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The incidence of cleft lip and/or palate among newborns in Lithuania, 1993–1997

Arûnas Vasiliauskas[1], Algirdas Utkus[2], Auðra Matulevièienë[2], Laura Linkevièienë[2,3], Vaidutis Kuèinskas[2]

[1] *Clinic of Orthodontics, Kaunas University of Medicine, J. Lukšos-Daumanto 6, Kaunas, Lithuania*
[2] *Department of Human and Medical Genetics, Vilnius University, Santariðkiø 2, Vilnius, Lithuania*
[3] *Institute of Odontology, Vilnius University, Vilnius, Lithuania*

Introduction. The clefts of lip, alveolar ridge and palate are the most common congenital anomalies in head and neck region. The incidence of cleft lip and/or palate nowadays is not falling and sometimes shows a tendency to an increase. There has not been any epidemiological survey on the incidence and distribution of cleft lip and/or palate over the last years in Lithuania. According to previous data, the cleft rate was 1 : 720–740 newborns. The aim of the survey was to establish the incidence rate of cleft lip and/or palate in Lithuania and in its separate regions during 1993–1997; to create a structural model registry and to perform a retrospective comparative analysis of lip and/or palate clefts.

Patients and methods. Material of the study was medical records of newborns with congenital cleft lip and/or palate, 1993 through 1997 and obtained from the Lithuanian Registry of Congenital Anomalies (LIRECA), Kaunas University of Medicine Clinic of Orthodontics and Clinic of Maxillo-facial and Oral Surgery, Institute of Odontology of Vilnius University, and Klaipëda City Center of Maxillo-facial Surgery. The aim of the study was to form a structural model registry of cleft lip and/or palate, to assess the incidence of cleft lip and/or palate in different regions of Lithuania and to perform a retrospective comparative analysis of cleft lip and/or palate incidence rates. Medical records of the total of 382 newborn with congenital cleft lip and/or palate, 1993–1997, were studied retrospectively. The type of cleft was classified according to Kernahan's, ICPRS and ICD-10 classifications. Additionally, syndromic clefts and lethality due to multiple congenital anomalies were assessed. Statistical analysis of the data was performed using the SYSTAT software package (license No. 41000 63920 82182 15191 00930 59324 71373 651).

Results. According to the data of the structural model registry of congenital cleft lip and/or palate for 1993 through 1997, the incidence of cleft lip and palate was 18.4 per 10 000, *i.e.* 1 : 544 live births. Due to improved diagnosis and registration of these anomalies the relative increase of syndromic cleft lip and/or palate cases in 1993 through 1997 made up 18.0% ($a = 0.05$; $b = 0.05$) as compared to the data of 1954 through 1964. According to the data on non-syndromic cleft lip and/or palate structural model registry in Lithuania, complete unilateral cleft lip and palate were found in 26.6% of all male newborns with cleft lip and/or palate, which exceeds that of female newborns with cleft lip and/or palate by 11.7% ($a = 0.05$; $b = 0.05$). Different regions of Lithuania were divided into four clusters, but due to a relatively small number of the observed cases incidence of cleft lip and/or palate cases per 1000 newborns in 1993 through 1997 did not differ statistically ($p > 0.05$) in the administrative regions of Lithuania.

Conclusions. The incidence rate of cleft lip and/or palate for 1000 livebirths in Lithuania during 1993–1997 was 1.84 (1 : 544 live births), and in separate regions of Lithuania the rate of clefts for 1000 live births was from 0.01 (Kelmë region) to 3.34 (Panevëþys region). Isolated lip and/or palate clefts formed 74.1% of all clefts. Syndromic clefts formed 25.9% of all clefts and comparing to the period 1953–1964 showed a statistically reliable increase owning to improved diagnostics and registration. Unilateral clefts of lip and/or palate are more frequent than bilateral, and the left unilateral cleft is more common than the right. The annual variation of cleft rate during the period 1993–1997 is statistically insignificant. The most common diagnoses were isolated palatal clefts forming 40.4% of all clefts and statistically reliably diagnosed more for female patients. Unilateral total upper lip, maxillary alveolus and palate cleft was diagnosed for 21.8% of all clefts and was statistically reliably more common for male newborns.

Key words: cleft lip and/or palate, registry, retrospective analysis

Address correspondence to: Prof. Vaidutis Kuèinskas, Department of Human and Medical Genetics, Vilnius University, Santariðkiø 2, LT-08661 Vilnius, Lithuania Tel.: +370-5 2365 195. Fax: +370-5 2365 199. E-mail: Vaidutis.Kucinskas@santa.lt

INTRODUCTION

Clefts of lip, alveolar ridge and palate are the most common congenital anomalies in the head and neck region. Because of the variety of cleft lip and/or

palate morphological and clinical aspects, it is difficult to apply a classification that could be suitable both for clinical use and statistical analysis (1, 2). The incidence of cleft lip and/or palate nowadays is not falling and sometimes shows a tendency to an increase. According to Scandinavian data, the increasing number of clefts is obvious (3, 4). Authors associate it with a decreased lethality of newborns, usage of teratogenic medicines during pregnancy, also with an increasing number of marriages between persons with clefts. Statistical data in Estonia also show that in the period from 1950 through 1980 the number of children with clefts relatively increased almost twice (5). Lately there is a discussion on the influence of statistical data concentration on the increasing number of clefts and data reliability in some registers (6–8). There were no epidemiological surveys on the incidence and distribution of cleft lip and/or palate over the last years in Lithuania. According to previous data, the cleft rate was 1 : 720–740 newborns (9, 10).

MATERIALS AND METHODS

The object of the study was data from LIRECA (Lithuanian Registry of Congenital Anomalies), questionnaires about congenital diseases and anomalies, also case-records from Kaunas Medical University departments of Orthodontics and Maxillofacial Surgery, Vilnius University Institute of Odontology and Klaipeda Hospital Centre of Maxillofacial Surgery of cleft patients born in 1992–1997 (total, 434 children).

The LIRECA contains records about stillborns, newborns, and children with developmental defects born in 1992 and later on. The data providers for LIRECA are Lithuanian health care specialists, who fill and send a special form to LIRECA after diagnosis of congenital diseases or anomalies. This form contains general data and special information on developmental defects, addictions, the course of pregnancy, previous gestations.

The aim of the survey was to establish the incidence rate of cleft lip and/or palate in Lithuania and in its separate regions during 1993–1997; to create a structural model registry and to perform a retrospective comparative analysis of lip and/or palate clefts.

Data on 434 children born in Lithuania during 1993–1997 were retrospectively analysed. Information was received from LIRECA and hospital registries. According to data found in these reports, the survey criteria were as follows:

– syndrome clefts and lethality of multiple developmental defects

– patients' sex and sex-related differences

– cleft type and cleft side (in case of unilateral cleft)

– cleft incidence and geographical distribution in different regions of Lithuania.

The clefts were divided according to Kernahan, ICPRS and International Statistical Classification of diseases and health problems (11–13). According to the affected structures and defect localisation, eight cleft types / groups were distinguished:

1. Bilateral total cleft lip, alveolar ridge and palate
2. Unilateral total cleft lip, alveolar ridge and palate (left or right side)
3. Unilateral partially cleft lip and palate (left or right side)
4. Unilateral cleft of lip and alveolar ridge (left or right side)
5. Bilateral cleft of lip and alveolar ridge
6. Bilateral cleft lip
7. Unilateral cleft of lip(left or right side)
8. Cleft of palate (soft or hard)

Syndrome clefts and lethality owning to multiple development defects were additionally evaluated.

The incidence of clefts during 1993–1997 was compared with epidemiological data of 1953–1964, and the relation of clefts spread in different periods of time in Lithuania was calculated. The data on the period 1953–1964 were collected from the archives of National Kaunas Clinical Hospital Departments of Dentistry (9).

The SYSTAT software was used for data statistical analysis, in which descriptive statistics was calculated, statistical hypotheses of differences between averages, frequencies and feature interdependence were evaluated. The calibre level of 0.5 was selected for statistical hypothesis verification.

To evaluate the output, the prospective groups n1, n2 and sort I mistake $\alpha = 0.05$ were included. If under such conditions the test output was higher than 0.8, it was maintained that sort II mistake $\alpha \leq \leq 0.2$ and the difference value was statistically reliable. The cluster analysis procedure was adjusted for dividing the regions according to the rate of cases for 1000 newborns and minimising one group dispersal and maximising scattering between the groups. The first step of this procedure was establishment of the optimal number of clusters (groups) according to the AIC (Akake's Information Criterion) criteria and the second was accomplishment of the classification.

RESULTS

The retrospective survey included 382 children born in Lithuania during 1993–1997 with the congenital cleft lip and/or palate. According to the data from

LIRECA's questionnaires, syndrome clefts and lethality from multiple developmental defects were evaluated. In Lithuania, in the period 1993–1997, 99 (25.9%) syndromic cleft lip/palate cases and 283 (74.1%) non-syndromic cleft lip and/or palate cases were registered. Table 1 shows lists the syndromic cleft lip and/or palate cases registered in Lithuania during 1993–1997.

According to data collected in 1953–1964 after examination of children with face clefts treated in Kaunas Clinical Hospital Dental Departments, syndromic cleft lip and/or palate cases with multiple developmental anomalies involved 56 (7.9%) of 713 children with cleft lip and/or palate.

In the period 1993–1997, 47 (12.3%) newborns with cleft lip and/or palate died and in 46 cases of 47 the clefts were syndromic with multiple congenital anomalies.

The lethality rate of clefts was 77 cases (10.8%) in 1954–1963. There was no statistical difference ($p = 0.47$) in lethal cases between data of 1953–1964 and 1993–1997.

In Lithuania, during 1993–1997, 207913 children were born (101115 (48.6%) female and 106798 (51.4%) male). The male to female proportion was 1.06:1.0. From cleft patients examined in 1993–1997, 162 (42.2%) were female and 220 (57.6%) male. The male to female proportion is 1.36 : 1.0. Respectively, in 1993 –1997 the cleft rate of male for 1000 newborns was 2.07 and madea 1 : 483 proportion with all male newborns. The cleft rate in females for 1000 newborns was 1.6 (1:625 cleft proportion to the total female newborns).

The nature of cleft was defined for 358 patients with cleft lip and/or palate born in 1993–1997, from which 155 were female and 203 male (Table 2).

Isolated palate clefts of various extent were most common in the group of patients with cleft lip and/or palate. Clefts of hard and / or soft palate in Lithuania during 1993–1997 formed a number of 145 (40.5%) patients, from which 71 (48.9%) were female and 74 (51.1%) male. Isolated palate cleft was diagnosed statistically reliably more frequently for female ($p = 0.048$) and made 45.8% of all female clefts. Unilateral total upper lip cleft, maxillary alveolar ridge and palatal cleft was diagnosed statistically more frequent – 11.7% ($\alpha = 0.05$; $\beta = = 0.15$) for male with cleft lip and/or palate and

Table 1. **Syndromic clefts according to LIRECA database, 1993–1997**

Syndrome	Code (ICD-10)	Number of patients
Pierre Robin sequence	Q87.0	13
Goldenhar syndrome	Q87.0	1
Orofaciodigital syndrome (I and II types)	Q87.0	2
Apert syndrome	Q87.0	1
Rubinstein Taybi syndrome	Q87.2	1
Frontonasal syndrome	Q87.7	1
Unusual face and femoral hypoplasia syndrome	Q89.7	1
Multiple congenital anomalies with clefts	Q98.7	65
Patau syndrome	Q91.7	6
Edwards syndrome	Q91.0	1
Partial trisomy	Q99.8	1
Klippel Feil syndrome	Q76.1	1
Proboscis	Q30.8	1
Amniotic amputations syndrome	Q79.8	1
Holoprosencephaly	Q04.2	3
Total		99

Table 2. **Distribution of non-syndromic cleft types by sex and location, 1993–1997**

Cleft type	Female	%	Male	%	Total	Total %
Bilateral total cleft lip, maxillary alveolus and palate	15	9.7	18	8.9	33	9.2
Unilateral total cleft lip, maxillary alveolus and palate	24	15.4	54	26.6	78	21.8
Unilateral partial cleft lip and palate	3	1.9	6	3.0	9	2.5
Unilateral cleft lip and maxillary alveolus	12	7.7	9	4.4	21	5.9
Bilateral cleft lip and maxillary alveolus	3	1.9	4	2.0	7	2.0
Bilateral cleft lip	4	2.6	2	1.0	6	1.7
Unilateral cleft lip	23	14.8	36	17.7	59	16.5
Cleft palate	71	45.8	74	36.6	145	40.4
Total	155	43.3	203	56.7	358	100.0

Table 3. **Distribution of non-syndromic cleft types, 1993–1997**

Cleft type	Number of clefts	%
Cleft lip and palate (Q37)	120	33.5
Cleft lip (Q36)	93	26.1
Cleft palate (Q35)	145	40.4

was 26.6% of all male newborns with cleft. The structural model of non-syndromic clefts in Lithuania during 1993–1997 is presented in Table 3.

Table 4 shows the distribution of non-syndromic clefts according to sex.

Unilateral clefts are more frequent than bilateral (3.5:1.0). In cases of unilateral cleft of lip and/or palate, the left unilateral defect is more frequent than the right one (2.2 : 1.0, p < < 0.05) irrespective of sex (Table 5).

Table 4. **Sex distribution of non-syndromic cleft types, 1993–1997**

Cleft type	Male (%)	Female (%)
Cleft lip and palate	38.5	27.1
Cleft lip	25.0	27.1
Cleft palate	36.5	45.8

Table 5. **Laterality pattern of non-syndromic clefts, 1993–1997**

Cleft type	%
Bilateral cleft lip and/or palate	22.0
Right cleft lip and/or palate	24.0
Left cleft lip and/or palate	54.0

Table 6. **Incidence of cleft lip and/or palate per 1000 live births in Lithuania, 1993–1997 (Confidence Intervals (CI) 95%)**

Years of birth	Number of clefts	Number of births	Incidence per 1000 live births (CI 95%)	Ratio to live births
1993	86	47 464	1.81 (1.43–2.12)	1:552
1994	94	42 376	2.22 (1.77–2.67)	1:451
1995	67	41 195	1.63 (1.24–2.02)	1:615
1996	56	39 066	1.43 (1.06–1.81)	1:698
1997	79	37 812	2.09 (1.63–2.09)	1:479
Total	382	207 913	1.84 (1.65–2.02)	1:544

χ^2 = 9.118; d.f. = 4; p = 0.058.

Table 7. **Incidence of clefts per 1000 live births in the districts of Lithuania, 1993–1997**

District	Number of clefts	Incidence of clefts per 1000 live birth
Alytus	12	1.02
Kaunas	78	1.83
Klaipëda	54	2.28
Marijampolë	29	2.33
Panevëþys	36	1.95
Šiauliai	26	1.10
Tauragë	14	1.67
Telšiai	24	1.98
Utena	18	1.79
Vilnius	74	1.65

The obtained data show that the annual variation of cleft rate is statistically insignificant (p > 0.05). Data are presented in Table 6.

The rate of lip and/or palate clefts in different districts of Lithuania during 1993–1997 is presented in Table 7. The 44 regions and 5 largest cities of Lithuania were divided into 4 groups according to the results of cluster analysis of cleft rate for 1000 newborns. Data are presented in Table 8.

DISCUSSION

Data of our study showed that the structure of syndromic and non- syndromic cleft lip and/or palate is similar if compared with other populations (14). Comparing syndromic and non-syndromic clefts of lip and/or palate in Lithuania during 1993–1997 with the data of the period 1953–

Table 8. **Mean values for cleft incidence per 1000 live births**

Cluster No.	Mean value	Standard error	Number of regions and cities	%
1	0.475	0.10	6 (Skuodas, Kelmë, Jurbarkas, Trakai, Varëna Lazdijai regions)	12.2
2	1.295	0.05	17 (Alytus, Kaiðiadorys, Utena, Rokiðkis, Kupiðkis, Pasvalys, Pakruojis, Joniðkis, Ðiauliai, Akmenë, Plungë, Klaipëda, Tauragë, Radviliðkis regions and Vilnius city, Kaunas city, Šiauliai city)	34.7
3	2.154	0.15	19 (Maþeikiai, Telðiai, Birþai, Zarasai, Ignalina, Ðvenèionys, Molëtai, Anykðèiai, Ðirvintos, Jonava, Këdainiai, Raseiniai, Ðakiai, Kaunas, Prienai, Marijampolë, Ðalèininkai regions and Klaipëda city, Panevëþys city)	38.8
4	2.97	0.30	7 (Kretinga, Ðilutë, Ðilalë, Panevëþys, Ukmergë, Vilkaviðkis, Vilnius regions)	14.3

(α < 0.001; β < 0.001)

1964, we established a comparative statistically reliable increase of syndromic cleft lip/palate to 18.1% (α = 0.05; β = 0.05), which can be explained by the improved diagnostics and more precise registration of such cases over the last years.

We defined a statistically reliable difference between all newborns of the same sex and children with cleft lip and/or palate while comparing differences between sexes of all newborns and children with cleft lip and/or palate in the study period.

If we compare the results with data from the period 1953–1964, we can see the same tendency. In 1953–1964 in Kaunas Clinical Hospital the overall birth rate was 26644 newborns, from which 36 were with cleft lip and/or palate; the cleft incidence proportion to all newborns was 1 : 740 and matched a 1.35 cleft incidence for 1000 newborns. Our data show that during 1993–1997 382 children with clefts were born. This formed a 1: 544 cleft proportion and the cleft incidence was 1.84 per 1000 newborns. Our results showed no statistically reliable difference from 1953–1964 data (p = 0.064), but we can see a tendency to an increase of cleft incidence rate for 1000 newborns. It can be explained by a more accurate registration of cleft cases in recent years.

The absolute number of new clefts per year is dependent on overall birth rate, which during the study period (1993–1997) decreased from 47464 in 1993 to 37812 in 1997.

In 1993–1997, the rate of clefts in the regions and largest cities of Lithuania showed no statistical difference (p > 0.05).

The findings of the study are important for the epidemiology of clefts, planning health care strategies and for monitoring the risk groups and their environment.

CONCLUSIONS

1. The incidence rate of cleft lip and/or palate for 1000 livebirths in Lithuania during 1993–1997 was 1.84 (1 : 544 live births).

2. In separate regions of Lithuania the rate of clefts for 1000 live births in 1993–1997 was from 0.01 (Kelmë region) to 3.34 (Panevëþys region).

3. Isolated lip and/or palate clefts comprised 74.1% of all clefts.

4. Syndromic clefts comprised 25.9% of all clefts, and comparing to the period 1953–1964 a statistically reliable increase of 18.1% (α = 0.05; β = = 0.05) can be explained by improved diagnostics and registration.

5. Unilateral clefts of lip and/or palate 3.5 times are more frequent than bilateral clefts; the left unilateral cleft is 2.2 times more common than the right side.

6. The annual variation of cleft rate during the period 1993–1997 is statistically insignificant (p > > 0.05)

7. In 1993–1997, the most common diagnoses were isolated palatal clefts, which comprised 40.4% of all clefts and were statistically reliably more frequent in female patients (p = 0.048). Unilateral total upper lip, maxillary alveolus and palate cleft was diagnosed for 21.8% of all clefts and was statistically reliably more frewuent for male newborns (α = 0.05; β = 0.05).

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A. Vasiliauskas, A. Utkus, A. Matulevièienë, L. Linkevièienë, V. Kuèinskas

LÛPOS IR (AR) GOMURIO NESUAUGIMØ DAÞNUMAS LIETUVOS NAUJAGIMIØ GRUPËJE 1993–1997 METAIS

S a n t r a u k a

Ávadas. Ágimti lûpos, alveolinës ataugos ir gomurio nesuaugimai yra daþniausia galvos ir kaklo srities anomalija. Lûpos ir (ar) gomurio nesuaugimø daþnumas ávairiose populiacijose nemaþëja, o kartais net didëja. Pastaraisiais metais Lietuvoje nebuvo epidemiologiniø tyrimø, ávertinanèiø lûpos ir (ar) gomurio nesuaugimø daþnumà ir paplitimà. Ankstesniø metø tyrimais, lûpos ir (ar) gomurio nesuaugimø atvejø buvo vienas ið 720–740 naujagimiø. Darbo tikslas – nustatyti naujagimiø lûpos ir (ar) gomurio nesuaugimø daþnumà visoje Lietuvoje ir atskiruose Lietuvos rajonuose 1993–1997 m., sudaryti struktûriná modeliná registrà ir atlikti retrospektyvinæ palyginamàjà analizæ.

Pacientai ir metodai. Tyrimo medþiagà sudarë LIRECA (Lietuvos paveldimø ligø ir ágimtø raidos anomalijø registras) duomenø bazës anketos, Kauno medicinos universiteto Ortodontijos klinikos, Veido ir þandikauliø chirurgijos klinikos, Vilniaus universiteto ligoninës Þalgirio klinikos ir Klaipëdos miesto ligoninës Veido-þandikauliø centro pacientø, gimusiø 1992–1997 m., ligos istorijos. Vertinant nesuaugimø pobûdá, jie suskirstyti pagal Kernahan, ICPRS ir TLK-10 klasifikacijas. Statistikos analizei naudota licencijuota SYSTAT programa.

Rezultatai. Retrospektyviai buvo iðnagrinëti 434 vaikø, gimusiø Lietuvoje 1993–1997 m. su ágimtu lûpos ir/ar gomurio nesuaugimu (L/Gn), anketø duomenys ir ligos istorijø áraðai. Nustatyta, kad L/Gn daþnumas Lietuvoje 1993–1997 m. 1000-iui gyvagimiø buvo 1,84 (1 ið 544 gyvagimiø). Izoliuoti L/Gn sudarë 74,1%, o sindrominiai – 25,9% visø nesuaugimø atvejø. Pagerëjus diagnostikai ir registracijai sindrominiø L/Gn, lyginant su 1953–1964 m., padaþnëjo 18,1%. Kasmetiniai L/Gn svyravimai 1993–1997 m. statistiðkai nereikðmingi. 1993–1997 m. daþniausiai diagnozuotas gomurio nesuaugimas, (40,5% visø nesuaugimø) statistiðkai patikimai daþniau nustatytas moteriðkos lyties naujagimiams. Vienpusis visiðkas virðutinës lûpos, virðutinio þandikaulio ataugos ir gomurio nesuaugimas diagnozuotas 21,8% visø nesuaugimø ir statistiðkai patikimai daþniau nustatytas vyriðkos lyties naujagimiams.

Iðvados. Lûpos ir (ar) gomurio nesuaugimø daþnumas Lietuvoje 1000-iui gyvagimiø 1993–1997 m. buvo 1,84 (1 ið 544 gyvagimiø) ir atskiruose rajonuose buvo skirtingas, taèiau statistiðkai nepatikimas. Izoliuoti lûpos ir (ar) gomurio nesuaugimai sudarë 74,1% visø nesuaugimø atvejø. Sindrominiai lûpos ir (ar) gomurio nesuaugimai sudarë 25,9% visø nesuaugimø atvejø ir, lyginant su 1953–1964 m., statistiðkai reikðmingai padidëjo dël pagerëjusios diagnostikos ir registracijos. Vienpusiai lûpos ir (ar) gomurio nesuaugimai daþnesni uþ abipusius nesuaugimus, o kairës pusës nesuaugimas daþnesnis uþ deðinës. Kasmetiniai lûpos ir (ar) gomurio nesuaugimai 1993–1997 m. statistiškai nereikšmingi. Daþniausiai diagnozuoti izoliuoti gomurio nesuaugimai statistiškai patikimai daþniau nustatyti moteriškos lyties naujagimiams. Vienpusis visiðkas virðutinës lûpos, virðutinio þandikaulio ir gomurio nesuaugimas diagnozuotas 21,8% visø nesuaugimø ir statistiðkai patikimai daþniau nustatytas vyriðkos lyties naujagimiams.

Raktaþodþiai: lûpos ir (ar) gomurio nesuaugimas, registras, retrospektyvi analizë