**DOSE BANDING – OPTIMISING DOSES IN CETUXIMAB OR BEVACIZUMAB REGIMENS**


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**Background**
The dosage of antineoplastic drugs has been historically based on body surface area or patient’s weight.

Lack of resources and increased workload at an Oncology-Haematology Day Hospital (ODH) are leading to the development of new strategies to optimise the processing. One of those approaches is the dose-banding (DB) method.

**Purpose**
Calculate Cetuximab (Cet) and Bevacizumab (Bev) doses using the DB method;

Compare initially calculated doses (ICD) with those obtained through DB and assess the economic impact.

**Material and methods**

**All ODH patients with ≥18 years**

Cet prescription from November 2017 to August 2018 or Bev from January 2018 to August 2018 were included. Patients with <45 kg or >100 kg were excluded.

The ICDs were initially calculated according to the summary of product characteristics. Then, using National Health Service England DB tables, ICDs were adjusted to a dose obtained by DB (DDB). The range recommended for dose adjustments is 5%–10%.

ICDs and DDBs were recorded.

Using the average price of the drug in our hospital, expenditures made with and without DB were calculated.

**Results**

Doses for 150 preparations of Cet and 406 preparations of Bev were calculated.

For Cet, the DDB were 2.8% lower than ICD, so less drug was used, which represents savings of €/16,409/year.

Regarding Bev, the DDB were 3.1% lower than ICD, which generates savings of €/63,343/year.

**Conclusion**

We found that the introduction of DB to have a noteworthy impact on oncology service total expenditures. Dose adjustments made were within the recommended range. The method has been used in Europe which has studies that support its applicability.

In our ODH there is a policy of using one vial for more than one patient, so the estimated savings may be slightly lower.

Additionally, DB adds another factor of variability to the final dose that will be administered to the patient.

The DB promotes rational drug use. This may be a future approach to other drugs in oncology.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**EXPERIENCE OF DUAL TARGETING USE OF NEOADJUVANT HER2-POSITIVE BREAST CANCER**

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**Background**
Neoadjuvant chemotherapy is the treatment of choice in locally advanced breast carcinoma. Pertuzumab is approved in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of patients with HER2 positive breast cancer.

**Purpose**
To evaluate the complete pathological response rate (pCR) obtained after therapy in combination with pertuzumab in our hospital.

**Material and methods**

Retrospective descriptive study of patients with confirmed diagnosis of HER2 positive breast cancer in treatment with pertuzumab in combination with trastuzumab and taxanes as neoadjuvant treatment (March 2017 to September 2018). Efficacy endpoint was the complete pathological response (pCR) that was related to efficacy and with a longer long-term survival. Adverse effects (AE) were collected for safety profile assessment.

**Results**

Twenty-eight patients were analysed. The median age was 50 years (31–74). All patients had an initial ECOG 0–1. Sixty-three per cent had positive hormone receptors. The mean LVEF of patients at the beginning of the treatment with pertuzumab was 61%. Of the total, n=25 received chemotherapy treatment with AC at dense doses for four cycles prior to the taxane sequence, two patients received TCH and one patient received FEC. Dose reduction was performed in 18% of patients. Paclitaxel weekly for 12 cycles was the taxane level administered in combination with pertuzumab and trastuzumab in 93% of the cases. Radiotherapy and hormone therapy were used when necessary. In general terms, pertuzumab in combination with trastuzumab and taxanes was well tolerated, with AE grade 1–2 such as neurotoxicity, nausea and diarrhoea. No adverse events in grade 3–4 were recorded. Currently, 17 patients have been operated on: in 13 cases with pCR, in three patients there was a Miller and Payner grade 4 response and in one patient grade 3. The rest of the patients will have surgery soon.

**Conclusion**
The data obtained so far are quite encouraging because of the good pCR rate obtained. However, we must treat them with caution due to the low number of patients who have received treatment up to now. But this treatment is going to improve the prognosis of the disease with a tolerable toxicity profile.

**REFERENCE AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**EXPERIENCE OF NAB-PACLITAXEL AND GEMCITABINE USE IN METASTATIC PANCREATIC CANCER**

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**Background**
Nab-paclitaxel is approved for first-line treatment of patients with metastatic pancreatic cancer (mCP).

**Purpose**
To evaluate the efficacy and safety of treatment with nab-paclitaxel and gemcitabine in patients with mCP.

**Material and methods**

Retrospective observational study of mCP patients treated with nab-paclitaxel and gemcitabine...
during the past 5 years. Collected variables: age, sex, ECOG, adjuvant chemotherapy, treatment line, dose reduction and adverse events (AE). Efficacy endpoints were progression-free survival (PFS) and overall survival (OS) obtained by the Kaplan–Meier method. Adverse effects (AE) were collected for safety profile assessment. Descriptive statistical analysis was performed using the SPSS Statistics program V22.0.

Results Forty-seven patients (30 men and 17 women) were included. The median age was 59 years (29–82). At the beginning of the treatment, more than 80% presented ECOG 0–1: 23.4% had received previous adjuvant chemotherapy (gemcitabine and/or fluoropyrimidines). They were treated with nab-paclitaxel 125 mg/m² and gemcitabine 1000 mg/m² on days 1, 8 and 15 every 28 days. In 89.4% of the patients it was prescribed as first-line treatment. Dose reduction was performed in 68.1%. The median duration of treatment was 4.5 months (0.5–22.9), with four long survivors (longer than 15 months). The median PFS was 9.1 months (95% CI 8.36 to 9.73) and the median OS was 9.11 months (95% CI 4.0 to 14.2). Eighty-three per cent of patients (n=39) had AE of some grade and 17% (n=8) of grade 3–4. The most common AE were: asthaenia (n=17), neutropaenia (n=16), thrombocytopaenia (n=15), neuropathy (n=13), alopecia (n=5), diarrhoea (n=7), mucositis (n=3), vomiting (n=3), oedema (n=3) and dermatitis (n=2). These were grade 3–4: neutropaenia (n=7), thrombocytopaenia (n=4), mucositis (n=1), alopecia (n=1) and neuropathy (n=1). The causes of treatment discontinuation were mainly due to progression in 42.6% and deterioration of general health in 29.8%. At the end of the study, five patients continued treatment.

Conclusion The PFS obtained in our study is greater than those described in the pivotal trial MPACT or CA046. This difference may be due to the four patients with a considerably longer treatment than the average and a small sample. Regarding OS, there are no significant differences with the pivotal trial. The AE described were similar to those published in the literature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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ERLOTINIB IN NON-SMALL-CELL LUNG CANCER WITHOUT EPIDERMAL GROWTH FACTOR RECEPTOR ACTIVATING MUTATIONS

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BACKGROUND

Erlotinib is indicated in patients without epidermal growth factor receptor (EGFR)-activating mutations who have had at least one previous chemotherapy treatment that has failed and when other treatments are considered unsuitable.

PURPOSE

To analyse the effectiveness and safety of erlotinib in non-small-cell lung cancer (NSCLC) in patients without EGFR-activating mutations.

MATERIAL AND METHODS

A retrospective observational study was conducted in a third-level hospital. We included patients treated with erlotinib without EGFR-activating mutations from August 2012 to August 2018.

Following variables were recorded: age, sex, ECOG, histopathology, progression-free survival (PFS), smokers/non-smokers or ex-smokers, type of previous chemotherapy regimens, reported adverse events (AEs) and dose reductions between cycles.

We obtained data from electronic clinical records, the software where we register chemotherapy treatments (chemotherapy management software Oncogest) and the optimised computerised order entry ATHOS software.

AEs were classified according to the National Cancer Institute of Canada Common Toxicity Criteria v4.0.

RESULTS

Thirty-seven patients were included, with a median age of 64 years and 70% men. Fifty-seven per cent of patients presented ECOG 0 and the rest ECOG 1–2. Seventy-eight per cent of patients were smokers and/or ex-smokers. Ninety per cent of patients received erlotinib as the second line of treatment or subsequently, and the median PFS was 9.3 weeks. Previous chemotherapy regimens used before erlotinib in NSCLC were: taxane-based-chemotherapy 60%, platinum-based-chemotherapy 83% and both 74%. Forty-eight per cent of patients had at least one AE during treatment. The most frequent was skin rash g1–2 (60%). Thirty per cent of patients had dose reductions due to toxicity.

CONCLUSION

In our patients, erlotinib median PFS was lower than in the BR21 trial. It could be explained because our patients received more previous regimens of chemotherapy for metastatic disease as well as our sample size was smaller. Regarding safety, erlotinib was well tolerated and in most of the cases, the AEs did not force a dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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COST-MINIMISATION ANALYSIS OF MAINTENANCE THERAPY OF ANTINEUTROPHIL CYTOPLASM ANTIBODY-ASSOCIATED VASCULITIDES

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BACKGROUND

The use of rituximab as maintenance treatment of antineutrophil cytoplasm antibody-associated vasculitides (AAVs) was supported by the MAINRITSAN trial. MAINRITSAN2 was a randomised, open-label, multicentre phase III trial which evaluated the difference between an individually tailored and a fixed-schedule maintenance therapy with rituximab. We found a large number of studies evaluating rituximab as a maintenance treatment in AAVs, but only a few looked at economic considerations. This cost-minimisation analysis (CMA) provides the best data available to date on the cost-saving option between a tailored-therapy and a fixed-schedule regimen with rituximab for the maintenance treatment of AAVs.

PURPOSE

The present study used a cost-minimisation approach to examine the real-world costs of an individually tailored therapy compared to a fixed-schedule therapy with rituximab for remission maintenance of AAVs.