enterocolitis and acute renal failure. The next day, hemicolec-
tomy had to be performed for signs of intestinal ischaemia.
Finally, the patient was discharged after multiple infectious
complications and 56 days of hospital stay.

The Naranjo algorithm established as ‘probable’ (score 6)
the relationship between docetaxel and neutropenic enterocoli-
tis. The Spanish Pharmacovigilance System was notified.

Conclusion and relevance In this case, docetaxel was probably
responsible for neutropenic enterocolitis. In order to know the
real incidence of adverse events listed as rare, it is essential
that healthcare professionals officially report suspected adverse
reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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SAFETY OF CYCLIN DEPENDENT KINASE INHIBITORS
IN THE TREATMENT OF BREAST CANCER WITH
POSITIVE HORMONAL RECEPTORS AND NEGATIVE
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2

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Background and importance Cyclin dependent kinase (CDK)
inhibitors are an innovative therapeutic target for the treatment
of locally advanced or metastatic breast cancer with positive hor-
monal receptors (HR) and negative human epidermal growth
factor receptor 2 (HER2). Some adverse reactions have been
reported than can decrease a patient’s functional status or even
lead to suspension of this line of therapy.

Aim and objectives To analyse the frequency of the main drug
adverse reactions described for the different CDK inhibitors
used for the treatment of patients with locally advanced or
metastatic breast cancer in a third level hospital.

Material and methods A retrospective observational study was
performed in patients who had started treatment with a CDK
inhibitor between 1 June 2018 and 30 September 2019. Dem-
ographic and clinical features were obtained from the elec-
tronic patient clinical history (DIRAYA) and the electronic
prescription programme (PRISMA) and recorded in an Excel
worksheet. Adverse reactions recorded were diarrhoea, diges-
tive disturbances, mucositis, asthenia, neutropenia, leucopenia,
anæmia, thrombocytopenia, nausea and vomiting, anorexia and
elevated transaminase blood levels.

Results Forty-two patients were found (41 women): 18
received palbociclib, 15 received ribociclib and 9 received abe-
maciclib. Average age was 56.8±10.0 years. Average length of
treatment was 135.4±92.5 days, with an average number of
cycles of 3.8±3.4. In 19% of patients, treatment was discon-
tinued due to death (50%), progression (25%) or toxicity
(25%).

The most frequent drug adverse reactions were neutropenia
(52.4% of patients), asthenia (40.5%) and anaemia (26.2%),
followed by thrombocytopenia (19%), nausea and vomiting (19%),
diarrhoea (16.7%) and elevated transaminase levels (9.5%). In
some cases, digestive disturbances (4.8%), mucositis (4.8%),
anorexia (2.3%) and leucopenia (2.3%) were reported.
Between the different drugs, diarrhoea and asthenia were the
most prevalent adverse reactions in patients receiving
abemaciclib (55.6% in each), and neutropenia in those receiv-
ing palbociclib (66.7%) and ribociclib (53.3%).

Conclusion and relevance According to our results, the main
adverse reactions should have been expected, in accordance
with the drug data sheets. Knowledge of possible RAM allows
us to improve patient safety. Nevertheless, it is necessary to
expand the study to have more information on the frequency of
these reactions during long term treatments.

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PANCREATITIS INDUCED BY IMMUNOTHERAPY? TWO
CASE REPORTS

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Background and importance Immunotherapy stimulates the
body’s natural defences to fight tumour cells. In the literature,
it is considered a safe drug. However, one of the adverse
reactions described in the data sheet as uncommon is autoim-
mune pancreatitis.

Aim and objectives To describe two cases of pancreatitis
related to immunotherapy.

Material and methods This was a descriptive retrospective
clinical study. Data were obtained from the clinical records. A lit-
erature search was conducted on the adverse effects of
immunotherapy. The causality of the adverse reaction was
established using the algorithm of Karch–Lasagne modified by
Naranjo.

Results A 67-year-old man was diagnosed with non-small
cell lung cancer and received palliative treatment with nivo-
lumab, 37 cycles. After 18 months of treatment, the patient
complained of abdominal pain the days following the infu-
sion. Analytical tests were performed showing an increase in
amylose and lipase. Gasoscopy was performed, confirming
the diagnosis of pancreatitis. The patient remained asympto-
matic, so no specific treatment was initiated, but nivolumab
was discontinued. A few weeks later, the patient arrived at
the hospital complaining of abdominal pain, nausea and
vomiting. The analysis showed a higher increase in both
enzymes. The diagnosis of immunomediated pancreatitis was
confirmed by gasoscopy. Enolic and lathisic origin were
ruled out, due to the absence of previous episodes. Cortico-
therapy was initiated, obtaining clinical and analytical
improvement.

A 58-year-old woman was diagnosed with poorly differenti-
ated carcinoma of probable pulmonary origin and received
palliative treatment with pembrozilumab, 25 cycles. She went
to the emergency room for abdominal pain and vomiting. A
CAT scan was performed where radiological findings compat-
ible with pancreatitis were found. High dose steroid therapy
and antibiotherapy treatment was initiated. She was left with
fluid therapy and days after she began a pancreatic diet. The
patient progressed favourably. After applying the Karch–
Lasagne–Naranjo algorithm, we established a probable causal
relationship between immunotherapy and pancreatitis.

Conclusion and relevance Immunotherapy has demonstrated
efficacy and a good safety profile in clinical trials but possible
adverse effects due to its use can be observed, with little evi-
dence described in the literature. In the event of any
Background and importance Ibrutinib is a tyrosine kinase inhibitor indicated for the treatment of chronic lymphocytic leukemia (CLL) among other pathologies.

Aim and objectives To assess the frequency and severity of adverse events (AEs) in CLL patients treated with ibrutinib.

Material and methods This was an observational, retrospective, descriptive study including all patients aged >18 years old diagnosed with CLL treated with ibrutinib 420 mg/24 hours in our hospital. The study period was July 2015–September 2019. Variables collected were sex, age, diagnosis and cytogenetics, previous treatment lines, duration of treat, AEs, dose adjustment, temporal discontinuations and definitive suspensions. AEs were classified following the National Institute of Cancer (NCI): Common Terminology Criteria for Adverse Events (CTCAE) V.5.0. Data were collected from the electronic clinical history, electronic prescribing software and drug therapy follow-up.

Results Thirty-one patients were included (9 women and 22 men) with an average age of 72 years (range 48–90). Poor prognostic cytogenetics was presented in 71% of patients: 45.16% had del (17p), 12.90% had del (11q) and 12.90% had both. Ibrutinib was prescribed as first-line treatment in 10 patients and as rescue treatment in 21 patients that had a median of 1 previous line (range 1–5).

Median length of treatment was 12.7 months (range 2–42.3). Nine patients suspended ibrutinib permanently: progression (n=5), death (n=2), grade 3/4 AEs (n=1), haemorrhagic and allogenic transplant (n=1). In addition, six patients discontinued ibrutinib because of grade 3/4 neutropenia (n=3), respiratory infections (n=2) and bleeding grade 3/4 (n=1). Twenty-two patients were continuing ibrutinib treatment when the study was closed.

AEs grade 1/2 included musculoskeletal AEs (muscle cramps (n=3), arthralgia (n=4), musculoskeletal pain (n=3)), haematologic AEs (neutropenia (n=1), thrombocytopenia (n=1)), gastrointestinal AEs (diarrhoea (n=1)) and infections (urinary (n=1), pericardic oedema (n=1)). One patient was diagnosed with atrial fibrillation and another with hypertension that required treatment.

Conclusion and relevance In our patients, ibrutinib had an adequate safety profile, highlighting haemorrhage as the most serious AE. Periodic follow-up of patients is necessary to assess adverse reactions and the need for temporary suspension in patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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