AMGLIDIA, a suspension of glibenclamide for patients with neonatal diabetes - Long term data on efficiency and tolerance

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INTRODUCTION:

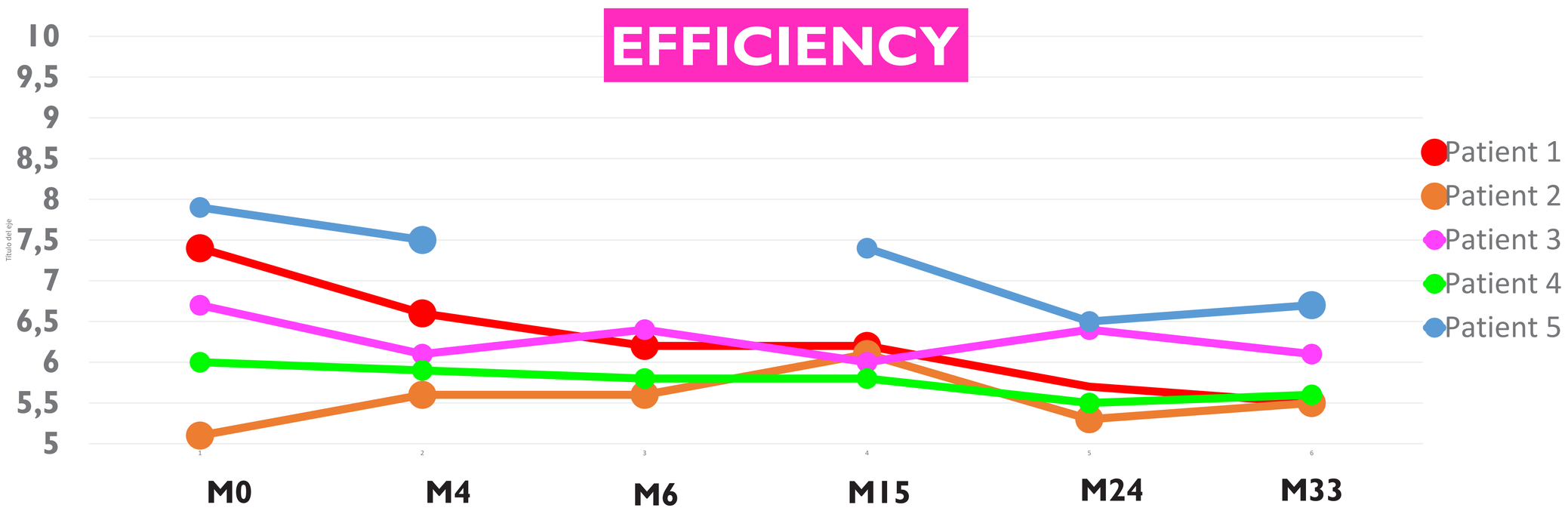
Glibenclamide has proven to be efficient for patients with neonatal diabetes owing to potassium channel mutations. We developed a suspension of glibenclamide fitting recommendations of drug administration to allow a precise dosage. Its use habe been recently approved throughout Europe by the EMA.
We reported it to be practical, efficient and well tolerated after 3 months of use.

AIM:

To determine long term efficiency and tolerance of a suspension of glibenclamide in patients with neonatal diabetes du to potassium channels mutation and previously treated by glibenclamide tablets

Patients		
N=	5	
Mutation	KCNJ11 (5/5)	
Characteristics	**Median**	**Range**
Sexe (M/F)	3 / 2	NA
Age at AMGLIDIA introduction (years)	1.63	0.6 – 1.8
Previous SU dosage (tablets) mg/kg/day	0.1	0.6 – 0.26
SU dosage at last visit (AMGLIDIA) mg/kg/day	0.08	0.6 – 0.27
AMGLIDIA treatment duration (month)	32.9	30 - 34.6

EFFICIENCY



Change in HbA1C in between Mont (M0) and Mont 33. Metabolic control was excellent.
Median HbA1C at M33 was 5.6% (5.5 to 6.7%) and dind't change significantly from M0

TOLERANCE

HYPOGLYCEMIA (below 70 mg/dl)

- **Very low occurrence of hypoglycemia**
- **Less than 5% of routine blood test**

SEVERE HYPOGLYCEMIA

- **2 patients experienced hypoglycemia below 35 mg/dl during the first month of use highlighting the need for dosage titration when switching from tablets to suspension.**
- **1 patient experienced hypoglycemia with neurological symptoms occurring during viral gastroenteritis**

OTHER:

- **Transient and non-severe abdominal pain or diarrhea occurred in 3 patients.**

CONCLUSION:

Glibenclamide suspension AMGLIDA allows an excellent long term metabolic control and is very well tolerated.
EMA marketing authorization throughout Europe was issued on May 24th 2018
AMGLIDIA (glibenclmaide) EMA product number: EMEA/H/C/004379
Product details: www.eam.Europa.eu – Contact: contact.france@amringpharma.com

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