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Original Article

Comparing the Characteristics of Neonates with False-Positive Congenital Hypothyroidism Screening Results with Affected Neonates

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Abstract

Background: Congenital hypothyroidism is one of the most common preventable causes of mental retardation. The present study aimed to compare the characteristics of neonates with false-positive congenital hypothyroidism screening test results with affected neonates in Kerman.

Methods: This cross-sectional study was conducted on neonates called to confirm congenital hypothyroidism from 2016 to 2017. The neonate characteristics (year and season of birth, sex, umbilical hernia, fontanelle conditions, constipation, jaundice, abnormalities, head circumference, height and weight at birth, gestational age, type of delivery, parental consanguinity, history of thyroid disease in the family, childbirth location, history of hospitalization, and place of residence) and maternal characteristics (age, number of deliveries, history of stillbirth, history of illness, and drug use during pregnancy) were extracted from their medical records. The collected data were analyzed with SPSS software (version 20) using the chi-square and independent samples *t* test.

Results: From a total of 985 neonates who had a positive screening test, congenital hypothyroidism was confirmed in only 58 neonates(5.9%), and the other 927 neonates(94.1%) only had a positive screening test. The neonates' and mothers' characteristics were not significantly different in the two groups, except for constipation, which had a higher frequency in the neonates with a positive congenital hypothyroidism screening results than in the affected neonates ($P=0.004$).

Conclusion: In this study, the characteristics of neonates who only had a positive hypothyroidism screening test result were not significantly different from those of the affected neonates. It is recommended that further studies be conducted over a longer period.

Keywords: Screening, Neonates, Congenital hypothyroidism

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Introduction

Congenital hypothyroidism is one of the most important problems in the health system, due to its high incidence and significant complications, including mental retardation. Congenital hypothyroidism can be easily identified through newborn screening tests. The congenital hypothyroidism screening program was integrated into Iran's health system in 2005 (1,2). Early diagnosis and treatment of congenital hypothyroidism prevents severe impairment of physical development and irreversible mental retardation (3,4).

The incidence rate of congenital hypothyroidism is estimated to be one in every three to four thousand births. This rate in Iran is higher than the global average (5,6). According to the national data obtained from newborn thyroid screening programs, the incidence rate in Iran is one per 1400 live births (7). Different prevalence rates of congenital hypothyroidism have been reported in domestic studies: one for every 293 live births in Kerman (3), one for every 313 live births in Fars Province from 2013 to 2016 (8), one for every 417 live births in Isfahan (9), one for every 542 live births in Gilan from 2006 to 2010 (10), and one for every 1250 live births in Hamedan from 2006 to 2013 (7).

Different risk factors are involved in the occurrence of congenital hypothyroidism. Baridkazemi et al showed that the season of birth (spring), place of residence (suburban and rural areas), hypertension, depression in the mother, and cousin marriage can be the main risk factors for congenital hypothyroidism. However, more studies are needed to confirm the findings of this study (11).

A study by Khanjani et al, using data from 2005 to

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2011 in Kerman Province, found no clear link between the incidence of congenital hypothyroidism and climatic factors in the province. However, the incidence rate was the highest in October (autumn) and the lowest in June (summer) (12).

Khammarnia et al found no significant relation between parental consanguinity, type of delivery, birth weight, height at birth, maternal age, sampling time, nationality, and season of birth and the risk of congenital hypothyroidism in Zahedan (13).

Rezaeian et al showed that twinning, birth season, term birth, jaundice at birth, birth weight, maternal age at the time of pregnancy, maternal anemia and goiter, gestational age, type of delivery, father's education and smoking status, and parental consanguinity are among the most important factors related to congenital hypothyroidism (14).

A review of the literature indicated most of the studies in Iran have addressed the prevalence of congenital hypothyroidism and its related factors. To the best of the researchers' knowledge, no study has compared the characteristics of neonates with false-positive congenital hypothyroidism screening test results with the infants whose hypothyroidism was confirmed according to the serum test. To this end, the present study aimed to compare the characteristics of neonates with false-positive congenital hypothyroidism screening test results with affected neonates from 2016 to 2017 in Kerman, Iran.

Methods

The present study was conducted using a cross-sectional (descriptive-analytical) research design. The research population consisted of all the neonates who were called from late March 2016 to December 2017 in Kerman for positive congenital hypothyroidism screening test results. The neonates were enrolled in the study by the census method. The criterion for inclusion in the study was positive congenital hypothyroidism screening test results in neonates, and the exclusion criteria were the unavailability of the required data in the neonate's medical records and the impossibility of contacting the parents to collect the data.

All called neonates are visited by a pediatrician who is focal point of the newborn screening program at Kerman University of Medical Sciences. Thus, the data about all these infants were recorded in their files. TSH, T4, and T3RU serum tests are performed for neonates with a positive screening test to confirm congenital hypothyroidism. Neonates with confirmed congenital hypothyroidism are treated with levothyroxine. In this study, the data related to the neonates who only had positive congenital hypothyroidism screening test results and the neonates who were diagnosed with the disease were extracted from their medical records and recorded in the data entry form for subsequent analysis.

The neonates' characteristics including the year, month, and season of birth, sex, fontanelle conditions, the presence of symptoms such as constipation, jaundice requiring phototherapy, umbilical hernia, the presence of abnormalities, head circumference, height and weight at birth, gestational age, type of delivery, parental consanguinity, history of thyroid disease in the family, place of delivery, hospitalization after birth, and place of residence, as well as the mother's characteristics including age, number of births, history of stillbirth, history of drug use during pregnancy, and history of illness during pregnancy were recorded.

The data collected in this study were analyzed with SPSS software (version 20) using descriptive statistics including mean, standard deviation, percentage, and frequencies, and inferential statistics including the Kolmogorov-Smirnov test, chi-square test, and independent samples t-test.

The protocol for this study was approved with the code of ethics IR.KMU.AH.REC.1398.104 in the organizational ethics committee of Kerman University of Medical Sciences. The data in this study were collected anonymously and strictly confidentially and were used only for research purposes.

Results

A total of 985 records of neonates with a positive screening test for congenital hypothyroidism were examined from 2016 to 2017. Of these, 927 neonates (94.1%) only had positive screening test results (no hypothyroidism) and 58 neonates (5.9%) had confirmed congenital hypothyroidism. Tables 1 and 2 shows the characteristics of the neonates in the two groups. As can be seen, the characteristics of the neonates in the two groups did not show a significant difference, except for constipation, which was significantly higher in the neonates with a positive screening test.

There was no significant difference between the two groups in terms of maternal characteristics. Specifically, the frequency of hypothyroidism in the mother ($P=0.68$) and the use of levothyroxine during pregnancy ($P=0.22$) were compared in the two study groups and there were no intergroup significant differences.

Discussion

The present study examined the screening data for all neonates admitted to the sampling centers of Kerman County for heel sampling from late March 2016 to December 2017. The results showed that 6% of neonates (5.6% in 2016 and 7.1% in 2017) who had positive screening test results, were treated with confirmation of congenital hypothyroidism. A study by Siami et al in Mazandaran province showed that 3.4% of 8438 neonates in the second call had congenital hypothyroidism,

Table 1. Comparing the neonatal and maternal characteristics in the two groups

Variable	Categories	False-positive hypothyroidism screening (%)	Congenital hypothyroidism (%)	*P* value
Year of birth	2016	517 (55.8)	29 (50.0)	0.70
	2017	410 (44.2)	29 (50.0)	
Gender	Female	383 (41.4)	20 (34.5)	0.30
	Male	544 (58.6)	38 (65.5)	
Season of birth	Spring	155 (16.8)	15 (25.8)	0.05
	Summer	231 (24.9)	13 (22.4)	
	Autumn	359 (38.7)	14 (24.1)	
	Winter	182 (19.6)	16 (27.6)	
Hospitalization	Yes	635 (68.5)	37 (63.8)	0.45
	No	292 (31.5)	21 (36.2)	
Type of delivery	Normal	451 (48.7)	34 (58.6)	0.14
	C-section	476 (51.3)	24 (41.4)	
Fontanelle conditions	Normal	912 (98.4)	56 (96.6)	0.30
	Abnormal	15 (1.6)	2 (3.4)	
Parental consanguinity	None	646 (69.7)	38 (65.5)	0.29
	3rd degree	40 (4.4)	5 (8.6)	
	4th degree	241 (25.9)	15 (25.9)	
Constipation	Yes	170 (18.3)	2 (3.4)	0.004
	No	757 (81.7)	56 (96.6)	
Umbilical hernia	No	885 (95.5)	57 (98.3)	0.31
	Yes	42 (4.5)	1 (1.7)	
Jaundice requiring phototherapy	Yes	280 (30.2)	16 (27.5)	0.73
	No	647 (69.8)	42 (72.5)	
Drug use during pregnancy	Yes	280 (34.3)	17 (29.3)	0.43
	No	609 (65.7)	41 (70.7)	
Maternal illness during pregnancy	Yes	346 (37.3)	17 (29.3)	0.23
	No	583 (62.7)	41 (70.7)	
Congenital abnormalities	Yes	16 (1.7)	2 (3.4)	0.17
	No	911 (98.3)	56 (96.6)	
Abortion/ stillbirth	Yes	30 (3.2)	1 (1.7)	0.16
	No	897 (96.8)	57 (98.3)	
Hypothyroidism in the family	1st degree	5 (0.5)	1 (1.7)	0.19
	2nd degree	90 (9.7)	1 (1.7)	
	3rd degree	8 (0.9)	-	
	4th degree	3 (0.3)	-	
	Non	821 (88.6)	56 (96.6)	

Table 2. Comparing pregnancy age, maternal age, and neonatal height, weight, and head circumference in the two groups

Variable	False-positive hypothyroidism screening (mean ± SD)	Congenital hypothyroidism (mean ± SD)	*P* value
Maternal age (y)	28.69 (5.68)	28.16 (6.48)	0.55
Gestational age (wk)	37.1 (2.5)	37.68 (2.9)	0.35
Birth weight (g)	2885.7 (674.5)	2986.7 (582.9)	0.26
Height at birth (cm)	48.7 (3.49)	49.1 (2.5)	0.63
Head circumference at birth (cm)	34.0 (1.8)	34.5 (1.7)	0.24

indicating a lower incidence rate than the rate reported in the present study (15). Another study by Akha et al in Mazandaran province showed 3.4% of neonates were diagnosed with congenital hypothyroidism (16). Mohammadi et al showed that 166 (9.8%) of 1689 neonates suspected of congenital hypothyroidism had the disease in Jiroft and Kerman counties in Kerman province (3). Similarly, the present study showed a higher frequency of congenital hypothyroidism among neonates. These findings seemed reasonable to some extent considering the higher prevalence of the disease in Kerman Province. Veisani et al did a systematic review and meta-analysis, and investigated the screening program in Iran. They stated that considering a cut-off point greater than or equal to 5 for TSH, which has a low positive predictive value, there is a need for further research to determine a more accurate level for calling neonates (2).

The present study showed that both positive screening cases and cases with confirmed congenital hypothyroidism were more common in male infants. However, there was no significant difference between the two genders. Hashemipour et al did a review study and investigated the risk factors for congenital hypothyroidism in newborns. The results indicated male gender was one of the risk factors for transient hypothyroidism and the female gender was one of the risk factors associated with consistent hypothyroidism associated with dysgenesis (17). Anastasovska et al showed that the risk of congenital hypothyroidism was higher in boys (18). The gender-related differences in the incidence of congenital hypothyroidism can be attributed to the role of sex hormones in this disease, probably providing a good basis for the occurrence of autoimmune disease and the provision of antigens necessary for the disease, as well as causing apoptosis in thyroid follicle cells (13).

Other risk factors for congenital hypothyroidism are delivery type and gestational age. The data in the present study did not show a significant difference between neonates with congenital hypothyroidism and those with false-positive results in terms of the type of delivery and gestational age. In a similar vein, Esmailnasab et al did not report any relation between the type of delivery and congenital hypothyroidism (19). However, Rezaeian et al and Masoomi Karimi et al showed that neonates born by cesarean have a higher risk of congenital hypothyroidism than neonates born normally. Some researchers believe that cesarean section can increase TSH levels. An increase in TSH levels can itself be a risk factor for congenital hypothyroidism (14,20).

Another risk factor for congenital hypothyroidism is parental consanguinity. The results of the present study did

not show a significant difference between cases diagnosed with congenital hypothyroidism and infants with positive screening test results in terms of parental consanguinity. A study by Dorreh et al in Markazi province from 2006 to 2012 did not show any significant relation between parental consanguinity and congenital hypothyroidism (21). On the contrary, a study in Shadgan, reported a significant relation between congenital hypothyroidism and parental consanguinity (22). Valizadeh et al showed that Iranian and Asian neonates are more at risk of congenital hypothyroidism than other ethnic groups. It is not clear why the Asian population is at higher risk of congenital hypothyroidism. One of the reasons can be due to a higher frequency of cousin marriages in these areas (23).

The mother's age at the time of childbirth has also been reported as one of the most important risk factors for congenital hypothyroidism. However, the data in the present study did not show a significant difference between cases with confirmed congenital hypothyroidism and infants with a positive screening test in terms of maternal age. Keshavarzian et al and Abedi et al found no relation between maternal age and congenital hypothyroidism (22,24). However, Rezaeian et al showed a significant relation between maternal age and congenital hypothyroidism (14). Moreover, Namakin et al showed that the mother's age under 35 years is a risk factor for congenital hypothyroidism (25).

The results of the present study did not show a significant difference between neonates with congenital hypothyroidism and neonates with positive screening test results in terms of height, weight, head circumference, and frequency of jaundice requiring phototherapy at birth. Dalili et al reported that low birth weight is more common in infants with congenital hypothyroidism (10). Abedi et al reported height and weight at birth were correlated with congenital hypothyroidism (24).

The season of birth has also been reported as a risk factor for congenital hypothyroidism. The present study did not show a significant difference between cases with congenital hypothyroidism and infants with positive screening test results in terms of the season of birth. Dalili et al and Keshavarzian et al have found seasonal changes to be effective in the occurrence of congenital hypothyroidism in Iran (10,22). The data in the present study showed that the frequency of constipation in neonates with congenital hypothyroidism was significantly lower than that of neonates with false-positive results. Previous studies in this field have only reported the prevalence of this condition and have not assessed it in healthy neonates and neonates with congenital hypothyroidism. Tahan et al investigated the complications of congenital hypothyroidism in a longitudinal study and reported constipation as one of the complications of this disease (26).

The present study found no significant difference between cases with congenital hypothyroidism and infants with a positive screening test in terms of the history of hospitalization after birth. In their study in southern Kerman, Amiri et al showed that the incidence of hypothyroidism was higher in infants admitted to the intensive care unit and premature infants (27). The present study assessed the history of hypothyroidism in other family members and found no significant difference between affected neonates and neonates with a positive screening test result. In their study in Iran, Taheri-Soodejani et al screened 5446 infants for congenital hypothyroidism from 2006 to 2014 and reported that 27% of the relatives of these infants were diagnosed with this disease, but found no statistically significant relation between the occurrence of congenital hypothyroidism and the history of the disease in family members (28).

The present study addressed other variables such as the mother's history of disease during pregnancy and the history of taking medication during pregnancy and found no significant difference between affected neonates and neonates with a positive screening test result for congenital hypothyroidism. Zhou et al found that thyroid disease or diabetes mellitus in the mother during pregnancy was associated with an increased risk of congenital hypothyroidism in China (29).

In the present study, there was no significant difference between affected neonates and neonates with a positive screening test result for congenital hypothyroidism in terms of umbilical hernia, fontanelle conditions, place of delivery, the number of births of the mother, and the history of stillbirth in the mother. However, many of these factors have not been addressed in similar studies.

One of the limitations of this study was that it was conducted on neonates in Kerman. Thus, its findings may have limited generalizability for other groups.

Conclusion

Most of the studies on congenital hypothyroidism in newborns have examined the characteristics of hypothyroid neonates. However, the present study compared the characteristics of neonates with false-positive congenital hypothyroidism test results with affected neonates. The results showed that the characteristics of these two groups were not significantly different, except for constipation, which had a higher frequency in neonates with positive screening test results. Future studies need to assess larger samples over a longer period. Furthermore, neonates with positive screening results should be followed up for a longer period.

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Authors' Contribution

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Competing Interests

The authors declared no conflict of interest.

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