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SAFETY PROFILE OF SUNITINIB IN REAL CLINICAL PRACTICE

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Background

In long-term safety studies of sunitinib, most adverse events (AE) occurred initially between the first 6 months and 1 year, and remained stable or decreased in frequency over time.

Purpose

To analyze the safety and tolerability of sunitinib in real clinical practice

Material and Methods

Retrospective descriptive and observational analysis.

April 2010 to September 2018

All patients trated with Sunitinib

To asssess safety:

- **-Frequency of adverse reactions**
- **-Median time to treatment suspension due to AE**
- **-Median time to dose reductions and the reasons**

Variables collected**

- **Sex, Age**
- **Diagnosis**
- **Line of treatment**
- **Date of beginning and end of treatment**
- **Reasons for suspension, dose reductions**
- **AE**

**from the electronic medical record (DIRAYA®) and the prescription program (FARMIS® and PRISMA®)

Results

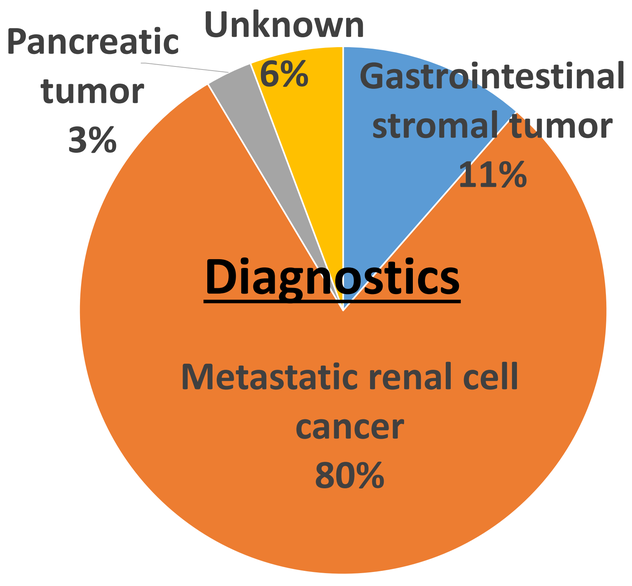
35 patients

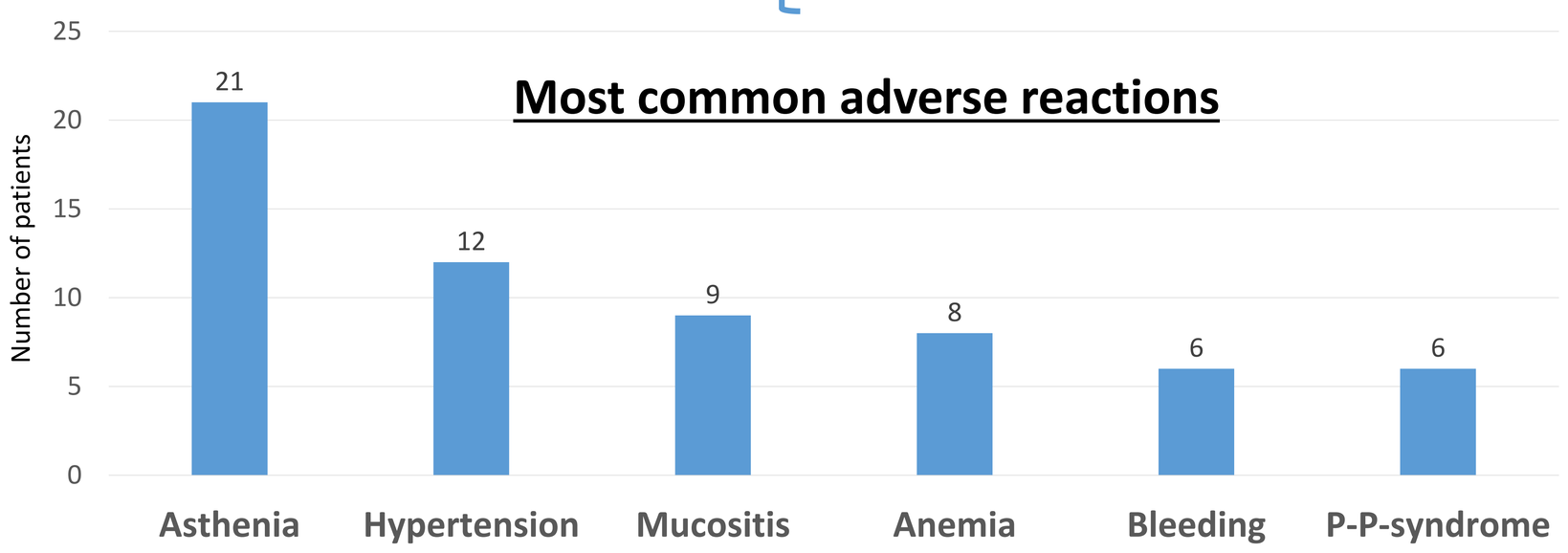
66% men

Average age: 62 years

Recibed sunitinib as

- **-First line: 77% (n=27)**
- **-Second line: 20% (n=7)**
- **-Third line: 3% (n=1)**





Ten patients discontinued treatment due to AE.

Median time to treatment suspensión due to AE was 3.42 months [0.47-95.43] because of poor tolerance, unacceptable toxicity, haemorrhages, osteonecrosis of the jaw, asthenia, mucositis, anorexia and liver toxicity. Of these patients, only three had previous dose reductions. Eight patients required dose reduction, with a median time to dose reduction of 1.78 months [0.97-87.37].

The main cause of reduction was asthenia (5/8). One patient had a second dose reduction one month after the first reduction due to poor quality of life.

Conclusions

Reported AE were within the expected, with asthenia and hypertension as the most frequent. About one third of patients discontinued treatment with sunitinib due to AE in the first four months of treatment and in most cases without prior dose reductions.

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