Conclusion and relevance This study had strong limitations: lack of placebo group, patients belonged to the same geographic zone and different adjuvant treatments were used. Strengths of the study were a balanced population, high prevalence of paediatric patients and a long monitoring period. CTOO+AT have shown effectiveness and safety, based on the outcomes considered, in IAOS. It might be a good alternative in cases of contraindications, poor tolerance or inefficacy to corticosteroids, especially in paediatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-319 PIRFENIDONE AND NINTEDANIB FOR THE TREATMENT OF THE IDIOPATHIC PULMONARY FIBROSIS: AN ITALIAN HOSPITAL EXPERIENCE

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Background and importance Idiopathic pulmonary fibrosis (IPF) is a severe pulmonary disease with few therapeutic alternatives and characterised by progressive decline in lung function. Pirfenidone and nintedanib are tyrosine kinase inhibitors that have been approved for clinical treatment in mild to moderate IPF in adults.

Aim and objectives The aim of this study was to review the use of pirfenidone and nintedanib in terms of effectiveness and safety in patients with mild to moderate IPF over 12 months of follow-up, through indicators such as the volume of air that can be exhaled with maximal effort (FVC) and the alveolar-capillary diffusion of carbon monoxide (DLco).

Material and methods A retrospective observational study was conducted in patients receiving treatment with pirfenidone and nintedanib from January 2018 to October 2020. Clinical data were collected from the electronic web based national register of Italian medicines. Measured variables were: age, sex, pathology severeness, forced vital capacity (FVC%), diffusion capacity of the lungs for carbon monoxide (DLco,%), before and after the start of treatment. The main outcome was the variation in FVC from baseline levels, considering it a positive response to the treatment if FVC did not decrease by more than 10%. The presence of adverse reactions was reviewed to assess safety.

Results In our hospital, we enrolled 70 patients receiving pirfenidone (50%) and nintedanib (50%). 81.4% of patients were men, with a mean age of 74 ± 8 years. 57.1% had moderate pathology and 42.9% had mild pathology. 2.8% of patients left by voluntary decision and another 3.1% had progression of the pathology. The initial median FVC was 79.63 ± 15.14 and median DLco was 51.74 ± 15.13 . After treatment, we obtained a median FVC of 78.31 ± 15.65 and a median DLco of 48.09 ± 16.38 . 83.8% of treated patients had a positive response with a decrease of no more than 10% of FVC, and 22.1% of treated patients had an improvement in FVC >5%. 11.8% of treated patients had an improvement in DLco >5%. 14 patients had adverse reactions. The most frequent was dyspepsia (36%), followed by rash (25%); less frequent side effect were headache (8.4%) and diarrhoea (8.4%).

Conclusion and relevance Pirfenidone and nintedanib showed benefit in decreasing progression of IPF and had effectiveness

and safety profiles similar to those of other studies, revealing that it is a well tolerated and effective drug. On the other hand, the adverse reactions were mild, but the rate of occurrence was high.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-320 IMPROVING MEDICATION ADHERENCE AND PATIENTS' EXPERIENCE AFTER HEART TRANSPLANT USING A MULTILEVEL EHEALTH INTERVENTION: THE MHEART CLINICAL TRIAL

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Background and importance Multimorbidity and therapeutic complexity are undermining health outcomes in chronic populations. Medication non-adherence may be a consequence of this complexity and is a direct cause of graft loss and death after a heart transplant (HTx). Effective interventions to improve medication adherence and lifestyle habits require a proactive interdisciplinary team and integrated care models. The development and implementation of internet based health technologies (eHealth) may lead to implementation of such chronic care programmes in clinical practice.

Aim and objectives To improve recipients' adherence to immunosuppressive medication (IS). Secondary objectives were to improve patients' experience of their therapeutic regimens (TR) and to optimise clinical practice.

Material and methods An eHealth model was implemented in a HTx hospital's outpatient clinic. The software developed (mHeart) was a mobile and website application (<https://n9.cl/ajut>). The model was validated previously in a pilot study.¹ For this purpose, an intensive, individually tailored, behavioural based multicomponent intervention performed using the mHeart features in an interdisciplinary environment was established. The study design is described in figure 1.

Results A total of 134 chronic stage HTx patients (mean age 55 (SD 14) years) were included (intervention n=71; control n=63). The mean follow-up was 1.6 (SD 0.6) years. At the end of the study, 86% were engaged with mHeart. Patients' experience of TR significantly improved in the intervention group (IG) versus the control group (CG): degree of inconvenience perceived by the patient (p=0.002), patient's knowledge of their regimen intakes (p=0.019), drugs names (p=0.006), drugs doses (p=0.030) and drugs indications remembered (p=0.003).

In addition, patient's awareness of the consequences of non-adherence significantly improved (p<0.01) and the number of adverse effects reported was significantly reduced to 3 ± 2 in all groups (p=0.000). The non-adherence rate significantly improved in the IG versus the CG according to the SMAQ questionnaire (85% vs 46%) (OR=6.7 (2.9; 15.8); p=0.000). Because of the online follow-up, patients' in-clinic appointment needs with the clinical pharmacist and the intensity of the follow-up were significantly reduced in the IG (65%) versus the CG (35%) (OR=3.4 (1.7; 6.9); p=0.001).

Abstract 4CPS-320 Figure 1 Patient allocation during the study period differed depending on the time post-transplant. Chronic-stage recipients (>1.5 years after HTx at the time of study inclusion) were included in the parallel RCT and were randomly assigned 1:1 to the control group or intervention group. Acute-stage recipients (<1.5 years after HTx at the time of study inclusion) were not included in the controlled trial and were directly offered the same treatment as the IG.

Face-to-face measurement points are shown as blue diamonds: T0 (baseline at study inclusion), T1 (at least 6 months after inclusion), T2 (at least 12 months after inclusion). The measures assessed during in-clinic visits are shown as grey squares. The treatments are shown as pictograms, i.e. in-clinic outpatient hospital, multidisciplinary team including the pharmacist, and the mHeart mobile application to interact with the pharmacist. The green diamonds show the interaction through the mHeart tool.

Conclusion and relevance mHeart has been demonstrated to improve recipients' adherence to IS (85% IG vs 46% CG), patients' experience of therapeutic regimens and to reduce in-clinic facilities because of the mHeart follow-up. Innovative research projects on health institutions are typically short lived practices with lack of scalability to usual care. This was a priority for the mHeart study, and the intervention was extended into clinical practice in January 2019.

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4CPS-321 ANAKINRA IN SEVERE COVID-19 PNEUMONIA: RETROSPECTIVE STUDY

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Background and importance Anakinra is a recombinant interleukin 1 (IL-1) receptor antagonist and might help to neutralise the acute respiratory distress syndrome (ARDS) related to the SARS-CoV-2 hyperinflammatory state.

Aim and objectives To evaluate the use of anakinra in severe COVID-19 pneumonia previously treated with tocilizumab.

Material and methods A retrospective study in a general university hospital with 503 beds was conducted. Patients or relatives gave oral consent for the use of anakinra. Posology was 100 mg/12 hours on day 1 and 100 mg/24 hours on days 2–5, given subcutaneously. All received thromboembolic

prophylaxis and were previously treated with hydroxychloroquine, azithromycin, corticosteroids and tocilizumab. Demographic variables, comorbidities, onset of symptoms and biochemical parameters (leucocytes, neutrophils, lymphocytes, platelets, haemoglobin, transaminases, LDH, creatinine, CRP, procalcitonin, CK, D-dimer, ferritin) at baseline and at discharge or death were recorded. The main outcome was mortality.

Results 17 patients were treated from 4 to 26 April. Median age was 69 years (IQR 12) and 11 (65%) were men. 15 (88%) patients had mechanical ventilation (MV). The main comorbidities were hypertension (8, 47%) and dyslipidaemia (11, 65%). 7 (41%) had two or more comorbidities. 11 patients (65%) were admitted after 7 or more days with symptoms, the median being 7.5 days (IQR 5.8). Median days of admission were 36 (IQR 35) and ICU admission was for 26.5 (IQR 35) days. Median days from the start of symptoms to treatment with anakinra was 18.5 days (IQR 6) and from the start of anakinra to discharge/death was 23 days (IQR 30.5). Baseline values of lymphocytes ($0.6 \times 10^9/L$, IQR 0.4), AST (38 U/L, IQR 28.5), ALT (59 U/L, IQR 99), CRP (1.6 mg/dL, IQR 9.6), LDH (735 U/L, IQR 368), D-dimer (1350 ng/mL, IQR 1734) and ferritin (928 $\mu g/L$, IQR 1736) were altered. At discharge/death, only lymphocyte count had improved significantly ($1.1 \times 10^9/L$, IQR 0.8, $p=0.003$). 10 patients (59%) died. Two patients did not finish treatment due to death, 3 due to elevated transaminases and 1 due to neutropenia.

Conclusion and relevance Mortality was high, but our population were critical patients with MV, ARDS and with a poor evolution despite having received other immunomodulatory treatments. Anakinra, like tocilizumab, must be used in earlier stages of the disease to reduce the inflammatory response. Delaying treatment does not provide benefits for patient cure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest