Background and Importance Trastuzumab associated with chemotherapy (platinum and fluoropyrimidine) is the standard first-line treatment in HER2-positive advanced oesophagogastric adenocarcinoma (AGA); however, its benefits are heterogeneous.
Aim and Objectives To develop and validate a predictive model for overall survival (OS) and progression-free survival (PFS) in patients with AGA treated with trastuzumab.
Material and Methods Patients from the Spanish Society of Medical Oncology (SEOM)-AGAMENON registry with HER2-positive AGA treated in first-line with chemotherapy and trastuzumab between 2008 and 2021 were selected for this study. An accelerated time-to-event model was developed to predict survival and represented as a nomogram and an online calculator. The nomogram was externally validated in an independent series from The Christie NHS Foundation Trust hospital in Manchester, England.
Results 737 patients were recruited (AGAMENON-SEOM, n= 654; Manchester, n= 83). In the referral cohort the median PFS and OS were 7.76 (95% CI, 7.13-8.25) and 14.0 months (95% CI, 13.0-14.9), respectively. Patients received a median of six cycles of platinum, eight cycles of fluoropyrimidine and trastuzumab for a median of 7.6 months (95% CI, 7.10-8.30).

In the validation cohort, the median PFS and OS were 8.1 (95% CI, 7.1-11.3) and 12.8 months (95% CI, 10.3-20.4), respectively. Patients received chemotherapy for a median of five cycles and trastuzumab for a median of 6.3 months.

Six covariates were significantly associated with OS and were used to construct the nomogram: neutrophil-lymphocyte ratio (time ratio (TR):0.73; 95% CI: 0.63-0.83), ECOG status (TR:0.59; 95% CI 0.48-0.73), Lauren histologic subtype (TR:0.73; 95% CI 0.57-0.94), HER2 expression (TR:0.85; 95% CI 0.73-1), histologic grade (TR:0.87; 95% CI 0.72-1.07), and tumour burden (TR:1.69; 95% CI 1.34-2.13). The AGAMENON-HER2 model demonstrated adequate calibration and fair discriminatory ability with a c-index for PFS and OS of 0.606 (95% CI 0.58-0.64) and 0.623 (95% CI 0.59-0.66), respectively. In the Manchester validation cohort, the model is well calibrated, with a c-index of 0.65 and 0.68 for PFS and OS, respectively.
Conclusion and Relevance HER2-positive AGA patients receiving trastuzumab and chemotherapy can be stratified according to their estimated survival endpoints using the AGAMENON-HER2 prognostic tool. This nomogram could be a valuable tool for making treatment decisions in daily clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

4CPS-222 HAPLOIDENTICAL HAEMATOPOIETIC CELL TRANSPLANTATION IN PATIENTS AGED > 55 YEARS WITH ACUTE MYELOID LEUKAEMIA

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Background and Importance In the elderly patients with AML, both the development of reduced-intensity conditioning (RIC) regimens and the use of haploidentical donors have improved their accessibility to allo-HCT.
Aim and Objectives To analyse the clinical characteristics and results of haploidentical family donor allo-HCT, performed in our hospital during the years 2014 to 2021, in patients with AML >55 years.
Material and Methods
Retrospective observational study. Data collected: age, sex, HCT status, time from diagnosis to transplant, ECOG Performance Status, comorbidity indexes (HCT-CI, EBMTs, DRindex), haematopoietic progenitor source (HPS), CMV-mismatch, conditioning regimen, graft-versus-host disease (GVHD) prophylaxis, and post-HCT complications. Overall survival (OS) and progression free survival (PFS) were analysed using Kaplan-Meier.
Results Thirty patients were included. Median (range): 64 (56–71) years, 57% women. 70.3% in first complete remission. Median (range) time from diagnosis was 6.5 (3.47-52.37) months.74% ECOG 0. 33% DR index high and very high 15% patients. The EBMTs >4 in 26% and the HCT-CI ≥3 in 56% patients. HPS was peripheral blood in 52% and bone marrow in 48%. 56% CMV-mismatch (donor -/patient +). All patients received a RIC regimen and post-HCT cyclophosphamide and 89% tacrolimus as the only immunosuppressant.

Major non-haematological toxicities included mucositis, gastrointestinal and liver toxicity in 26%, 19% and 7% of patients, respectively. 19% patients developed haemorrhagic cystitis, one patient underwent thrombotic microangiopathy, 41% developed acute GVHD and 37% patients presented chronic GVHD cmv infection occurred in 78% of patients.

Median (range) follow-up was 21.55 (1.67-89.80) months, OS at 1 year was 65% (95% CI, 46-83%), at 2 years 56% (95% CI, 36-75%). PFS at 1 year was 61% (95% CI, 42-80%), at 2 years 48% (95% CI, 28-68%). 48% are still alive and all in complete remission.
Conclusion and Relevance The small sample prevents numerous affirmations from being emphatically extracted, but the results obtained, which are very comparable to the published experiences, support the use of this type of donor in this patient population. Currently, we should not delay transplantation in elderly patients with AML trying to find an HLA-identical donor. If the experience of the Centre is extensive, performing a transplant from a haploidentical donor should be considered in the algorithm of the Allo-HSCT procedure.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

4CPS-223 BOTULINUM TOXIN TYPE A: THE NON-INVASIVE SUCCESS FOR OVERACTIVE BLADDERS

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Background and Importance Intradetrusor injections of botulinum toxin type A (TBA) have significantly changed the management of overactive bladder (OAB), allowing the acquisition of urinary continence and control of renal risks. This technique makes it possible to avoid bladder replacement surgery by

enterocystoplasty. HAV incurs direct and indirect costs to society.

Aim and Objectives Our study has two main objectives: to evaluate the improvement of the handicap of patients with urinary incontinence by bladder hyperactivity, after injection of botulinum toxin A then to evaluate the cost effectiveness ratio.

Material and Methods A retrospective observational study of 74 patients, who received education on self-catheterisation and treated with TBA at the Urology Department of between January 2018 and August 2022. A model was developed to estimate costs by comparing the cost of TBA versus a standard protocol (involving behaviour al therapy, incontinence pads, anti-cholinergic treatment and, catheters) excluding loss of productivity. A quality of life questionnaire was also administered to patients at the follow-up visits.

Results Profiles of TBA use: Primo-injection in 83.78%.For the indication, AVH without leakage in 32.43%, urinary incontinence by AVH in 35.14%, multiple sclerosis in13, 51%and spinal cord injury in 18.92%. The injections were performed in the operating room. A median paramedical time of30min to prepare the patient and the product. Injection conducted endoscopically lasted a median of8minwith a median hospital stay of 2 days.Clinical improvement in81% with a median duration of efficacy of98days.For adverse events: hypo or a contractile bladder requiring self-catheterisation (n=81%), generalised fatigue (n=40%) and muscle weakness (n=35%).Calculated costs: The cost of an injection is 7000MAD (price produced with the hospital package).The cost of standard treatment without self-catheterisation is 2340MAD (for anticholinergic treatment associated with behavioural therapy). If use of catheters the cost of the injection is8340MAD. If urinary retention occurs, the cost is 13000MAD. Our study shows that the hospital cost is higher than the standard treatment without self-catheterisation and less expensive if catheterisation was previously used, but with a significant improvement in the quality of life according to the questionnaire results.

Conclusion and Relevance For our centre, since 2014, TBA represents a new therapeutic option in second-line treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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Conflict of Interest No conflict of interest

4CPS-225 HEALTH IMPACT OF TREATMENT FOR INFLAMMATORY BOWEL DISEASE WITH BIOLOGICAL AGENTS FROM THE PATIENT'S PERSPECTIVE: A CROSS-SECTIONAL STUDY USING PATIENT REPORTED OUTCOME MEASURES (PROMS)

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Background and Importance The clinical manifestations of inflammatory bowel disease (IBD) compromise patient's daily life. In this regard, the use of Patient Reported Outcome Measures (PROMs) to determine health status, quality of life and treatment effectiveness from the patient's perspective can add significant value in clinical practice.

Aim and Objectives Assess disease impact in patients affected with IBDs using PROMs.

Material and Methods Cross-sectional study including outpatients treated with biological agents for ulcerative colitis (UC) and Crohn's disease (CD) ≥18 years. Socio-demographic and clinical characteristics were collected from clinical records: age, gender, type of IBD, diagnosis year, biological treatment, starting date of biological treatment, previous biological treatment, concomitant immunosuppressive treatment, previous surgeries due to IBD and smoking habits. We used 2 questionnaires to evaluate PROMs: IBD-Control (IBD-Control-8 sub-score plus visual analog scale (VAS), that range from 0-16 and 0-100, respectively, higher scores representing better disease control) and IBD-Disk (that ranges from 0-100, higher score representing higher IBD daily-life burden).

Results 42 patients with CD and 21 with UC were included (mean age 44.25 ± 14.67, 54% men). 44 patients were treated with infliximab (69.84%), 9 with ustekinumab (14.29%), 7 with vedolizumab (11.11%), 2 with golimumab (3.17%) and 1 with adalimumab (1.59%). 22 (34.92%) were previously treated with biological agents. 4 were diagnosed during the last 18 months while others were diagnosed before. 44 patients (69.84%) took oral immunosuppressant. 60 were treated >6 months with their current biological agent, the other 3 cases for 3-5 months.

Mean IBD-Control-8 score was 12.41 ± 3.87. Mean VAS score was 87.19 ± 18.17. Mean IBD-Disk score was 33.22 ± 25.95 (69.84% of patients being below 50 points). 4 out of 63 cases had worse overall measurements (IBD-Control-8 score ≤7, VAS score ≤60 and IBD-Disk score ≥63). 3 were women with CD and smoking habits (2 current smokers and 1 ex-smoker). 3 of them were treated with infliximab and 1 with vedolizumab (3 requiring concomitant immunosuppressants). 2 required previous surgery.

Conclusion and Relevance This study adds novel literature on health status of these patients using PROMs. Measurements were generally favorable but 4 patients out of 63 had worse overall measurements. Literature on this topic is scarce. PROMs are useful tools that could be incorporated in pharmaceutical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-227 REAL WORLD EVIDENCE OF THE USE OF DEFIBROTIDE FOR PROPHYLAXIS OF VENO-OCCLUSIVE DISEASE AFTER POST-HAEMATOPOIETIC STEM-CELL TRANSPLANTATION IN CHILDREN

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Background and Importance Hepatic veno-occlusive disease (VOD) is a life-threatening condition caused by the obstruction of liver sinusoids.

Since 2014, in Italy the standard of care for the management of VOD is represented by defibrotide. Recent evidence suggested that defibrotide could help preventing the onset of hepatic VOD when allogeneic haematopoietic stem cell