

SAFETY OF SUNITINIB IN RENAL CELL CARCINOMA

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Objetives: Renal cell carcinoma (RCC) represents only 2-3% of all cancers. Sunitinib is the standard initial therapy in advanced and metastatic renal cell carcinoma. A retrospective review was performed to evaluate sunitinib safety in RCC.

Methods: RCC patients undergoing sunitinib treatment and follow-up for at least one month. Data: sex, age, nephrectomy status, histology, risk group, metastatic sites, sunitinib starting dose, % adverse events (AE) from Common Terminology Criteria for Adverse Events (CTCAE version 4.0), % grade 3-4 AE, % starting dose reduction, % extra week rest period and % colony stimulating factors (CSF) used for toxicity management. Statistical analysis by SPSS® 18.0.

Results: 19 patients were analysed. Median sunitinib cycles received were 4.3. Toxicity management consisted in dose reduction 38.4%, extra week rest period 57.6%, none patient required CSF as filgrastim or epoetina.

Table 1. Baseline characteristics

| Baseline characteristics (n=19) | Results |
|---------------------------------|---------|
| Male | 73.7% |
| Median age (years) | 62 |
| Nephrectomized | 94.7% |
| Histology CCRC | 79.0% |
| Median metastasic sites | 3 |
| Lung | 68.4% |
| Liver | 47.4% |
| Soft tissues | 26.3% |
| Bone | 21.1% |
| Pleura | 21.1% |
| Brain | 10.5% |
| Skin | 10.5% |
| Heart | 10.5% |
| Risk Group Classification | 57.9% |
| Favourable | 15.8% |
| Intermediate | 26.3% |
| Unfavourable | 15.8% |

Figure 1. Sunitinib starting dose

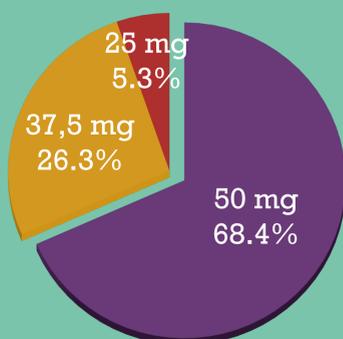
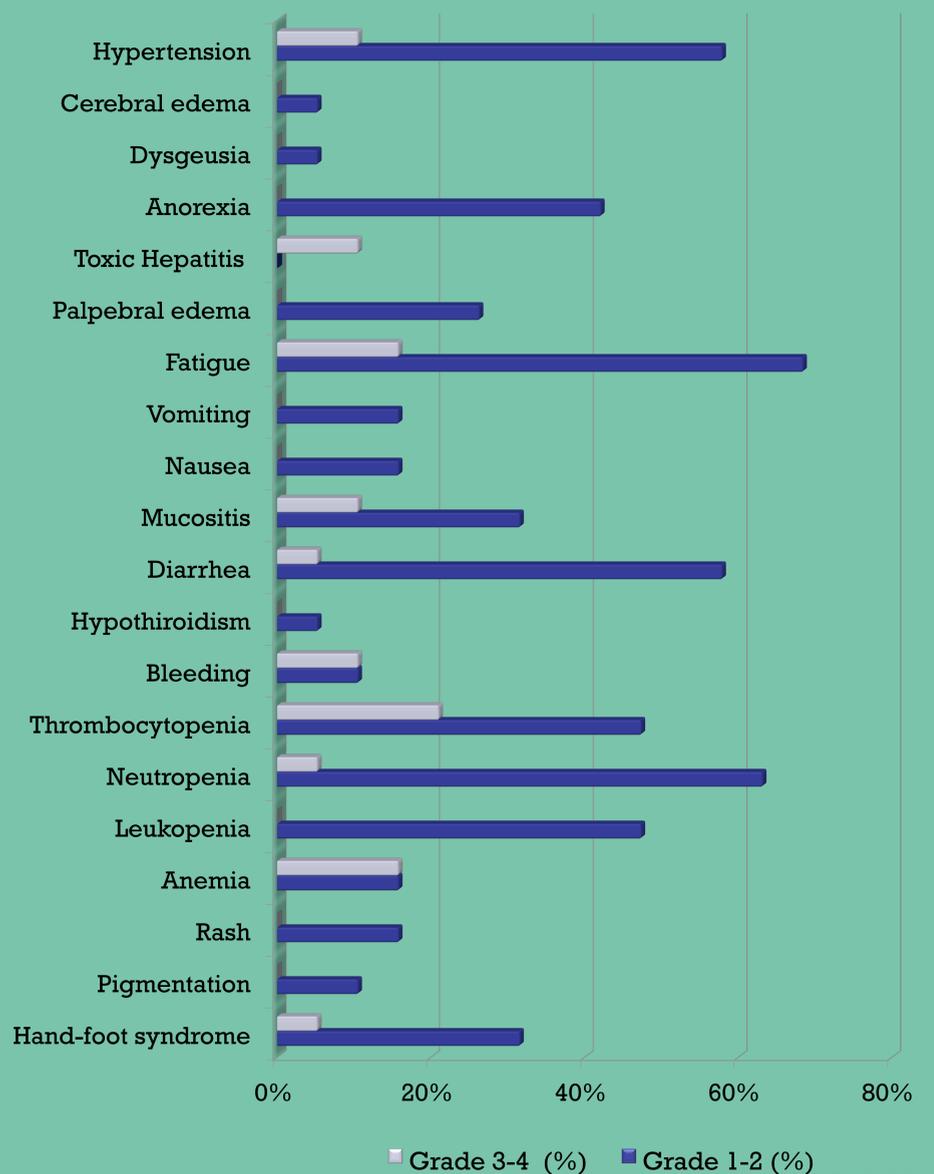


Figure 2. Adverse events



Conclusions:

- Sunitinib adverse events as hematologic toxicity, asthenia, hypertension and gastrointestinal events were common.
- Toxicity management included dose reduction or additional rest period.