THERAPEUTIC RECOMMENDATIONS of the GFAOP (Groupe Franco-Africain d'Oncologie Pédiatrique) for patients with BURKITT LYMPHOMA (BL) treated in SUB-SAHARAN PEDIATRIC ONCOLOGY UNITS (POU): SYSTEMATIC DATA REVIEW

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I have nothing to disclose

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INTRODUCTION

- B-cell non-Hodgkin's lymphoma (NHL) in children, particularly Burkitt lymphoma (BL), is a frequent cancer in Sub Saharan Africa (SSA).

- Since the creation of the « Groupe Franco-Africain d'Oncologie pédiatrique » (GFAOP) in 2000, BL has been treated with successive protocols based on the SFOP/SFCE LMB regimen.

BACKGROUND

1st GFAOP study

- 2001- 2004 : 306 patients
- 5 units from Maghreb & 3 SSA
- LMB based +/- doxo

61% OS (Sub-Saharan pts : **44%**)
From the 1st to the 3rd year :
Toxic death rate : 27% → **10%**
OS : 54 % to **73%**

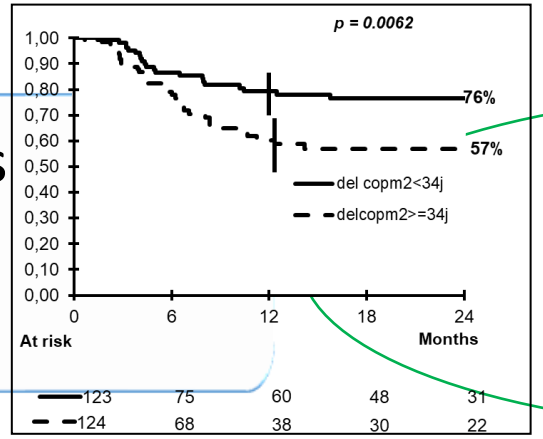
2nd study
CYCLO BURKITT

- 2004-2009 : 178 patients,
- 6 SSA units
- Cyclo. alone +/-"rescue"

33% OS with cyclo alone
50% including rescue

3rd study (GFA LMB 2009)

- 2009-2015 : 400 pts, 7 SSA units
- Bulky stage II, Stages III and IV
- LMB based with no doxo



60% OS,
abandonment 22%
toxic deaths 12%,
early dose intensity +++

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M Harif et al, PBC 2008; F Traore et al , PBC 2011; C Bouda et al, JGO 2019

Current therapeutic recommendations (GFA LMB2019) :

Protocol similar to the previous one, LMB based, with HD MTX ($3g/m^2$) and no doxo except in very advanced stages.

CT dose intensity is adapted to 3 therapeutic groups based on stage.

The GFA LMB2019 protocol was opened for registration in November 2020.
Each participating unit is opened after completion of regulatory documentation.

Patients must be initially registered in the GFAOP Registry, and, if the inclusion criteria are met, are registered in the specific recommendation database.

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OBJECTIVES of the GFA LMB2019 recommendations

- **Main objective is to** :

- verify that the correct application of therapeutic recommendations leads to **improve patient survival,** compared to the previous LMB protocols, with a treatment intensity adaptation according to **3** different therapeutic groups (low, intermediate and high risk) and *to obtain "clean, rigorous and high quality data".*

- **Secondary objectives are to**:

- evaluate the **ability** of participating units to **apply** therapeutic recommendations and **report** data in real time.

- evaluate the ability of units to **manage** the various **side effects** of the GFA LMB 2019 therapeutic regimen.

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How does it work?

- In the GFA LMB2019 recommendations, special attention is paid to correct diagnosis, supportive care, CT dose intensity, parent/child information and **data quality**.

- To address these points:
  - Dr C. Patte, medical expert (ME) carries out regular reviews of the registered data, and queries are sent to the units.
  - Cyto-histopathology reports must be uploaded, as well as the significant radiology reports.
  - A **2 hour teleconference** for data validation is planned, between the local clinical research assistant (CRA) and physician, Dr Patte and the data manager. Medical files must be available for these sessions. If complete, data are "**locked**".

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Results

- The study was opened in 8 POU at different times from November 2020 to April 2022 : Two units have not yet enter data.

- **188** patients were registered (predominantly from Ouagadougou and Abidjan), by February 2024.
- **17** teleconferences and **2** on site validation sessions.
- **169** patient files from 3 units (Ouagadougou, Abidjan and Antananarivo) were locked which represent ≈ **90%** of their patients.
- Data from the other units were reviewed by the ME, but not yet validated in a validation session because too incomplete.

	Registered pts	Med expert review	validated data by visio conf	Validated data on site	% validated data
Total	**188**	**188**	**134**	**35**	**90%**
Center					
Abidjan	***54***	*54*	*18*	*34*	*96%*
Antananarivo	*1*	*1*	*0*	*1*	*100%*
Conakry	*2*	*2*	*0*		*0%*
Dakar	*6*	*6*	*0*		*0%*
Kinshasa	*8*	*8*	*0*		*0%*
Ouagadougou	***117***	*117*	*116*		*99%*

Total n° of validation sessions		**17 by visio+ 2 local**
	in 2024	1 visio + 2 Local
	in 2023	13 visio
	in 2022	3 visio

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Conclusion

- This systematic review & validation process promotes improvement in data quality.
- Despite the time spent, these sessions are appreciated by the local staff, recognizing that it improves their knowledge and practice. Indeed, it allows to raise medical questions/“difficulties” which generate significant discussion.
- Most of the data were validated in the 2 units which included the majority of patients and the data validation process will be continued for the other units with the same aim of data quality and improved knowledge and care.
- Since the GFA LMB2019 study is still on going, results are not shown here.
- But based on good quality data, it will be possible to introduce rituximab & conduct an comparison observational study to assess its potential benefice.

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Thank you!

Foundation THE sanofi COLLECTIVE | My child matters

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GUSTAVE ROUSSY
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