Material and methods We analysed 148 patients treated with pirfenidone (72% men; 28% women) and 120 treated with nintedanib (77% men; 23% women) from September 2016 to September 2019. The average age of the patients treated with pirfenidone and nintedanib was 72.7 and 74.4 years, respectively. Drug tolerability was compared by a Student’s t test considering the average number of days of treatment (DOT) for patients who started the therapy since September 2016 (n=88 pirfenidone; n=120 nintedanib). The safety of the two treatments was compared by analysing the adverse drug reactions (ADRs) reported. ADRs were classified as: nausea/vomiting (NV), diarrhoea, rash, weight loss (WL) and non-specific gastrointestinal disturbance (nsGID). We also considered the type of action taken (interruption, reduction of dosage) and compared the frequencies using a $\chi^2$ test.

Results The Student’s t test showed no statistically significant difference in the average DOT between the two treatments ($t=0.9803$, df=206, $p=0.3281$). We detected 30 ADRs in 148 patients treated with pirfenidone (4 of which were severe) and 66 in 120 patients treated with nintedanib (1 severe). Nintedanib showed a greater percentage of ADRs at the gastrointestinal level (NV 18%, diarrhoea 42%, WL 23%, nsGID 39%) compared with pirfenidone (NV 17%, diarrhoea 7%, WL 13%, nsGID 20%). Pirfenidone instead showed a greater percentage of rash (43%) compared with nintedanib (8%). The $\chi^2$ test carried out on type of action taken showed a statistically significant difference in the distribution of patients who suspended or reduced the dosage for the two drugs ($\chi^2$ (96)=9.329, $p<0.0023$, df=1). Nintedanib showed a higher percentage of patients who reduced the dosage (70%) compared with pirfenidone (37%), probably due to the different dosage titrations. The percentage of patients who suspended therapy was higher for pirfenidone (63%) than for nintedanib (30%).

Conclusion and relevance Although the tolerability of the drugs was comparable, nintedanib showed a higher incidence of ADRs compared with pirfenidone but with a lower severity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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