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P19 Real life effectiveness and safety of pembrolizumab used as monotherapy in the first-line treatment of metastatic non-small cell lung cancer

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Introduction

Lung cancer is the third most common malignancy in Europe. In 2023, 42,500 new cases of lung cancer were estimated in our country (29,500 in men and 13,000 in women).
In 2018, our country's drug regulatory agency authorized the reimbursability of pembrolizumab, a humanized monoclonal antibody that binds to the PD-1 (programmed cell death-1) receptor and blocks its its interaction with the PD-L1 ligand, in the first-line use of metastatic non-small -cell lung cancer.

Material and method

The aim of the study is to evaluate the effectiveness and safety of pembrolizumab as monotherapy in the first-line treatment of metastatic non-small cell lung cancer in patients treated in our hospital with tumour proportion score >= 50 % in the absence of tumor positive for EGFR mutation or ALK.
Retrospective observational study conducted from 2019 to 2023.
Computerised prescriptions, eligibility forms were used for data analysis.
To assess efficacy, we calculated the median progression-free survival (PFS) rate and for safety, the adverse reactions experienced by patients.

Results and discussion

38 patients were treated with intravenous administration every 21 days of pembrolizumab at a dose of 200mg.
34% of the patients were female with a mean age of 66 years and ECOG values between 0 and 1.
66% of patients were male with a mean age of 71 years and ECOG values between 0 and 2.
27% of treated patients are in treatment with pembrolizumab (60% female and 40% male) while 73% progressed (70% male and 30% female).
The median PFS in patients still in treatment was 31.5 months vs 11 months of those in progression.
The most common side effects include fatigue (80%), decreased appetite (7%), dyspnea (10%) and cough (3%).

Conclusion

The adverse reactions observed in patients treated in our hospital were mild and no one discontinued treatment because of them.
The median PFS observed in patients still on treatment is very high (31 months vs 11 months).
As the proportion of patients progressing is much higher than those on treatment (73% vs 27%) further retrospective studies should be conducted to confirm our data.

P20 REAL WORLD EXPERIENCE OF NILOTINIB AND DASATINIB IN THE 1ST-LINE TREATMENT OF ADULT PATIENTS WITH CHRONIC MYELOID LEUKEMIA

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Introduction
Chronic myeloid leukemia (CML) is a clinical pathological condition determined by the uncontrolled monoclonal proliferation of a single multipotent cell that has undergone neoplastic transformation. According to IARC (International Agency for Research on Cancer) CML accounts for about 15-20 % of all cases of leukemia. It is relatively rare and affects about 1-2 people per 100,000 in our country, with a higher frequency among men.

Material and method
Retrospective observational study conducted from September 2021 to December 2023 using medical prescriptions as the database and using the PICO method to obtain data on the cost and efficacy of these treatments based on the percentage of progression free survival (PFS) and overall survivall (OS) after 12 and 24 months of patients treated in our hospital.

Results and discussion
20 patients were treated with nilotinib; 30% (n=6) are women with a mean age of 58 years, and 70% are men with a mean age of 59 years.
55% (n=11) of patients are still on treatment; 27.3% are women while 72, 7% are men.
19 patients were treated with dasatinib; 47% (n=9) are women with a mean age of 63 years and 53% (n=10) are men with a mean age of 65 years.
31.6% of patients are still on treatment; 33.3% are women while 66.7% are men.
In Nilotinib treatment, women showed a mean Progression Free Survivall (PFS) of 14.5 months while men 21.4 months (p value=0.092 with 95% CI).
In Dasatinib treatment, on the other hand, women showed a mean PFS of 23.3 months while men 17 months. (p value=0.083 95% CI).
Overall survival (OS) after 12 months was 80% while after 24 months 50% with nilotinib.
In contrast, with Dasatinib, the overall survival after 12 months was 84% while after 24 months it was 37%.
The cost of nilotinib per patient per month is 2128.56€, of dasatinib 2716.95€.

Conclusion
It was found that nilotinib can be considered a better therapeutic choice in terms of efficacy than dasatinib considering the % of patients still on treatment (55% vs 31.6%) and OS at 24 months (50% vs 37%). In terms of drug price, dasatinib costs 27.6% more than nilotinib, so nilotinib can be considered the most appropriate therapeutic choice to ensure more patients have access to treatment.

P21 Exploring the Potential of Myeloid Suppressor Cells in Personalized Oncology

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Introduction

Myeloid-derived suppressor cells (MDSC) are a heterogeneous population of immune cells generated in chronic inflammatory conditions such as cancer and autoimmune diseases. Found in tumors or the blood of cancer patients (pt), MDSCs are linked to poor prognosis and treatment resistance, including to immunotherapies. The aim of this study is to correlate the levels of granulocytic MDSC (CD15+LOX-1+) and monocytic MDSC (CD14+PD-L1+ and CD14+HLA-DR- cells) with the clinical outcomes of patients with cancer (PFS, OS) and to assess their correlation with resistance to therapies.

Material and method

Blood samples from 183 healthy donors and 105 cancer pt were compared by cytofluorimetry analysis using a specific panel of antibodies designed to detect M-MDSC and PMN-MDSC. Blood were taken before the first and second treatment cycles (T0 and T1), at 3 months for disease assessment (T2), and additionally in case of progression disees (PD).Of these pt, 31 had metastatic melanoma, 43 NSCLC (lung), 12 head and neck cancer (H&N), and 19 urothelial or renal carcinoma (RCC/UC).Treatments included immunotherapy for 73 pt, targeted therapy for 26, and chemotherapy for 26, and chemotherapy for 5.

Results and discussion

Our results show a significant increase in MDSC frequency in cancer patients at T0 across all tumor types compared to healthy donors. Notably, the myeloid index score including CD14+HLA-DR- was much higher in cancer patients (116.5 ± 121.2 cells/µL) compared to healthy donors (23.25 ± 17.57 cells/µL). Similarly, CD14+PD-L1+ levels in patients were 17.81 ± 26.11 cells/µL versus 5.454 ± 6.51 in healthy donors, and CD15+LOX1+ were 269.9 ± 307.7 in patients compared to 75.66 ± 64.58 in healthy donors. This pronounced increase in specific MDSC subsets like CD14+HLA-DR- and CD14+PD-L1+ indicates strong immunosuppression in cancer patients. However, no significant differences were found between different cancer types. Additionally, an age-related increase in CD14+HLA-DR- among healthy donors points to age impacting the myeloid compartment.

Conclusion

The data collected provides the basis for the definition of cut-off values for MDSCs, which may be useful as prognostic markers to predict treatment responses and optimize strategies. Further research is still needed, but the ability to make this analysis available to pharmacologists could be a strategy for the personalisation of cancer treatment.

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P22 REAL-WORLD REVIEW OF THROMBOCYTOPENIA ASSOCIATED WITH LONG ACTING GRANULOCYTE COLONY-STIMULATING FACTOR IN EPITHELIAL OVARIAN CANCER PATIENTS

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Introduction
Thrombocytopenia is a common hematologic complication in cancer patients undergoing chemotherapy, and its occurrence is further complicated by the administration of long-acting granulocyte colony-stimulating factor (G-CSF). However, its incidence and associated risk factors remain understudied, particularly in diverse clinical contexts. This retrospective study aimed to investigate the incidence and patterns of thrombocytopenia associated with the use of long-acting G-CSF in patients with epithelial ovarian cancer (EOC) using real-world data.

Material and method
This retrospective study included 62 patients aged 18 years or older with a diagnosis of EOC who received pegfilgrastim, pegteograstim, and eflapegrastim between January 2021 and December 2023 at a tertiary hospital in South Korea. Eligible patients had baseline platelet counts above 100,000/mm3, with subsequent measurements during treatment. Thrombocytopenia was defined as platelet counts below 75,000/mm3 with a rating of "possible" or higher on causality assessment. The Cox proportional hazards model was used to identify risk factors for thrombocytopenia.

Results and discussion
Among the 62 patients meeting inclusion criteria, 27.4% developed thrombocytopenia during long-acting G-CSF therapy. Of these, 12.9% required platelet transfusions, and two patients needed chemotherapy adjustments due to thrombocytopenia. The median time to onset of thrombocytopenia was 7 days, with a median recovery time of 13.5 days. Risk factors identified included advanced age (crude hazard ratio [HR] 15.0, 95% confidence interval [CI] 1.3-172.6) and obesity (crude HR 9.6, 95% CI 1.3-70.2).

Conclusion
In this real-world based retrospective study, it showed more than a quarter of EOC patients receiving long-acting G-CSF experienced thrombocytopenia. However, the study also indicates that while the use of long-acting G-CSF in chemotherapy patients may lead to thrombocytopenia, it has minimal impact on treatment schedules and dose intensity.

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P23 Significant Response in MSI-H/dMMR mCRC with Pembrolizumab Immunotherapy: A Case Study

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Introduction
Metastatic colorectal cancer (mCRC) is a leading cause of cancer-related deaths globally. In the last two decades, advancement in molecular analysis has led to development of more personalized treatment strategies by identifying novel predictive biomarkers for CRC. Incorporating new anti-EGFR, anti-VEGF agents and most recently, immunotherapy in the treatment of mCRC significantly improved the prognosis of patients with mCRC with median overall survival exceeding 30 months.
Immunotherapy with ICI has the potential of long term durable response in a subset of patients with MSI-H or dMMR mCRC.

Material and method
We present a case of a 39-year-old woman with microsatellite-instability–high (MSI-H) and mismatch-repair–deficient (dMMR) recurrent and metastatic colorectal cancer. The patient initially underwent neoadjuvant chemoradiotherapy and laparoscopy-assisted lower anterior resection with diverting loop ileostomy. However, tumor recurrence was observed, and the patient underwent rectal amputation with definitive colostomy. PET/CT scan two months after surgery revealed tumor infiltration of the colostomy and metabolic activity in the umbilical region at the anterior abdominal wall.

Results and discussion
Partial response was evident within the first 6 weeks of treatment, with significant regression of skin tumor infiltration. After 6 months of immunotherapy with pembrolizumab, complete regression of the skin lesion at the colostomy site was observed, and PET/CT scan showed significant metabolic and morphological regression. The patient has been tolerating immunotherapy well without severe adverse events.

Conclusion
This case highlights the potential of immunotherapy in providing long-term durable response in a subset of patients with MSI-H/dMMR mCRC. Further research is needed to better understand the molecular pathways of immune checkpoint inhibitors and identify predictive biomarkers for optimal patient selection and treatment outcomes.

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P24 The Use of Low-Dose Monoclonal Antibodies in Advanced Metastatic Colorectal Cancer and Treatment Outcome

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Introduction
Colorectal cancer (CRC) is a leading cause of cancer-related morbidity and mortality worldwide. The standard treatment for advanced metastatic colorectal cancer (mCRC) often includes a combination of chemotherapy, targeted therapies, and immunotherapies. Monoclonal antibodies (mAbs) targeting specific cancer pathways have significantly improved survival rates. However, the high doses commonly used can lead to severe toxicities, limiting their tolerability and accessibility.
This research was to investigate the potential of low-dose monoclonal antibody therapy in mCRC to reduce adverse effects

Material and method
This study employed a multicenter, randomized, controlled trial design. Eligible patients with confirmed mCRC were randomized to receive either standard-dose or low-dose mAb therapy. The monoclonal antibodies included in this study were bevacizumab, cetuximab, and pembrolizumab, administered in combination with standard chemotherapy regimens. Primary endpoints include progression-free survival (PFS) and overall survival (OS).

Results and discussion
Preliminary data suggested that low-dose mAb therapy is associated with a comparable PFS and OS to standard-dose therapy, significantly reducing grade 3 and 4 adverse events. Patients receiving low-dose therapy reported better overall quality of life scores. Cost analysis indicates reduced treatment-related expenses, making the therapy more accessible.

Conclusion
The use of low-dose monoclonal antibodies in the treatment of advanced metastatic colorectal cancer shows promise in maintaining efficacy while reducing toxicity. These findings support the potential for low-dose regimens to enhance patient quality of life and provide a more cost-effective treatment option.
Further research is needed to validate these results and optimize dosing strategies. Identifying predictive biomarkers for response to low-dose therapy could tailor treatments to individual patient profiles, improving outcomes.

Clinical evaluation

P25 Efficacy and safety of ruxolitinib in glucocorticoid-refractory acute graft-versus-host disease in a terciary hospital

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Introduction
Acute graft-versus-host disease (aGVHD) remains a significant complication following allogeneic hematopoietic stem cell transplantation, with few therapeutic options and dismal outcomes. Ruxolitinib (RUX), a Janus kinase inhibitor, has been approved for the treatment of steroid-refractory (SR) aGVHD grade (gd) II to IV based on the findings of the REACH2 trial. This study aims to evaluate the real-world (RW) efficacy and safety of RUX in the treatment of SR aGVHD and compare these outcomes to those reported in the pivotal trial.

Material and method
This retrospective study included all patients diagnosed SR aGVHD treated with RUX in our institution. Data on patient/disease characteristics, previous therapies, response rates and adverse events (AE) were collected from clinical files. The primary endpoints were overall response rate (ORR) at d28 and 56 and overall survival (OS). Secondary endpoint was safety profile (SP). Response criteria were defined according Mount Sinai Acute GVHD International Consortium standards. AE were classified according National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).

Results and discussion
Our study included 2 patients with gd IV SR aGVHD treated with RUX. Patient A, aged 43, diagnosed with ALL Ph-like, was treated with PETHEMA<55y+ HSCT(FB4+ATG)+ DLI at day (d) 120. Patient B, aged 67, diagnosed with undiferentiated AML FLT3-/NPM1-, was treated with "7+3"+ 5-AZA+ HSCT(FB2+ATG)+ DLI at d120. Patient A responded to RUX at day 28 and 56, with improve of gd IV mucocutaneous (to gd I d28 and gd I d56), gr III hepatic (to gd 0 d28 and gd I d56) and gd IV gastrointestinal aGVHD (to gd I d28 and gd 0 d56). Patient B, didn´t respond to RUX at d28 or 56 due to insufficient follow up time before death. In our 2 patients, ORR at d28 and at d56 was 50%, while the REACH2 trial reported 62% and 40%. OS of our patients was 43 days, lower than the median of 11.1 months observed in pivotal trial. AE observed in our patients were anemia, CMV/EBV infections, hipogamaglobulinemia and pain in extremities (50%) while in REACH2 were trombocytopenia (33%), anemia (30%) and CMV infections (26%).

Conclusion
Our study´s main limitation was the sample size and follow up time. It showed an ORR to RUX at d28 and d56 slightly lower and an OS significantly lower than observed in REACH2, probably due to early death of both patients (d70 and d16). SP was generally consistent to the pivotal trial. Future studies with larger cohorts are needed to better understand RW RUX efficacy and safety in SR aGVHD.

P26 The clinical efficacy study of fruquitinib combined with capecitabine in the third line therapy for advanced colorectal cancer

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Introduction

The efficacy of third line therapy for advanced colorectal cancer is limited. Fruquitinib is recommended as a third line therapy in guidelines, but the single drug has a short response time and cannot meet clinical needs. Capecitabine is a commonly used chemotherapy drug in the treatment of advanced colorectal cancer. Previous research has revealed that the combination of anti-angiogenic drugs and chemotherapy has a synergistic anti-tumor effect. The aim of this study is to explore the clinical efficacy and safety of the combination of fruquitinib and capecitabine in the third line therapy

Material and method

This open label, dual arm, phase II study is recruiting advanced colorectal cancer patients who have progressed after standard second-line treatment.The patients were randomly divided into two groups, The observation group was treated with a combination of fruquitinib and capecitabine, while the control group was treated with fruquitinib. Take 3-5mg of fruquitinib orally for three weeks and stop for one week, with a 28 days cycle. Capecitabine 1250 mg/m2, taken orally for two weeks and stopped for one week, with a cycle of 21 days. Until the disease progresses or unacceptable toxicity appears.

Results and discussion

Until January 31,2024, two groups have completed the first stage of enrollment (15 cases in each group) and conducted efficacy and safety analysis.the ORR and DCR of the control group were 6.67%, 33.33%, and the median PFS was 3.5 months. the ORR and DCR of the observation group were 13.33%, 86.67%, and the median PFS was 9.8 months. There was no significant difference in ORR between two groups, while the difference in DCR and PFS was statistically significant. The main adverse reactions in both groups were hand and foot skin reactions, proteinuria, bone marrow suppression and oral mucositis. Both groups of patients had tolerable adverse reactions. Compared with the control group, 8 patients experienced I-II grade bone marrow suppression, which recovered after treatment with granulocyte colony-stimulating factor.

Conclusion

Compared with fruquitinib, the combination of capecitabine on this basis may prolong the progression free survival of patients with advanced colorectal cancer, and adverse reactions can be tolerated. The combination of fruquitinib and capecitabine as a posterior therapy option may become a new strategy for advanced colorectal cancer.

Clinical evaluation

P27 Occurrences of neoplasms in patients undergoing biological therapies: experience from a Rheumatology Unit

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Introduction

Rheumatoid arthritis (RA), ankylosing spondylitis (AS), and psoriatic arthritis (PsoA) are rheumatologic diseases whose treatment may involve the use of biological agents, such as tumor necrosis factor alpha inhibitors (TNFi). These medications may increase patient risk of some malignancies; and also have immunosuppression as a side effect, raising concerns about their use in patients with a history of cancer, and currently avoided due to fear of recurrence.

Material and method

A retrospective study of clinical records of patients with rheumatologic diseases treated with biological agents at Amato Lusitano Hospital, totaling 111 patients, of whom 11 developed neoplasms during biological therapy. Period of study: march.2011- december.2023

Results and discussion

Of the 111 patients studied, 67,6% were female (n=75) and 32,4% were male (n=36). Median age: 55,2 years. 38.7% had some comorbidities (HTA was the most frequent). The majority had RA (48.6%) and was undergoing treatment with TNFi (76.6%), as well as some form of combined treatment (72.9%). Only 9.9% (n=11) of patients developed cancer during treatment: 4 in the group of RA and AS, each; and other 3 in PsoA. The majority of these patients was nonsmoker (72,7%).

The contribution of TNFi to cancer risk is not clear, but previous studies have found no significant differences in patients undergoing such treatment, as corroborated by this study, with only 9.9% of patients in treatment developing cancer. The type of cancer that the 11 patients developed during treatment was highly varied, and their TNM staging was scattered. Only one patient died, and the majority discontinued biological agent treatment, with none resuming.

Conclusion

This study did not show apparently an increase in the incidence of neoplasms associated with the use of biological agents.

P28 Study of risk factors related to hypersensitivity reactions induced by Chemotherapy

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Introduction
Hypersensitivity reactions induced by chemotherapy (HRIC) are unpredictable, frequent and could have severe issues. Many factors could be associated with this side effect. The aim of our study was to determine the risk factors related to HRIC

Material and method
This was a descriptive and transversal study conducted at the Medical Oncology Department of the Salah Azaiez Institute in Tunisia, during six months from Mai 2022 to October 2022. Data were collected with a questionnaire. The criteria of inclusion were patients aged more than 18 years old and having at least one cure of chemotherapy. The data analysis was done with the SPSS software.
Univariate and multivariate analysis were performed to determine risk factors associated with HRIC.

Results and discussion
A total of 131 patients were included in the study. Female gender was predominant with sex ratio equal to 4. The mean age was 53 ± 15 years, ranging from 21 to 83 years. The majority of patients (80 per cent) were aged less than 65 years old.
The univariate analysis demonstrated a significant association with female gender (p=0.038), type of cancer (p=0.006), inter cure delay (p=0.033), chemotherapy regimen (p=0.003), presence of taxane in the regimen (p=0.008) or presence of platinium in the regimen (p=0.004).
Multivariate analysis demonstrated that patients with an age superior to 65 years were three times more exposed to HRIC (OR adjusted = 2,98 ; IC 95% [0,983 ; 9,057] ; p= 0,05).
Furthermore, the presence of platinium molecules in the regimen (Carboplatine and Oxaliplatine) exposed the patients six times more to HRIC (OR adjusted= 6,63 ; IC 95% [0,994 ; 44,224] ; p= 0,05).

Conclusion
Patients aged upper to 65 years old and under Taxanes or Platinium regimens are associated with HRIC. Hence, a particular vigilance and specific recommendations should be proposed to these patients

P29 Efficacy and safety of mogamulizumab for cutaneous T-cell lymphoma: a single-center experience

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Introduction

Mycosis fungoides (MF) and Sézary syndrome (SS) are rare cutaneous T-cell lymphomas that require a multidisciplinary team approach with dermatologists, haematologists and pharmacists to manage them. Mogamulizumab is the first anti-CCR4 monoclonal antibody approved for the treatment of adult patients with MF or SS who have received at least one prior systemic treatment and was designated orphan medicine by EMA (European Medicines Agency).
The aim of the study was to evaluate the efficacy and safety of mogamulizumab in the treatment of MF or SS in clinical practice in a tertiary care hospital.

Material and method

An observational retrospective study was conducted. Patients with MF or SS treated with mogamulizumab until March 2024 were included. Efficacy was evaluated following the International Society for Cutaneous Lymphomas (ISCL) consensus criteria into complete response (CR), partial response (PR), stable disease (SD) or progressive disease (PD). Safety was analyzed collecting the reason for dosage adjustment and suspension. The data were obtained from the electronic medical record.

Results and discussion

Eight patients were included, 50 % (4/8) were women. Median age was 78 years (67-83). Diagnosis: SS 87,5 % (7/8) and MF 12,5 % (1/8). Stage: IVA1 87,5 % (7/8) and II-B 12,5 % (1/8). Median number of previous treatments was 1 (1-7). Mean mogamulizumab cycles received were 18. Of 8 patients, 3 obtained CR, 4 PR, and 1 PD as maximal response. The mean time to reach a response was 3 months. Dosage adjustment was made by reducing the frequency of treatment due to good response in 3 (37,5 %) patients. Median duration of response was 18 months (3-33). In other 3 cases, dosage adjustment was made because of adverse effects: 2 (25 %) skin toxicity and 1 (12,5 %) liver toxicity. With a median follow-up of 21 months, 62,5 % (5/8) of the patients progressed during treatment and suspended treatment.

Conclusion

In our cohort mogamulizumab showed favorable efficacy and safety results, consistent with those of the MAVORIC pivotal study. According to the efficacy data, the median duration of response of 18 months is comparable to the 14 months of the MAVORIC study. Skin toxicity is the most frequently observed adverse effect found both in our cohort and in the pivotal trial.

Clinical evaluation

P30 Overall Survival in Patients with Metastatic Castration Sensitive Prostate Cancer Treated With Apalutamide versus Abiraterone Acetate – A Head-to-Head Analysis of Real-World Patients in the United States

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Introduction

Androgen-receptor pathway inhibitors (ARPIs) are effective treatment options for patients with metastatic castration-sensitive prostate cancer (mCSPC). So far, no head-to-head studies have compared survival (OS) outcomes between different ARPI agents. The primary objective of this study was to compare OS by 24 months of initiating apalutamide or abiraterone acetate in ARPI-naïve patients with mCSPC.

Material and method

Patients with mCSPC were identified in two de-identified linked healthcare databases (PPS Analytics and Komodo). The index date was defined as the first date with a prescription for apalutamide or abiraterone acetate. Patients were excluded if they were castration resistant, had prior use of an ARPI or other advanced treatment, or had another primary cancer. OS was compared between apalutamide and abiraterone acetate patients using a weighted Cox proportional hazards model. For the primary objective, a 24-month observation period was used. As an exploratory analyses, all follow-up was used.

Results and discussion

Overall, 1,879 patients initiating apalutamide and 2,073 patients initiating abiraterone acetate were identified (3,952 total patients). After applying inverse probability of treatment weighting to balance treatment cohorts, at the index date the mean age was 72 years; ~62% were White, ~18% were Black; ~66% had bone metastasis; 53% had nodal metastasis, ~22% had visceral metastasis and ~77% had prior use of androgen deprivation therapy. By the pre-specified 24-month timepoint, patients initiating apalutamide had a statistically significant reduction of 26% in risk of death compared to abiraterone acetate (hazard ratio [HR]: 0.74; 95% confidence interval [CI]: 0.59, 0.93; P=0.010). When considering all follow up data available, findings were consistent (HR: 0.72; 95% CI: 0.59, 0.88; P<0.001).

Conclusion

In this real-world retrospective head-to-head analysis of more than 3,900 patients initiating apalutamide or abiraterone acetate in the United States, patients initiating apalutamide had a statistically significant reduction of 26% in risk of death in patients with mCSPC at 24 months post-treatment initiation, when compared with abiraterone acetate.

P31 Real-World Head-to-Head Analysis of Overall Survival in Patients with Metastatic Castration-Sensitive Prostate Cancer Initiated on Apalutamide versus Enzalutamide in the United States

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Introduction
Multiple treatment options exist for the management of metastatic castration-sensitive prostate cancer (mCSPC), however no head-to-head studies have compared survival outcomes between different androgen-receptor pathway inhibitors (ARPIs). The primary objective of this study was to compare overall survival (OS) by 24 months of initiating apalutamide or enzalutamide in ARPI-naïve patients with mCSPC.

Material and method
A retrospective analysis was conducted to compare OS in ARPI-naïve patients with mCSPC in two large, de-identified linked healthcare databases (PPS Analytics and Komodo). The index date was defined as the apalutamide or enzalutamide first prescription date. Patients were excluded if they were castration resistant, had prior use of an ARPI or other advanced treatment, or had another primary cancer. OS was compared using weighted Cox proportional hazards models. For the primary objective, the observation period was limited to 24 months; for exploratory analyses, all follow-up was considered.

Results and discussion
A total of 3,719 ARSI-naïve patients were studied (1,810 initiating apalutamide; 1,909 initiating enzalutamide). Population characteristics were similar in both cohorts after applying inverse-probability of treatment weighting. At treatment initiation, mean age was 73 years; ~60% were White, 23% were Black; ~72% with bone metastasis; ~49% had nodal metastasis, ~20% had visceral metastasis and ~81% use androgen deprivation therapy at the time of index. By the pre-specified 24-month timepoint, a statistically significant reduction of 23% in the the risk of death was observed in patients initiating apalutamide as compared to enzalutamide (hazard ratio [HR]: 0.77; 95% confidence interval [CI]: 0.62, 0.96; P=0.019). Results remained consistent when evaluating OS using all follow-up (HR: 0.77; 95% CI: 0.64, 0.93; P=0.008).

Conclusion
This real world retrospective head-to-head analysis of more than 3,700 ARPI-naïve patients with mCSPC initiating apalutamide or enzalutamide found that at 24 months post-treatment initiation, when compared with enzalutamide, patients initiating apalutamide had a statistically significant reduction of 23% in risk of death.

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P32 APALUTAMIDE EFFECTIVENESS AND SAFETY: REAL-WORLD DATA IN METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (mHSPC) IN SPAIN

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Introduction
Prostate cancer is the most common cancer among men, with high mortality worldwide. Hormone-sensitive metastasic advanced disease often requires hormone therapy, using androgen receptor-targeted agents (ARTAs) like apalutamide (APA) combined with androgen deprivation therapy (ADT). Clinical pharmacists could play a role in monitoring treatment and mitigating potential adverse effects during initial and follow-up visits.
This study aims to assess APA's effectiveness and tolerability in routine clinical practice for mHSPC patients in a third-level hospital.

Material and method
Retrospective observational study including male mHSPC patients starting APA between 2022-2023. Data on age,ECOG performance status,diagnosis type(de novo/recurrence after local treatment),ISUP grade,metastasis location and tumor burden at treatment initiation were collected from clinical records. Tumor burden was classified as high/low(CHAARTED trial criteria).Effectiveness was measured by PSA reduction(PSA50, PSA90, undetectable PSA<0.2 ng/mL)and disease progression at months 1, 3, 6 and 12. Safety was assessed until data cut-off(01/2024) by toxicity, dose reductions and discontinuations.

Results and discussion
Thirty-four patients were included (median age:72 years[52-86]). All patients had 0-1 ECOG. Tumor recurrence after local treatment was present in 55.9% of patients, 70.6% had grade 4-5 (Gleason $\geq$8), 50% had lymph node metastasis(M1a) and 50% had bone metastasis(M1b) and 82.4% had low tumor burden. The mean baseline PSA level was 13.29 ng/mL[0.21-82.82].
Median follow-up time was 13.7 months. During this period, four patients discontinued APA due to treatment-related toxicity and one experienced disease progression with PSA elevation. PSA values are described in Table 1:

Month	1	3	6	12
PSA50(%)	84.8	96.9	93.1	100
PSA90(%)	51.5	90.6	93.1	95.8
Undetectable(%)	48.5	75.7	82.7	87.5
N(patients)	34	32	29	24

Regarding safety data, 44.1%(15/34) experienced G1-G2 toxicity. Dose was reduced in 5.9%(2/34) and 14.7%(5/34) discontinued treatment without previous dose reductions, with 3 switching to another ARTA.

Conclusion
Despite the small sample size, our cohort offers valuable real-world evidence on APA's effectiveness, consistent with clinical trials.Most PSA values were undetectable at 12 months. Safety data suggest it is well tolerated; however, most patients who experienced toxicity discontinued treatment without prior dose reduction. Clinical pharmacist interventions could reduce or delay discontinuations.

P33 REAL-LIFE EFFECTIVENESS AND SAFETY OF PARPis IN FIRST-LINE MAINTENANCE OVARIAN CANCER

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Introduction

Ovarian cancer is the fifth leading cause of cancer death in Europe, with an age-standardized incidence of 8.6/100,000 and mortality of 4.3/100,000 women in 2022, most cases due to BRCA1/2 mutations. This study evaluated the effectiveness and safety in real life of human poly-ADP-ribose polymerase inhibitors (PARPis) as maintenance therapy after first-line chemotherapy in advanced ovarian cancer.

Material and method

Observational, retrospective, single center study of ovarian cancer patients in first-line maintenance with PARPis. The primary endpoint was progression-free survival (PFS) fixed by the Response Evaluation Criteria in Solid Tumors (RECIST) criteria 1.1. Secondary endpoints were safety data graded using the Common Terminology Criteria of Adverse Events (CTCAE) 5.0, while dose reductions/delays and interruption due to adverse events (AE) were also evaluated. Data were obtained in April 2024 from electronic health records Farmis-Oncofarm and Millennium. Statistic analysis was done using SPSS 5.0

Results and discussion

From 01/01/2019 to 04/18/2024, 23 ovarian cancer patients (median age 64 [range 56-83], FIGO III=14, IV=9) who received first-line maintenance PARPis, were analized. Of these, 15 were BRCA1/2 carriers; 14 received olaparib (all carriers BRCA1/2) and 9 niraparib (8 non-carriers, 1 carrier).Median follow-up was 7.6 months [4-29.63]. Median PFS was 10.3 months (95% CI 6.45-13.42) for niraparib, while median was not reached for olaparib (95% CI 19.32-not reached).

In the niraparib group (n=9), all patients experienced AE, 6 hematologic and 3 non-hematologic. In terms of severity, 5 graded as 3-4, one of whom required hospitalization for hypovolemic shock. Eight patients required dose reduction or treatment delay from the second cycle and one patient stopped treatment due to AE. In the olaparib group (n=14), 3 patients experienced AE related to treatment: 2 hematologic and 1 non-hematologic, all graded as 1-2 and required dose reduction.

Conclusion

In our study, effectiveness and safety aligns with pivotal trials: olaparib median not reached vs 56 months (95% CI 41.9–not reached) in SOLO-1 trial; niraparib median PFS 10.3 vs 13.8 months (95% CI 11.5-14.9) in PRIMA trial. Niraparib had 100% AE, 60% grade 3-4, requiring dose reductions, like PRIMA (70% grade 3-4 AE, 70.9% dose reductions). More studies are needed with larger sample size.

P34 Cancer therapy related cardiovascular adverse events and toxicity in individuals receiving systemic anti-cancer therapy with anthracycline chemotherapy, HER2-targeted therapies and immune checkpoint inhibitors.

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Introduction
Cancer therapy-related cardiovascular toxicity (CTR-CVT) are known treatment-related side effects in individuals recieving systemic anti-cancer therapy (SACT) with anthracycline (AC) chemotherapy and HER2-targeted therapies. Immune-related cardiovascular adverse events (IrAEs) from treatment with immune checkpoint inhibitors (ICIs) have also been reported, and may lead to life-threatening cardiovascular complications. The prevention and management of CTR-CVT has a great impact on the type of SACT that patients can receive as well as the long-term morbidity and mortality outcomes of patients.

Material and method
A single center retrospective study was conducted at Landspitali. A five-year summary was made for 2017-2021 from a cardiotoxic SACT database and medical records. The following CTR-CVT related data and risk factors were collected based on each patients ID number, for breast cancer patients on AC chemotherapy and HER2-targeted therapies and all patients on ICI therapies: Heart failure (HF) diagnosis, test results (NT-pro-BNP, ECHO, EF, hs-TNT24), the severity classified according to NCI CTCAE, prescribed medication to treat HF, follow up data and the relationship of underlying risk factors.

Results and discussion
374 patients received AC chemotherapy and/or HER2-targeted therapies for breast cancer in 2017-2021. Seven (2%) were diagnosed with HF after starting therapy, severity of symptoms mostly grade 3 and timing from a few days up to ≈4 years from therapy start. All were admitted to hospital, six prescribed new HF medication and followed-up with ECHO from 1 month to 1 year after diagnosis. Other studies have found 18% of patients developing anthracycline-induced cancer therapy-related cardiac dysfunction (CTRCD) and 6% HF after AC chemotherapy. 395 patients received ICIs and 12 (3%) were diagnosed with HF after starting therapy. Severity of symtoms were mostly grade 3 and timing of symptoms from 17 days to 2 years from therapy start. All were admitted to hospital, six prescribed new HF medication and four followed-up with ECHO from 1-5 months after HF diagnosis. Research indicates that cardiac IrAEs are rare (<1%) and can occur at any time during therapy or after therapy has ended.

Conclusion
HF attributed to AC, HER2-targeted and ICI therapies is serious at the time of diagnosis. The incidence of HF is lower, in comparison to other studies, for AC and HER2-targeted therapies, but higher for ICI therapies. A cardiovascular toxicity monitoring procedure, emphasizing on the work-up and follow-up of patients, to prevent and/or diagnose HF early is important, as symptoms can be chronic.

Clinical evaluation

P35 IMPACT OF COVID-19 PANDEMIC ON SMALL-CELL LUNG CANCER (SCLC): OBSERVATIONAL RETROSPECTIVE STUDY IN A HOSPITAL IN NORTHEN ITALY

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Introduction
Covid19 has severely strained health care systems. SCLC is a malignant epithelial tumor, representing 15% of all lung cancers globally diagnosed, characterized by rapidly proliferating cells; this implies a short response to the standard of care, with a 5-year survival rate of less than 7%. The standard therapy regimen consists of a platinum agent combined with etoposide, eventually associated with immune/radio-therapy. Due to the lack of literature about Covid19-SCLC, this study focuses on the impact that pandemic has had on the diagnosis and prognosis of SCLC patients in an Italian hospital.

Material and method
This observational, retrospective, single-center study includes patients with metastatic SCLC who started first line treatment from 01/01/2019 to 30/06/2022 at a small Italian hospital. Data were collected with the patient's informed consent, after approval from the local Ethics Committee, processed and anonymized on spreadsheets. The start and the end date of therapy and disease progression were extracted from the patients' electronic medical records. Based on this information, overall survival (OS) was calculated. A specific software was used for statistical analysis.

Results and discussion
76 patients with a mean age of 73 years (range 33-94), 39.5% women and 60.5% men, were enrolled. Of these: 81.6% at the time of diagnosis were stage IV disease with ECOG$\geq$2 for 26%. New diagnosed patients in the following years: 21 in 2019, 24 in 2020, 13 in 2021, 14 in 2022. The 1st-line drug therapy used in 78.9% was the combination of platinum+etoposide. In 9.2% of cases, prophylactic radiotherapy to the head was also performed. In 10.5% of cases, the chemo-immunotherapy combination was used.8% of patients completed the course of therapy, 9% died during treatment, while 71% progressed, 8% were lost to follow-up. 4% of patients contracted Covid19. 72% died. OS was 6.8 months. Data collected are in line with the literature to date for SCLC except the median survival which is inferior to published prospective trials. However, this study has several biases: single-center retrospective study, low sample size and a reduced care capacity of the hospital due to the pandemic.

Conclusion
The study shows a correlation between pandemic-SCLC diagnoses: new diagnoses decreased in 2020 and 2021. In the first 6 months of 2022, the data seems to realign to the pre-covid results. This could be due to the restart of full-scale hospital activity. Due to the limited literature on Covid19-SCLC correlation, further analysis, particularly the OS data, are needed to validate our results.

P36 Indirect Survival Analysis of Patients with Melanoma: The Impact of Adjuvant Therapy

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Introduction
In recent years, the therapeutic options available for the adjuvant setting in melanoma patients have significantly increased. The improved efficacy of these treatments has led to enhancements in key time-dependent evaluation parameters such as Recurrence-Free Survival (RFS), Distant Metastasis-Free Survival (DMFS), and Overall Survival (OS). The aim of this study was to perform an indirect analysis of the main therapeutic options available and to compare subgroups of the population with particular clinical interest.

Material and method
The literature search was conducted using the PRISMA methodology to select the most relevant articles for the setting under analysis. Kaplan-Meier (K-M) curves of interest were analyzed using the validated, flexibility and accurance IPDfromKM methodology, which consists of extracting raw data coordinates from published K-M curves and reconstructing individual patient data. These data were then used to indirectly compare the outcomes of different studies. SPSS® software was used for constructing the survival curves.

Results and discussion
The present project has included five experimental studies, which also represent the registration trials of the main drugs available in the adjuvant setting. Kaplan-Meier curves representing the general study population, as well as those including specific subgroups, were considered to extract raw data coordinates and reconstruct individual patient data using the proposed method. Specifically, the analysis was focused on: i) patients in stage II; ii) patients in stage III; iii) patients with any type of BRAF mutation. While no statistically significant differences were observed between the drugs included in the analysis for the first two subgroups, a statistically significant difference in DMFS was observed for BRAF-mutant melanoma between the combination of Dabrafenib and Trametinib compared to Nivolumab.

Conclusion
Indirect evidence analysis is a valuable tool for early-stage complementary data to those available in the literature, using validated methods and time-dependent parameters, offering an added value over meta-analyses. The present analysis has enabled indirect comparisons of molecules within a specific therapeutic setting, including some compared only versus placebo in registration clinical trials.

P37 Fruquintinib: The first Portuguese case

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Introduction
Fruquintinib is an orally administered, selective tyrosine kinase inhibitor of vascular endothelial growth factor receptors (VEGFR). It is indicated for adult patients with metastatic colorectal cancer, who progressed after prior chemotherapy, anti-VEGFR therapy, and, if RAS wild-type and medically appropriate, anti-EGFR (endothelial growth factor receptors) therapy. Antiangiogenic activity was observed on preclinical and clinical studies such as the FRESCO-2 trial (Fruquintinib vs placebo), an international, phase 3 study, which demonstrated that Fruquintinib improved overall survival (OS).

Material and method
Research on the clinical file data using SClinico information system, HS-PLH patient prescription program, and Clinidata.net for laboratory results was conducted. The literature search was performed on PubMed using the terms "Fruquintinib", "metastatic colorectal cancer", "FRESCO-2", in May 2024.

Results and discussion
A 72-year-old female with history of metastatic colorectal cancer, diagnosed in 2020 in England, moved to Portugal in 07/2022. Disease progression ocurred after chemotherapy with Capecitabine,Irinotecan and Oxaliplatin.The treatment plan proposed after arrival in Portugal was Trifluridine-Tipiracil+Bevacizumab. After several cycles patient had disease progression in 12/2023 and was included in a compassionate use program, initiating Fruquintinib in 02/2024, experiencing several adverse events (AE), namely hypertension (grade 3-4) and vomiting, which aligns with those described in the summary of product characteristics of Fruzaqla® and FRESCO-2 trial. After 2 months, the clinical condition declined severely and the patient was hospitalized due to a complex gastrointestinal fistulisation, that resulted in death. An improvement had been observed in tumor marker levels, which often correlates with a positive response to treatment, indicating that the therapy is having an anti-tumor effect.

Conclusion
Therapy with Fruquintinib provides a new alternative for patients who progressed in all previously available treatment options. Additionally it is a selective therapy unlike trifluridine/tipiracil and the previous options used.As more clinical trials and information is being generated, we believe that treatment with Fruquintinib might be introduced in a near future as an earlier line of treatment.

P38 The Prophylactic Effect of Different Hydration Regimens on the Toxicity of High-Dose Cyclophosphamide in Hematologic Malignancies (HYDRA-CYC)

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Introduction

Cyclophosphamide treatment is associated with side effects such as hemorrhagic cystitis (HC) and hyponatremia. In clinical practice, extensive hydration is employed to prevent HC. However, using hydration with lower sodium concentrations, in combination with the sodium-lowering effects of cyclophosphamide, can lead to hyponatremia and/or overfilling in patients. We recently revised the hydration protocol to include a higher sodium concentration and a lower potassium dosage while simultaneously reducing the total fluid volume administered.

Material and method

The hydration protocol transitioned from 0.45% NaCl/2.5% dextrose at 5 L/day (liberal protocol) to 0.65% NaCl at 1.5 L/m²/day (restricted protocol). Mesna doses remained constant while potassium administration decreased from 100 mmol/day to 60 mmol/day. Relevant data were collected from 455 patients (liberal protocol: 386, restricted protocol: 69) using theelectronic health record system, including demographics, electrolyte levels, physician-diagnosed HC, and furosemide use to measure fluid overload. Statistical testing was done with Rstudio to determine differences between the two protocols.

Results and discussion

The study found no significant differences in HC incidence between treatment groups (p=0.89). Comparison of post-hydration sodium levels showed no significant difference (p=0.34). CTCAE grading of lowest sodium levels and delta-sodium also showed no significant differences (p=0.41 and p=0.98, respectively). Differences in potassium levels and delta-potassium were not significant (p=0.87 and p=0.1, respectively). Fluid overload was comparable between groups (p=0.75), but patients who received the most furosemide were only seen in the liberal protocol. Despite no significant differences, the data suggests fewer clinically relevant cases of hyponatremia and fluid overload in the restricted protocol.

Conclusion

Conclusion The study concludes that the restricted hydration protocol demonstrates equivalent prophylactic activity. Further research with a larger population in the restricted protocol might identify significant differences. The current results provide no indication to revert to the liberal protocol.

P39 **Associations between hydration regimen and cisplatin dose-limiting toxicity in patients with head and neck squamous cell carcinoma requiring chemoradiation**

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Introduction
Chemoradiotherapy (CRT) with cisplatin is a treatment with curative intent in advanced head and neck squamous cell carcinoma (HHPCC). Cisplatin causes nephro- and ototoxicity, among other things, which may require early cisplatin discontinuation. Dose-limiting toxicity (DLT) due to nephrotoxicity can potentially be reduced by hydration. The purpose of this study is to investigate whether a short hydration regimen of 5 hours leads to less DLT and higher cumulative cisplatin dose compared with a long hydration regimen of 59 hours.

Material and method
This retrospective cohort study collected data in four Dutch head and neck treatment centers from patients who received CRT treatment with cisplatin between 2020 and 2023. DLT was scored based on clinical assessment. Differences in cumulative cisplatin dosage and occurrence of DLT between long and short hydration were examined by Student-T and Chi square tests. Regression analyses were performed to determine associations between hydration schedules, patient characteristics and cisplatin doses.

Results and discussion
A total of 389 patients were included; of these, 213 (55%) patients were administered short and 176 (45%) long hydration, and 173 (46%) patients had DLT. Significantly less nephrotoxicity (5% vs. 95%; $p < 0.001$) and more ototoxicity was observed in the group with DLT and short hydration (36% vs. 3%; $p < 0.001$) compared to the group with long hydration. There were no statistically significant differences found in cumulative cisplatin dose between the short and long hydration (246.2 ± 61.9 versus 248.2 ± 59.0 mg/m2; $p = 0.748$). No associations between cumulative cisplatin dose (>200 mg/m2) and the occurrence of DLT by hydration regimen were found ($p = 0.74$ and $p = 0.64$).

Conclusion
Significantly less dose-limiting nephrotoxicity and more ototoxicity was seen in HHPCC patients undergoing CRT with cisplatin with a short hydration schedule compared with a long hydration schedule. Overall DLT did not differ between the schedules. Our results open the possibility to administer cisplatin in an ambulatory setting, even in patients who receive high doses (up to 100 mg/m2 per cycle)

P40 Real world patient outcomes on the efficacy of lanreotide treatment for neuroendocrine tumors: the influence of BMI, BSA and renal function

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Introduction
Lanreotide is an effective and safe first-line therapy to treat patients with a neuroendocrine tumor (NET). Precision oncology may be used to provide each patient with the right dosage. Pharmacokinetic data suggest lower exposure in higher weight patients. However, no recommendations for dose individualization in specific patient groups exist. Therefore, we aimed to investigate the association of Body Mass Index (BMI), Body Surface Area (BSA), and renal function on the efficacy and toxicity of lanreotide treatment for neuroendocrine tumors.

Material and method
NET patients on lanreotide treatment at the Amsterdam UMC from 2016-2022 were included. Outcome measures were primarily PFS and secondarily OS and toxicity. Kaplan Meier analyses and Cox's proportional hazard models were used to calculate median PFS/OS and compare subgroups based on BMI, BSA, and renal function.

Results and discussion
A total of 122 patients with NETs of diverse origin, functionality and grade were included with a median PFS of 28 months (95%CI, 19.3-36.7). The median OS was not reached. No statistically significant difference in PFS among BMI subgroups was observed although obese patients had the longest PFS (52 months, 95%CI, 27.4-76.7) compared to other BMI categories. No relation between BSA/renal function and PFS or toxicity was found

Conclusion
This large real world data cohort of NET patients treated with lanreotide found no association of BMI, BSA or renal function with PFS. Dose individualization of lanreotide treatment based on the patient characteristics BMI, BSA or renal function does not seem rational based on these findings.

Clinical evaluation

P41 Real-World Evaluation of Abiraterone Acetate and Enzalutamide in mCRPC: Comparative Safety and Effectiveness

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Introduction
Metastatic castrate-resistant prostate cancer (mCRPC) is a challenging form of prostate cancer that progresses despite androgen deprivation therapy (ADT). Two androgen receptor signaling inhibitors (ARSIs), abiraterone acetate (AA) and enzalutamide (ENZ), have improved overall survival and advanced mCRPC treatment. However, direct comparisons of their real-world effectiveness are limited. This study aimed to evaluate the safety and effectiveness of both treatments in real-world settings.

Material and method
A retrospective, real-world observational study on patients with mCRPC from August 2017 until July 2024 was conducted. This study included chemotherapy-naïve patients with mCRPC treated with AA or ENZ in first line treatment in combination with ADT. Demographical and patient's clinical basal characteristics, PSA levels, disease progression and adverse events (AE) were retrospectively collected. Progression-free survival (PFS) was estimated with Kaplan Meier. Patients receiving concomitant treatment with other ARSIs were excluded.

Results and discussion
Of 69 patients, 44 were on treatment with AA and 25 with ENZ, with a median treatment time of 18.0 [10.8-32.5] and 14.0 [8.0-36.0] months, respectively . Both treatments reduced PSA compared to baseline, although there was no difference between treatments in PSA dynamics. 58% of the patients progressed and no differences were found on PFS between treatments (median time: AA, 23 [19.0-48.0]; ENZ, 46 [13.0-Na] months, log-rank p=0.607). Progressors had lower proportion of patients achieving PSA90 (30.3% vs 61.1%, p=0.010) and higher percentage of patients with baseline Gleason score ≥8 (62.2% vs 21.4%, p=0.001), which was identified as a prognostic factor of disease progression (HR=3.98 [1.1-14.7], p=0.012). HR of PFS in patients not achieving PSA90 was 3.74 (1.7-8.0, log-rank p=0.001) based on Kaplan-Meier estimates. Regarding treatment safety, AA patients reported 34% AEs vs. 54% AEs for ENZ, with asthenia being the most common AE in both treatments.

Conclusion
Our real-world study suggests that AA may demonstrate comparable treatment effectiveness and safety to Enz in the context of mCRPC, where patients achieving PSA90 have a lower risk of disease progression.

P42 EFFICACY AND SAFETY OF PEMBROLIZUMAB IN COMBINATION WITH LENVATINIB IN THE TREATMENT OF ENDOMETRIAL CARCINOMA

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Introduction
The combination of pembrolizumab with lenvatinib has been indicated and funded in Spain since October 2023 for the treatment of advanced or recurrent endometrial cancer (EC) in adult women with disease progression. Before the funding decision, a pharmacoclinical protocol was available for its use. The aim of this study is to analyze the efficacy and safety of this combination in the treatment of endometrial cancer.

Material and method
This is an observational, retrospective study that included all patients with EC who started treatment with pembrolizumab + lenvatinib and were followed up until March 2024. Demographic, disease and treatment variables were collected. For efficacy analysis, a Kaplan-Meier survival analysis was performed Response was evaluated by CT scan, defining disease control as complete response (CR), partial response (PR), or stable disease (SD) according to RECIST 1.1 criteria. Safety was assessed by the occurrence of adverse reactions (AR), as well as dose modifications, delays, and treatment suspension

Results and discussion
A total of 12 patients with a mean age of 68.9±8.3 years were included. The most frequent subtype was endometrioid (10 (83.3%)), followed by serous (2 (16.7%)). 7 (58.3%) were grade 2; 4 (33.3%) grade 3, and 1 (8.3%) grade 1. The mean follow-up time was 8.7±4.1 months. During this period, a total of 7 (58.3%) patients discontinued treatment: 2 (16.7%) due to progression, 1 (8.3%) due to death, and 4 (33.3%) due to toxicity. At the end of the follow-up, a total of 5 (41.7%) patients were still on treatment. The mean duration was 4.05±4.04 months.
The median PFS was not reached. There was one death during follow-up, with a median OS not reached. The overall survival for this patient was 0.4 months.
Regarding safety, 10 (83.3%) patients reported some AR. 4 (33.3%) patients discontinued treatment due to toxicity, and in 4 (33.3%) patients, toxicity caused cycle delays or dose modifications. The most common ARs were hypothyroidism (2 (16.7%)), asthenia (2 (16.7%)), and diarrhea (2 (16.7%))

Conclusion
The initial efficacy data of the combination of pembrolizumab and lenvatinib in EC are promising in terms of progression-free survival, overall survival, and disease control. However, its toxicity profile may limit optimal efficacy. Continued study is necessary to evaluate predictive factors for toxicity and efficacy.

P43 Management of venetoclax ramp-up schedule and tumor lysis syndrome monitoring: a real-world retrospective study in CLL in university hospital

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Introduction
BCL2 inhibitor Venetoclax (VEN) is an effective therapy for chronic lymphocytic leukemia (CLL), combined with anti-CD20 Mab Obinutuzumab GA101 (GVEN) or rituximab. In order to minimize the risk of tumor lysis syndrome TLS, a risk stratification was developed along with dose ramp-up (20 mg, to 400 mg) over 5 weeks. Adherence to this dosing strategy, combined with TLS prophylaxis with hypouricemic drugs, and hydration, has allowed VEN to be safely administered.
In this retrospective real-world observational study, we aim to determine patterns of TLS monitoring and dosing modifications of VEN.

Material and method
We included 55 VEN-treated patients with CLL who initiated VEN combined to anti-CD20 therapy in frontline (Group1, n=24) and relapsed/refractory settings (Group2, n=31). All patients, disease characteristics, and TLS risk stratification were summarized descriptively (patients with high tumor burden are hospitalized first 48h when first dose of 20 mg and 50 mg week steps).
Causes of failure to reach final dose of 400 mg VEN, and percentage of patients requiring hospitalization or prolongation of hospitalization were evaluated.

Results and discussion
The group was 67% male, median age at VEN initiation was 71 years (range 36 - 87). 29% of patients had TP53 mutation, 38% had unmutated IGVH (42% with missing data), and 59% had baseline renal dysfunction (creatinine CKD-EPI equation < 80 mL/min).
TLS risk classification at time of initiation of VEN was intermediate in 18% patients, mainly in Group 2, and low in other patients (having received anti CD20 before VEN for Group1). Clinical TLS occurred in only one patient with creatinine clearance 25mL/min.
No interaction with CYP3A4 inhibitors was identified and allopurinol was combined with VEN in all patients.
20% patients required dose reduction (25 to 50%) and did not reach 400mg dose due to an adverse effect, mainly digestive (diarrhea) or hematologic (neutropenia). 14% patients required hospitalization or prolongation of planned hospitalization during VEN ramp up. Complete remission was achieved in all evaluated patients of Group 1 at 12 months.

Conclusion
Proper use of VEN and TLS prophylaxis are well followed (dose ramp-up, identification of risk factors for TLS, allopurinol) and only one TLS was identified . Discussion is open to reduce number of 48h planned hospitalizations in some patients. Our data suggest that, when clinically indicated, VEN dose reduction do not appear to adversely impact outcomes.

P44 Real-world experience of use, safety and effectiveness of methadone for cancer pain: retrospective study in french university hospital

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Introduction

Methadone displays unique analgesic properties as μ- and δ-opioid agonist, and anti-NMDA properties. Methadone has been reported to be very effective in opioid switching, specifically when high doses of opioids are already used. However, the conversion from other opioids to methadone is not easy and because of its complex pharmacokinetic profile, methadone prescription should be made by pain specialists.
In this retrospective, real-world observational study, we aimed to determine profile of patients, patterns of methadone monitoring and respect of recommendations in our hospital

Material and method

All cancer patients starting antalgic methadone between February 2021 and June 2024 were included. Demographics, cancer and pain characteristics, history of prior antalgics, cross titration between previous opioid to methadone, side effects and patient outcomes were summarized descriptively and collected from the electronic health records.

Results and discussion

50 patients were included (50% male, median age 55y). Majority of cancers were sarcoma (49%).Indications for switching opioid to methadone was ineffectiveness of previous opioid (98%) combined with adverse events (70%). Morphine was most commonly used previously (86%). Mixed pain was reported in all patients and neuropathic pain was treated most frequently with gabapentinoids, serotonin reuptake inhibitors. Regarding methods of methadone titration, complete switch was used in 50% patients and adjuvant analgesy (methadone used in conjunction with opioids) in 50%.
Methadone was well-tolerated with no significant side effect in 69% patients. 24% of patients reported manageable side effects (most common were somnolence, nausea, QT interval prolongation) and 6% (n=3) side effects leading to methadone discontinuation (severe sedation, myoclonus). 90% of patients reported successful longterm analgesia. Methadone was continued until the late stages of cancer and death of patient (63% patients)

Conclusion

Appropriate use of methadone was confirmed, by integrating cardiovascular risk, interacting medications, clear conversion methods, electrolytes monitoring. Furthermore, methadone as adjuvant analgesic is an interesting option with only a low dose required to improve pain control.
Study showed the effectiveness and safety of methadone, as a valuable analgesic in patients who are opioid-tolerant.