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RESEARCH ARTICLE

How the training of ultrasonographers influences the certainty of prenatal detection of congenital malformations of interest to the pediatric surgeon

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Abstract

Background: *The training needed for doing obstetric ultrasounds is rarely reported. The aim of this study was to determine whether the training of the ultrasonographer influences the prenatal diagnostic certainty of some congenital malformations.* **Methods:** *We conducted a retrospective evaluation of antepartum sonographic findings of newborn infants found ultimately to have a congenital anomaly in a tertiary level pediatric reference center. Data were collected on admission for consecutive patients at a tertiary-level pediatric reference center. The mother´s pregnancy and birth demographic variables and those of the prenatal ultrasound (PUS) were analyzed and correlated with the final diagnosis.* **Results:** *Sixty-seven neonates were included. All cases underwent PUS with a mean of 4.6. Prenatal diagnosis was established in 24 cases (35.8%). Thirteen surgical anomalies were detected, particularly anorectal malformation and gastroschisis. The accuracy of PUS was associated with the training of the physician performing the PUS, whereby PUS with the greatest accuracy were performed by gynecologists and maternal-fetal specialists against radiologists and general practitioners (p = 0.005). Patients without an accurate prenatal diagnosis had a greater risk of presenting comorbidities (relative risk [RR]: 1.65, p = < 0.001, 95% confidence interval [CI]: 1.299-2.106).* **Conclusions:** *In our setting, prenatal diagnosis of these malformations is directly determined by the training of the person performing the ultrasound.*

Keywords: *Academic training. Congenital abnormalities. Observer variation. Prenatal diagnosis. Ultrasound.*

Cómo el entrenamiento del ultrasonografista influye en la certeza de la detección prenatal de malformaciones congénitas de interés para el cirujano pediatra

Resumen

Introducción: *Con poca frecuencia se ha reportado el entrenamiento necesario para realizar ultrasonido (US) obstétrico. El objetivo de este estudio fue determinar si el entrenamiento del ultrasonografista influye en la certeza del diagnóstico prenatal de algunas malformaciones congénitas.* **Métodos:** *Se llevó a cabo una evaluación retrospectiva de los hallazgos ultrasonográficos prenatales de neonatos que tuvieron malformaciones congénitas en un hospital de referencia pediátrico de tercer nivel. Se realizó al ingreso de neonatos consecutivos en un hospital de referencia de tercer nivel. Se recolectaron y analizaron datos del embarazo y alumbramiento, así como los de los ultrasonidos prenatales (USP) correlacionando con el diagnóstico final.* **Resultados:** *Se incluyeron 67 neonatos. Todos tuvieron USP con media de 4.6. Se realizó diagnóstico prenatal en 24*

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casos (35.8%). Se detectaron 13 malformaciones congénitas, predominando malformación anorectal gastrosquisis. La certeza del USP se asoció con el entrenamiento del individuo que realizó el US y la mayor certeza se encontró cuando lo realizaron ginecólogos y especialistas materno-fetales contra radiólogos y médicos generales (p = 0.005). Los pacientes sin diagnóstico prenatal certero tuvieron mayor riesgo de presentar comorbilidades (riesgo relativo [RR]: 1.65, p = < 0.001, 95% intervalo de confianza [CI]: 1.299-2.106). **Conclusiones:** *En nuestro medio, el diagnóstico prenatal de estas malformaciones está determinado directamente por el entrenamiento de la persona que realiza el ultrasonido.*

Palabras clave: *Entrenamiento académico. Malformaciones congénitas. Variación del observador. Diagnóstico prenatal. Ultrasonido.*

Introduction

Prenatal ultrasound (PUS) has significantly evolved in the last decades. In the late 80s, a multicenter randomized clinical trial conducted in the USA reported no apparent benefit of ultrasound (US) in women with low-risk pregnancies. A European trial conducted in the early 90s revealed that the routine US detected 73% of all major fetal malformations. The difference between these two studies hinged on the fact that the European study used trained sonographers, unlike the American trial[1]. Subsequent reports showed how PUS modified the age at birth in congenital malformations (CM)[2], and improved advice to parents, thus avoiding postnatal transfers[3]. PUS currently can detect many CM between the 11th and 14th week of pregnancy[4].

The PUS detection rate of the main CM requiring neonatal surgery varies between 31-100%[5-7] but does not specify the characteristics of the ultrasonographer. In our country, official regulations establish that diagnostic ultrasound (DUS) may be performed by physicians specialized in ultrasound or diagnostic imaging; other specialists must provide a certificate of specialization in DUS in the context of their specialty. A general physician trained to perform the diagnostic US, must have a certificate from an accredited institution and have coursed a minimum of one thousand hours of training in DUS[8]. Our hospital is a tertiary care referral pediatric center with no maternity services and the majority of CM that arrive at our hospital requiring neonatal surgery do not have an accurate prenatal diagnosis. We hypothesized that the low certainty of prenatal diagnosis is related to the training of the doctor performing the ultrasound, so this study aimed to determine whether the training of the ultrasonographer influences the diagnostic certainty of some congenital malformations.

Methods

This study was considered without risk for the patients, so it got a formal review and approval by the institutional research committee.

Setting: Tertiary-level pediatric reference center. We retrospectively evaluated antepartum sonographic findings of newborn infants found ultimately to have a congenital anomaly. Data collection was made on admission for consecutive patients between June 1, 2018, and May 31, 2019. The mother´s pregnancy and birth demographic variables as well as those of the prenatal ultrasound (PUS) were collected, analyzed, and correlated with the final diagnosis of the malformation established at our center.

Inclusion criteria: Neonates whose diagnosis upon admission included: anorectal malformation, esophageal, duodenal, or intestinal atresia, intestinal duplication, abdominal wall defects, diaphragmatic hernia, vascular malformations, and tumors.

Once a neonate fulfilled the selection criteria, the patient´s mother completed a questionnaire on her history of prenatal ultrasounds. When the mother was unavailable, the questionnaire was applied to the relative accompanying the baby during the transfer. The questionnaire included demographic information, the performance and findings of prenatal ultrasounds, and the level of care in the labour process. Upon the neonate´s admission, we documented: age at admission, a final diagnosis of the anomaly according to clinical, surgical, imaging, and pathology findings at our hospital, the correlation of the final diagnosis with the prenatal diagnosis, whether the prenatal diagnosis benefitted the patient by modifying the delivery plan, or whether the lack of a prenatal diagnosis led to an untimely transfer (after 2 days of age) or neonatal morbidities.

Statistical analysis

A descriptive analysis was made, and between-group comparative analysis was conducted with the Student's t or Mann-Whitney U tests in the case of quantitative variables, and categorical variables were analyzed by chi-square or Fisher´s exact test with a p-value < 0.05 considered significant. The effect size was quantified with Cramer's V, and relative risks (RR) were calculated if needed.

Results

Sixty-seven consecutive patients were included. The source of information was the mother in 86.6%. The education level of informants was grade school (10.4%), middle school (49.2%), high school (26.8%), and college (13.4%).

The median maternal age was 23 years (IR: 8), 49.3% were primigravidae, and 97% had prenatal control, 71.8% of whom were at a primary care level. Most cases of prenatal care were managed by a general physician. All pregnant women underwent at least one prenatal ultrasound, with a mean of 4.6 ± 2.6 PUS during gestation, and 53.7% obtained at least one ultrasound per trimester (Table 1).

The US was performed by a radiologist (RX) in 47.8% of cases, an Ob-Gyn in 35.8%, a general practitioner (GP) in 13.4%, and 3% by a maternal-fetal medicine specialist (MFS).

Childbirth occurred in a secondary care public hospital in 61.2% of cases, in a tertiary care public hospital in 22.4%, and in a private hospital in 16.4% of cases.

Of the 67 neonates, 60% were male, the average weight was 2.7 ± 0.62 kg, the average height was 47.6 ± 3.2 cm, and the average gestational age at birth was 37.6 ± 1.9 weeks gestation (WG). Upon admission to our hospital, the median age was 1 (IR: 3) day, and the postnatal diagnosis of malformation was established at a median of 2 (IR: 1) days of life.

According to the final diagnosis, 13 surgical pathologies were detected; the most frequent was anorectal malformation (ARM), followed by gastroschisis (Table 2). In eight patients (11.9%), two associated surgical pathologies were documented: three patients had ARM + type III esophageal atresia, three patients had gastroschisis + intestinal atresia, one patient had omphalocele + intestinal atresia, and one presented duodenal atresia + type III esophageal atresia. These eight patients were classified by the first-mentioned pathology, which was also with the greatest probability of detection by PUS.

Detection of congenital malformations

A malformation or abnormal finding by PUS was reported in 24 patients (35.8%), and the greatest percentage of structural anomalies was detected in the second (41.6%) and third trimesters (45.8%), with a median of 22.5 (IR: 17) WG. One ultrasound finding was reported in 19 cases and two findings were detected in five cases; the PUS diagnosis was correct in 17/19 patients with one finding. In the other two cases, US findings guided the diagnosis, so they were also classified as a correct diagnosis. In these five patients with two findings, the diagnosis was correct for both findings. Among patients with a prenatal diagnosis, 83.3% benefitted from the diagnosis since it modified the childbirth date or site.

Table 1. Epidemiological data

Variable	Sub variable	n (%)
Gestation	Primigravidae	33 (49.3)
	Multigravidae	34 (50.7)
Prenatal control	Yes	65 (97)
	No	2 (3)
Level of care where the pregnancy was followed	Primary care level	48 (71.8)
	Secondary care level	14 (20.9)
	Tertiary care level	3 (4.5)
Training of whom controlled pregnancy	No control	2 (3)
	General practitioner	40 (59.7)
	Ob-Gyn	23 (34.3)
	Maternal-fetal specialist	2 (3)
Pregnant females with ultrasound in each trimester	First trimester	43 (64.2)
	Second trimester	60 (89.6)
	Third trimester	60 (89.6)

Ob-Gyn: obstetrician-gynecologist.

Table 2. Frequencies of diseases by final diagnosis

Postnatal diagnosis	n (%)
Anorectal malformation	15 (22.3)
Gastroschisis	12 (17.9)
Esophageal atresia	12 (17.9)
Bochdalek hernia	8 (11.9)
Omphalocele	6 (8.9)
Duodenal atresia	3 (4.4)
Intestinal atresia	3 (4.4)
Neck vascular malformation	2 (2.9)
Abdominal wall vascular malformation	2 (2.9)
Hepatic hemangioendothelioma	1 (1.4)
Cloacal exstrophy	1 (1.4)
Sacrococcygeal teratoma	1 (1.4)
Intestinal duplication	1 (1.4)
Total	67 (100)

The lack of a prenatal diagnosis occurred in 43 patients (64.2%) and led to complications in 17 (39.5%); the most frequent complications were intestinal necrosis in three patients, pneumonia in three, and sepsis in three, many due to delay in the suspected diagnosis or transfer to our center. A delay in transfer occurred in 27 patients (40.3%), 10 of whom had a prenatal diagnosis while 17 did not, without statistical significance.

Aside from the malformations of interest to be corrected by the neonatal surgeon, there were another 46 associated anomalies detected postnatally: heart disease (28) and renal (five) among others. Only two (4.3%) were correctly diagnosed prenatally. Five (7.4%) patients died, one patient with ARM suffered a delayed transfer, and intestinal perforation, dying because of sepsis; the remaining four deaths were unrelated to the CM.

Accuracy of prenatal ultrasound

For comparative analysis, we divided the patients into those with/without an accurate prenatal diagnosis. The variables associated with an accurate diagnosis were the training of the individual performing the ultrasounds, the training of the individual following the pregnancy, and the level of childbirth care (Table 3). The rest of the variables didn't show statistical association with the accurate diagnosis.

Some malformations such as duodenal atresia, arterio-venous malformations, cloacal exstrophy, and hepatic hemangioendothelioma were associated with an accurate prenatal diagnosis while intestinal atresia, the sacrococcygeal tumor, and the intestinal duplication, were not diagnosed prenatally ($p = 0.005$, Cramer's $V = 0.648$) (Table 4).

We did establish, however, that if there is no accurate prenatal diagnosis, there is a greater risk of developing complications ($p = < 0.001$, RR: 1.654, 95% confidence interval (CI): 1.299-2.106).

Discussion

Prenatal diagnoses and therapies have transformed the practice of neonatal surgery, allowing for the modification of the childbirth plan and, occasionally, fetal intervention leading to a better neonatal outcome[9]. Surprisingly, all our pregnant cases obtained at least one PUS, with a mean of 4.6, reflecting the available windows of opportunity to establish an accurate US diagnosis; however, the percentage of CM detection in our sample was low compared with other CM detection series[10-11].

Comparing our detection rates with the literature, we found some certainties better than the averages reported, like in duodenal atresia (100% vs. 50%)[12] and AVM (100% vs. 88.1%)[13], but there were few patients with each entity. Conversely, the detection rates were lower than those reported in ARM (6.7% vs. 87%)[14], esophageal atresia (16.7% vs. 31%)[5], jejunoileal atresia (0% vs. 50.1%)[15], abdominal wall defects (44.4% vs. 90%)[6,7], and diaphragmatic hernia (50% vs. 70%)[16]. Although there was statistical significance and a good effect size between the diagnostic accuracy of various pathologies or lack thereof (Table 4), these results may need to be revised, given the small number of cases, and a possible referral bias as our hospital is a tertiary-level national referral center.

In our country, government regulations on pregnancy care promote the prenatal detection of anomalies via a minimum of five consultations and at least one obstetric US per trimester[17]; in our study, 86.9% of women obtained a PUS during the second and third trimesters, and still, two-thirds of CM were undetected.

Although all of our patients had a CM, we found three statistically significant variables associated with an accurate prenatal diagnosis: when the pregnancies were followed by a gynecologist/obstetrician or FMS rather than a GP and also when the birth took place in tertiary care hospitals; more than a cause-effect we think that when a CM was detected, the patient was referred to tertiary care as previously reported[18,19]. The training level of the individual performing the PUS was another variable associated with diagnostic accuracy. The number of correct diagnoses increased if it was performed by an Ob-Gyn or MFS rather than an RX or GP; surprisingly, no GP with a US diplomate reached a single correct diagnosis, and radiologists were accurate in only 28.1% of cases. The size effect of this association was moderate (Cramer's $V = 0.440$).

Regarding the qualifications required by an individual that performs PUS to detect CM, Katerndahl stated 40 years ago that a "probable sonographer" must begin by clearly understanding longitudinal and transverse anatomy and possess the ability to modify the study *in situ*. At the time, the American College of Radiology proposed a short-term course for radiologists emphasizing the role of experience and the performance of many studies[20].

In 1999, Grandjean et al. reported a PUS sensitivity of 56.2% in the detection of CM, referring that the PUS had been performed by "qualified personnel, trained in

Table 3. Variables associated with prenatal accurate diagnosis

Variable	Sub variable	With prenatal diagnosis n (%)	Without prenatal diagnosis n (%)	p	Cramer's V
Training of who controlled the pregnancy	GP	11 (27.5)	29 (72.5)	0.047	0.307
	Ob-Gyn	11 (47.8)	12 (52.2)		
	MFS	2 (100)	0 (0)		
Training of who performed the PUS	GP with diplomate	0 (0)	9 (100)	0. 005	0.440
	Radiologist	9 (28.1)	23 (71.9)		
	Ob-Gyn	13 (54.2)	11 (45.8)		
	MFS	2 (100)	0 (0)		
Childbirth hospital level of care	Private hospital	2 (18.2)	9 (81.8)	< 0.001	0.644
	Secondary care public hospital	8 (19.5)	33 (80.5)		
	Third care public hospital	14 (93.3)	1 (6.7)		

GP: general practitioner, MFS: maternal-fetal medicine specialist, Ob-Gyn: obstetrician-gynecologist, PUS: prenatal ultrasound.

Table 4. Prenatal diagnosis related to each malformation

Variable	Sub variable	With prenatal diagnosis n (%)	Without prenatal diagnosis n (%)	p	Cramer's V
Congenital malformation	Duodenal atresia	3 (100)	0 (0)	0.005	0.648
	Hepatic hemangioendothelioma	1 (100)	0 (0)		
	Neck VM	2 (100)	0 (0)		
	Cloacal exstrophy	1 (100)	0 (0)		
	Abdominal wall VM	2 (100)	0 (0)		
	Intestinal atresia	0 (0)	3 (100)		
	SCT	0 (0)	1 (100)		
	Intestinal duplication	0 (0)	1 (100)		
	ARM	1 (6.7)	14 (93.3)		
	Esophageal atresia	2 (16.7)	10 (83.3)		
	Bochdalek hernia	4 (50)	4 (50)		
	Gastroschisis	6 (50)	6 (50)		
	Omphalocele	2 (33.3)	4 (66.7)		

ARM: anorectal malformation, SCT: sacrococcygeal teratoma, VM: vascular malformation.

high-quality equipment" without specifying what exactly they referred to[21].

In the first years of this century, reports on CM detection still failed to specify the sonographers´ training[22-26]. In 2010, the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) emphasized the need for specialized training in the practice of DUS in pregnancy and to establish the following qualifications: training in DUS and its related safety issues, regularly performing fetal ultrasounds and participating in continuous medical education activities[27-28].

In 2016, the American College of Obstetricians and Gynecologists and the American Institute of Ultrasound in Medicine established that the sonographers must be licensed in the practice of Medicine, understand the study´s indications, the complete obstetric US, and be familiar with the study's limitations[29].

In 2021, the Society of Radiographers in conjunction with the British Medical Ultrasound Society defined the "sonographer" as a healthcare professional possessing recognized qualifications in the medical US, capable in a competent manner, to perform the US within their field. The term "sonographer" instead of "ultrasound practitioner" refers to the lengthy training required for the professional certification to be protected under the law[30].

Our results show that, in our milieu, diplomate courses in the US for general physicians are useless in detecting CM in pregnancy. Government regulations are not always followed, and something must change for the diplomate courses to train adequately GPs in detecting CM or leave these specialized studies in the hands of more thoroughly trained personnel. It is pertinent to summon the directors of the medical schools/faculties so that they may implement the subject of ultrasound in their undergraduate training programs, as well as the councils and government agencies to review the current criteria to issue an ultrasound diplomate and certify sonographers.

One of our study´s strengths is its prospective data collection and its conduction in a national referral center. It is limited by the sample size and the fact that all patients harbor a CM, thus precluding the predictive values of PUS; the relation between the physician who followed the pregnancy and the individual who performed the PUS was not further investigated. A possible referral bias could explain the diagnostic accuracy in some pathologies. The study furthers the available information on individuals performing PUS training requirements.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. This study involved a retrospective review of medical records, for which approval was obtained from a formally constituted review board (Institutional Review Board or Institutional Ethics Committee).

Conflicts of interest

The authors declare no conflicts of interest.

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