PCN20

REAL LIFE TREATMENT DURATION OF SORAFENIB OR SUNITINIB IN FIRST LINE METASTATIC RENAL CELL CARCINOMA PATIENTS—A COMPARATIVE ANALYSIS

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OBJECTIVES: The Israeli National Health Insurance Law stipulates a National List of Health Services that all residents are entitled to. In March 2008, two tyrosine kinase inhibitors (TKIs), sorafenib and sunitinib, were added to the formulary indicated and limited for first-line treatment of metastatic renal cell carcinoma (mRCC). Oncologists could prescribe only one TKI, and patients are not eligible to subsequently receive the other. After 15 months on the formulary, we compared oncologists' prescribing preferences, treatment duration (TD), and survival in patients with mRCC treated with sorafenib or sunitinib. **METHODS:** We used demographic and claims data from Clalit Health Services' 3.5 million client computerized database to identify all mRCC patients treated with either sorafenib or sunitinib since March 2008. Mean and median TD and patient survival were calculated and compared using a Kaplan-Meir analysis. **RESULTS:** Through the end of May 2009, 134 patients received sunitinib as initial therapy for mRCC, 29 patients received sorafenib. The two groups had similar demographic characteristics: mean (SD) age was 66.2 (±12.8) for sunitinib patients and 69.4 (±10.7) for sorafenib patients (p = 0.212). Approximately 63% of the subjects in each group were males. Mean TDs were 8.0 months (95% CI 6.8–9.0) and 5.7 months (95% CI 3.8–7.8) for sunitinib and sorafenib, respectively (p = 0.071). Median TDs were 7.0 months (95% CI 4.4–9.6) and 3.0 months (95% CI 1.4–4.6) for sunitinib and sorafenib, respectively. Mean survival times were 11.3 months (95% CI 10.4–12.2) and 8.1 months (95% CI 6.1–10.1) for sunitinib and sorafenib patients, respectively (p = 0.023). **CONCLUSIONS:** Our retrospective analysis suggests that Israeli oncologists strongly prefer prescribing sunitinib for first line treatment of mRCC. Mean and median TDs and survival were longer for patients treated with sunitinib. Future analyses must control for patient clinical characteristics, which may have been a major factor in treatment preferences, and might have influenced TD and survival.

PCN21

NUMBER NEEDED TO TREAT (NNT) ANALYSIS COMPARING BENEFITS OF LETROZOLE WITH ADJUVANT CHEMOTHERAPY IN PATIENTS WITH NODE-POSITIVE BREAST CANCER

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OBJECTIVES: For pts with N+ BC, CT with a taxane is a standard treatment, followed by endocrine therapy as indicated. Letrozole (LET) has shown an overall survival (OS) benefit relative to tamoxifen (TAM) in postmenopausal women with N+ BC. To assess the relative survival benefits of these interventions, we calculated the NNT to prevent one death. **METHODS:** Five-year survival data was taken from a pivotal randomized controlled trial (RCT) for LET (N+ pts from BIG 1-98, TAM arm censored for crossover to LET) and from three RCTs of adjuvant taxane CT regimens (AC-T, FEC-D, and DAC). These studies were selected based on comparable follow up and exclusion/inclusion criteria. NNT was calculated with respect to OS at 5 yrs; outcome is presented as the NNT to save a life. **RESULTS:** The NNT for OS for adjuvant LET *vs.* TAM was 27 based on BIG 1-98 in N+ BC pts; this was comparable to the NNTs for taxane based therapies as shown below. **CONCLUSIONS:** The magnitude of OS benefit seen with LET over TAM in BIG 1-98 is similar to that seen with adjuvant taxane based CT regimens. Taxanes are part of standard management of adjuvant BC. These data support the standard use of LET/AIs as well. The studies BIG 1-98[1]: **LET** *vs.* TAM, 27; **PACS01**[2]: **FEC-D** *vs.* FEC, 25; **BCIRG 001**[3]: **DAC** *vs.* FAC, 17; **CALGB 9344**[4]: **ACäT** *vs.* AC, 34 for Exp vs. Controls, OS NNT. **F** = Fluorouracil E = Epirubicin C = Cyclophosphamide D = Docetaxel T = Paclitaxel A = Doxorubicin. [1]Mouridsen 08 [2]Roche 06 [3]Martin 05 [4]Henderson 03.

PCN22

COMPARING THE SURVIVAL BENEFIT OF LETROZOLE AND ANASTROZOLE: A NUMBER NEEDED TO TREAT ANALYSIS

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OBJECTIVES: Large multinational clinical trials, namely ATAC and BIG 1-98, demonstrated that anastrozole (ANA) and letrozole (LET) were superior to tamoxifen (TAM) in preventing disease recurrence in postmenopausal women with early breast cancer. The number needed to treat approach (NNT) is an effective method to express multiple findings from randomized trials in a clinically meaningful way. LET and ANA had comparable NNT for all recurrences at 2 and 2.5 years, respectively; however, NNT for distant recurrence was 3-fold fewer with LET *vs.* ANA. Long term follow-up (FU) of BIG 1-98 and ATAC trials suggested potential differences between LET and ANA in overall survival (OS). In this exploratory analysis, the NNT approach was used to compare LET and ANA in avoiding death. **METHODS:** An essential requirement for NNT analyses is to consider outcomes over similar FU periods. The OS data for ANA from ATAC (median FU: 68 months; HR = 0.97) and for LET from BIG 1-98, (median FU: 76 months; HR = 0.81) were used in this analysis. In the BIG 1-98 trial the censored analysis was included as it remained unblinded (similar to ATAC trial). In the ATAC trial only data for HR+ve subanalysis was included. Nearly all pts in BIG 1-98 (99%) were HR+. **RESULTS:** Fewer pts needed to be treated with LET than ANA to avoid one death compared to TAM, 63 (95% CI: 39–500) and 161 (95% CI: 38–∞) pts respectively; representing a 2.5-fold difference. **CONCLUSIONS:** The lower NNT associated with LET in BIG 1-98 to avoid one death compared to ANA in ATAC could be due to the significant reduction in early distant recurrence observed with LET, which may translate into a survival benefit.

PCN23

PHARMACOEPIDEMIOLOGY OF PATIENTS TREATED WITH TEMOZOLOMIDE

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OBJECTIVES: Temozolomide (TMZ) is an oral alkylating cytotoxic agent prescribed in monotherapy or in association with radiotherapy. TMZ is indicated in the treatment of high-grade brain tumours (glioblastoma multiforme and astrocytomas). However, TMZ is also used off-label. The main objective of this observational study was to assess the conformity of the use of TMZ in clinical practices. The secondary objective was to identify all indications in which TMZ was prescribed. **METHODS: A French** prospective multicenter study related to consecutive patients treated by TMZ was performed in 21 hospitals. Patients' characteristics and drug prescriptions parameters, in terms of indications, dosages, treatment length, association with other drugs, side effects and prophylactic drugs, were collected. The level of conformity was analyzed in comparison with the market authorization and a prescription guideline elaborated by clinical experts and pharmacists. **RESULTS:** A total of **831 patients (median age** 56 y; men: 57%) representing a total of 5982 TMZ cures were registered. TMZ was mainly prescribed in glioblastoma multiforme newly diagnosed or in relapse (51%), in anaplastic oligodendrogliomas (27%) and in anaplastic oligoastrocytomas (10%). TMZ was prescribed in malignant melanomas in 3% of cases. During monotherapy, the mean daily dose was 173 mg ± 35 mg/m^2. Ninety percent of patients received the planned duration of cycle. Thirty-three percent of side effects were observed. More than half of patients were co-treated by antiemetics (86%) and antiepileptics (63%). Indications were conformed to the guideline in 91% of cases but only in 54% in accordance with the market authorization. As compared to the market authorization, conformity rate was respectively observed in 76%, 84%, 90% 88% and 78% in terms of dosages, TMZ duration, cycle duration, associations, total length of treatment, leading to a global conformity of 54%. **CONCLUSIONS: In this study, TMZ prescrip**tion appears highly conform to the guideline but lower when compared to the market authorization.

PCN24

CLINICAL OUTCOMES AND HEALTH CARE RESOURCE UTILISATION OF PATIENTS RECEIVING LAPATINIB FOR BREAST CANCER IN FRANCE: THE LAPS STUDY (LAPATINIB ATU PARCOURS DE SOINS)

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BACKGROUND: lapatinib (Tyverb®) is an oral small molecule inhibitor of ErbB1 and ErbB2. Lapatinib in combination with capecitabine has been approved for the treatment of patients with HER2+ advanced or metastatic breast cancer (MBC). Since January 2007 prior to its European registration, lapatinib was made available to patients through the (ATU). The full oral course of lapatinib + capecitabine does not require any hospital infusion. This may have a positive impact on care consumption. **OBJECTIVES:** To describe clinical outcomes and health care resource utilisation of patients receiving lapatinib in the scope of the ATU, an everyday practice setting. **METHODS:** Observational, retrospective study in patients who entered the ATU between January 1, 2007 and September 30, 2007. Data were collected from patients' medical files between February 21, 2008 and April 30, 2008. **RESULTS:** A total of **198 patients were included (mean age** = 55yrs). Most patients had already received 4 prior metastatic regimens. At this time, patients presented liver (53%), bone (52%) and brain (40%) metastases. 49% of patients responded positively to the treatment. The study showed a median TTP of 23 weeks. A median OS of 41.6 weeks was estimated with Kaplan-Meier survival analysis. While receiving lapatinib, 53% of patients had no hospitalization and 19% had only day admissions. In 70% hospitalizations were associated with disease progression while day admissions were associated with treatment follow-up (74%). Only 11% of hospitalizations and 2% of day admissions were associated with toxicity. Sixty-eight of patients had a consultation (inside or outside hospital). **CONCLUSIONS:** this study provides the first data on health care resource utilisation with lapatinib use in the French current medical practice. Clinical outcomes are consistent with trial results for advanced treatment lines. The study shows a limited care consumption driven by a very low rate of hospitalization.