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' prescriptions, treatment duration (TD), and survival in patients with mRCC treated with sorafenib or sunitinib. METHODS: We used demographic and claims data from Clarith 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-Meier 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 7.5 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 11.5 months (95% CI 10.4-12.2) and 9.1 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.

NUMBER NEEDED TO TREAT (NNT) ANALYSIS COMPARING BENEFITS OF LETR佐LE 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 pivoted 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, FAC, and DACT). 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 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 vs. LET vs. TAM, 27; PACS01 vs. FEC-D, 25; BIRC5 G001 vs. FAM, 17; CALGB 9344 vs. AC, 34 for Exp vs. Controls, OS NNT. F = Fluorouracil E = Epirubicin C = Cyclophosphamide D = Doctaxel T = Paclitaxel A = Dexorubicin. *Mouridsen 08 Roche 06 Martin 03 Henderson 03

COMPARING THE SURVIVAL BENEFIT OF LETR佐LE AND ANASTROZOLE IN PATIENTS 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 maximum clinical benefit of 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 concerning the NNT. 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 unbiased (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 39–50) and 161 (95% CI 98–247) pts respectively; representing a 2.5-fold difference in NNT. The lower NNT associated with LET in BIG 1-98 to avoid one death compared to ANA in BIG 1-98 could be due to the significant reduction in early distant recurrence observed with LET, which may translate into a survival benefit.