INTRODUCTION

Cleft lip and palate are the most common congenital malformations in the head and neck throughout the world. Surgical techniques for the appropriate treatment of cleft lip and palate have developed very rapidly, but the epidemiologic study for prevention remains in its infancy. Both genetic and environmental influences are believed to cause cleft lip and palate (1-3). Many authors have investigated the epidemiology and etiologic factors of cleft lip and palate. Though several investigations have been performed in Korea, the epidemiologic studies of cleft lip and palate have been based on only one or a few hospitals (4-8). Hence, the previous data do not represent the nationwide epidemiologic status in Korea. Since 1989, National Federation of Medical Insurance (N FMI) system has been operative in Korea. A nationwide investigation of the prevalences of other congenital malformations was performed with using this medical insurance data (9). Therefore assuming that the N FMI’s data has about 80% accuracy, we used the following method to decide the sample size to study the validity, and to get precise information from medical records. We wanted to estimate validity with 95% confidence interval.

MATERIALS AND METHODS

We could obtain the annual birth rates and the number of the babies with cleft lip and palate from the N FMI in Korea from January 1, 1993 through December 31, 1993. In 1993, the number of total live births was 715,817. And from 1993 through 1995, a total of 1,293 new patients with cleft lip and palate who were born in 1993 were identified. The incidence of cleft lip and palate was 1.81 per 1000, that is, 1 per 554 live births. The cleft lip: cleft lip and palate: cleft palate alone ratio was 1.13:1:1.19. The male: female ratio was 2.1:1 in the cleft lip group, and 2.5:1 in the cleft lip and palate group. We could detect a male predominance in both groups. In contrast, the ratio was 0.95:1 in the cleft palate group. The left: right: bilateral ratio was 1.9:1:0.23 in cleft lip group, and the ratio was 2.2:1:1.1 in the cleft lip and palate group. This is the first nation-wide study to provide detailed data on the incidence of cleft lip and palate in the live births in the Republic of Korea.

Key Words : Cleft Lip; Cleft Palate; Incidence; Korea; Epidemiology
50 S. Kim, W.J. Kim, C. Oh, et al.

allowing 5% measured error (d=0.05). We knew that estimated $P^*$ is about 0.8 based on the previous studies (Rue 2000, Lee 1994). Using following sample size equation $N > P^* (1-P^*) \frac{Z^2}{d^2}$ ($Z=$cumulative normal distribution), we concluded that more than 256 cases were required to satisfy the condition. So we visited 9 hospitals from all over the country and reviewed 351 candidate cases of cleft lip and palate who were born in 1993 by cluster random sampling. We found that only 299 babies were compatible with the diagnosis of cleft lip and palate. Therefore the validity of the NFMI’s cleft lip and palate data was estimated to be 85%. So we estimated that 1,293 babies (85% of the 1,526 babies who were born in 1993 and diagnosed with cleft lip and palate in their first 3 yr of age) had cleft lip and palate. Then the patients were subdivided as having cleft lip, cleft lip and palate, and cleft palate. The incidence, sexual ratio, laterality pattern, family history, and associated anomalies and syndromes were investigated.

RESULTS

According to the data from NFMI, the number of total live births in 1993 was 715,817. And we identified 1,293 new patients with cleft lip and palate who were born in 1993 during the period from 1993 to 1995. So the overall incidence of cleft lip and palate was 1.81 per 1,000, that is, 1 per 554 live births. In Korea, previous investigations reported that the incidence of cleft lip and palate was from 1.16 to 1.77 per 1000 (4-8). These studies were based on a few hospitals or limited area except Min’s reports which was not based on all live births in one year but cumulative live births data from 1984 to 1994 (5).

Also we could get more detailed epidemiologic information through a supplementary inspection of the selected medical records (299 patients) among the newly identified 1,293 cases with cleft lip and palate.

Among the 299 cases, there were 102 cases of cleft lip, 90 cases of cleft lip and palate, and 107 cases of cleft palate (Table 2). The male: female ratio was 2.1:1 in the cleft lip group, and was 2.5:1 in the cleft lip and palate group. In contrast, the ratio was 0.95:1 in the cleft palate group (Table 3). We also observed that the unilateral cleft lip occurred more frequently on the left side than on the right side in both cleft lip only and cleft lip and palate group. Bilateral cleft cases were more frequent in the cleft lip and palate group than in the cleft lip only group (Table 4). The family history of cleft lip and palate was detected in 21 out of 299 cases. The frequency of positive family history was higher in the cleft lip group than in the other groups (Table 5).

In this study, we included the cases of cleft lip and palate in association with other anomalies and recognized syndromes. A total of 25 out of 299 (8.4%) cases of cleft lip and palate were associated with other anomalies. Congenital heart dis-

| Table 1. The chronological distribution of the cases of cleft lip and palate |
|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Birth year | 1991 | 1992 | 1993 | 1994 | 1995 | Total |
|-------------|-----|-----|-----|-----|-----|-------|
| 1991 | 244 | 217 | 290 | 118 | 68 | 937 |
| 1992 | 0 | 429 | 554 | 204 | 39 | 1,226 |
| 1993 | 0 | 0 | 841 | 543 | 142 | 1,526 |
| 1994 | 0 | 0 | 0 | 895 | 457 | 1,352 |
| 1995 | 0 | 0 | 0 | 0 | 710 | 710 |

| Table 2. The distribution of the cleft types |
|------------------------|------------------------|------------------------|------------------------|------------------------|
| Type | Frequency | Percent |
| Cleft lip | 102 | 34.1 |
| Cleft lip and palate | 90 | 30.1 |
| Cleft palate | 107 | 35.8 |
| Total | 299 | 100 |

| Table 3. Sexual distribution |
|------------------------|------------------------|------------------------|------------------------|
| Male | Frequency | Percent | Female | Frequency | Percent |
| Cleft lip | 69 | 67.7 | 33 | 32.3 |
| Cleft lip and palate | 64 | 71.1 | 26 | 28.9 |
| Cleft palate | 52 | 48.6 | 55 | 51.4 |

| Table 4. Laterality pattern of the cleft deformities |
|------------------------|------------------------|------------------------|------------------------|------------------------|
| Type | Frequency | Percent |
| Cleft lip | 60 | (58.8%) |
| Cleft lip and palate | 42 | (46.7%) |
| Cleft palate | 19 | (21.1%) |

| Table 5. The frequency of positive family history |
|------------------------|------------------------|------------------------|
| Case | Percent |
| Cleft lip | 11/102 | 10.8 |
| Cleft lip and palate | 6/90 | 6.7 |
| Cleft palate | 4/107 | 3.7 |
| Total | 21/299 | 7 |

| Table 6. Associated anomalies |
|------------------------|------------------------|------------------------|
| Anomalies | Frequency | Percent |
| Congenital heart disease | 16 | 5.4 |
| Short frenulum | 5 | 1.7 |
| Hernia | 1 | 0.3 |
| Accessary ear lobe | 1 | 0.3 |
| Congenital megacolon | 1 | 0.3 |
| Extremity malformation | 1 | 0.3 |
| None | 274 | 91.6 |
Cleft lip and palate incidence in the Republic of Korea

Cleft lip and palate incidence in Korea might be the result of different genetic background. It is rather higher than in other Asian countries, especially the neighboring country,Japan. N aume reported the incidence of cleft lip and palate among Japanese people as 1.65 per 1000, or 1 out of 607.6 newborns (15).

The review by Apostole suggests that the incidence of cleft lip and palate differs among races (16). The American Indians showed the highest values followed by the Japanese, the Maoris, and the Chinese. The Whites showed lower values and the Blacks the lowest values. The incidence of cleft lip and palate in Korea may be ranked between the American Indians and Japanese.

In conclusion, from the nationwide epidemiologic study in 1993, we could determine the incidence of cleft lip and palate in the Republic of Korea as 1.81 per 1000 or 1 out of 554 live births. Genetic influence was suggested as an etiology of the relatively high ratio of cleft palate in the Republic of Korea, and this needs to be verified by a further prospective epidemiologic study.

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