



The utility & efficacy of Miltefosine as a 1st line therapy for Kala-azar in Nepal

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INTRODUCTION

- ❖ Miltefosine (MIL), the only oral anti-leishmanial drug, is the recommended 1st line therapy within the kala-azar (KA) elimination programme in the Indian sub-continent.
- ❖ Currently, free treatment with MIL is available in public health facilities from the level of primary health care centers and above in KA endemic districts of Nepal. Though considered safe, side effects are common and sometimes can be life threatening.
- ❖ It is contra-indicated in pregnancy and breast feeding women due to its teratogenic effect. MIL has a long-half life and requires a long treatment course therefore there are concerns of development of parasite resistance and treatment failure is usually delayed occurring months after completion of therapy.
- ❖ However assessment of outcome at 6 months after therapy though recommended is not routinely recorded in health facility reports.
- ❖ In this context, we aimed to find out the proportion of KA cases currently being treated with MIL and document the clinical outcome at 6 months after the completion of therapy.

RESULTS

1.

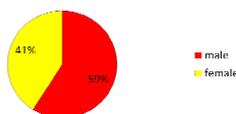


Fig 1: Sexwise distribution of KA patients

2.

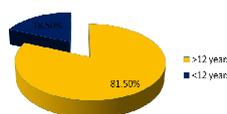


Fig 2: Agewise distribution of KA patients

3.

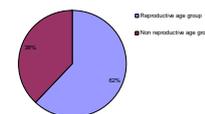


Fig 3: Female reproductive age group distribution of KA patients

4.

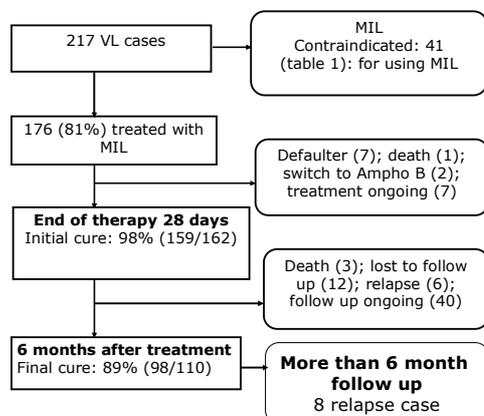


Fig 4: Outcome of MIL therapy (6 month follow up)

5.

	No. of cases (%)
Very sick	13 (6)
Deranged biochemistry	11 (5)
LFT (AST/ALT > 3 times normal)	8
RFT (> upper limit of normal)	2
Both LFT and RFT	1
Low Hb (< 5 gm %)	3 (1.3)
Pregnancy	1 (0.4)
Lactating	4 (1.8)
Others	9 (4)
One year old infant	1
Unavailability of 10mg formulation	6
Physicians decision to start Amphotericin B	2

Table 1: Contraindications to use MIL

6.

Side effects	CTC grading	NO. of cases (%) N=176
Vomiting, diarrhoea	I	17 (9.6)
	II	1 (0.5)
	III	1 (0.5)
Hepatotoxicity	I	7 (4)
	II	4 (2)
	III	2 (1)
Hypokalemia	II	1 (0.5)
Renal toxicity	I	4 (2)
	III	1 (0.5)

Table 2: Adverse events of MIL treated cases

7. Out come of MIL therapy in < 12 years age group

- At the end of treatment: 96% (23/24) initial cure
- 6 month follow up: 89% (8/9) final cure, no relapse cases
- More than 6 month follow up: 3 relapse cases

CONCLUSIONS

- ❖ Miltefosine being an oral drug is very convenient but over one-fifth of KA cases didn't receive this drug due to its contraindications. Also with one-quarter of the KA cases being females in the reproductive age group, facilities for counseling and providing contraception needs to be in place within the health facilities.
- ❖ Miltefosine showed an excellent initial cure rate but the final cure rates were not comparable. Moreover, with more cases relapsing after 6 months long term monitoring is crucial to estimate the true efficacy of this drug.

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