

Feasibility study for dose-banding of Oxaliplatin - Dose standardization project of the hospital's Chemotherapy Preparations Unit

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Introduction

A range of studies have demonstrated the safety and efficacy of dose-banding (DB) in chemotherapy. DB is a system whereby patients receive standard doses of intravenous cytotoxic drugs that are determined by rounding up or down individual calculated doses. Traditional calculation of chemotherapy doses is based on personal weight or body surface and such specific dosing increases not only time and costs but also calculation errors. Therefore, the Chemotherapy Preparations Unit has led a dose standardization project in which Oxaliplatin is one of the selected molecules.

Objective

This DB scheme for Oxaliplatin aims to improve patients' care by proposing standard doses with bands that could be accepted by local oncology teams.



Material and Method

All Oxaliplatin preparations in 2019 were extracted from a regional prescription base for chemotherapy. An analytic study of extraction enabled us to determine the dose bands and to propose standard doses. Subsequently, the team was commissioned to bring the DB into production.

Results and Discussion

Throughout the year 2019, our hospital pharmacy prepared 1,729 IV bags of Oxaliplatin dosed from 59.5 mg to 261.5 mg. A lot of patients (n=381) aged from 2 to 88 years (M=67; m=65; SD=12; Male/Female=7/5) were treated with this drug. Most preparations were made for Day Hospitals (1451/1729, 83.9%) and Oxaliplatin was also prepared for some clinical trials (126/1729, 7.3%).

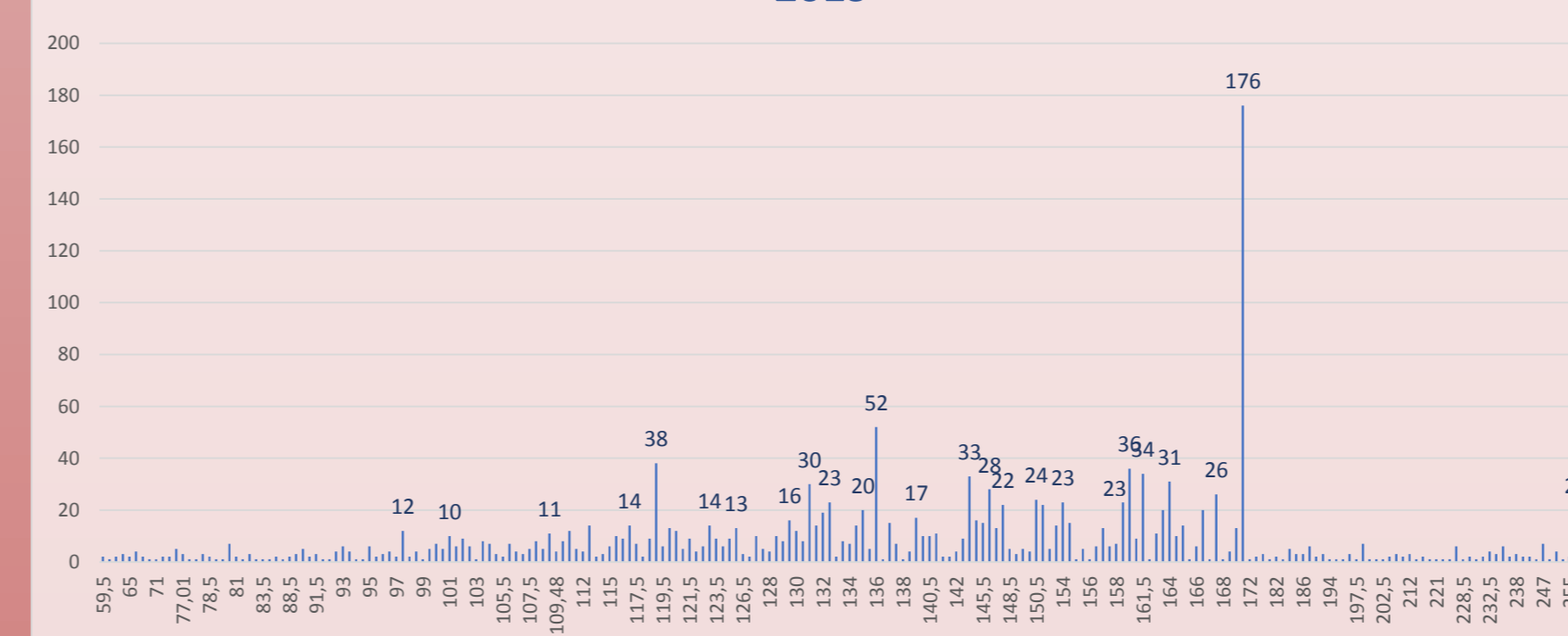
According to the bibliographic research, Oxaliplatin infusion's shelf-life is 84 days^[1] when stored at 2 – 8°C in polyolefin bag.

Four DB examples were presented and the selected one proposes the following standard doses with the maximum deviation of 6.9%: 100 mg, 115 mg, 130 mg, 150 mg and 170 mg (preparations in 250 ml of glucose 5%). These doses could cover a large part of annual preparations, e.g. in 2019 (1553/1729, 89.8%). A test phase validated production of the series of 20 IV bags per dose and each infusion bag must be dosed with HPLC.

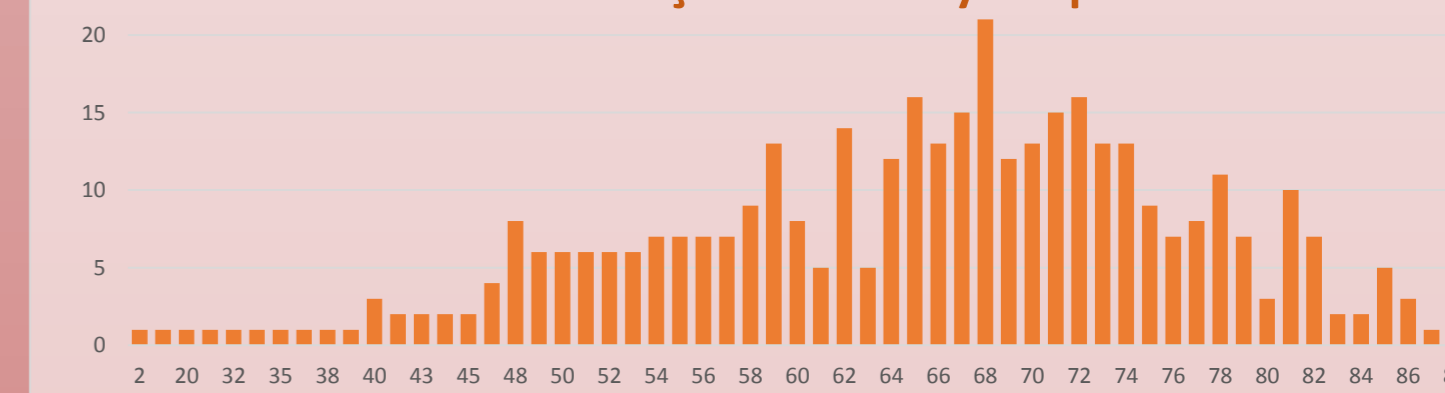
An audit on the routine preparation of chemotherapy showed that patients had to wait generally 1 hour and 25 minutes and the time required for a preparation is about 28 minutes.

According to the statistics from 2019, Oxaliplatin whose stability is suitable for being prepared in advance is a widely used antineoplastic drug. Having the standardized products ready to use is also approved by medical teams. Available dose-banded preparations can reduce patients' waiting times for their treatment. This standardized approach minimizes pharmacy preparation workload and maximizes financial efficiency by reducing drug wastage. DB reduces dose calculation errors and ensures the quality of drugs through end-product controls and dosage.

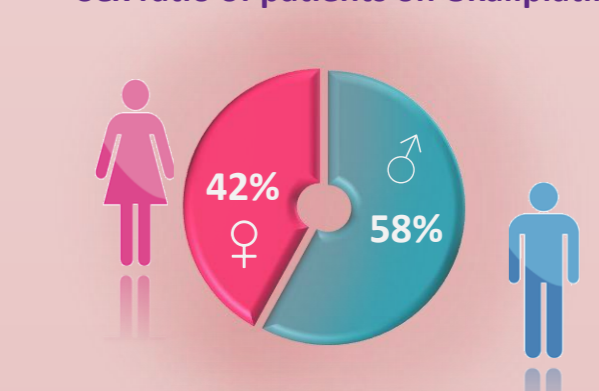
Distribution of doses administered according to the number of Oxaliplatin preparations at the Besançon University Hospital in 2019



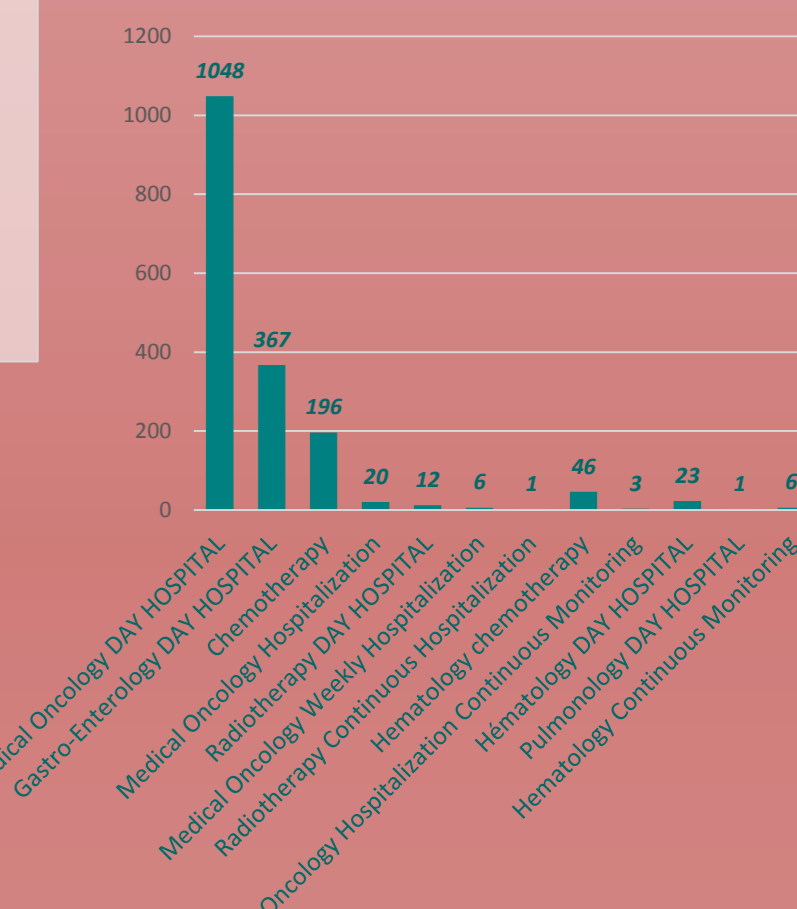
Age distribution of patients on Oxaliplatin in 2019 at the Besançon university hospital



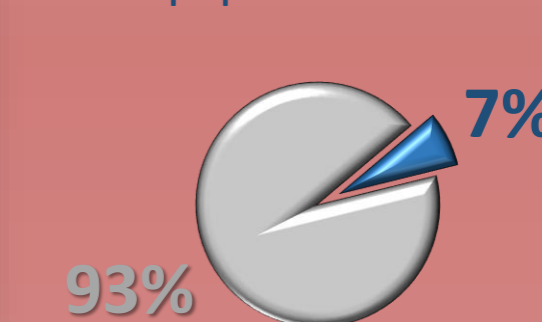
Sex ratio of patients on Oxaliplatin



Distribution of Oxaliplatin preparations in 2019 according to the care unit

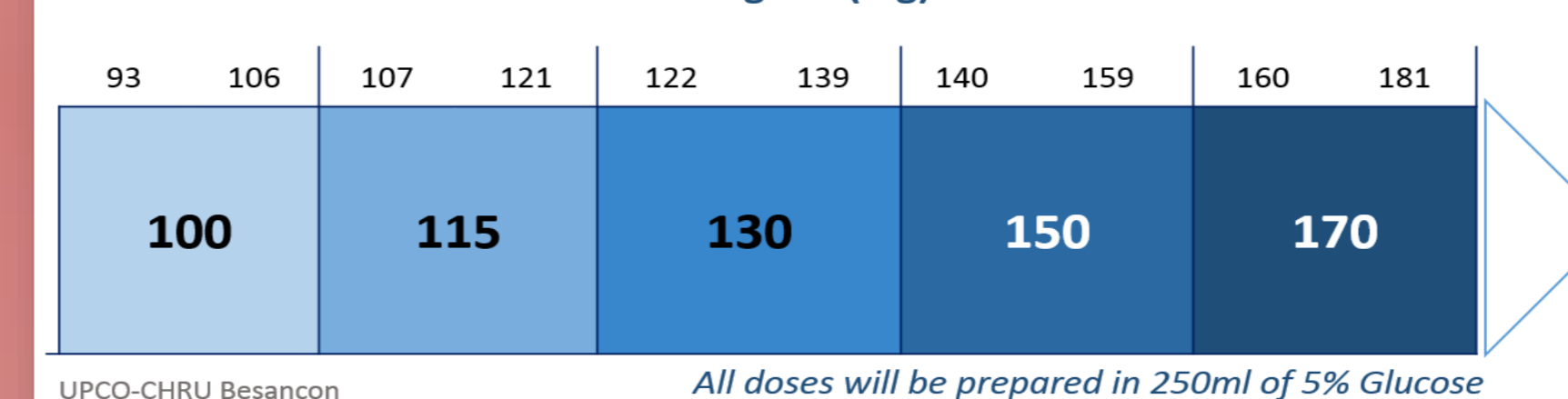


Proportion of clinical trials in Oxaliplatin preparations in 2019



Oxaliplatin Dose-banding

Unit: milligram (mg)



Conclusion

Finally, the introduction of Oxaliplatin DB scheme into clinical practice achieved its objectives. Moreover, it is intended that the hospital continue the standardization project for other anticancer drugs.

^[1] Sewell G, Massimini M. Studies on the stability and compatibility of cytotoxic drug infusions with the Tevadaptor device. Eur J Oncol Pharm. 1 jan 2014;8:26-30.