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Economic evaluation of sunitinib vs. interferon-alfa (IFN-α) in first-line metastatic renal cell carcinoma (mRCC)

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Background: A randomized phase III trial of sunitinib vs. IFN-α as first-line therapy for patients with mRCC is ongoing. An interim analysis of this study demonstrated superiority for the primary endpoint, progression-free survival (PFS), in the sunitinib arm vs. the IFN-α arm (median PFS = 11 months [95% CI: 10−12] vs. 4 months [95% CI: 4−6]; P < 0.000001). Because of the clinical significance of these results, the objective of this study was to demonstrate the economic value of sunitinib vs. IFN-α in this setting from a US third-party payer perspective.
Methods: A Markov model with a 10-year time horizon was developed to evaluate the cost-effectiveness of sunitinib vs. IFN-α. The model projected survival and costs in 6-week cycles based on extrapolation of the trial survival data. The following trial endpoints were used to value model outcomes: PFS; overall survival (OS); quality of life; adverse events (AEs) and related dose reductions or cycle interruptions. The model looked at first-line treatment, second-line treatment and palliative care. Effectiveness was measured in terms of progression-free months (PFM), life-years (LY) gained and quality adjusted life-years (QALY) gained. Resource utilization included drugs, tests, scans, monitoring, physician visits, hospitalizations and treatment of AEs. Costs and survival benefits were discounted annually at 5%. All costs were adjusted to 2006 US dollars. The results of these analyses were expressed as incremental cost-effectiveness ratios (ICERs) and incremental cost-utility ratios (ICURs). Scenario and probabilistic sensitivity analyses were conducted.
Results: Projected PFS and OS were longer for sunitinib than for IFN-α. The incremental cost-effectiveness ratios of sunitinib vs. IFN-α over 10 years were $1,551/PFM, $67,215/LY and $52,593/QALY gained. Based on the probabilistic sensitivity analysis, sunitinib has a 45.9% and a 64.9% probability of being cost-effective compared with IFN-α at the threshold of $50,000 and $100,000/QALY, respectively. The key drivers of the model results were survival and sunitinib drug costs, in addition to cost of best supportive care.
Conclusions: The evaluation found that sunitinib is a cost-effective alternative to IFN-α as first-line treatment in mRCC, with cost-effectiveness ratios within the established threshold that society is willing to pay for health benefits (i.e. $50,000–100,000/LY or QALY).

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Zoledronic acid is cost saving and improves quality-adjusted survival in the prevention of skeletal related events in patients with bone metastases secondary to advanced renal cell carcinoma: a German perspective

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Background: Previous analyses have shown that zoledronic acid (ZA) therapy is cost effective in patients with bone metastases secondary to breast, prostate, or lung cancer. ZA has recently been shown to significantly reduce the risk of new skeletal related events (SREs) in patients with bone metastases secondary to renal cell carcinoma (RCC). The present study assessed the cost effectiveness of ZA in this population, adopting a German health care payer perspective.
Materials and Methods: This analysis was based on a retrospective analysis of a multicenter, randomized, placebo-controlled study of ZA in RCC patients with bone metastases. Patients were randomized to receive ZA (n = 27) or placebo (n = 19) with concomitant antineoplastic therapy every 3 weeks for 9 months. A model was developed to simulate the costs and quality-adjusted life-years (QALYs) of the patients included in the trial. The costs of SREs (including vertebral and non-vertebral fractures, radiotherapy, bone surgery, and spinal cord compression) were estimated by pooling SRE data from four different studies in the Netherlands (n = 114) and Portugal (n = 143). These estimates were supplemented with literature-based costs. Drug, administration, and supply costs were obtained from published sources and tariffs. Consistent with similar economic analyses, patients were assumed to experience quality of life decrements lasting 1 month for each SRE experienced. Discounting was applied at 3.5%/year for both costs and benefits. Uncertainty surrounding outcomes was addressed via bootstrapping of the trial data and multivariate sensitivity analyses (MSA), which involved 10,000 model simulations using input values drawn from probability distributions.
Results: Patients on ZA and placebo experienced on average 0.64 and 1.74 SREs, respectively. ZA and placebo patients experienced 0.518 vs. 0.393 discounted QALYs, respectively. Discounted SRE-related costs were substantially lower among ZA than placebo patients (3,924 € v. 10,687 €, respectively). Thus, after taking into consideration drug therapy costs, ZA saved 3,111 € and increased QALYs by 0.124 over the rest of patients' lives. In the MSA, therapy with ZA saved costs in 80.9% of simulations. The cost per QALY gained was below the 50,000 € per QALY gained threshold in 94.8% of MSA simulations.
Conclusions: The present analysis suggests that ZA saves costs and increases quality-adjusted survival compared to placebo in German RCC patients with bone metastases.

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Characteristics and outcome of bilateral germ cell testicular tumors (BGCTT)

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Background: We examined the incidence, clinical and histological characteristics, treatment and long-term follow-up in patients (pts) with BGCTT.
Materials and Methods: Between 1982 and 2003, 1543 pts with GCTT were treated with standard therapeutical strategies according to clinical stage (CS).656 seminoma (S):377 irradiation, 177 carboplatin (CBDCA) chemotherapy (CHT) and 102 cisplatin (CDDP)-based CHT. 887 nonseminoma (NS): 162 RPLA, 60 surveillance and 665 CDDP-based CHT. Contralateral biopsy at GCTT diagnosis was not performed in any pts. Organ preserved operation for 2nd GCTT was done in 5 pts.
Results: BGCTT occurred in 49 pts (3.2%) with median follow-up (MFU) of 150 months (mo) (range 20−35): 7 (0.45%) synchronous and 42 (2.75%) metachronous. Of the 7 pts with synchronous GCTT [median age 36 years (y)], 2 pts had discordant histology (leydigeoma/NS, S/NS) and 5 concordant histology (4 S, 1 NS). 4 pts presented in CS-A (52.1%). After MFU of 88 mo, 4 pts (57.1%) are alive and free of ds (AFD) and 3 pts died (2 of GCTT, 1 of intercurrent ds). The GCTT in the contralateral testis occurred more frequently if the 1st GCTT was NS (9.8 vs 2.6%) (in the 1st and 2nd GCTT in 59.5% and 52.4%, respectively). 17 pts (40.1%) had discordant and 25 concordant histology (10 S, 15 NS). Occurrence of the 2nd GCTT was higher in pts presented initially in CS-A (3.3% vs 1.9%). The median age at diagnosis of the 1st GCTT was 27.1 y and of the 2nd GCTT 31.8 y (31.5 and 36.5 in S vs 24.1 and 28.6 mo in NS group, respectively). The mean free interval (MFI) between 1st and 2nd GCTT was 56.9 mo (range 4–175) (62 mo for S and 53 mo in NS group). When the histology of the 2nd GCTT was S, the MFI was 110 mo vs only 40 mo for NS (p = 0.007). 23 pts (54.8%) presented within 5 y after the 1st GCTT (in 16.6% >10 y). Of the 1st metachronous GCTT 71.4%, 23.8% and 4.8% are classified to be in CS A-C ds, respectively. The majority of 2nd GCTT presented as low CS, namely 83.3%, 9.5% and 7.2%, respectively. The treatment of the 2nd GCTT was modified regarding initial approach for the 1st GCTT in 28 pts (66.6%) (surveillance in 50% pts). 38 pts (90.5%) are AFD and 4 pts died (3 of GCTT progression, 1 of intercurrent ds). 1 pt with organ preserved operation had local relapse with progression in pelvic LN and is rendered free of ds with CDDP-based CHT. Overall of the 49 pts, 42 (85.7%) had NED and 7 (14.3%) were dead at last follow-up.
Conclusions: Pts with history of GCTT require long term follow-up monitoring of the contralateral testis due to the risk of bilateral ds and potentially long latent period between 1st and 2nd GCTT. The greatest number of pts, particularly in metachronous group, presented in low CS of ds and carries a good prognosis. This results claim in favor of organ sparing surgery in strictly selected pts.