

Production time assessment of a VYXEOS® cycle versus “3+7” regimen in the induction treatment for acute myeloid leukemia

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Introduction

« 3+7 » regimen: standard of care in the induction treatment for AML

10 preparations administered over 7j:
→ 3 days of daunorubicin + 7 days of cytarabine (syringe pump over 24h)



Pharmaceutical production:
6 preparations at D1 and 4 at D4

VYXEOS®: innovative pharmaceutical form



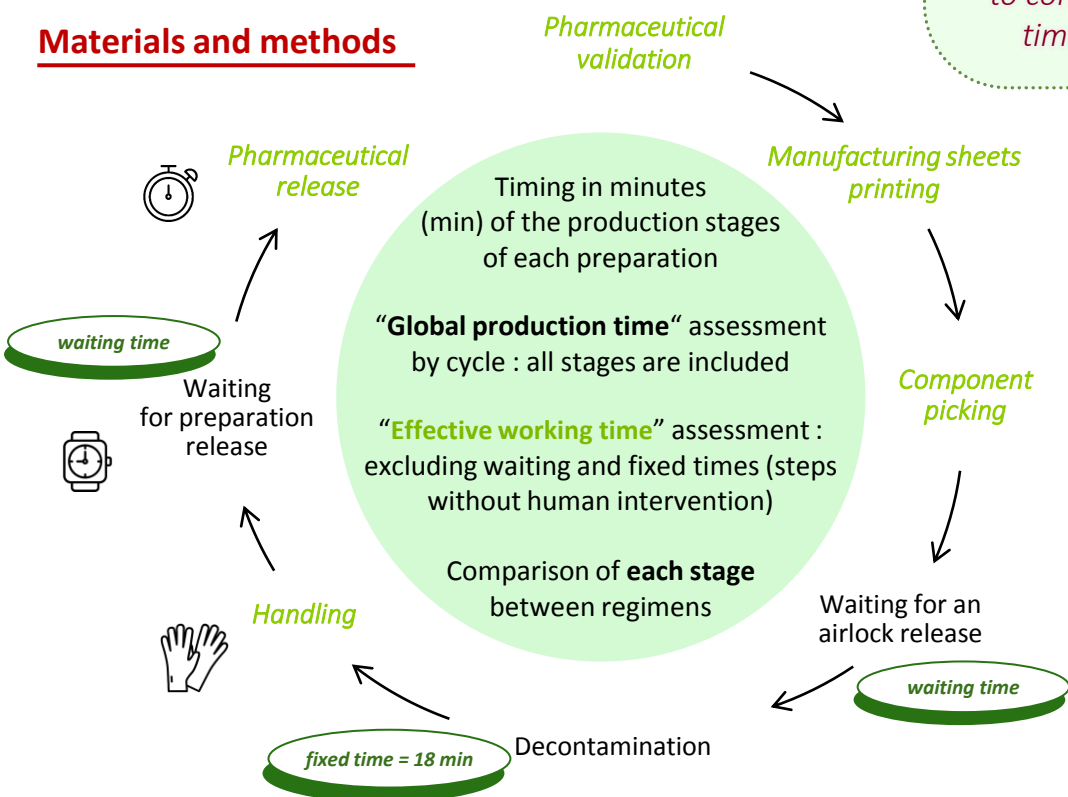
Liposomes of daunorubicin 44mg + cytarabine 100mg
Production over 3 days
Administered at D1-D3-D5 : 1 bag a day in IV over 1h30min

The aim of the study is to compare the production time of both regimens

Results

Average time (min) ± standard deviation	« 3+7 » regimen n=6 patients	VYXEOS® n=6 patients	p-value Two-tailed Student's t-test	S / NS
Global production time	191.8 ± 22.5	231.3 ± 24.8	p < 0.05	S
Effective working time	81.0 ± 19.5	97.7 ± 6.6	p > 0.05	NS
Validation	3.7 ± 1.2	3.7 ± 1.6	p > 0.05	NS
Manufacturing sheets printing	8.8 ± 4.2	3.7 ± 1.6	p < 0.05	S
Picking	6.5 ± 1.4	3.3 ± 0.5	p < 0.005	S
Handling	50.0 ± 12.8	83.5 ± 6.5	p < 0.001	S
Release	12.0 ± 6.3	3.5 ± 0.8	p < 0.005 (Mann-Whitney)	S

Materials and methods



Conclusion

- Significant difference on **global production time** : shorter duration for « 3+7 » regimen → production **already optimized with only two days of production** in our unit.
- Longer production time for VYXEOS® due to handling obligations: 30min rest at room temperature before handling and 15min after reconstitution ;
→ those waiting times are minimum and are **not offset by shorter steps** in VYXEOS®' production but as human intervention is not required, others activities can be performed during those times ;
- Organisational obstacle for VYXEOS® : only 5h30min stability.
- No significant difference between the regimens in terms of **effective working time**.

To assess the whole circuit, delivery time and administration time by nurses (probably in favour of V) still have to be evaluated.