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## Temporal Trends in Diagnosis and Management of Ankyloglossia in United States: 2003-2012\*

*\*Presented at the 2015 Pediatric Academic Societies Annual Conference, San Diego, USA*

By Ramesh Vidavalur, MD, MBA; Sailaja Malla, MD; Nitin Wadhwa, MD

### Background

Ankyloglossia or Tongue-tie is a congenital oral anomaly characterized by persistence of abnormally short, thickened or tight sublingual frenulum that restricts the movement of the tongue to a varying degree. Ankyloglossia in newborns has been associated with multiple morbidities including: ineffective latch, inadequate milk transfer, maternal nipple pain in post-partum period. Moreover, it has been implicated in speech problems and abnormal dentition in later postnatal life. Frenotomy (also known as frenulotomy) is often performed to alleviate feeding problems, but concerns remain high regarding indications, timing, utility and efficacy of surgical management.

The prevalence of Ankyloglossia varies between 0.6%-12%, depending on the type of various definitions used.<sup>1</sup> The detrimental effects of Ankyloglossia on breastfeeding has been debated for many years,<sup>2,3,4,5</sup> and it is estimated that 25-80% of infants diagnosed with ankyloglossia will have breastfeeding difficulties.<sup>2,6</sup> With the recognition of potential benefits of breast milk and renewed efforts to improve the breast feeding rates across American hospitals, various attempts have been made to estimate the efficacy of frenotomy on breastfeeding success and associated long-term outcomes. Several systematic reviews and meta-analysis studies<sup>7,8,9,10,11</sup> done to evaluate the indications and potential benefits of frenotomy have been inconclusive, including the recent study done under effective health care program by AHRQ-Agency for Healthcare Research and Quality.<sup>12</sup>

### Objective

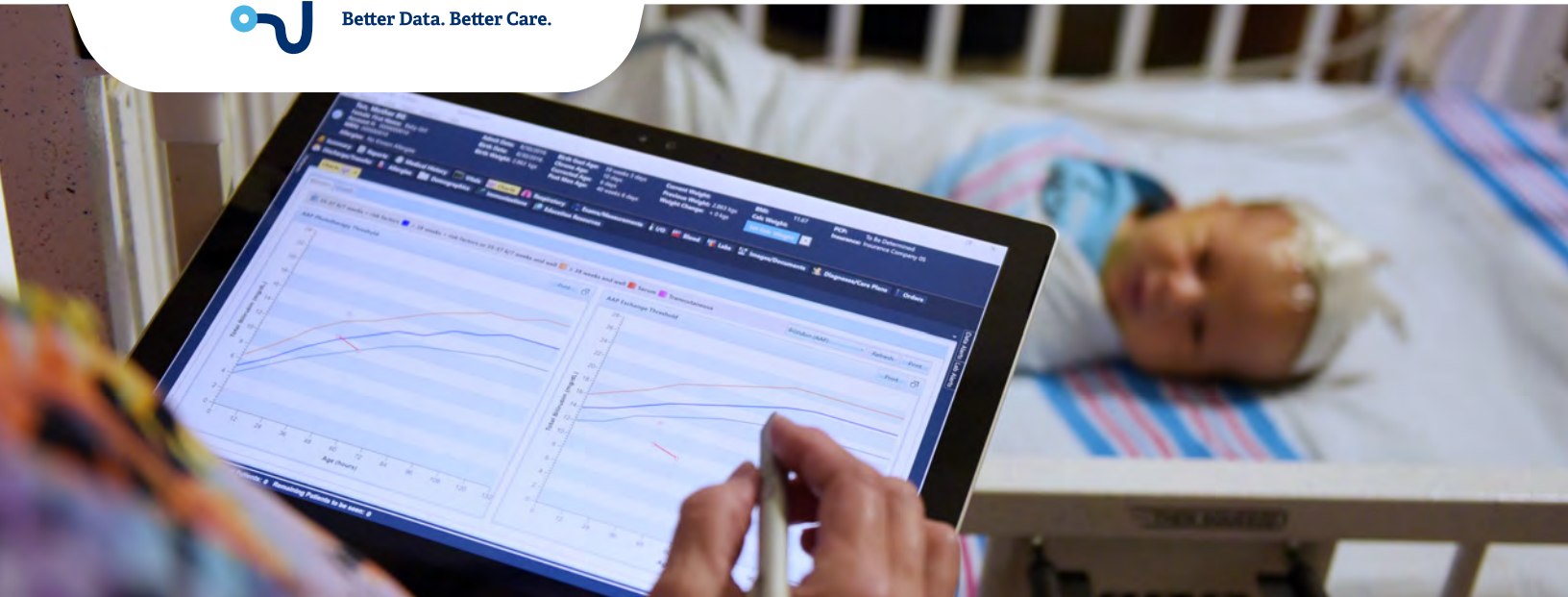
The main objective of our study was to determine the temporal trends in diagnosis of Ankyloglossia and treatment with frenotomy

among hospitalized children aged <1 year in the United States for years 2003-2012.

### Design/Methods

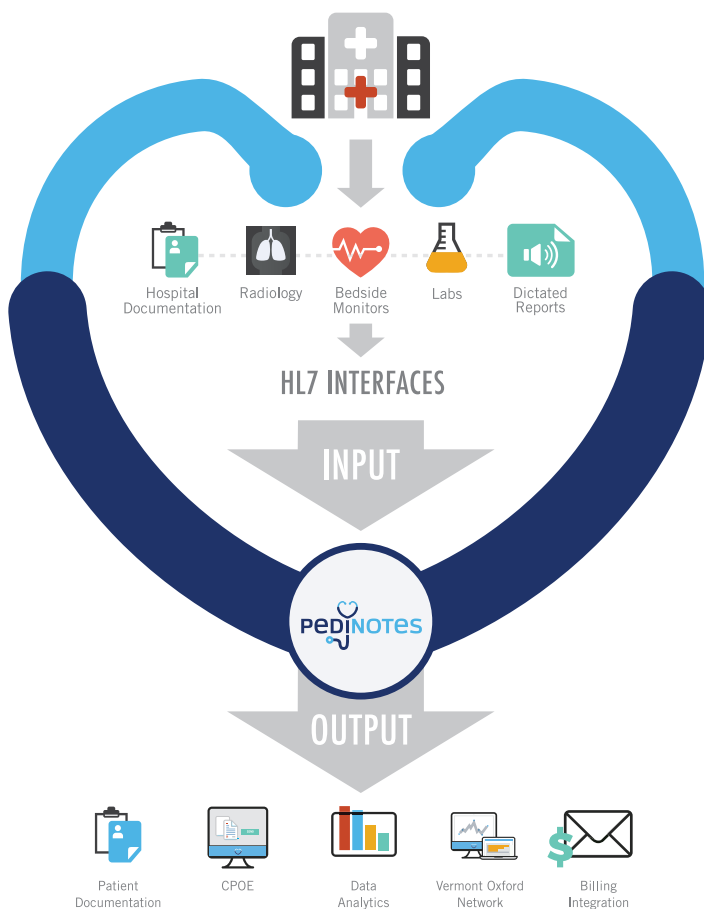
A retrospective cross-sectional analysis of Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient database (2003-2012), which represents weighted national estimates from >6 million children hospitalizations annually, was performed. With this database, we can describe national trends in rates of inpatient diagnoses; trends in hospital charges/costs; payer characteristics. We examined pediatric hospitalizations using ICD 9 diagnosis code for Ankyloglossia (750.0) and ICD 9 procedure code for frenotomy (25.91) and frenectomy (25.92). Frenotomy is mainly done by pediatricians, neonatologists, and both the procedures are done by ENT surgeons, Maxillo facial surgeons, and dentists in both inpatient and outpatient settings. Chi square, t-test and appropriate non-parametric tests were performed to determine the significance of data.

***“Ankyloglossia or Tongue-tie is a congenital oral anomaly characterized by persistence of abnormally short, thickened or tight sublingual frenulum that restricts the movement of tongue to varying degree. Ankyloglossia in newborns has been associated with multiple morbidities including: ineffective latch, inadequate milk transfer, maternal nipple pain in post-partum period.”***



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## Epidemiology of Ankyloglossia in United States, 2003-2012

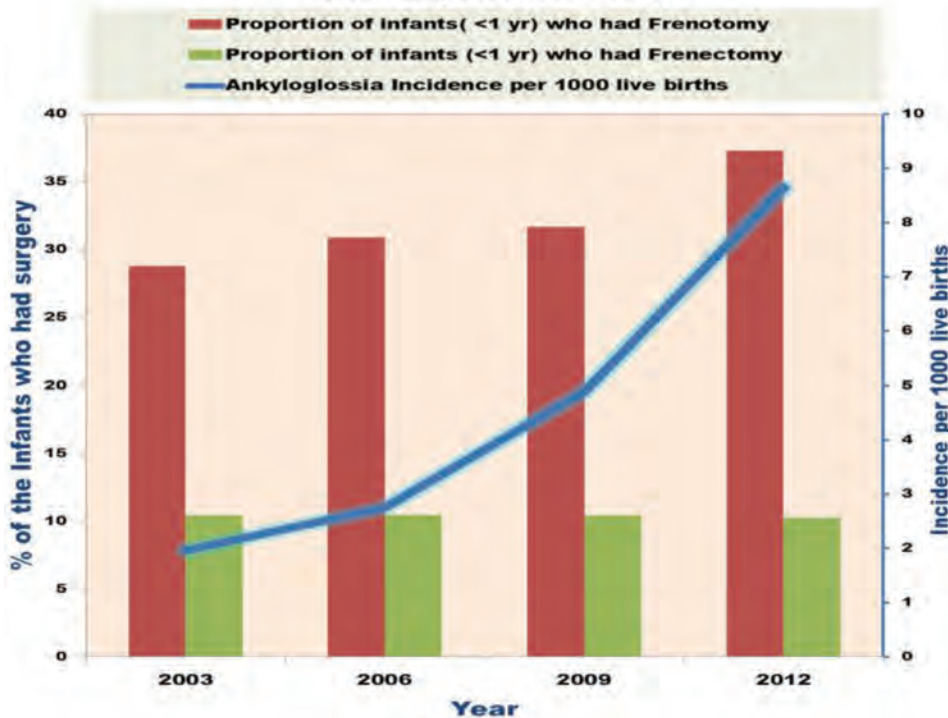


Figure 1. Trends of ankyloglossia, frenotomy and frenectomy.

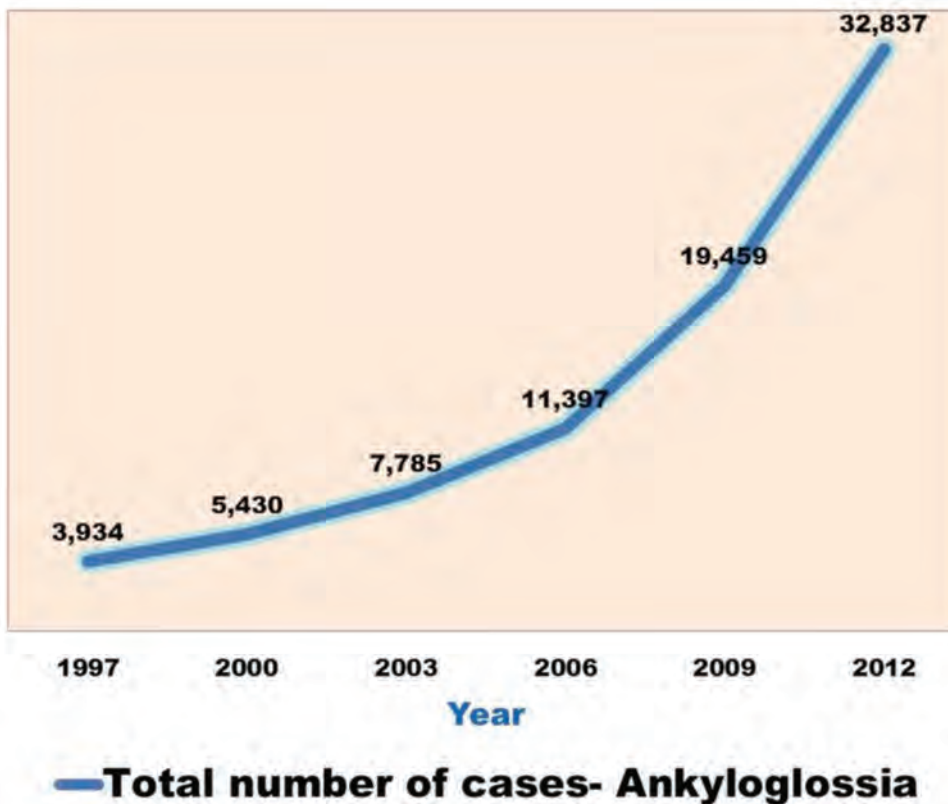


Figure 2. Total number of discharges with diagnosis of Ankyloglossia (ICD-9 code 750) over years.

## Results

The nationally weighted diagnosis rates of Ankyloglossia increased exponentially from 1.9 per 1000 live births in 2003 to 8.6 per 1000 live births in 2012. Over the same period, there was significant proportional increase in number of frenotomies (28.8% vs 37.3%;  $p < 0.01$ ), but not on frenectomy (10.4% vs 10.2%;  $p < 0.64$ ) procedures (Figure 1). There was 10-fold increase in overall number of infants with diagnosis of Ankyloglossia (Figure 2). Many previous studies reported male preponderance of Ankyloglossia. Our study also confirmed that incidence of Ankyloglossia is more common in male infants ( $64.4\% \pm 0.93$  vs  $35.3\% \pm 0.95$ ;  $p < 0.001$ ) throughout study period. Privately-insured infants are more likely to be diagnosed with Ankyloglossia ( $62.6\% \pm 2.2$  vs  $30\% \pm 2.8$ ;  $p < 0.001$ ) and tend to have surgical repair ( $62.4\% \pm 3$  vs  $29.7\% \pm 3.7$ ;  $p < 0.001$ ) infants from the Medicaid population (Figure 3).

## Discussion

There has been a lot of controversy regarding treatment of Ankyloglossia in newborns and often the main indication for surgical correction tends to be feeding problems in the immediate postnatal period. The decision to subject an infant to frenotomy is also complicated by polarizing views of intra and inter-specialty experts who argue that Ankyloglossia should always or never be divided.

Our study shows that there has been consistent increase in diagnosis rates of Ankyloglossia in infants across United States in the last decade and increasing number of infants underwent frenotomies. The diagnosis rate had multiplied more than four-fold over the study period, along with significant proportional increase in the number of infants undergoing surgery.

Our estimates suggest that almost one in three infants diagnosed with Ankyloglossia had frenotomy done and we speculate that this increasing rate of therapeutic interventions is secondary to: increased awareness of the clinical condition, improved availability of lactation consultants to conduct thorough breastfeeding assessment, growing acceptance of high potential benefit and low risk of complications by pediatric care providers. An extensive literature review including recent NICE guidelines,<sup>11</sup> a comparative effectiveness study by AHRQ<sup>12</sup> and the Canadian Pediatric Society<sup>13</sup> indicate that there is overall low-moderate quality of evidence supporting the effectiveness of frenotomy for the treatment of breastfeeding difficulties in infants with Ankyloglossia.

## Ankyloglossia- Gender and Payor differences

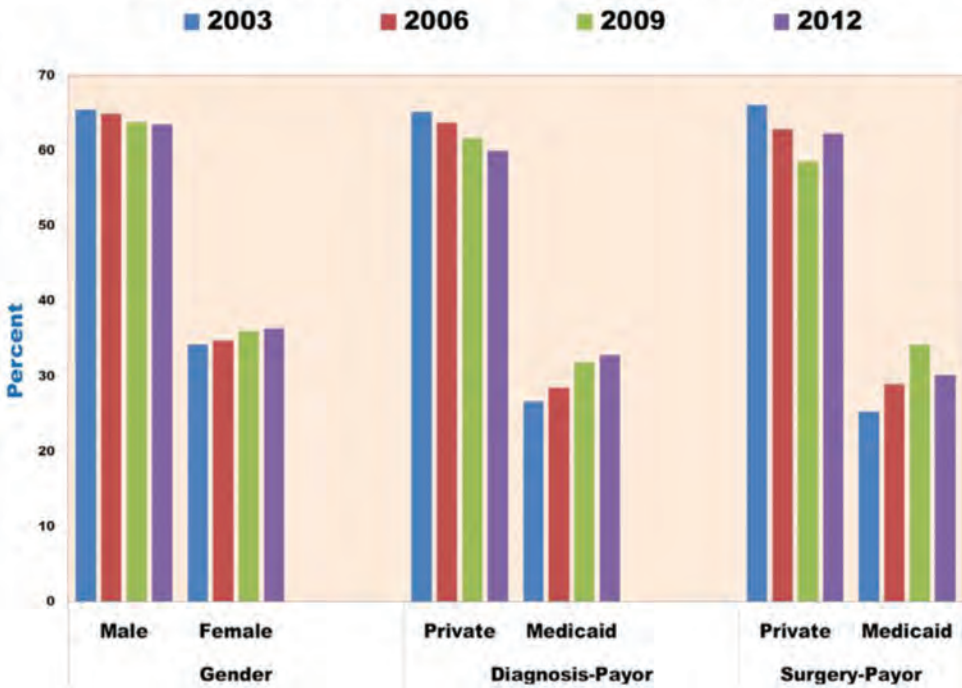


Figure 3. Gender and Payor differences in infants diagnosed with ankyloglossia.

### Conclusions

At present, there is no conclusive evidence to support prophylactic frenotomy in cases of Asymptomatic Ankyloglossia. Considering low morbidity and the perceived holistic nature of benefits, frenotomy should be considered in a particular set of symptomatic infants with breastfeeding difficulties, after especially breast feeding difficulties after accurate assessment utilizing available breastfeeding assessment tools. With increased awareness and education campaigns by professional bodies like the International Affiliation of Tongue-tie Professionals (IATP) and the Academy of Breastfeeding Medicine, we hope that providers would be able to reach a consensus regarding significance of Ankyloglossia and indications for its treatment. Future studies are warranted to evaluate the long-term effects of frenotomy on improvement in breastfeeding, speech, language development and associated Ankyloglossia related comorbidities.

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**“Future studies are warranted to evaluate the long-term effects of frenotomy on improvement in breastfeeding, speech, language development and associated Ankyloglossia-related comorbidities.”**

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If there is an unexpected change in NO<sub>2</sub> concentration, or if the NO<sub>2</sub> concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO<sub>2</sub> analyzer should be recalibrated. The dose of INOmax and/or FiO<sub>2</sub> should be adjusted as appropriate.

#### Worsening Heart Failure

Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

### ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

### DRUG INTERACTIONS

#### Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

### OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO<sub>2</sub>. Elevated NO<sub>2</sub> may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO<sub>2</sub> levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

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# Arterial Switch in a Low-Birth-Weight Neonate

By David Kalfa, MD, PhD

## Background

Transposition of the Great Arteries (TGA) accounts for approximately 4% of all congenital heart defects.<sup>1</sup> While outcomes for neonatal cardiac surgery have improved over the past 20 years, low weight remains a risk factor for increased mortality in neonates and infants undergoing cardiac surgery.<sup>2</sup> In a study using the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database (consisting of 32 participating centers), the average operative mortality rate in patients weighing <2.5 kg at surgery was as high as 16%.<sup>3</sup> We recently showed that a dedicated, multidisciplinary, neonatal-cardiac program can yield good outcomes for neonates and infants weighing <2.5 kg, independent of STAT risk category and uni/biventricular pathway. In this study, lower gestational age at birth was an independent risk factor for hospital mortality.<sup>4,5</sup>

## Case Report

In this report, we describe an arterial switch operation (ASO) performed in a 2.1-kg female neonate born at 38 weeks' gestation. TGA with an intact ventricular septum was diagnosed prenatally. After birth, the child was admitted to a Neonatal Intensive Care Unit that specializes in low-birth-weight babies. The child was significantly hypoxic despite the use of prostaglandin and underwent a balloon atrial septostomy.

The ASO was performed on Day Five of Life. ASO is typically performed during the first two weeks of life while the left ventricle is still capable of supporting the systemic circulation. Our policy is not to delay surgery despite low birth-weight to avoid the potential deleterious consequences of desaturation and cyanosis. Several studies have shown that delaying surgery does not improve outcomes.<sup>6,7</sup> In addition, a recent study conducted at our institution, showed that patients weighing less than 2.5 kg can have good outcomes from ASO. Poor outcomes were more closely associated with low gestational age and extracardiac anomalies.<sup>4</sup>

Prior to the surgery, an echocardiogram showed a significant commissural malalignment between the aortic and pulmonary valves and normal coronary artery anatomy. The ASO was performed without technical difficulty. The coronary arteries were reimplanted in the same sinus close to the commissure because of the commissural malalignment. The perfusion of the myocardium and the hemodynamics

were excellent after surgery, requiring a low dose of pressors. We delayed sternal closure by one day due to swelling of the heart and were able to close the chest the day after surgery.

The postoperative course was straightforward, without any major complications. The patient was extubated at Day Three post surgery and discharged ten days post surgery.

At a five-month follow-up visit, the baby is doing well and growing. Her echocardiographic results were excellent, showing good biventricular function and no obstruction of the left- or right-ventricular outflow tracts.

## Summary

We have shown that ASO can be performed safely and with excellent outcomes in low-birth-weight neonates. In our experience, it is not advisable to delay the operation solely due to low birth-weight.

## Bio

Dr. David Kalfa is a board-certified cardiothoracic surgeon with a subspecialization in pediatric cardiac surgery. He is an Assistant Professor of Surgery in the Section of Pediatric and Congenital Cardiac Surgery, Columbia University, and Adjunct Assistant Professor of Surgery in the Department of Cardiothoracic Surgery, Weill Cornell Medical College. Dr. Kalfa's clinical interests center around complex neonatal procedures, valve repair in children, hybrid procedures, minimally invasive congenital cardiac surgery and heart failure surgery with ventricular assist devices. Dr. Kalfa's research interests focus on tissue engineering, precision medicine and the development of innovative and disruptive surgical devices in the field of congenital cardiac diseases in order to improve clinical outcomes in patients with congenital heart diseases.

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Dear Colleagues,

The Organizing Committee is pleased to announce the **7<sup>th</sup> World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS)**, which will take place on July 16 - 21, 2017, in the Centre Convencions Internacional de Barcelona (CCIB), Barcelona, Spain. The aim of WCPCCS is to bring together all professionals involved in the care of children's heart disease and congenital heart disease of all ages, from the fetus to the aged. The Congress will provide a unique opportunity to meet the leaders of specialties worldwide; to learn about the latest innovations and the results of procedures; and to contribute to the discussions, debates and plenary sessions with renowned speakers.

The central philosophy of the Congress is "bridging together" all major specialties in the field. Accordingly, the scientific program is carefully planned to address all interests and expertise with concentration streams on pediatric cardiology, pediatric cardiac surgery, adult congenital heart diseases, anesthesia, intensive care and nursing.

We are excited to offer the scientific and cultural feast of a lifetime to one of the most refined crowd in the profession, in one the most welcoming, inimitably exciting venues of the world. Come to Barcelona in July 2017 and join us in forging this unforgettable experience.

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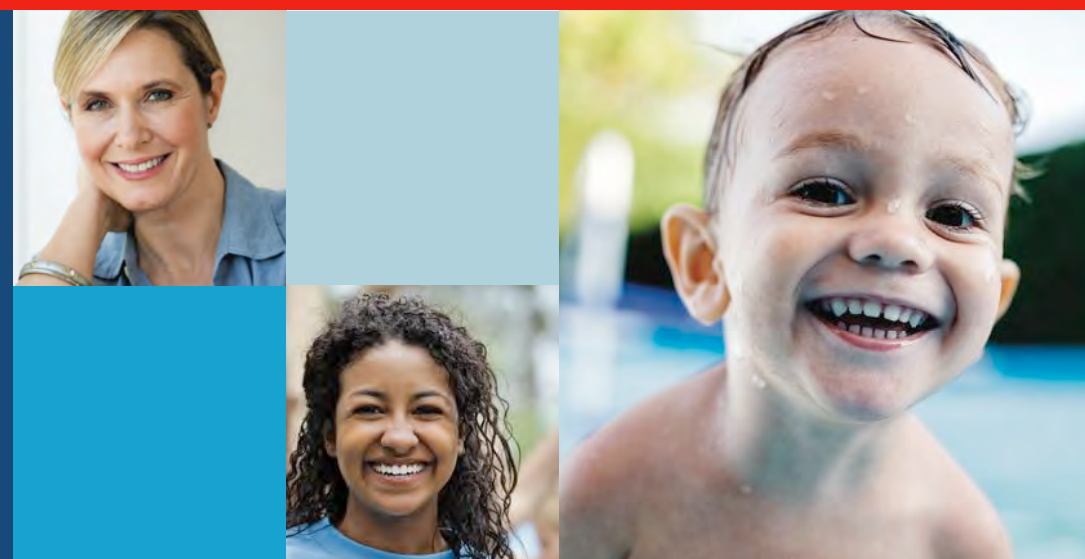
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# Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

## Routine Pulse Oximetry Screening to Detect Critical Cyanotic Congenital Heart Disease in Neonates After Birth – Why is it Important for an Obstetrician to be Aware?

Pulse oximetry screening of newborns to detect Critical Cyanotic Congenital Heart Diseases has become a standard of care in many developed countries after recent guidelines. We undertook this to see if this is feasible in Indian circumstances and also wanted to see the cost implications of the same.

### Setting

Tertiary Maternity Hospitals in Bangalore, India.

### Participants

All babies born above 36 weeks at the hospital and were with the mothers during the first few days – and not requiring NICU admission.

### Main Outcome Measures

The economic feasibility of the results of our protocol is reviewed after 2 years.

### Results

Screening by pulse oximetry was done for a total of 22,601 neonates between June 2012 and Oct 2016 (study period). Thorough clinical examination done by the neonatologists for the 14 neonates who failed screening, revealed that three babies had a pulmonary condition requiring treatment (false-positive cases) and 11 babies were investigated with an Echocardiography by a Paediatric Cardiologist. One infant had PDA with no other abnormalities; one had a VSD, with a small PDA, but no other abnormalities; and the remaining nine infants were diagnosed with CCHD. Three were found to have Transposition of Great Vessels (TGV) (3), two were found to have Total Anomalous Pulmonary Venous Drainage (TAPVD) (2), one baby was found

to have Fallott's Tetralogy (TOF), one baby had PDA, an ASD, Patent Foramen Ovale with pulmonary hypertension, one baby had severe pulmonary hypertension (PAH) and two babies had pulmonary stenosis (PS).

**Conclusion:** Our data shows evidence for pulse oximetry screening of apparently healthy newborns to become a standard of care in India like many developed countries and that it is very cost-effective and is affordable.

**Key words:** Congenital Heart Disease (CHD), Critical Cyanotic Congenital Heart Disease (CCCHD), newborn, Pulse Oximetry, screening.

### Already Known About this Topic

1. Pulse oximetry screening has been shown to improve the prognosis of early-diagnosed Critical Congenital Cyanotic Heart Disease (CCCHD) in newborn babies.
2. Barriers to implementation include concerns about increased workload on echocardiography services.
3. Screening programs are being implemented in most developed countries.

### What this Paper Adds

1. Pulse Oximetry screening does improve early diagnosis of CHD with minimal increase in cost and the burden on echocardiography services.
2. It is equally effective in improving early diagnosis of other, mainly respiratory, pathologies.
3. There is enough evidence to suggest a national recommendation for Pulse Oximetry screening in India.

Congenital Heart Disease (CHD) is an important cause of death and morbidity in early childhood with a prevalence of 5-10 per 1000 live births worldwide.<sup>1</sup> One-fourth of these have

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major CHD (defined as requiring surgery or catheter intervention in the first year of life). In India, heart disease in young children accounts for more than 10% of all childhood deaths due to late presentation or diagnosis.<sup>2,3</sup>

Early diagnosis can prevent progression to cardiac failure, cardiovascular collapse, neurological sequelae and death.<sup>2,3</sup> Currently screening for CHD relies on antenatal ultrasonography in the mid-trimester and post-natal clinical examination. Antenatal scans have a diagnosis rate of up to 44%, while newborn examination diagnoses less than 50% of CHD and have a false positive rate of 1.90%.<sup>4,5</sup> Pulse oximetry screening of newborns has been shown to be a non-invasive test that increases the ability to identify infants with major CHD before clinical presentation with collapse, which may result in long-term complication.<sup>2,5</sup>

In 2012, a chain of tertiary maternity hospitals in India reviewed the published evidence of the benefit and decided to implement this practice into routine care, especially after one of their parents was upset and they alleged that we had 'missed' diagnosing their baby with Critical Cyanotic Congenital Heart Disease at birth. These parents were quite upset when they learned that a simple non-invasive test could have helped their baby to be diagnosed at birth instead of at the age of 2 ½ months when the baby was diagnosed because of a murmur. We present our Indian experience.

This paper describes a post-implementation review of the first 52 months of Pulse Oximetry screening of well newborns at these hospitals. The aim is to describe the implementation of the screening programme and review whether the outcomes were consistent with those described in the literature in our setting & the cost implications for doing that screening.

## Methods

The study population included all babies born at the four maternity tertiary care hospitals between June 2012 and October 2016. A group of tertiary maternity hospitals {four of which are located in Bangalore (one each at Old Airport Road, Malleshwaram and two in Jayanagar)}, delivering over 5,000 babies a year, provide maternal fetal medicine service, including screening for high-risk births & cardiac screening.

## Pulse Oximetry Screening

Screening was initiated in June 2012, in all the four hospitals after deliberations of the evidence available so far in the literature and discussions among peers as to its feasibility. Pulse oximetry screening was conducted according to the Royal College of Paediatrics and Child Health (RCPCH) recommendations by placing the pulse oximeter sensor initially on one foot, obtaining a post-ductal oxygen saturation read-

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ing, and then immediately moving the sensor to the right hand to obtain a pre-ductal oxygen saturation reading.<sup>6,7</sup> Then the other 2 limbs saturation were also measured to increase accuracy.

Screening was considered positive if:

1. Oxygen saturation measure is <90% (in the initial screen or in repeat screens);
2. Oxygen saturation is <95% in the right hand and foot on three measures, each separated by one hour; or
3. >3% absolute difference exists in oxygen saturation between the right hand and foot on three measures, each separated by one hour.

A neonate was categorized as having passed the screening if SaO<sub>2</sub> was more than 95% in all limbs and if the difference in SaO<sub>2</sub> was less than 3%. Screening of newborns between 24-48 hours of age or at the time of discharge was performed by specially-trained nurses. (i.e the nurses weren't 24-48 hours of age). When screening was positive, the neonate underwent a thorough physical examination by a neonatologist, and if indicated, a chest radiograph and an electrocardiogram was done. If no pulmonary condition was found, the neonate was immediately referred for a complete echocardiogram by a pediatric cardiologist, as applicable.

#### Data Collection and Analysis

The results of screening were entered into the HIS (Hospital Information System) database and stored. For this study we derived descriptive statistics for the number of babies screened, their demographics, the results of the screening, and the associated variables.

#### Ethics and IRB Approval

The parents or guardians of each child were informed about the screening using a printed brochure prior to the screening. Ethical Committee approval for retrospectively analyzing the stored screening data was obtained.

This screening was done between 24 and 48 hours of life. For babies going home on early discharge (discharge before 24 hours), the oximetry was performed prior to discharge and then repeated within the first 3-5 days by the home care team.

A GE saturation monitor with Masimo probe was fixed to the portable trolley of examination equipment, which was used for newborn examination. At the start of the examination, a reusable probe was attached to one foot of the baby with disposable tape (one-inch self-adherent wrap manufactured by 3M); the oximeter was switched on and oxygen saturation documented when the reading stabilized with a strong plethysmographic signal. This typically took between 2 and 4 min. This post-ductal saturation was entered into the hospital clinical records and also was recorded in the parent-held baby booklet – a personal health record given by the hospital. The probe was cleaned between babies with 70% isopropyl alcohol wipes.

The screening protocol is shown in Figure 1. If the post-ductal saturation was 95% or more, the result was assigned as a pass. Readings between 90% and 95% lead to a repeat saturation measurement in the next 2 to 6 hours. If the post-ductal saturation remained below 95% on repeat testing, the baby was reviewed by a senior neonatologist without waiting for a repeat test.

The hospital electronic, clinical database was searched for all saturation readings performed since commencement of the screening programme. Medical records were searched if further information

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was needed. Information was collected on the oxygen saturation, the subsequent management, review by senior neonatologist, further management and need for echocardiography. We calculated the sensitivity, specificity, positive and negative predictive values, and a false positive rate.

## Results

There were a total of 22,821 babies born after 36 weeks in the study period. Of these, 22,601 babies had saturation screening performed. Of the 220 babies not screened, 207 had been admitted to the nursery and did not qualify for screening, as per our criteria. Screening was missed in 12 babies {not performed because of non-consent by parents (11), performed but not recorded (1)}. Of the 22,601 babies screened, 22,579 (99.9%) passed the test, and 22 babies (0.1%) were referred. These were babies who had failed the screening protocol, as their initial saturations were difficult to obtain for whatever reason or was <90% or 90-95% on two occasions. Of the 22 cases who were referred, repeat saturation monitoring after few hours was normal in eight babies and abnormal in 14 babies. Of the 14 babies with abnormal saturations, an examination by a neonatologist found that three had low saturations secondary to a previously unrecognized pulmonary cause, which was diagnosed following review - these included persistent pulmonary hypertension of the newborn in one, Transient tachypnea of newborn in one and congenital pneumonia with sepsis in the other.

The other 11 babies who failed oxygen saturation screening underwent a detailed echocardiography by the Paediatric Cardiologist and one infant had PDA with no other abnormalities, one had VSD with a small PDA but no other abnormalities and the remaining nine infants were diagnosed to have CCHD, three were found to have Transposition of Great Vessels (TGV) (3), two were found to have Total Anomalous Pulmonary Venous Drainage (TAPVD) (2), 1 baby was found to have Fallot's tetralogy (TOF), one baby had VSD, ASD, Patent Foramen Ovale with pulmonary hypertension, one baby had severe pulmonary hypertension (PAH) and two babies had pulmonary stenosis (PS).

Among these 11 infants, five had been picked up by antenatal scans by our fetal medicine specialists in the anomaly scans. All the infants were followed up by the Paediatric Cardiologist and five were referred for emergency cardiac surgery. Three underwent surgery on the 3rd day of life and are currently alive and thriving. One underwent surgery on Day seven and is currently doing well. The other underwent surgery on the 9th day of life, but unfortunately, died from post surgical sepsis.

Analyzing the accuracy of Pulse Oximetry screening in the detection of major CHD, the sensitivity was 89%; specificity was 99.8%; positive predictive value was 0.6% and a negative predictive value was 99.9%. The false positive rate was 0.13%. The routine use of Pulse Oximetry screening in a maternity hospital with over 5,000 deliveries per annum resulted in three extra ultrasounds of structurally normal hearts over the first 52 months.

## Discussion

This is the first Pulse Oximetry screening series from India and included 22,601 neonates. Pulse oximetry screening of healthy newborns provided early alerts to diagnose life-threatening conditions-both cardiac and respiratory. Successful pulse oximetry screening needs appropriate equipment and training. Our study showed similar accuracy for those reported in the recent meta-analysis of 13 studies, which showed a sensitivity

of 76.5%, specificity of 99.5% and a low false positive rate of 0.14%.

The 11 cases with major CHD who were identified by pulse oximetry were all identified prior to discharge from our service with the clinical alert in all being triggered by the saturation reading, and though our fetal medicine experts had picked up five cases antenatally. All 11 cases would probably have been discharged without a diagnosis, had this been in a rural setting without fetal medicine specialists. The timely management of these cardiac conditions was vital in optimizing the prognosis for these babies.

We took a pragmatic approach at implementation into the current practice of pulse oximetry as one more test in normal newborn examination. The programme did involve employing one extra nurse, and the average procedure time estimated was 8-12 minutes. The main financial costs were the salary to the nurse at Rs. 15,000 per month and the purchase of a GE pulse oximeters with Masimo probes at an approximate cost of Rs. 50,000 each (though as per new NRP guidelines all maternity hospitals need to have this as part of their NRP guidelines).

The false positive rate was extremely low in our study, which was consistent with the rest of the literature. 'False positive' is really a misnomer in the context of this test. This test is screening for hypoxaemia, which is never normal in a newborn baby. Such hypoxaemia has many causes, just one of which is CHD, and early detection of these other causes can be just as important. Overall, in published series of 'false positive' cases (e.g. those with low saturations but a normal heart), about 50% will have some other pathology. The study of Grenelli et al showed a low false positive rate of 0.17% and that 31/69 'false positives' had other pathology. Our data are consistent with this as three of 14 cases (21%) with low saturations and a normal heart had previously unrecognized respiratory pathology, some of which was serious and in which timely management was equally important.

There was just one case of significant CHD identified that was not diagnosed prior to discharge. This was the baby with a large VSD, as this complied with our definition of CHD (need for surgery in the first year of life). Parents were upset that this was not diagnosed despite delivering in a tertiary centre and doing all the tests. We identified it as a false negative case, but saturation screening would not be expected to detect acyanotic congenital heart lesion at birth. It is a limitation of this study.

In the face of consistent evidence of the benefits of this test, it is reasonable to ask why implementation has been slow in India. The main barriers referred (in informal discussions) in meetings were lack of echocardiography availability, increased workload for paediatric cardiology services and paediatric registrars, cost of equipment or concerns about the validity/usefulness of screening and the low rate of positive screens. These barriers are consistent with those described in the 2012 survey of UK practice published by Singh and Ewer<sup>8</sup>. We have looked at these concerns and in the context of our experience have tried to answer them here.

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## Staffing and Equipment Cost

This was implemented in our services with the need for one additional nursing staff – but this nurse was also involved in administering BCG vaccine to the babies and also conducting the hearing test for the newborns. There are relatively minor equipment costs as previously detailed. The total cost to be invested is around Rs. 80,000 per 2 years – and even if it is charged at Rs. 50 per baby (less than \$1 per baby) – the cost will be “recovered” with 1,600 deliveries!

## Paediatric Cardiology and False Positive Rates

The main concern is paediatric cardiologists’ availability and increased burden on echocardiography services. Notwithstanding, most ‘false positive’ have some other significant pathology. The false positive rate for CHD in this study, as in the rest of the literature, is extremely low.

## Lack of Availability of Echocardiography

A low saturation screen is not a trigger for an immediate referral for echocardiography. Rather, it should trigger a clinical review by an experienced neonatologist, appropriate investigations and possibly a period of observation. If the clinical pointers are towards CHD or no other cause can be found, then a referral for echocardiography should be requested. At our hospital, we have facilities for paediatric cardiology services with less than 4 hours notice. Also elective referral to a Paediatric Cardiologist is better than a collapsed baby with CCCHD.

**Workload:** This was a concern when we first implemented, and for this reason, we incorporated screening into the routine newborn examination and employed one dedicated paediatric nurse to do the test. Once the benefits were seen, there was quick acceptance amongst the staff & obstetricians regarding the value of this test, and this played an important role in promotion of the test.

**Cross-infection risk:** We adopted a pragmatic approach with re-useable probes and cleaning between patients. The cost is a fraction of what it would be to use disposable probes. There were no cross-infection issues that we are aware of during or since the period of this review.

**Discharge delay:** This has not been a concern in our set up because the screening was incorporated seamlessly into our baby checks & BCG vaccination after 24 hours. This will clearly vary between services depending on the availability of nursing staff.

The optimal timing of screening remains a controversy. Earlier screening (<24h) results in more false positives, but many of these are important non-cardiac pathology. A late screening results in a lower false positive for CHD and may be more accurate for diagnosis of obstructive left heart lesions, particularly coarctation of the aorta. Prudhoe et al showed that pulse oximetry is relatively insensitive in detection of coarctation of aorta/interrupted aortic arch (95% confidence interval (CI) 24-50%) and TOF (95% CI 24-58%). The AAP recommends screening at 24-48 h. We implemented this as ‘late’ screening for largely pragmatic reasons. Thus, since 2012, all babies have a saturation measure on the post-natal ward performed by the trained paediatric nurse after 24 hours of birth.

There is increasing evidence to justify pulse oximetry screening as the standard of care.<sup>9,10,11,12,13</sup> As a screening tool, pulse oximetry fulfills the requirements. It is inexpensive and easy to use with a low false positive rate, allows diagnosis of an important disease process (CCCHD) which has a defined natural history, a suitable confirmatory test, and is treatable. In 2011, the US Health and Human Services Secretary recommended that pulse oximetry



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etry screening be added to the Recommended Uniform Screening Panel. In the UK, there remains a wide variation in practice mainly due to a difference in timing of screening. We believe that apart from detecting CCCHD, pulse oximetry screening also picks up other important pathology which was previously categorized to be ‘false positive’. In our study of the 14 babies with abnormal saturations, 11 had cardiac disease, and the three “false positives” actually had unrecognised pulmonary pathology.



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### Conclusions

This post-implementation review shows that pulse oximetry screening can be introduced into Indian practice with minimal cost and minimal extra burden to echocardiographic services. Our findings mirror those in the rest of the literature with cases of major CCCHD that might have been missed, being diagnosed prior to discharge.<sup>12</sup> The 'false positive' rate is extremely low, but the term 'false positive' is a misnomer in this context

as over half of these babies had some other pathology. This screening practice should be seen as a test of neonatal well-being not just for CHD and should become a standard of care in India, especially now with new IAP NNF NRP guidelines, saturation monitoring at birth has become mandatory. There is no reason why this cannot be done.

For Obstetricians this is even more important since they are concerned about the survival of the baby and both mother & baby being normal – this gives extra confidence as one cannot diagnose CCCHD otherwise at birth. This being an inexpensive test and no other new equipment is required, all obstetricians should make it mandatory for their babies to undergo this test which will go a long way to achieve our Millennium Development Goals (MDG) in reducing our infant mortality and help India achieve the goals.

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# Weed in Need is a Foe Indeed: Neonatal Seizure Secondary to the Antenatal Marijuana Exposure

By Shabih Manzar, MD; Liaqat H. Khan, MD

## Case

At 20-hours of life, a female infant while being cared by mother in the room, observed to have cessation in breathing and color change. The infant was immediately returned to the nursery and placed on monitor. Infant had similar episode associated with bradycardia and desaturation.

At this point, the infant was transferred to the Neonatal Intensive Care Unit (NICU). The infant was born to an 18-year old gravida 1, para 0. All antenatal labs including HIV, Hepatitis B, rapid plasma reagin were negative. There was no history of sexually transmitted diseases. No drug screening was done at delivery. The baby was delivered vaginally with Apgar score of 8 and 9 at one and five minutes respectively. Cord blood gas pH 7.27, pCO<sub>2</sub> of 47, PO<sub>2</sub> of 40 and base excess of -4.8. Infant was appropriate for gestation age with birth weight of 3079 grams, head circumference of 32.5 centimeters and length of 49.5 centimeters.

On admission to the NICU, physical examination was normal except for a soft murmur. Septic work-up was done including Complete Blood Count (CBC) and blood culture, and infant was started on antibiotics. Blood gas on admission was pH of 7.46 pCO<sub>2</sub> of 34 PO<sub>2</sub> of 59 and HCO<sub>3</sub> of 25 in room. Chest X-ray was normal. An echocardiogram showed Atrial Septal Defect (ASD) with no other abnormalities. CBC and electrolytes were within normal limits. Infant was placed on high flow nasal cannula with flow of 4 liter per minute and 25% oxygen. In view of apnea, an otolaryngologist was consulted. The endoscopy showed no airway anomalies. Sleep study was performed that was reported as normal. The following day, the infant had two episodes of apnea with posturing associated with bradycardia and desaturations. A detailed work-up was initiated. Head ultrasound showed no bleeding. Video Electro-Encephalogram (EEG) showed some sharp and spiking activity from the right hemisphere. Infant was started on Phenobarbital after consultation with a Neurologist. Lumbar puncture was performed and fluid sent for PCR for Herpes simplex virus. Infant was started on IV Acyclovir. The HSV PCR and CSF cultures were negative.

Magnetic Resonance Imaging (MRI) of brain was normal. The MRA/MRV views of brain were limited due to infant's movements. The complete metabolic work-up, including blood gas, serum lactate, ammonia, serum amino acid profile and urine organic acid profile were all reported as normal.

On Day 4 of Admission, the meconium drug screen results came back as positive for marijuana ("weed"). The ARUP Laboratories cutoff is 5 ng/g, and the infant was found to have 22 ng/g, 4 times higher values. On further questioning, the teenage mom revealed smoking weed throughout the pregnancy.

The Infant was started on feeds, and was gradually weaned of nasal cannula. The phenobarbital maintenance dose was started with adequate blood level of 23 mcg/ml. Infant remained seizure free for 4 days and tolerated PO feeds well. Infant was discharge home at Day 11 of Life in stable condition with followup with a Pediatric Neurologist.

## Discussion

Marijuana, although being legalized in some states, is not free of associated health problems. A recent review by Volkow et al<sup>1</sup> has

addressed these problems in detail. They highlighted on the negative effect of marijuana on the functional connectivity of the brain particularly if the use starts in adolescence and young adulthood. Another review by Jaques et al<sup>2</sup> describes the effect of cannabis on developing fetal brain. The committee on Fetus and Newborn recently published the short and long-term effects on fetuses exposed to prenatal substance abuse.<sup>3</sup>

We looked at the all the possible causes of neonatal seizure in this infant. A detailed work-up was negative for the known causes. The result of positive drug screen for marijuana, four times the normal and mother admitting to chronic use of marijuana during pregnancy, lead us to postulate seizure to be secondary to use of marijuana. The cause and effect relationship between marijuana and seizure is difficult to establish in neonates after prenatal exposure. Similarly, the exact pathophysiology seizure could only be postulated basing of the earlier reports of potential chemical effect of marijuana on the brain synapses, especially in the developmental state. A literature review looking for marijuana and seizure revealed that is has been used in treating epilepsy dating back to 1800 B.C.E.<sup>4</sup> However, Cochrane review was inconclusive.<sup>5</sup>

The main purpose of this case report is to enlightened the awareness about potential association of marijuana and neonatal seizure. The other intention is to highlight on the need for continued extensive counseling to the parents and teens about marijuana and its potential effects on the developing fetus, as indicated by the Committee on Substance use and Prevention, American Academy of Pediatrics recently.<sup>6</sup>

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## NT

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## Upcoming Medical Meetings

### 14<sup>th</sup> National Advanced Practice Neonatal Nurses Conference

*Apr. 19-27, 2017; Waikiki Beach, HI USA  
www.academyonline.org*

### 1<sup>st</sup> World Congress on Maternal Fetal Neonatal Medicine

*Apr. 23 - 26, 2017; London, UK  
www.worldmfnm.eu*

### 15<sup>th</sup> Annual AirBorne Neonatal and Pediatric Transport Conference in

*May 10-12, 2017; Austin, TX USA  
http://int-bio.com/events-news/airborn  
e-conference/*

### The 28<sup>th</sup> Annual Meeting of the European Society of Paediatric and Neonatal Intensive Care (ESPNIC 2017)

*Jun. 6-9, 2017; Lisbon, Portugal  
http://espnice2017.kenes.com*

### 3<sup>rd</sup> International Neonatology Association Conference (INAC 2017)

*Jul. 7-9, 2017; Lyon, France  
http://2017.worldneonatology.com/*

### 6<sup>th</sup> National Neonatal Simulation Conference

*Sep. 26-27, 2017; Southampton, UK  
www.mproveonline.com/conference*

### 7<sup>th</sup> International Arab Neonatal Care Conference

*Sep. 29-Oct. 1, 2017; Dubai Festival City  
http://ancc2017.info*

### 8<sup>th</sup> Phoenix Fetal Cardiology Symposium

*Oct. 27-31, 2017; Phoenix, AZ USA  
www.fetalcardio.com*

### 20<sup>th</sup> International Conference on Neonatology and Perinatology

*Dec. 4-6, 2017 Madrid, Spain  
http://neonatology.conferenceseries.com*

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