Conclusion and relevance Ziv-Aflibercept (Zaltrap) remained stable for 14 days regarding visual appearance, LMW aggregates, particulate and conformation when stored at 4°C. However, storage at room temperature promoted ziv-aflibercept modifications. This result encourages more studies with samples stored at 4°C to establish the stability of opened vials of Zaltrap.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-014 USE OF CABAZITAXEL AND REDUCTION OF WASTE: THE POTENTIAL OF DRUG DAY

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Background and importance Cabazitaxel is an antineoplastic agent indicated for the treatment of adult patients with metastatic castration resistant prostate cancer, previously treated with a docetaxel containing regimen. The formulation available on the market consists of a vial of concentrate which, after dilution, makes 60 mg of drug available. The recommended dose of cabazitaxel is 25 mg/m^2 administered every 3 weeks and generally doses range from 20 to 50 mg. This results in waste with a strong economic impact considering the cost of the drug. From January to September 2019, 12 patients were treated with cabazitaxel in hospital for a total of 64 administrations (average dose of 37 mg) on 49 different days. Consumption was increased compared with the previous year (in 2018 from January to September 7 patients were treated and 42 administrations). It is appropriate to check the advantages of introducing drug day (administration of the drug on the same day of the week for all patients requiring therapy).

Aim and objectives The objective of the study was to verify the current wastage of cabazitaxel, and the potential waste with the introduction of drug day.

Material and methods Leftover drug was calculated for each day of administration (49 days). In the case of multiple administrations on the same day, leftover drug was calculated based on vial sharing. The same method was used to calculate leftover drug for every week of therapy, as if the therapies had been administered on the same day (drug day).

Results In 9 months, 2370 mg of cabazitaxel were administered and the waste calculated from leftover of single therapy days was 1350 mg (+57% compared with ideal consumption). Projecting consumption and waste at 12 months gives an annual consumption of 4960 mg of cabazitaxel (83 vials, of which 30 are considered waste).

With the introduction of drug day, waste would decrease to 810 mg (+34% compared with ideal consumption) and the projection would lead to an annual consumption of 4240 mg (71 vials, of which 18 would be considered as waste).

Conclusion and relevance The introduction of drug day for cabazitaxel is fundamental to reduce waste, optimise resources and safeguard costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-015 SHORT TERM STABILITY OF DILUTED SOLUTIONS OF THE MONOCLONAL ANTIBODY DARATUMUMAB

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Background and importance Monoclonal antibodies (mAb) are biotechnological products used as therapeutic agents. Because of their nature, mAb may go through a variety of chemical and physical degradation processes on handling. For this reason, extended in use conditions are not included in stability assessments prior to regulatory approval. Daratumumab, a CD38 targeting human IgG1κ mAb, is used in the treatment of multiple myeloma. After dilution in saline (0.9% sodium chloride) solution using the appropriate aseptic technique, it is reported to be physically and chemically stable for 24 hours under refrigerated conditions (2–8 °C) protected from light.[1]

Aim and objectives We conduct a study to evaluate the physicochemical stability of daratumumab diluted at clinically relevant concentrations over a 14 day period.

Material and methods Daratumumab was diluted to concentrations of 1.2 and 2.0 mg/mL in a low density polyethylene (LDPE) infusion bag in saline solution for intravenous injection. To determine changes in physicochemical properties over a 14 day period, various methods were used—that is, size exclusion chromatography-high performance liquid chromatography (SEC-HPLC), dynamic light scattering (DLS), nanoparticle tracking analysis (NTA), turbidimetry, pH and osmolality. They were selected based on the preliminary results of a forced degradation study.[2]

Results All samples remained clear with no precipitates or particulate matter detected with the naked eye. No change in colour or turbidity was observed. The pH of both dilutions shifted from 5.5 to 5.8, while the osmolality value ranged from 296 to 313 mOsm/kg. SEC-HPLC did not show the formation of aggregates or fragmentations. The ratio between the major peak (retention time=13 min) and a minor signal (retention time=11 min) remained constant over time. No clear trend in the presence of sub-visible particles was observed by DLS. Indeed, the main peak of daratumumab was detected at about 13 nm which accounted for up to 98% and 95% for the 1.2 mg/mL and 2.4 mg/mL solutions, respectively. These results were in agreement with the NTA data.

Conclusion and relevance No physicochemical variations were evident in daratumumab solution at 1.2 mg/mL and 2 mg/mL stored in an LDPE infusion bag at 2–8°C. Evaluation of the biological activity is required to confirm the extended in use stability.

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No conflict of interest.