Sensitivity of Clinical Assessment in Term Neonates by General Pediatric Residents

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Objectives: *To determine the accuracy of physical examination in detecting congenital heart diseases by pediatric residents and identify risk factors of congenital heart diseases.*

Material and Method: *Five hundred term infants (GA ≥ 37wks) who were born at Phramongkutklao Hospital from July 1st, 1999 to June 30th, 2000 were examined by pediatric residents and pediatric cardiologists within the first week of life. The echocardiography was performed in all 500 infants for definite diagnosis. The accuracy of physical examination was determined by comparing with echocardiographic finding and presented as sensitivity and specificity.*

Results: *Congenital heart diseases were found in 18 of 500 term infants (3.6%). The physical examination by pediatric residents and pediatric cardiologists showeds a sensitivity of 39% and 94% and the specificity of 98% and 97%, respectively. After excluding spontaneously closed PDA within 2 weeks, the first and second most common congenital heart diseases in infants were Ventricular septum defect (VSD) (44%) and Patent ductus arteriosus (PDA) (33%). The positive other cardiovascular signs, such as cyanosis or abnormal pulses with heart murmur were significantly associated to diagnosis of congenital heart diseases.*

Conclusion: *Although echocardiography is the major tool to determine the definite diagnosis, most congenital heart diseases can be well detected during physical examination by skilled physicians. As a result, the value of physical examination of the cardiovascular system should be emphasized in training general pediatricians concerning lower costs and early detection of congenital heart diseases.*

Keywords: *Clinical assessment, Heart murmur, Neonates, Pediatric residents*

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Congenital heart disease is one of the most common causes of death in newborn infants. The incidence of congenital heart disease has been reported 6-8 in every 1000 live born babies[1], but most are asymptomatic at birth[1-5]. The report of

The Third Joint Working Party on Child Health Surveillance[6] recommended that auscultation and careful attention on the physical examination before discharge from hospital provide an opportunity for early diagnosis. Cardiovascular examination in neonates is difficult and requires special clinical experience because the rapid heart rate and transitional period after birth may mask pathologic heart murmur in neonates. The prevalence of heart murmur was found 0.9-77.4% from previous studies[7-8]. The wide range of prevalence depends on the experience in cardiovascular examination and timing at examination. Ainsworth S.B. et al[8] showed a sensitivity of the examination for detection of congenital heart diseases during infancy was 44 % and the specificity was 99.7% and the positive predictive value was 54 %. An echocardiography becomes the gold standard for diagnosis of congenital heart disease among the neonates who have heart murmurs[9]. However, the use of echocardiography as a screening test in all infants is costly and requires operator expertise. Timing of physical examination is very important. Because early discharge to home is currently common in general practice, some of the cardiovascular signs may not present at the time of discharge. As a result, some infants with serious congenital heart diseases unexpectedly died at home. The strategy to minimize unexpected cardiac causes of neonatal death is careful examination with suspicious attention on cardiovascular system in neonates before discharge to home.

The causes of congenital heart diseases have been still unknown. Frequently, cardiac defects are associated with chromosomal anomalies. A previous study[10] found chromosome abnormalities in 12% of infants with tetralogy of Fallot (TOF), 69% with TOF and absent pulmonary valve and 44% with interrupted aortic arch. A study from three large registries of congenital malformations[11] showed the congenital heart defects in infants with Down's syndrome, not only was endocardial cushion defect (ECD) more common, but also the severe cardiac defects - hypoplastic left heart syndrome (HLHS), common truncus, transposition of great vessel (TGV) and double outlet of right ventricle (DORV). Khoury et al[12] found the mother's diabetes to be a risk factor among infants with common truncus, TGV or TOF (OR = 5.6, 95 % CI = 2.5 - 15.6). The exogenous factors and teratogens during pregnancy are risk for cardiac defects, such as retinoic acid (conotruncal anomaly), Lithium (Ebstein's anomaly)[13] and antiepileptic drugs[14]. Smoking in the family can cause heart diseases in children. Alcoholic mothers can cause fetal-alcohol syndrome and it is usually associated with congenital heart diseases.

There is no previous study that compared the accuracy of clinical assessment to detect congenital heart diseases in neonates by pediatric residents and by pediatric cardiology specialists. In addition, the risk factors of congenital heart diseases in newborns are still unclear. The aim of the present study was to determine the sensitivity and specificity of clinical assessment to detect heart murmurs in infants by pediatric residents and to determine the risk factors of congenital heart diseases.

Material and Method

Study design

The authors performed the screening of physical examination to detect congenital heart diseases in term infants by pediatric residents who were trained in a pediatric residency program at Phramongkutklao Hospital (PMK) during the study period. Term infants (gestation age $\geq$ 37 weeks) who were born at Phramongkutklao Hospital from July 1st, 1999 to June 30th, 2000 were enrolled in the present study with parental consent.

The exclusion criteria included infants who had serious major congenital anomalies that cannot

survive, twins and triplets or died in hospital from non-cardiac causes or had Apgar scores at 5 minutes less than 5, or admitted to the neonatal intensive care unit immediately after birth. Informed consents were obtained from one of the parents after the brief explanation about the study. The authors interviewed the parents and recorded the data including patents' characteristics, incomes, educational levels, smoking and drinking habits, history of antenatal care (ANC), and parents' health status. The mode and complications of deliveries, and apgar scores were reviewed from the obstetric records. Pediatric residents examined all infants before discharge to home (age less than 7 days) as part of the routine newborn care at PMK Hospital. The oxygen saturation (O_2 sat) and blood pressure of 4 extremities were recorded in all infants who had a heart murmur detected by pediatric residents. A cardiologist who was blinded to the result of physical examination by the pediatric residents performed cardiac examinations prior to echocardiograms. The details of physical examination by pediatric residents and a cardiologist were recorded in separate data sheets. Neither the pediatric residents nor the cardiologist knew the results of the examination by the other.

The authors used echocardiography as a gold standard for diagnosis of congenital heart diseases. The echocardiograms were performed in 500 infants for accurate information of cardiac anatomy. Parents of infants who had no cardiac anomalies were reassured. For those infants who had congenital heart diseases, the cardiologist explained the cardiac anatomy, nature of the specific cardiac lesion and plan of treatment to the parents. The results of physical examinations by the pediatric residents and by the cardiologist were compared with echocardiograms for diagnostic accuracy. The follow-up appointments with a pediatric cardiologist at 1, 3, 6 and 12 months were organized on all infants who had a diagnosis of congenital heart diseases.

Statistical Analysis

Data were described as frequencies and means with standard deviations as appropriate. Sensitivity and specificity of heart murmurs were calculated for each group (pediatric residents and cardiologist). The accuracy of physical examination was calculated by using echocardiography as a gold standard method. Chi-square and student t-test were used for comparison data. The present study was approved by the Phramongkutklao medical ethic committee and Excel and SPSS version 11.0 were used for data analysis.

Sample size calculation

The sensitivity of clinical assessment of heart murmur approximated 82% from a previous report[10]

$N = Z\alpha\ 2\ PQ / d^2 \rightarrow N = 227$

N = number of infants with heart murmur

Q = 1 - P = 1 - 0.82 = 0.18

P = sensitivity of clinical assessment of heart murmurs (0.82)

$Z\alpha$ = 1.96 (standard constant value), d = 0.05

As the previous report[15] showed that there were 16 infants who had congenital heart diseases from positive heart murmur in infants 37 cases, the authors calculated the appropriate sample sizes in the present study which approximated 500 cases.

Results

A total of 3,525 newborn infants were born at PMK Hospital from July 1st, 1999 to June 30th, 2000. The authors excluded 396 preterm infants (GA < 37 weeks), 7 infants with major abnormalities those who did not survive, 64 twins and triplets, 25 neonatal deaths and 423 infants admitted in a neonatal intensive care unit from the

present study. There were 500 from 2,610 term infants enrolled into the present study with permission. There were 269 male infants (54%), the mean gestational ages (GA) were 38.57 ± 1.33 weeks and birth weights were 3.17 ± 0.43 kg. Mean age at examination was 2.44 ± 0.96 days. Most of the infants were born by vaginal delivery (62%) and all infants had normal Apgar score at 1 and 5 minutes. Mean age of the fathers and mothers was 28.49 ± 5.5 and 31.75 ± 6.67 years, respectively. Most of the fathers smoked cigarettes (41%) and drank alcohol (44%). Maternal educational levels mostly were more than high school (75%) and the family incomes were less than 20,000 Baht/month (82%). All mothers had no serious underlying diseases and had good antenatal care histories. The results of heart murmur detected by pediatric residents and by a cardiologist are shown in Fig. 1. The results of positive heart murmur by physical examination compared to diagnosis of congenital heart diseases by transthoracic echocardiography are shown in Fig. 2 and Table 1. The sensitivity of cardiac examination by pediatric residents and a cardiologist was 38.9% and 94.4%, respectively (Table 2). The cardiologist could not detect a heart murmur in only one patient who had patent ductus arteriosus (PDA). All patients who had positive clinical signs such as cyanosis and abnormal pulses with heart murmur were not missed by both. There were 18 patients (3.6%) who had congenital heart defects in this study and confirmed by echocardiograms. Types of congenital heart diseases are shown in Table 3. The first and second most common lesions were ventricular septum defect (VSD) (44.4%) and PDA (33.3%) after excluding spontaneously closed PDA in 1-2 weeks of age. During the follow-up periods, there were 2 of 18 infants (11%) who had definite diagnosis of congenital heart diseases but were lost to follow-up from the present study. Those were infants who had corrected TGA (ccTGA or L-TGA) and perimembranous VSD. Among 16 infants, 4 of 6 infants having PDA had no symptoms with spontaneous closure within 1 year of age. One of two infants had late spontaneous PDA closure at the age of two years. The other infant with Downs syndrome had symptomatic PDA and underwent surgical closure at one year of age.

There were 3 infants with perimembranous VSD and 5 with muscular VSD. One of the

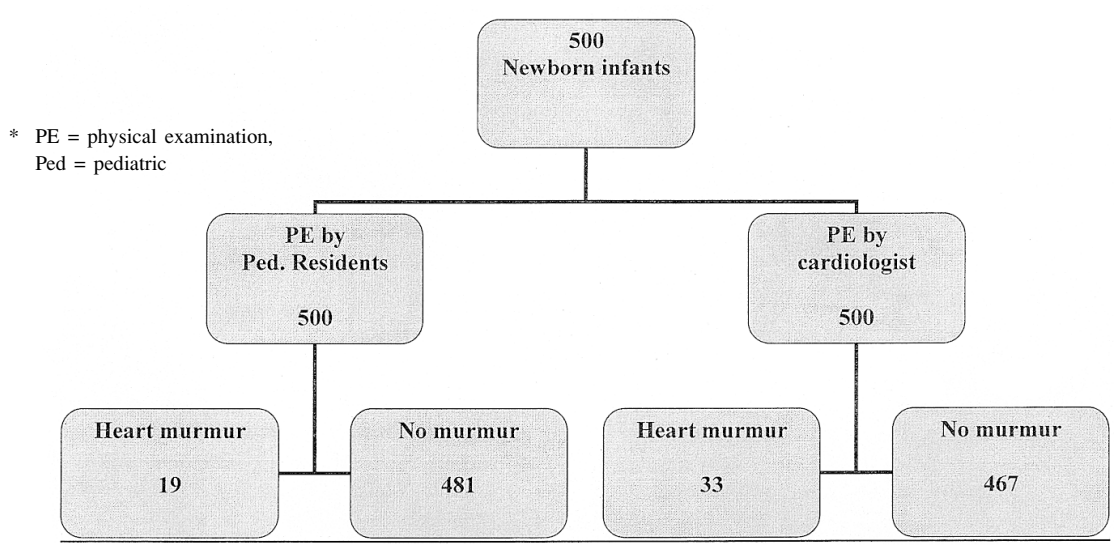

Fig. 1 Detecting heart murmur in 500 infants by pediatric residents and pediatric cardiologist

* CHD = congenital heart disease,
Echo = echocardiography,
PE = physical examination

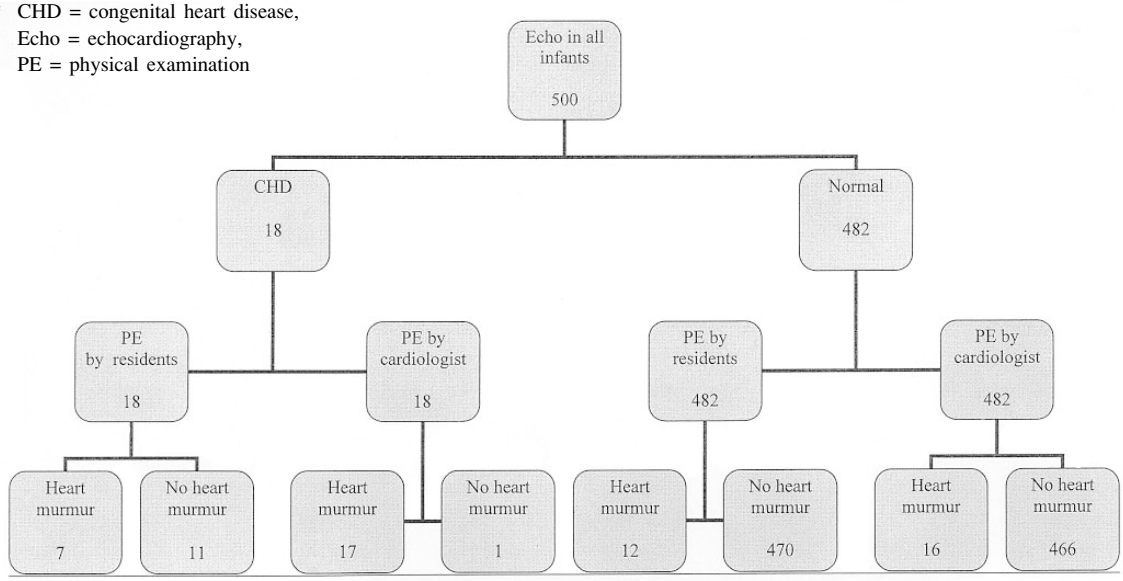

Fig. 2 Detecting heart murmur and echocardiographic finding in 500 term newborn infants

Table 1. Comparison of accuracy of physical examination between pediatric residents and cardiologist

Echocardiogram	Normal (n=482)	Cong. heart disease (n=18)
Physical exam by residents		
Normal	470	11
Cong. heart disease	12	7
Physical exam by cardiologists		
Normal	466	1
Cong. heart disease	16	17

Table 2. Diagnostic percentage of physical examinations by pediatric residents and cardiologist

Diagnostic values	By residents	By cardiologists
Sensitivity	38.9	94.4
Specificity	97.5	96.7
Positive predictive value	36.8	51.5
Negative predictive value	97.7	99.8

perimembranous type was lost to follow-up. One of the muscular VSD had spontaneous closure at 6 months of age. The authors followed another 6 infants who had VSD until two years of age. All of them still had a heart murmur without symptoms and echocardiogram confirmed small defects. There were 3 infants having complex congenital heart diseases and all of them needed surgical correction. One infant with a large VSD with mild pulmonary valve stenosis (PS) and PDA underwent PDA ligation and PA banding at the age of one year and was clinically well until the age of 2 years. One infant who had single ventricle and pulmonary atresia underwent modified Blalock-Taussig shunt at one month and followed by Glenn operation at the age of 2 years. The last patient who had Shone's anomaly and presented symptoms of heart failure and cyanosis at the age of 2 days died at 6 days of age after surgical correction. The causes of death were sepsis and multi-organ failure.

Table 3. Congenital heart diseases were diagnosed by echocardiograms, by physical examination of residents and cardiologist

Diseases	By echocardiogram	By residents	By cardiologists
VSD	8	3	8
PDA	6	2	5
Complex heart	1	0	1
VSD+ PS+ PDA	1	1	1
LTGA + PDA	1	0	1
Shone's anomaly	1	1	1
Total (%)	**18 (100)**	**7 (38.9)**	**17 (94.4)**

Table 4. Comparison between infants with congenital heart diseases and normal infants

Characteristics	Congenital heart disease (n=18)	Normal (n=482)	p value
Infant's data			
Sex : Male	10 (55.6)	259 (53.7)	0.88
Delivery : cesarean	6 (33.3)	182 (37.8)	0.89
Age at exam < 3 days	18 (100)	476 (96.4)	0.63
Apgar score : 5 min < 7	1 (5.6)	1 (0.20)	0.07
Physical examination			
Cyanosis	1 (5.6)	0 (0.00)	0.036
Abn. pulses 5	(27.8)	22 (4.60)	< 0.005

Table 5. Comparison of risk factors of congenital heart diseases between infants with congenital heart diseases and normal infants

Characteristics	Cong. heart disease (n=18)	Normal (n=482)
Maternal age >35 yr	4 (22.2)	47 (9.75)
Maternal abortion	6 (33.3)	109 (22.6)
Maternal HBsAg +	0 (0)	7 (1.5)
Maternal Anti HIV +	0 (0)	3 (0.6)
Maternal drug use	5 (27.8)	140 (29.1)
Maternal diseases	0 (0)	61 (12.7)
Maternal smoking	0 (0)	11 (2.3)
Father smoking	6 (33.3)	198 (41.1)
Maternal alcohol Drinking	0 (0)	10 (2.1)
Maternal education (Bachelor or higher)	7 (38.9)	114 (23.7)
Family income > 20000 baht /month	4 (22.2)	85 (17.6)

Other positive physical findings, such as cyanosis and abnormal pulses which related with heart murmur were significantly associated to the diagnosis of congenital heart diseases in infants (Table 4). Sensitivity and specificity of clinical assessment were not related to the following characteristics: mode of delivery, Apgar score, sex and the age that the murmur was detected, parents' education, smoking, alcohol and incomes, history of previous abortion, history of ANC, maternal age and medication during pregnancy.

Discussion

Auscultation and cardiac examination is an important clinical skill for a routine practice by all pediatric residents and general pediatricians, yet the accuracy of clinical assessment in the hands of non-cardiologists could not compare with specialists. Clinical assessment of heart murmur is the primary clinical evaluation tool used for early diagnosis of congenital heart diseases. A previous report showed that electrocardiography and chest X-ray provided only 10% of sensitivity for cardiac abnormalities detection in well babies with heart murmur[16-20]. The present study used echocardiography as a gold standard for diagnosis of congenital heart diseases and compared results of physical examinations to the tests in sensitivity and specificity. The results showed lower sensitivity of heart murmur detection by pediatric residents when compared to the cardiologist's results. The sensitivity of 39 % implies that 61% of infants with congenital heart diseases would be missed. However, the specificity of 98% implies that almost all infants who had a heart murmur detected had significant cardiac defects. There were 2% of those infants who might have

innocent or physiologic heart murmurs. The sensitivity of clinical assessment by the cardiologist was 94% and specificity was 96% which were similar to a previous report. Hanson et al[21] studied 100 children and found sensitivity and specificity of clinical assessment by cardiologists to be 96% and 68%, respectively. Another four prospective descriptive studies found sensitivity of clinical assessment by 3 to 8 pediatric cardiologists ranged between 92-96% and specificity between 82-95%[16,17,22,23]. Giving a low sensitivity and accuracy of clinical assessment by pediatric residents in training, educational interventions targeted at improving the diagnostic skills of general pediatricians, pediatric residents and medical students should be considered. The training of clinical skills and experiences in cardiac examinations should be started in early clinical medical students. Recent practice at this institution, teaching of cardiovascular physical examination on real patients has been introduced in the third year pre-clinical medical students before they step in to the clinical year. The frequent practices to gain more experiences and confidence are important for medical students and pediatricians to improve the accuracy of clinical assessment.

Unfortunately, the results showed mode of delivery, apgar score, sex, the age at murmur was detected, parents' education, smoking, alcohol and incomes, history of previous abortion, history of ANC, maternal age and medication during pregnancy were not significantly associated with the incidence of congenital heart diseases. The causes and risk factors of congenital heart diseases are still unknown from the present results the same as many previous reports. The small number of infants and shortness of the study period may affect this finding. A larger sample size and molecular study may give the specific risk factors and benefit in preventive diseases.

Although, double blind clinical assessment by pediatric residents and a cardiologist decreased the bias in the present study, the results of this study have some limitations. The authors enrolled patients by using convenient sampling within only one-year period, it was possible that the prevalence in the present study did not represent the prevalence of the geneneral population. Patent foramen ovale (PFO) was not classified as one of the pathologic lesions in the present study because it was difficult to differentiate from atrial septal defect (ASD) in the newborn. Therefore, the authors could miss the diagnosis of ASD. Although only one cardiologist participating in the present study minimized inter-observer variations, pediatric residents were aware of this study and possibly paid more meticulous attention on their physical examination during the period of the present study. A study conducted in one institution might not represent the whole pediatric residency training in Thailand. Furthermore, the accuracy of clinical assessment may vary and depends on clinical skills of residency levels. The comparison between each level of pediatric residents might show improvement in accuracy of physical examination across the years. A multi-center study and larger sample size should be considered to evaluate and improve the standard of the pediatric training program in Thailand.

In summary, the causes and the risk factors of congenital heart diseases are still unclear. Although echocardiography is the best technique to determine the definite diagnosis, it still needs expertise and has a higher cost. The present study shows most congenital heart diseases can be well detected by skilled physicians. However, the value of physical examination on the cardiovascular system should be emphasized in training general pediatricians.

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ความไวของการวินิจฉัยโรคหัวใจพิการแต่กำเนิดในเด็กทารกแรกคลอดครบกำหนดจากการตรวจร่างกายของแพทย์ประจำบ้านกุมารเวชศาสตร์

อังคณา เก่งสกุล, เฉลิมเกียรติ ตันตระกูล, สุรีย์พร คุณาไทย, สันต์ หาอุปละ, แสงแข ชำนาญวนกิจ

วัตถุประสงค์: *เพื่อศึกษาถึงความไวของการวินิจฉัยโรคหัวใจพิการแต่กำเนิดในเด็กทารกแรกคลอดครบกำหนดจากการตรวจพบเสียงฟู่ของหัวใจโดยแพทย์ประจำบ้านกุมารฯ และศึกษาถึงปัจจัยเสี่ยงของการเกิดโรคหัวใจพิการแต่กำเนิดในทารก*

วัสดุและวิธีการ: *ศึกษาเปรียบเทียบผลการตรวจร่างกายทางระบบหลอดเลือดและหัวใจ ที่พบเสียงฟู่ของหัวใจ (heart murmur) โดยแพทย์ประจำบ้านกุมารฯ และแพทย์ผู้เชี่ยวชาญทางด้านโรคหัวใจในเด็กในทารกแรกเกิดคลอดครบกำหนด (อายุครรภ์ มากกว่า 37 สัปดาห์) ในโรงพยาบาลพระมงกุฎเกล้าจำนวน 500 คนที่บิดาหรือมารดาอนุญาตให้เข้าร่วมงานวิจัย โดยคำนวณหาความไวในการวินิจฉัยโรคหัวใจพิการแต่กำเนิดเปรียบเทียบกับการตรวจวินิจฉัยด้วยเครื่องอัลตราซาวด์หัวใจ (Echocardiography) และได้ศึกษาติดตามผลการรักษาภายหลังการวินิจฉัยในกลุ่มที่มีความผิดปกติต่อไปอีกเป็นระยะเวลาอย่างน้อย 1 ปี*

ผลการศึกษา: *พบทารกแรกเกิดครบกำหนดมีโรคหัวใจพิการแต่กำเนิดจำนวน 18 ราย ในจำนวนทารกทั้งหมด 500 ราย ความไวในการวินิจฉัยโรคหัวใจในเด็กจากการตรวจร่างกายโดยแพทย์ประจำบ้านกุมารฯ และแพทย์ผู้เชี่ยวชาญทางด้านโรคหัวใจในเด็กมีค่าเป็น 39% และ 94% ตามลำดับ โดยที่ค่าความเฉพาะเจาะจงอยู่ที่ 98% และ 97% ตามลำดับ โรคหัวใจพิการแต่กำเนิดชนิดที่พบบ่อยได้แก่ Ventricular septal defect (VSD) (44%) และรองลงมาคือ Patent ductus arteriosus (PDA) (33%) จากการศึกษานี้ไม่พบปัจจัยเสี่ยงของการเกิดโรค แต่การพบความผิดปกติอื่น ๆจากการตรวจร่างกาย เช่นภาวะเขียว, ความผิดปกติของชีพจรอาจเป็นข้อบ่งชี้สำคัญของการเกิดโรคหัวใจพิการแต่กำเนิดในทารก*

สรุป: *จากการศึกษานี้พบอุบัติการณ์การเกิดโรคหัวใจพิการแต่กำเนิดในทารกแรกเกิดสูงกว่าอุบัติการณ์โดยทั่วไป ถึงแม้ว่าการตรวจวินิจฉัยด้วยเครื่องอัลตราซาวด์หัวใจ จะให้การวินิจฉัยเฉพาะโรคที่ถูกต้องและแม่นยำแต่ยังจำเป็นต้องอาศัยผู้เชี่ยวชาญ รวมทั้งมีค่าใช้จ่ายค่อนข้างสูง อย่างไรก็ตาม การตรวจร่างกายทารกอย่างละเอียดและด้วยความชำนาญจะสามารถให้การวินิจฉัยโรคเบื้องต้นได้อย่างถูกต้อง ดังนั้นการให้ความสำคัญและเน้นย้ำให้มีการฝึกปฏิบัติให้เกิดความชำนาญในการตรวจร่างกายของนักศึกษาแพทย์ และแพทย์ประจำบ้าน จึงเป็นสิ่งที่ควรตระหนักในการปรับปรุงหลักสูตรการเรียนการสอนของแพทย์ต่อไป*