PRELIMINARY MICROBIOLOGICAL STUDY OF INJECTABLE CHEMOTHERAPY DOSE-BANDING

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Background

In our medical center, the production of injectable antineoplastic rose 20% between 2015 and 2017. As a consequence the dispensing delay increased. It has therefore been decided to implement dose-banding. In order to guarantee the sterility of preparations after storage, we did a preliminary study of microbiological stability 28 days after making the preparation.

Objectives

The study of microbiological stability of injectable chemotherapy produced at oncological pharmacy after 28 days of storage.

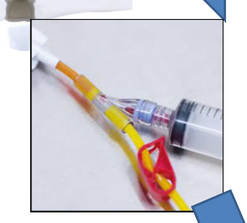
Material and Methods

We simulated the production of antineoplastic preparation with dextrose 5% to avoid chemotherapy contamination at the hygiene laboratory.

50 %
Room - temperature

DAY 0
56 infusion bags were produced in positive air pressure isolator

50 %
4°C



20mL samples were taken and inoculated under laminar flow at the pharmacy

20 mL

20 mL

Day 0, 2, 7, 14, 21, 28 and 42.

This volume represents 10% of the final volume of the bag according to the the **2.6.1 chapter of sterility test of the European Pharmacopeia 9.7.**

The samples are sent to the hygiene laboratory the day of inoculation

- Liquid medias used are thioglycolate and trypticase.
- Fertility and sterility of these medias was checked. American Type Culture Collection strains were used to test the fertility of these medias.
- Liquids medias were incubated at the hygiene laboratory for 14 days at 22°C and 34°C.
- The positivity of the liquid medias was observed by the appearance of a turbidity, visible to the naked eye.

Results

Fertility and sterility controls were validated. After 14 days of incubation, no microbiological growths were observed. The main limit of this study is the decision to use 1 media per bag, to avoid accidental contamination at sampling time.
According to a previous study (1) carried out in our medical center, the majority of the centers that use “dose-banding”, have only achieved a chemicophysical stability study. Since sterility control can’t be performed systematically, it seemed important to us to prove the microbiological stability of these preparations.

(1)

Conclusion

This preliminary study proves the sterility of chemotherapy bags after 28 days of storage. It allows dose banding in order to shorten waiting periods for dispensation.

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