

to 8.31) and 7.61 ng/ml (95% CI: 7.35 to 7.87). Mean number of plasmatic determinations: 13.71 (95% CI: 12.89 to 14.54), 4.72 (95% CI: 4.18 to 5.26), 5.24 (95% CI: 4.66 to 5.83) and 5.45 (95% CI: 4.87 to 6.04). Percentage of concentrations lower than 5 ng/ml: 13.51% (95% CI: 11.28 to 15.74), 9.28% (95% CI: 6.49 to 12.06), 13.12% (95% CI: 9.73 to 16.51) and 12.81% (95% CI: 9.35 to 16.27). Mean CV: 43.55% (95% CI: 41.29 to 45.81), 25.41% (95% CI: 23.09 to 27.74), 25.38% (95% CI: 22.99 to 27.77) and 24.43% (95% CI: 22.11 to 26.75). Percentage of patients with CV >30%: 80.25% (95% CI: 75.21 to 85.29), 31.75% (95% CI: 25.42 to 38.09), 29.86% (95% CI: 23.63 to 36.08) and 30.48% (95% CI: 23.82 to 37.14).

**Conclusion** FKplasm and IPV during induction are higher than in EM and LM. However, patients with CV >30% remain in the maintenance periods between 29.9% and 31.8%, and with values <5 ng/ml between 9.3% and 13.1% which would justify a greater need for pharmacokinetic monitoring and therapeutic control, in order to preserve a longer graft survival and to minimise the events of pharmacological adverse reactions.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-150

#### EVALUATION OF INTRA-PATIENT VARIABILITY OF THE TACROLIMUS PLASMATIC LEVELS IN DIFFERENT PERIODS AFTER LIVER TRANSPLANT

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**Background** Immunosuppressive therapy in liver transplant patients (LTP) is divided into several temporary periods after surgery. The priority is to avoid acute rejection in the earliest stages, and advancing in time, to preserve a longer graft survival and to minimise pharmacological adverse events.

**Purpose** To assess the mean concentration, intra-patient variability (IPV) of serum levels of tacrolimus (FKs) and their evolution during the different periods after liver transplant to evaluate the therapeutic situation of LTP.

**Material and methods** Observational retrospective study since January 2015, with a minimal post-transplant follow-up of 1 year. Clinical data was collected from the hospital's medical records.

Variables of the study were calculated considering different periods of liver post-transplant according to our hospital's medical protocol: 0–1 month (S1), 1–3 months (S2), 3–6 months (S3), 6–9 months (S4) and 9–12 months (S5). FKs mean, coefficient of variation (CV), proportion of patients with CV >30% (CV30), estimated daily area under the curve (AUCd) and proportion of FKs values <5 ng/mL (P5) per patient were calculated. CV was used to characterise the IPV. Therapeutic control was considered inadequate if CV values were >30% or P5 >20%.

Variance analysis and the Kruskal–Wallis test were used to compare quantitative variables (SPSS).

**Results** Eighty-eight patients and 1206 measures of FKs were included. The values of variables analysed – mean FKs, P5, estimated AUCd and CV30 – were expressed in the temporal order of the follow-up period – S1, S2, S3, S4, S5 – as follows:

Mean FKs: 7.5 ng/mL (95% CI: 7.0 to 8.0), 8.0 ng/mL (95% CI: 7.6 to 8.6), 7.0 ng/mL (95% CI: 6.5 to 7.4), 6.5 ng/mL (95% CI: 6.0 to 7.0) and 6.5 ng/mL (95% CI: 5.9 to 7.1).

P5: 30.0% (95% CI: 25.0 to 35.0), 18.4% (95% CI: 12.7 to 24.2), 21.4% (95% CI: 14.2 to 28.6), 23.3% (95% CI: 15.1 to 31.4) and 29.5% (95% CI: 19.2 to 39.8).

AUCd: 7.1 ng/mL.day (95% CI: 6.5 to 7.7), 7.8 ng/mL.day (95% CI: 7.1 to 8.5), 6.1 ng/mL.day (95% CI: 5.5 to 6.7), 7.9 ng/mL.day (95% CI: 6.5 to 9.3) and 9.1 ng/mL.day (95% CI: 7.4–10.9).

CV30: 89.8% (95% CI: 83.3 to 96.2), 41.2% (95% CI: 30.5 to 51.9), 37.7% (95% CI: 27.1 to 48.2), 13.9% (95% CI: 6.1 to 21.7) and 21.5% (95% CI: 11.3 to 31.8).

Technically, for each period: 89.8%, 43.5%, 44.7%, 27.9% and 40% patients had poor FKs control levels (CV >30% or P5 >20%).

Mean FKs, P5, AUCd and CV30 observed varied widely among periods, achieving statistical differences for almost all parameters: p<0.001, p<0.001, p=0.002 and p<0.001.

**Conclusion** CV30 and P5 during the earliest periods after liver transplant remain higher than in the latest, and up to 89.8% of patients have a poor therapeutic control. The detection of patients with high IPV or analytical values <5 ng/mL during the different stages of liver post-transplant could justify a greater need for therapeutic control, since these are associated in the long term with a worse prognosis, leading to chronic rejection and/or greater pharmacological toxicity.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-151

#### INFLUENCE OF THE ROUTE AND PHARMACEUTICAL PREPARATION IN INTRA-PATIENT VARIABILITY OF TACROLIMUS SERUM LEVELS IN THE LIVER TRANSPLANT PATIENT

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**Background** In the earliest stages, immunosuppressive therapy in liver transplant patients (LTP) is targeted to avoid acute rejection, to preserve graft survival and to minimise the risk of pharmacological adverse reactions. The use of different administration routes or immediate-prolonged release preparations could influence tacrolimus serum levels (FKs) and variability.

**Purpose** To assess the mean concentration and the intra-patient variability (IPV) of FKs after their administration through immediate-prolonged release preparations and/or different administration routes in LTP.

**Material and methods** Observational retrospective study including LTP within 2015–2017.

Clinical data was collected from the hospital's medical records, including: type of transplant, date of surgery, tacrolimus pharmaceutical form (TacPP), administration route and FKs values within 1 month after liver transplant.

FKs mean levels, coefficient of variation (CV), proportion of patients with CV >30% (CV30) and proportion of FKs values lower than 5 ng/mL (P5) per patient were calculated.

The influence of the TacPP administered (immediate/prolonged/extended release) and the administration route (oral/nasogastric tube), in case of immediate-release tacrolimus form was also analysed.

Therapeutic control was considered inadequate if CV30 occurred, or P5 was higher than 20%.

Statistical analysis was done using SPSS. Variance analysis and the Kruskal–Wallis test were used to compare quantitative variables.

**Results** Eighty-four patients were included. The values of the variables analysed – mean FKs, P5 and CV30 observed – were 8.0 ng/mL (SD, 4.2), 19.3% (SD, 39.6) and 66.0% (DE, 46.9). Technically, 68.3% patients had poor FKs control levels.

According to TacPP, values for mean FKs, P5 and CV30 observed were:

Immediate-release tacrolimus: 8.5 ng/mL (95% CI: 6.2 to 10.9), 28.6% (–95% CI: 12.8 to 44.3) and 58.1% (95% CI: 39.7 to 76.5).

Prolonged-release tacrolimus: 7.9 ng/mL (95% CI: 6.2 to 10.9), 10.5% (95% CI: 1.0 to 25.6) and 66.7% (95% CI: 55.0 to 78.3).

Extended-release tacrolimus: 9.6 ng/mL (95% CI: 8.0 to 11.3), 8.3% (95% CI: 0.0 to 27.0) and 83.3% (95% CI: 58.6 to 100.0).

According to the administration route (immediate-release tacrolimus form), values for mean FKs, P5 and CV30 observed were:

Oral: 8.5 ng/mL (95% CI: 6.2 to 10.9), 28.6% (95% CI: 6.7 to 24.9) and 58.1% (95% CI: 40.0 to 76.5).

Nasogastric tube: 6.8 ng/mL (95% CI: 5.5 to 8.0), 32.3% (95% CI: 14.8 to 49.7) and 76.0% (95% CI: 58.0 to 94.0).

Mean FKs, P5 and CV30 observed varied widely among the TacPP and administration route: statistical differences were only achieved for P5 within TacPP ( $p=0.044$ ).

**Conclusion** Taking into account the limitations of this study, our findings suggest that high IPV of FKs exist, at least within the first month after the transplant date. Moreover, the IPV of FKs after their administration through immediate-prolonged release preparations and/or a different administration route shows a wide range of variability that in concrete cases (P5) raises statistical significance.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-152

#### CHEMOTHERAPY PHARMACEUTICAL CONSULTATION: PHARMACEUTICAL INTERVENTIONS AFTER 18 MONTHS OF IMPLEMENTATION

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**Background** In January 2017, our pharmacy department implemented an oral chemotherapy pharmaceutical consultation in which the order was checked, a medication review was done and drugs information provided (toxicity, taking drug, drug-drug interaction) and completed by an information sheet for patients. In order to promote therapy monitoring, side-effects' management and treatment adherence, we contacted health professionals: nurse, physician, oncologist and community pharmacist.

**Purpose** Eighteen months after the implementation of the pharmaceutical consultation the purpose was to assess pharmaceutical interventions on patients, oncologists, physicians and community pharmacists.

**Material and methods** Revision of our consultation sheets from January 2017 to June 2018.

Sixty-four pharmaceutical consultations occurred for 56 patients (33 males; 28 females; mean 69 years (33–93) with an average time of 33.4 min.

**Results** Seventy-nine medication-related problems were reported: 31 side effects, 15 drug-drug interactions, 10 absences of adapted comedication and eight inobservances.

One-hundred and two pharmaceutical interventions had been achieved: 51 on patients, 28 on oncologists, 18 on community pharmacists, four on nurses and one on a physician. During pharmaceutical consultation 51 patient information sheets on oral chemotherapy were given to patients, who mostly had medium or bad theoretical ( $n=31$ ) and technical ( $n=22$ ) knowledge about their oral chemotherapy, which could reduce its efficacy. Twenty-eight feedbacks were transmitted to oncologists by phone, face-to-face or secure mail. Eighty-two per cent of pharmaceutical interventions were accepted by oncologists. Eighteen community pharmacists had been contacted by phone. A consultation report condensed and patient information sheets were sent to them by fax ( $n=15$ ) or secure e-mail ( $n=3$ ). Four nurses had received information by phone on modalities of storage, administration, waste and side-effects' management. One physician was contacted for a drug-drug interaction.

Our first results showed the quantitative and qualitative importance of pharmacist interventions with patients and other health professionals. However, to improve the quality of our consultations we must develop a systemic and easy feedback to these professionals. A follow-up for the patients during the treatment will be useful.

**Conclusion** Completed by patient information sheets and feedback, the pharmaceutical consultations appear essential to facilitate care by other health professionals and to give patients significant information concerning their health.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

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#### COMPARATIVE ANALYSIS BETWEEN ORIGINATOR AND BIOSIMILAR INFlixIMAB ACCORDING TO TROUGH LEVELS IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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**Background** The introduction of biosimilar infliximab (IFX-B) has led to a decrease in the costs of patients with inflammatory bowel disease (IBD). The molecular complexity in the manufacture of biological drugs makes it difficult to verify the similarity between the different drugs. Infliximab (IFX) therapeutic drug monitoring allows for objective decision-making in patients with IBD.

**Purpose** To compare the percentage of patients in therapeutic IFX concentrations, between originator infliximab (IFX-O)