

Lack of digital ECGs slows roll-out of anti-TB drug

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According to an RTI filed, 81 patients have died while on treatment with Bedaquiline - istock.com/JK1991

The Centre has provided around 400 out of the 6,000 ECGs needed

The roll-out of crucial anti-tuberculosis drug, Bedaquiline is slow because of a substantial lack of digital electrocardiogram (ECG) machines on field.

While Bedaquiline is one of the last resort medicines for tuberculosis (TB) patients in which first-line drugs have failed, it may also cause a patient's heart rhythm to go awry, a serious adverse event (SAE) known as 'QTC prolongation,' that can even prove fatal.

QTC prolongation

Ideally 6,000 digital ECGs must be installed at block-level set-ups for measuring QTC prolongation.

However, the centre has been able to provide only around 400 ECGs (6.6 per cent of the total requirement).

It is upto the States to procure the machines and the movement has been slow, a senior official in the Union Ministry of Health and Family Welfare (MoHFW) told *BusinessLine*.

While the QTC interval can be calculated on a normal ECG strip as well, officials point out that even a small error pertaining to a few millimeters on the strip can throw up an erroneous result and therefore a digital ECG which does auto-calculation is pertinent.

The MoHFW estimates that upto 14,000 patients require Bedaquiline every year. In a reply to an RTI filed by *BusinessLine*, the MoHFW said that upto 1,964 (14 per cent) patients have been put on treatment between January 2015 to October 2018. Meanwhile, the supply of Bedaquiline is more than adequate with 7,000 courses of drug being available.

One course fulfills the drug requirement for one patient.

“The scale-up of Bedaquiline in our programme is slow. We have staggered the additional supply of 3,500 more courses to come until March 2019. This is because of lack of digital ECG machines, unpreparedness of the staff to roll it out because of training issues and so on. We are fixing these issues. Also, there are apprehensions about the drug, especially when the patient has to undergo an ECG every month, and in cases of adverse events every fortnight. As of now, patients have to travel long distances to undergo ECG because the facility is available only at district level nodal drug-resistant TB centres,” said another official.

Side effects

According to latest estimates drawn by the MoHFW, the official said that while there have been side-effects in few patients, 80 per cent of the patients have reportedly been cured because of the drug.

However, it is of utmost importance to monitor patients on the drug as according to the RTI, 81 patients have died while on treatment with Bedaquiline containing regimen of the initial 620 patients enrolled till August 2017.

“The details of the cause of death of these patients is under review by the Drug Safety and Monitoring Committee.”

The RTI reply further said that while 252 serious adverse events were reported till the end of April 2018, of which 81 (31 per cent) were attributed to Bedaquiline.

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