Do we Need to be More Updated in Pediatric Tuberculosis?

We read with interest the recent review article by Khurana, *et al*. [1], published in *Indian Pediatrics*. Pediatric tuberculosis (TB) used to be a neglected topic; however, it is heartening that national and international bodies are now taking interest in it and providing practical guidelines and their updates. In this article, the authors had presented a review of new developments in pediatric TB, which may prove to be very helpful for the general pediatricians. However, the recently updated guidelines developed jointly by Revised National Tuberculosis Control Programme (RNTCP) and Indian Academy of Pediatrics (IAP), and WHO Consolidated Guidelines on drug-resistant TB 2019 have provided some more changes that have not been incorporated in this review article [2,3].

1. There is a substantial change in the new case definition of presumptive pediatric TB; it refers to children with persistent fever and/or cough for more than two weeks with loss of weight / no weight gain and/ or history of contact with infectious TB cases. In this article [1], cough was given more importance; however, fever is a more significant symptom of pediatric TB. Furthermore, authors did not mention about history of contact with infectious TB cases, which is an important supportive feature in the diagnosis of pediatric TB [3].
2. In newly updated guidelines, chest *X*-ray and tuberculin skin test are advised to be performed upfront in cases of presumptive pediatric TB, which is considered as a significant change from the earlier guidelines. If *X*-ray is highly suggestive of TB (miliary, hilar or mediastinal lymphadenopathy, fibro-cavitory lesion) or shows persistent non-specific shadow even after a course of antibiotics, only microbiological sample is recommended [2,3]. However, this review article suggests that both smear examination and chest *X*-ray should be done upfront.
3. In previous guidelines and as per this review [1], Cartridge based nucleic acid assay (CBNAAT) is to be performed on the second sample if the first smear is negative, while as per the newly updated guidelines, CBNAAT is considered as the investigation of choice, and it should be ordered upfront in the first sample. Furthermore, in new guidelines, the preferred term is WHO-approved Rapid Diagnostic Test (WRDT), which also include Line probe assay (LPA) and Loop-mediated isothermal amplification (LAMP) apart from CBNAAT [2,3].
4. Category II anti-tubercular therapy (ATT) which was used to treat previously treated cases of TB has been withdrawn from newly updated guideline as it may lead to increased incidence of drug-resistant TB (DRTB) at the cost of low success rate [2]. In such cases, both WHO and RNTCP guideline now recommend that treatment should be guided by drug susceptibility test.
5. In contrast to what authors have mentioned, there are also significant changes in the treatment of DRTB. Now, the second line of drugs has been reclassified. As per new guidelines, Bedaquiline may be used in children 6-17 years of age with MDR TB. Delamanid may be included in the longer regimen for the treatment of MDR/RR-TB patients aged ≥3 years [4]. Furthermore, for the treatment of isolated isoniazid (INH) resistance, the new guidelines recommend replacement of INH with levofloxacin only [2].
6. In this article, there is no mention about pyridoxine supplementation, which is recommended in all pediatric TB cases as INH is now being used in a higher dose (10-15 mg/kg/day), and high prevalence of coexisting malnutrition increases the risk of INH toxicity. Furthermore, latent TB gets priority in the updated guideline, and INH prophylaxis is now recommended even in children ≥5 years of age with a positive skin test and history of TB contact, after exclusion of active TB [5].

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Updated Pediatric Tuberculosis Guidelines

We read with interest the review article by Khurana, *et al.* [1], published recently in *Indian Pediatrics.* We would like to highlight the recent changes in the management of pediatric tuberculosis (TB) based on Revised National Tuberculosis Control Programme (RNTCP) Updated Pediatric TB Guidelines 2019 and WHO consolidated guidelines on drug resistant tuberculosis treatment 2019 [2].

Changes in diagnostic algorithm: As tuberculosis is a paucibacillary disease in children, performance of smear microscopy and culture is poor. Hence, Cartridge based nucleic acid assay (CBNAAT) is the preferred investigation of choice over smear examination (and best yield when ordered based on positive chest *X*-ray). If CBNAAT is not available, smear microscopy is to be performed.

Newer classification of drugs: The drugs for multidrug resistant tuberculosis (MDR-TB) have been recategrized into three groups. Thus, Box 2 of the review article needs revision.

Changes in treatment approach for previously treated cases: Previously treated TB includes (recurrence, treatment after loss to follow-up and treatment failure). All these children need to be evaluated for drug-resistant TB. In case they are found to be drug sensitive, they shall be started on the same regimen as for a newly diagnosed case. Category II has been now withdrawn from RNTCP. Streptomycin is now considered as second-line medicine, and should be used only as a substitute for Amikacin, when it is not available or confirmed resistance to it.

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AUTHORS' REPLY

We agree with the readers about the issues that have been mentioned. As our manuscript was drafted and submitted for publication much before the new revised RNTCP–IAP guidelines were released, these changes could not be incorporated in the review article. Further, we would like to add a few more updates:

1. Presumptive drug-resistant tuberculosis (DRTB) is diagnosed in a patient who needs to be subjected to genotypic (CBNAAT, LPA) or phenotypic (LC-DST) drug sensitivity tests (DSTs) while probable MDR-TB is diagnosed in a patient, who after getting the results of the above tests, cannot be microbiologically confirmed and needs to be started on DRTB regimen based on their clinical and /or radiological deterioration (clinically diagnosed case of MDR TB).
2. Drugs used for second-line Anti-tubercular therapy (ATT) have been re-categorized as group A (Levofloxacin/Moxifloxacin, Bedaquiline and Linezolid), group B (Clofazimine and Cycloserine/ Terazodone) and group C (Ethambutol, Delamanid, Pyrazinamide, Amikacin/Streptomycin, Para-amino salicylic acid, Imipenem Cilastin/Meropenem and Ethionamide/Prothionamide). This re-grouping is more relevant to design longer duration standard MDR-TB regimens. Group A drugs are most relevant to design longer duration MDR-TB regimens followed by group B; group C drugs are used only if other cannot be used for some reason [1]. The shorter MDR regimen of 9-12 months with seven second-line ATT drugs has gained acceptance by the WHO as well as RNTCP. The 4-6 months intensive phase consists of Moxifloxacin, Ethambutol, Clofazimine, Pyrazinamide, Kanamycin, high-dose Isoniazid, and Ethiomanide. The continuation phase of 5 months consists of former four drugs only. This shorter regimen has been included for pulmonary pediatric MDR-TB patients or those with isolated lymph nodes or pleural effusion.
3. Delamanid may be included in the treatment of MDR/ RR-TB patients aged 3 years or more on longer

regimens. ECG monitoring for QTc prolongation should be done at the baseline and then on a monthly basis for children receiving Delaminid [2].

4. Bedaquiline may also be included in longer MDR-TB regimens for patients aged 6–17 years. (need for more data before considering an upgrade of this recommendation to a strong one) [2].

5. Hearing loss can have a permanent impact on the acquisition of language and the ability to learn at school, and therefore should amikacin or streptomycin use be resorted to in children, regular audiometry is recommended [2].

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Balancing the Covariates in Studies on Enteral Feeding in Preterm Neonates

We congratulate Modi, *et al*. [1] for their work on early aggressive enteral feeding in neonates, published recently in *Indian Pediatrics* [1].

Successful establishment of enteral feeding and prevention of the dreaded complication of necrotizing Enterocolitis (NEC) in very and extreme preterm neonates is dependant on a multitude of factors. Some of the factors that can modify the risk of NEC as well as mortality include the use of maternal antibiotics, extended use of empirical antibiotics in the neonatal period, delayed cord clamping and probiotic use [2,3]. However, the above mentioned parameters fail to find a mention in the baseline characteristics in the present article, thus making it unclear if the covariates were equally balanced amongst the two groups. Though this trial is a randomized controlled trial (RCT), even RCTs are not immune from imbalance in baseline characteristics between the two treatment groups [4]. This imbalance is known to occur more frequently in trials with small sample sizes [4].

In spite of enrolling sick preterm neonates by the investigators, the NEC incidence rate of the subjects in either of the two groups was very low (1.5-3%). The Vermont Oxford Network and the National Institute of Child Health (NICHD) had reported the incidence of NEC to be 7.4% and 7% respectively in their cohort of very low birth weight (VLBW) neonates [5]. The ADEPT (Analysis of prospectively collected data from a randomised feeding trial, the Abnormal Doppler Enteral Prescription) trial, which had enrolled growth restricted preterm neonates <35 weeks gestation with antenatal doppler abnormalities had reported a NEC incidence rate of 18% in the early feeding group and 15% in the late feeding group [6]. Despite a higher percentage of growth retarded preterm neonates and the use of preterm formula milk as the second choice for enteral feeding in this study, the incidence rates of NEC are significantly lower than that reported from the Western literature. Could the authors dwell upon this unexpected finding of their study?

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AUTHOR'S REPLY

We appreciate the readers' critical appraisal of our study by reader. Maternal antibiotics were administered only for medical or obstetric indications such as Premature rupture of membranes (PROM), and chorioamnionitis. The frequency of PROM was comparable in the two groups. Use of antibiotics was restricted to those who had a diagnosis of probable or definite sepsis; the proportion of such babies being 43.9% in the aggressive group and 65.9% in conservative regimen (P=0.16). Delayed cord clamping and use of probiotics were not in practice during the study period. The low occurrence of NEC rates in the present study could be due to several reasons. The study enrolled neonates eŠ750 g birth weight, and none of them were <26 weeks. These are the neonates at the highest risk of NEC. Further, mortality in the present study was much higher compared to Vermont Oxford data or ADEPT cohort with few extremely preterm survivors. Neonates who survived had a mean (SD) gestation 32 (2.2) weeks compared to those who had died 29 (2.5) weeks.

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Can Small for Gestational Age Status Affect the Weight-based Formula for Calculation of Insertional Length of Endotracheal Tube in Neonates?

The normative data for placement of endotracheal tube published recently in Indian Pediatrics [1] paves the way for a less invasive alternative of diagnosing a very commonly encountered issue of endotracheal tube (ET) malposition, that too in a time bound manner. However, we have the following queries:

1. The anatomical measurements of larynx and trachea based on gestational age of a neonate are considered to be more accurate than the weight-based measurements as the later can be influenced by intrauterine growth retardation [2] *e.g.,* a 28 weeks, 700 grams small for gestational age (SGA) neonate will have a lengthier larynx and trachea compared to a 26 weeks appropriate for gestational age (AGA) neonate of the same weight. This issue is of more significance in countries where the incidence of SGA is high [3]. Approximately, 20% of the neonates in this study [1] were SGA. We would like to know if these SGA neonates were excluded while calculating the weight-based formula for ET tube insertion depth?

2. The authors have calculated the sample size based on a pilot study including only two groups of neonates based on weight alone (<1500 g and >1500 g). However, in the final results, they have provided nomograms for multiple subgroups based on weight as well as gestational age. We would like to point out that based on the calculated mean and SD of some of these subgroups, the required sample size falls short in some of them.

3. While deriving the regression equation for insertion length from the various anthropometric parameters, mean age of enrolment at baseline, which might determine some of the factors affecting the head circumference such as caput succedaneum, cephalhematoma and subgaleal bleed, was not mentioned [4]. Moreover, amongst the enrolled neonates, almost 75% are males. As female neonates are constitutionally smaller compared to their male counterparts, can these nomograms be extrapolated to female neonates?

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AUTHORS' REPLY

We thank the readers for critically evaluating our research study [1]. The queries raised are addressed below:

1. Small for gestation age (SGA) infants are anatomically and physiologically distinct from appropriate for gestational age (AGA) infants [2]. However in our study, on calculating regression equation predicting insertional length (IL, in cm) from the weight (kg) among AGA and SGA neonates, the results remained similar (both regression coefficient and intercept) as follows:

   IL (overall population, cm) = wt (kg) +4.95

   IL (AGA population, cm) = 1.1×wt (kg) +4.928

   IL (SGA population, cm) = 1.1×wt (kg) +4.922

2. We accept that the sample size required in different groups (calculated *post hoc* from our results) is more than the number of infants enrolled. However, there was no prior study that had reported gestation or weight-based normograms of optimally placed endotracheal tube on ultrasound to guide us. Therefore, we conducted a pilot study on 15 infants in two weight categories. To derive adequate sample size in five weight categories and four gestation categories, a pilot study would require about 80-100 infants, which was not feasible for us.

3. Median (IQR) day of enrollment of the neonates was 3 (1-9) days. None of the study subjects had cephalhematoma or subgaleal bleed. Neonates with caput succedaneum enrolled on day 1 had their head circumference measurement repeated after 48 hours of life, not only for our study but also as a standard clinical protocol because resolution of caput succedaneum takes few days [3]. We agree that our study had male preponderance and the possibility of calculating sex-specific normative data of optimally placed endotracheal tube on ultrasound based on adequate sample size needs to be explored.

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Periviable Birth – The Ethical Conundrum: Few concerns

The article by Nimbalkar and Bansal [1], published recently in *Indian Pediatrics,* must have caught attention of many clinicians. We were looking forward to discussions around real time delivery room dilemmas in day-to-day life as well as some operational working algorithms/flowcharts that would help making decisions easier in such difficult situations. Through this communication, we have tried to complement the content in this article. Nevertheless, we agree with the author that there is an imminent need to collect our own outcome data in extreme preterm infants to enable framing national guidelines for management of periviable babies.

1. In the section on "The Ethics of Decision-making in the Delivery Room" authors have made a generic discussion around the principles of ethics rather than some practical ethical dilemmas faced by a clinician in a delivery room.

2. At the outset, it may have been good to define a 'live birth', What are 'signs of life', what constitutes providing either 'full life support' or 'comfort care' *etc*. While the Neonatal Resuscitation Program (NRP) guidelines mention first examination of 'Heart Rate' after the end of initial steps, do we really examine heart first when dealing with difficult situations of periviability to assess signs of life?

3. Authors have majorly (and infact theoretically rightly so) used gestational age (GA) cut-offs as the main guiding criteria that dictate decisions and actions in tricky situations around periviability. But surely such

utopian situations are not invariable. GA is often not known. Hence, a broad framework based on weight cut-offs (which is reliably obtained in all cases at birth) may be more useful and desirable for guiding decisions initiating resuscitation or continuing life support. Another not so uncommon situation is an unbooked pregnant woman who comes and delivers a periviable extreme preterm who needs immediate resuscitation before an informed consent can be obtained.

4. Translating available literature [2] to operational guidelines in our Indian context, we propose the following algorithm:
   - *Ideal situation when GA is known and a timely consent can be* obtained: Obtain informed consent in all cases at the limits of viability before initiating resuscitation as well providing life sustaining intervention.
   - *For 22-25 weeks gestation*: obtain informed consent before providing full armamentarium of life-sustaining interventions.
   - *When either GA is not precisely known or there may be no time to obtain consent*: (*i*) Initiate resuscitation in all babies weighing ≥500 g (10^{th} centile as per Fenton's chart [3]) and/or born after 22 completed weeks of gestation; (*ii*) for babies born between 500-600 g, full armamentarium of life- sustaining interventions should be provided till informed consent is obtained; and (*iii*) provide full armamentarium of life-sustaining interventions in all babies at ≥25 weeks' GA and/ or ≥600 g (10^{th} centile as per Fenton's chart [3]) of birth weight.
5. In Table I in 3rd row, 2nd column; *i.e.* "provide treatment unless provider declines to do so" is probably not justified as ethical principles do not allow the provider to decline treatment particularly when parents prefer to accept treatment.

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AUTHOR'S REPLY

We are happy to receive comments from the readership and respond to them pointwise. For the sake of brevity, we will not elucidate on the queries. We also look forward to more discussion from readers.

1. Our intention in this write-up [1] was to bring this concept into discussion and not discuss practical ethical dilemmas faced, as these will vary with the settings even in geographically localized areas. A sound knowledge of ethics in this area would allow the readers to apply them to their situation. We do not intend to be prescriptive in any way.
2. The article was reviewed twice and it was probably felt that Live Birth and Signs of Life were not required to be defined. We would even now baulk at defining 'full life support' and 'comfort care' due to reasons mentioned in the article at the end under "Complexity of the Indian Scenario." Concerning examination of heart rate (HR), in an unpublished study from our center, HR was not assessed in 39% of normal delivery care. However, all resuscitations that required ventilation had HR assessed as per NRP guidelines [2]. This study is an audit of random videos and hence participants were not aware that the video would be analyzed.
3. Weight has a similar fallacy as gestational age. In a neonate requiring resuscitation, weight is often guessed rather than measured before initiating resuscitative measures. Hence, it will always be worthwhile to ensure that we follow guidelines used across the world since gestational age rather than weight correlates with long-term neurodevelopmental outcomes. Even after completion of resuscitation, weight measurement may not be accurate in peripheral centers.
4. We would not agree to many points provided in the proposed algorithm. We need to decide which methods of gestational age assessment are to be relied upon. We have already shown our hesitation to use weight as a deciding criteria. As we have suggested, instead of few experts putting forth a recommendation, it is necessary to have a consultation process probably over a period of 6 months to one year among all stakeholders (including nurses, hospital administrators, ethicists, lawyers, parent groups, *etc.*), and following standard guideline development

processes. A recommendation that comes out of a broader consultation is likely to be accepted.

5. In cases when there is no therapy that can benefit an infant (anencephaly/certain severe cardiac deformities/ non-viable GA), a decision by care providers not to try predictably futile endeavors is ethically and legally justifiable. As such therapies do not help the child, are sometimes painful for the infant (and probably distressing to the parents), and offer no reasonable probability of saving life for a substantial period. Ethical principle applied here is beneficence and non-maleficence.

   The table was proposed by President's commission 1983 [3]. It mentions that sometimes parents may want to consider treatment when its believed futile by physicians. As long as this choice does not cause substantial suffering for the child, providers should accept it; although, individual health care professionals who find it personally offensive to engage in futile treatment may decline the treatment and arrange to withdraw from the case.

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Are we Missing Neonatal Dengue?

Early recognition of dengue illness in neonates due to perinatal transmission deserves special attention as it can be missed [1]. Onset of fever in the newborn varies from 1 to 11 days after birth with an average of 4 days and lasts 1-5 days. Falsely-negative dengue serology on first two days of life may be due to low viremia at that time [2]. The duration of viremia and febrile phase lasts longer in newborns experiencing primary infection due to more gradual antibody or cellular response.

We recently managed two neonates who were asymptomatic at birth but after one week, they developed signs and symptoms of severe dengue infection; one of them developed severe thrombocytopenia and encephalopathy. Both these neonates were negative for dengue infection by routine screening at birth and were missed. Hence, screening for NS1 antigen at birth in newborns of mothers with dengue illness may not be sufficient. Non-structural antigen (NS1) can become positive even up to 7 days after birth peaking at the 5th day [3]. IgM and IgG antibodies can take 2-3 weeks to be positive. Dengue virus illness hence, can be easily missed in the early newborn period if we do not follow-up closely.

One should carefully observe the baby born to a mother with dengue infection for a minimum period of two weeks after birth with periodic checks, and screen again for Dengue serology at 2 weeks of age. This strategy can help in diagnosis of this potentially devastating illness, and will contribute to early appropriate management and significant reduction of neonatal morbidity and mortality [4,5].

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Double Aortic Arch Causing Prolonged Cough in a Child

A 7-year-old girl presented in the pediatric tuberculosis clinic with cough for 15 days. There was no fever or contact with an adult having tuberculosis. She was tested in another hospital with a Mantoux test that was positive, and was referred to us to start anti-tuberculous therapy. On examination, weight was 20 kg with no abnormal findings. Chest *X*-ray showed superior mediastinal widening. High resolution computed tomography (HRCT) of chest showed a double aortic arch forming a vascular ring (the right arch measured 14 mm and the left arch measured 12 mm) around the lower trachea and proximal thoracic esophagus with the right arch indenting upon and causing mild narrowing of the tracheal lumen (***Fig.* 1**). She was subsequently referred to the cardiac surgeon for further treatment.

Double arched aorta is a rare congenital cardiovascular abnormality. Embryologically, one aortic branch arises from each of the 4th branchial arches. Double aortic arch occurs as a result of failure of involution of the right sided aortic branch which persists beyond the embryonic stage. These two separate aortic arches may join each other to form a vascular ring that can compress over the trachea and esophagus manifesting as stridor, cough, wheezing and recurrent pneumonias and/or with symptoms of esophageal compression resulting in obstructive symptoms such as choking, regurgitation and dysphagia [1]. All of these symptoms are non-specific; hence, these patients can remain undiagnosed for many years. Chest *X*-ray may show right sided aortic arch indenting the trachea and an increase in paratracheal soft tissue thickness; sometimes bilateral aortic notches can be seen at the level of aorta. A contrast enhanced computed tomography (CT) or Magnetic resonance imaging is required to confirm the diagnosis as well as aid in planning of surgical management, depending on the type of arch dominance [2]. Management of these patients is surgical with most patients having an excellent outcome and good long-term prognosis [3].

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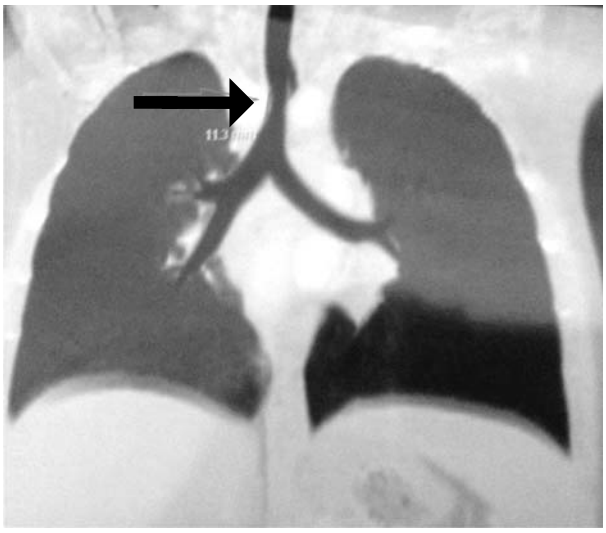
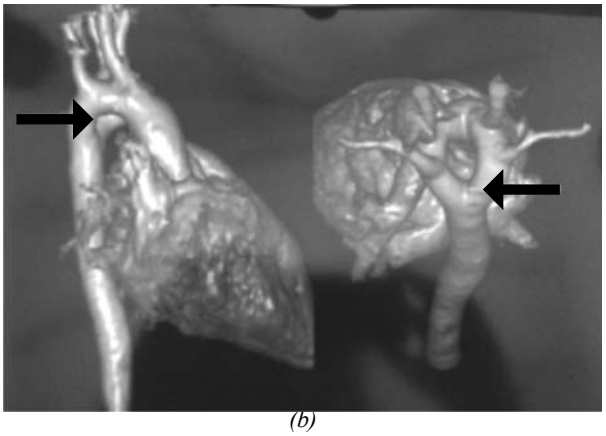


(a)



(b)

FIG. 1 *(a) CT chest showing mild narrowing of the tracheal lumen (arrow); 3D-reconstruction from CT chest showing vascular ring around the lower trachea and proximal thoracic esophagus (b).*

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