients (pts) treated with intraarterial cisplatin and epirubicin, and oral capecitabine (ECX) regimen.
Materials and Methods: We evaluated 5 polymorphisms in 4 genes (ERCC1, XPD, XRCC1 and TS) in 75 unresectable BTC pts treated upfront with ECX. Univariate/multivariate analyses compared clinical (age, sex, performance status (PS), CA19.9, cycle numbers) and genetic parameters with clinical response, overall and progression-free survival (OS, PFS).
Results: Patients harbouring a higher number of repeats in the TS promoter enhancer region (e.g., TSER 3R3R or 2R3R) experienced a significantly lower rate of clinical benefit (54 vs. 80%, $P = 0.03$) and shorter OS ($P = 0.001$, with median OS of 6.7, 9.0 and 19.3 months in pts with TSER 3R3R, 2R3R and 2R2R genotypes, respectively). CA19.9 levels above 100 U/ml were also associated with lower rate of clinical response and shorter OS, while no correlations were observed for all the other parameters. TSER polymorphic variants and CA19.9 remained as independent predictors for death-risk at Cox multivariate analysis, with HR = 0.440, 95% CI, 0.237–0.818 for 2R2R vs. 2R3R/3R3R pts ($P = 0.009$).
Conclusions: TSER polymorphisms have been already associated with differential outcome in cancer pts treated with fluoropyrimidine-based regimens, but this is the first evidence about their predictive role in BTC pts treated with ECX regimen. Since BTC are such a dismal disease, any biomarker that can help to better stratify patients might have crucial clinical applications. The validation of the role of these polymorphisms in well-planned prospective trials will offer new tools for optimization of currently available treatments in selected patients.

Oral Presentations (Sun, 25 Sep, 09:00−10:20)
Genitourinary Malignancies − Prostate Cancer

7000 ORAL

Final Overall Survival (OS) Analysis of COU-AA-301, a Phase 3 Study of Abiraterone Acetate Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer (mCRPC) Pretreated With Docetaxel

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Background: Abiraterone acetate (AA) is a selective androgen biosynthesis inhibitor that blocks the action of CYP17, thereby inhibiting adrenal and intratumoral androgen synthesis.
Materials and Methods: COU-AA-301 is a randomised, double-blind study of AA (1000 mg + prednisone [P] 5 mg po BID) vs placebo + P administered to men with mCRPC progressing post-docetaxel. 797 patients were randomised to AA and 398 to placebo. OS was the primary end point. At a preplanned interim analysis, AA improved OS (de Bono, ESMO 2010). The present report describes the final OS analysis at 775 events (prior to crossover from placebo to AA).
Results: At median follow-up of 20.2 mos, OS for the AA + P group was superior to the placebo + P group [median OS 15.8 vs 11.2 mos; HR = 0.74 (0.64–0.86), $p < 0.0001$]. The difference in median OS between the 2 groups improved to 4.6 mos from 3.9 mos (interim analysis). Mean duration of treatment was 10.1 cycles AA vs 6.7 placebo. Subgroup analyses for OS are presented in the table.

		Median OS (mos)			
Baseline variable	Subgroup	AA	Placebo	HR	95% CI
All subjects		15.8	11.2	0.74	0.64–0.86
Brief Pain Inventory-worst pain (BPI-SF)	<4	18.4	13.9	0.69	0.56–0.85
	⩾ 4	13.3	9.3	0.78	0.63–0.96
Prior regimens	1	17.1	11.7	0.71	0.59–0.85
	2	14.2	10.4	0.80	0.61–1.03
Type of progression	PSA only	18.3	13.6	0.63	0.47–0.84
	Radiographic	14.8	10.5	0.78	0.65–0.93
Age, y	<65	15	11.2	0.69	0.53–0.91
	⩾ 65	16.2	11.1	0.76	0.63–0.90
	⩾ 75	15.6	9.3	0.64	0.48–0.85
Visceral disease at entry	Yes	12.9	8.3	0.79	0.59–1.05
	No	17.1	12.3	0.69	0.58–0.82

AA was well tolerated. Mineralocorticoid-related adverse events were more common with AA vs placebo. Grade 3/4 hypokalaemia (4.4% vs 0.8%), and grade 3/4 hypertension (1.3% vs 0.3%) were infrequent. Liver function test

abnormalities were observed in 11.3% AA vs 8.9% placebo, and cardiac disorders were observed in 15.9% AA vs 11.7% placebo patients.
Conclusions: AA statistically significantly prolonged median OS in patients with mCRPC who have progressed post-docetaxel. With longer follow-up, the magnitude of the treatment effect of AA on OS increased and no new safety issues were detected. The OS benefit demonstrated across subgroups was generally consistent with that seen in the overall patient population. Clinical benefit was maintained in older patients and in those with visceral disease. The present results further confirm the benefit provided by AA in patients with mCRPC.

7001 ORAL

Abiraterone Acetate Improves Functional Status in Patients With Metastatic Castration-resistant Prostate Cancer (mCRPC) Post-docetaxel − Results From the COU-AA-301 Phase 3 Study

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Background: Abiraterone acetate (AA) is a potent, selective androgen (CYP17) biosynthesis inhibitor, shown in the COU-AA-301 trial to improve overall survival (HR = 0.646) in mCRPC progressing after docetaxel (D). Here we retrospectively assess the impact of AA on patient-reported functional status in that study.
Material and Methods: COU-AA-301 is an international, randomised, double-blind study of AA (1 g QD) + prednisone (P; 5 mg BID) vs placebo + P in mCRPC post-D. Functional status was assessed at baseline, Cycles 4, 7, 10, and treatment discontinuation using the Functional Assessment of Cancer Therapy-Prostate (FACT-P) questionnaire. All analyses were conducted using responder definitions of clinically significant changes (improvement/decline compared to baseline) in eligible patients; definitions were based on literature [Cella D, et al. Value Health 2009;12:124−9] and distribution-based calculations.

FACT-P measure	AA N = 797	Placebo N = 398	p Value
FACT-P total score			
Improvement, n/eligible (%)	268/563 (48)	87/273 (32)	<0.0001[a]
Time to decline [median], days	363	253	<0.0001[b]
Physical WB			
Improvement, n/eligible (%)	285/616 (46)	83/295 (28)	<0.0001[a]
Time to decline [median], days	339	240	<0.0001[b]
Social/Family WB			
Improvement, n/eligible (%)	158/292 (54)	63/130 (49)	0.284[a]
Time to decline [median], days	168	89	0.397[b]
Emotional WB			
Improvement, n/eligible (%)	80/147 (54)	24/62 (39)	0.0380[a]
Time to decline [median], days	424	226	<0.0001[b]
Functional WB			
Improvement, n/eligible (%)	212/487 (44)	83/249 (33)	0.0076[a]
Time to decline [median], days	337	169	<0.0001[b]
FACT-G Scale			
Improvement, n/eligible (%)	235/568 (41)	78/283 (28)	<0.0001[a]
Time to decline [median], days	424	274	<0.0001[b]
Prostate Cancer Subscale			
Improvement, n/eligible (%)	321/554 (58)	101/255 (40)	<0.0001[a]
Time to decline [median], days	262	142	<0.0001[b]

[a] Chi squared test; [b] Log-rank test.

Results: 797 patients were randomized to AA and 398 to placebo, with respective median treatment durations of 8 and 4 months. Baseline FACT-P scores (for all 7 measures) were similar between groups. AA significantly improved functional status from baseline at each assessment and delayed time to decline in the majority of FACT-P measures, except the social/family well-being (WB) subscale where there was no difference (Table).
Conclusions: In post-D mCRPC, therapy with AA + P yields significantly greater improvements in patients' functional status and forestalls functional decline, compared to P alone. The extent of these benefits is likely to be considered important to patients.

7002 ORAL

Time to Disease-related Pain After Sipuleucel-T in Asymptomatic Patients With Metastatic Castrate Resistant Prostate Cancer (mCRPC): Results From 3 Randomized Phase III Trials

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Background: Sipuleucel-T, an FDA-approved therapy for men with asymptomatic or minimally symptomatic mCRPC, has a demonstrated survival benefit. In addition to survival data, 3 completed Phase III, randomized, controlled trials sponsored by Dendreon Corp. also collected data on time to disease-related pain (TDRP).
Materials and Methods: Studies D9901 (NCT00005947) and D9902A (NCT01133704) enrolled only asymptomatic pts; TDRP was a secondary endpoint. Pain status was collected until disease-related pain or 4 weeks following disease progression, whichever occurred first. The IMPACT study (NCT00065442) originally enrolled only asymptomatic pts with a co-primary endpoint of TDRP; it was later amended to include minimally symptomatic pts and to remove the TDRP endpoint. Pts were treated with 3 infusions of sipuleucel-T or control at approximately 2-week intervals, and were then followed for safety and clinical endpoints. Pain status for pts enrolled prior to the amendment was collected until disease-related pain was observed. TDRP was assessed in all studies by pain logs and adjudicated by blinded independent reviewers. TDRP was analyzed using the Kaplan–Meier (KM) method and log rank test; hazard ratio (HR) was derived from an unadjusted Cox regression model. Analyses were based on all randomized pts on D9901 (n = 127) and D9902A (n = 98), and on IMPACT pts randomized prior to the amendment (n = 203).
Results: TDRP results were: D9901 HR = 0.68, D9902A HR = 1.39, and IMPACT HR = 0.80. Integrated results were HR = 0.84 ([95% CI: 0.64, 1.12]; P = 0.24). Separation in the KM curves was seen at approximately 6 months. Median TDRP was 5.6 vs 5.3 months. At 12 months 39.3% of sipuleucel-T vs 18.9% of control pts were estimated to be pain-free. Significant independent baseline predictors of earlier TDRP were higher PSA, higher alkaline phosphatase, lower age, bisphosphonate use, and prior radiation therapy. When adjusted for these clinical factors, the adjusted treatment HR = 0.80 ([95% CI: 0.60, 1.08]; P = 0.14).
Conclusions: The trend towards a delay in TDRP beginning 6 months after randomization is consistent with the potentially delayed anti-tumour effect of immunotherapy. These data provide support for a potential effect of sipuleucel-T on a clinically relevant endpoint proximal to the demonstrated benefit in overall survival. Lack of statistical significance could be due to limited sample size, high rate of censoring, or delayed treatment effect.

7003 ORAL

Denosumab and Bone Metastasis-free Survival in Men With Castrate-resistant Prostate Cancer − Subgroup Analyses From an International, Double-blind, Randomized, Phase 3 Trial

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Background: Bone metastases are common in men with castrate-resistant prostate cancer (CRPC). Suppression of osteoclast activity by inhibiting RANKL, the key mediator of osteoclast survival, may inhibit release of growth factors from bone and delay onset of bone metastasis. We assessed the ability of denosumab (XGEVA™), a fully human monoclonal anti-RANKL antibody, to prolong bone metastasis-free survival in men with