# Delamanid use in children aged 0-3 years with preXDR-TB: case series report

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## Background

Multidrug-resistant tuberculosis (MDR-TB) in children under 3 years of age presents a significant treatment challenge. Delamanid has shown promise in the treatment of MDR-TB in adults, but data on its use in young children are scarce, especially among preXDR children less 10 kg body mass. This report aims to describe the experience of using delamanid in young children with MDR/preXDR-TB.

## Cases description

This case series includes 10 pre-XDR patients aged 7-34 months who received delamanid-containing treatment as part of individualized treatment regimens were documented in Yekaterinburg, Russia from June 2022 to November 2024. The legal representatives gave written voluntary consent to the use of off-label drugs. Delamanid is currently approved for use in children from 3 years of age according to the National Clinical Guidelines in Russia.

The average age of the children was 14.3 months, (5 children under the age of 1 year, 3 children from 1 year to 2 years, 2 children older than 2 years). Three girls and seven boys. The average weight at the beginning of treatment was 9.3 kg, at the end of usage of delamanid 11.6 kg. All patients were HIV-negative, (2 children from perinatal HIV contact). Nine children have primary lung forms of tuberculosis, 1 child has generalized tuberculosis.

All children underwent multiple studies of gastric lavage waters: luminescent microscopy, PCR examination, culture on liquid and dense nutrient media. MBT culture with HRSEAmCmLfxMfx (Tab. 1) resistance was isolated in 2 children; HRSELfxMfx resistance in 2 children; HRSEAmLfxMfx resistance in 1 child. Eight children were in close contact with patients with RR-TB and half of them were in contact with pre-XDR patients.
(Fig.1).

All children were prescribed delamanid 25 mg QD 6 months. Three children have completed the course of tuberculosis treatment effectively. Eight children have completed a six-month course of delamanid and continue treatment with other drugs. All bacterial isolators show culture conversion within 2 months from the start of delamanid. All children have positive clinical and radiological dynamics, confirmed by CT control.

Adverse events were monitored daily. The instrumental and laboratory methods used at least once a month. Adverse events associated with taking delamanid have not been reported. Four children had adverse events associated with taking other drugs: 1 child – cefotaxime, imipenem + amoxicilline, PASC; 1 child – levofloxacin, cycloserine; 1 child – amikacin, 1 child - protionamide.

## Conclusion

The use of delamanid in young children under 3 years old under 10 kg of weight was effective and did not lead to the development of adverse events within the observed group.

For discussion

**Figure 1.** MTB resistance

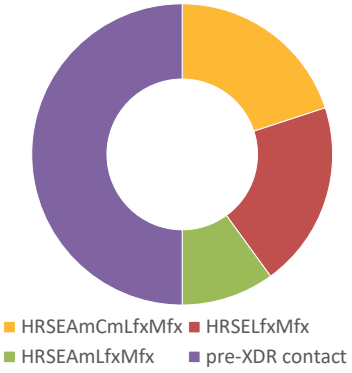


**Table 1.** TB antibiotics abbreviations

| Abbreviation | Medication |
|---|---|
| H | Isoniazid |
| R | Rifampicin |
| S | Streptomycin |
| E | Ethambutol |
| Am | Amikacin |
| Cm | Capreomycin |
| Cs | Cycloserine |
| Lfx | Levofloxacin |
| Mfx | Moxifloxacin |
| Imp | Imipenem/cilastatin |
| Amx | Amoxicillin/clavulanic acid |