ANALYSIS OF THE INCIDENCE OF HEPATOTOXICITY ASSOCIATED WITH THE USE OF TOCILIZUMAB

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BACKGROUND AND IMPORTANCE

Prolonged treatment with tocilizumab has been associated with cases of severe hepatotoxicity with liver failure and hepatitis, characterised by elevated hepatic transaminases (GOT/AST and GPT/ALT).

AIM AND OBJECTIVES

To analyse the incidence of elevation of liver enzymes and the presence of severe liver damage in patients treated with tocilizumab, in a third level hospital.

MATERIAL AND METHODS

A descriptive, observational, 10 year study that included all patients treated with tocilizumab for more than 6 months, from January 2009 to August 2019, was carried out.
Patients in whom the drug was used under special conditions of use and those with abnormal transaminase values prior to the start of treatment were excluded. The variables recorded were age, sex and duration of treatment.

Liver function values (GOT/AST and GPT/ALT) were analysed every 4 weeks in the first 6 months of treatment and every 12 weeks after 6 months of treatment.

Alterations in these values were classified:

- Mild: 1–3 × normal upper limit (NAL)
- Moderate: 3–5 × NAL.
- Severe : >5 × NAL.

Data were collected from a database in Excel® format.

RESULTS

135 patients treated with tocilizumab (TCZ)

84 IV TCZ

51 SC TCZ

77 total patients incluiding in the final analysis

48.1% (n=37) showed alterations in liver parameters during treatment.

56 patients excluded

- 28 for receiving treatment for 6 months
- 19 for off-indication regimens
- 9 for elevation of liver enzymes prior to drug initiation

Mean duration of treatment was 40.44 months

- **First 6 months of treatment**: 22.1% of patients (n=17) showed an increase in GOT/AST and GPT/ALT levels.
(82.4% mild (n=14), 11.8% moderate (n=2) and 5.9% severe (n=1)).

- **After 6 months of treatment**: 44.2% of cases (n=34) levels of GOT/AST and GPT/ALT increased.
(88.2% mild (n=30), 11.8% moderate (n=4)).

CONCLUSIONS

Our study showed that the rate of liver toxicity in patients treated with tocilizimumab was about 50%. Severe toxicity was identified in only one patient. These results, as indicated by the European Medicines Agency, show the need for liver function monitoring in patients treated with tocilizumab

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