Original Article

Evaluating the Feasibility of Clinical Studies on Cleft Lip and Palate Patients Based on the Hospital Records

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ABSTRACT

Background: Policy makers, researchers and health care professionals are faced daily with the challenge of how to prioritize their activities and actions in different areas of their responsibilities. In the field of health, their decisions are often influenced by the reality of population needs on the one hand and limited resources on the other. The correctness of decisions is completely dependent on the quality and accuracy of information from the target population. Patient registries, have for decades been an important source of data needed to evaluate clinical practice, evaluate health service delivery, and assess policy implications at the local, regional, national, and international levels.

Method: Based on the research objectives, fourteen registration forms consisting of 790 variables were designed. The data of cleft lip and palate patients who underwent surgery in Hazrat Fatemeh Hospital during the year 2022, in Tehran, Iran, were collected and entered into the registration system, and then the amount of recorded data was assessed based on the research objectives.

Results: Only 28% of the data of cleft lip and palate patients were recorded in the clinical files during their hospital stay, and 72% of the required data are not recorded. However, the accuracy of the recorded data and their validity has not been evaluated.

Conclusion: In order to obtain the necessary data for the designed objectives, the data recorded in the hospital are not sufficient and accurate, and a registry is needed to record accurately the data of cleft lip and palate patients.

KEYWORDS
Registry; Cleft lip; Cleft palate

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INTRODUCTION

Cleft lip and palate is one of the most common congenital malformations of the skull, jaw, and face, which is caused by a disturbance in the embryonic development of soft and hard tissues around the oral cavity and facial area[1,2]. cleft palate and lip are congenital defects that affect the upper lip and the roof of the mouth. In addition, they happen when the tissue that forms the roof of the mouth and the upper lip does not join before birth. This problem can range from a small fissure in the lip to a groove that goes

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to the roof of the mouth and nose. A cleft can affect a child's appearance. It can also lead to problems eating, speaking, and ear infections [3]. The rate of oral cleft (OFC) in Western society is usually about 1 in 700 live births (1.4 per 1000 live births)[1]. A study of 30 European registration programs has shown that this varies both within and between countries with a reported average of 1.52 per 1,000 live births. However, a range from 0.63 in Valles, Spain to the highest percentage of 2.62 in Finland has been reported[4]. The incidence of this abnormality varies from one in five hundred births to one in a thousand births depending on the geographical location and ethnic characteristics of people[1].

The cause of cleft lip and palate is not fully known, but researchers believe that these defects occur due to both genetic and environmental factors[1]. In addition, various environmental factors during pregnancy can increase the probability that the child will have a cleft palate or lip. Factors that researchers believe may cause clefts include: smoking, drinking alcohol, drug use, diabetes, not getting enough prenatal vitamins such as folic acid, etc[4,5].

A disease registry system (DRS) is a system that collects standardized data about a specific disease in an organized manner for specific purposes in a specific population. These systems are important for various clinical and health research purposes. DRSs may be clinical-based, used to evaluate health care or population-based, to estimate incidence and prevalence. These systems can generally be used to monitor the quality of care and provide relevant feedback, describe treatment plans, observe the natural course of diseases, monitor clinical safety, assess disease burden, health outcomes, and costs of diseases[6].

A registry system plays an effective role in diagnosing and measuring the prevalence of a specific disease or a health event in the society and enables the health system to monitor the quality of health services provided, better and more effective. The registry system also provides a suitable source for diagnosing patients in order to conduct subsequent research studies such as cohort studies and clinical trials. Programs for registering diseases and health consequences can play an important role in solving health problems and produce the necessary evidence for the decisions of managers and various stakeholders; on the other hand, the role of these programs in the development of a database and clinical science researches is undeniable[6].

With the aim of better treatment and managing this disease, it seems necessary to create a registration system for patients referring to Hazrat Fatemeh Hospital as the main center for cleft lip and palate in the Iran. Therefore, this study was carried out as the first stage of designing a registry program for cleft lip and palate patients in Hazrat Fateme Plastic Surgery Hospital in Tehran, Iran.

METHODS

The clinical and research goals of the hospital were presented as proposals based on the priorities of the center and trending in the field of cleft lip and palate including:

1. Relationship between the age of parents at the time of pregnancy and the incidence of cleft lip and palate abnormality
2. The relationship between medication and diseases during pregnancy and cleft lip and palate abnormalities
3. The Relationship between Smoking and Alcohol Consumption in Parents and Cleft Lip and Palate
4. The Role of Geographic and ethnic Differences in Cleft Lip and Palate
5. Finding relationship between the type of surgical repair and clinical and speech outcomes
6. Finding the appropriate surgical technique by studying clinical and speech outcomes
7. Study of complications including fistula and its relationship with surgical technique
8. The effect of Aloderm on improving the treatment outcomes of fistula
9. The effect of topical drugs on bleeding during surgery

Based on them, 14 forms including 790 variables were designed by the surgical, orthodontic and speech therapy groups, and then, for ease of data recording, the forms were designed on web and patient data was entered into the registry system.

In order to conduct the study, first, list of the all cleft patients of Hazrat Fatemeh Hospital who underwent surgery in 2021 were taken from the medical records unit, which included 69 cleft palate patients and 109 cleft lip patients. The scanned images of the files including all pages of the file, studied, and the required data based on the previously designed forms were entered from the files into the registration system.

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Data from the first page of the files including age, province of residence, gender, date of birth and surgery, were entered in forms. In the history sheet, data related to the disease, patient history, medications. The presence of the disease in the family, the complaints and problems of the patient, the presence of other diseases and accompanying syndromes, as well as the habit history of the parents such as alcohol and smoking were searched and recorded if any. The operation notes, which contains the surgical information and the type of surgical technique, was also studied. The surgical technique was recorded in the system if it was mentioned, and if the name of the technique was not mentioned, the type of surgical technique was determined and recorded by studying the operation note.

In order to check the complications, the course sheet of the files studied, and the complications after surgery, if any, were recorded.

The age of the patient during the surgery was determined by determining the difference between the date of birth and the date of surgery and was recorded in the system.

If the data was recorded in the clinical files, it was registered, and if the data required in the forms, was not present in the file, the answer field was left blank. Finally, after recording the existing data of these patients in the hospital files, Excel output was taken from all the forms and after sorting the data, it was entered into the SPSS version 27 (IBM Corp., Armonk, NY, USA) and analyzed.

RESULTS

After exclusion of unrelated files, which were grouped as cleft patient, hospital files of 91 patients (42 and 49 cleft lip and cleft palate respectively) included to be studied and registered into the web-based forms.

The average age of cleft lip patients, including children and adults with incomplete clefts who referred for treatment late in life, was 30 months and after excluding 10 patients older than 2 years, the average age of patients was 4.7 months. There were 20 patients with left side cleft, 14 patients with right cleft, two patients with bilateral cleft, two patients with unilateral cleft without mentioning the affected side, one case with cleft without mentioning its type and one case with cleft number 7.

Sixty seven percent of cleft lip patients were girls and thirty three percent were boys. Sixty percent of patients referred to Hazrat Fatemeh Hospital were residents of Tehran and Alborz provinces and forty percent of patients were residents of other cities.

The technique used in repairing the cleft lip was obtained by studying the operation notes. Nineteen patients underwent Millard technique and 5 underwent rotation advancement flap surgery, while the surgical technique of the remaining 18 patients was not mentioned.

In 1401, 49 cleft palate patients underwent surgery, including 22 primary cleft palate patients, twenty-six palatal fistula patients, and one VPI patient. The average age of cleft palate and palatal fistula patients is 3.6 years and 17.2 years, respectively. Forty nine percent of cleft palate patients were female and 51% were male.

The most common technique used in these patients was two flaps, which was used in 55% of primary cleft palate patients. In 36% of patients (8 primary cleft palate patients), Ventilation Tube (VT) implantation was done at the same surgery.

The amount of recorded data was evaluated based on the designed forms; the patients' file records only 28% of the required data, and 72% of the data related to disease and surgery is not recorded. Above-mentioned information is all that could be obtained from studying clinical records in hospital.

It was Impossible to evaluate effectiveness of treatments, frequency of complications, speech outcomes, etiologies and risk factors because of lack of data on hospital files.

DISCUSSION

Cleft lip and palate is a global problem and approximately every 3 minutes a child is born with some form of cleft lip. In the world, more than 10 million lives are affected by this anomaly[7]. The cause of the cleft is unknown. There is well-known racial and geographic variation and associations with environmental exposures and socioeconomic status[7].

Oral clefts can be divided according to phenotype into cleft lip (CL), with and without cleft palate, and these clefts may be complete or incomplete, unilateral (UCLP) or bilateral (BCLP)[7]. Cleft palate (CPO) can also occur in isolation. The frequency of these phenotypes varies by population, highlighting the importance of registration and surveillance

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as these studies may provide epidemiologic and genetic clues to find the cause[8].

The United Kingdom is currently conducting one of the largest registry projects for cleft lip and palate patients, during which, in addition to recording surgical, speech and psychological data, blood samples and the child and parents' saliva is collected for genetic testing[9].

Cleft is a debilitating abnormality that affects almost all aspects of the patient's life, and need for finding appropriate algorithms to the treatment of these patients, increases the importance of registering these patients[10,11].

A study was conducted to investigate the coverage of the cleft lip and palate patient registry plan in Sweden and based on the data recorded in the Swedish Central patient registry. The cleft palate patient registry program, which is performed in 6 reference centers, registers 95% of patients and the information obtained from it can be considered as a reliable source for health policy[10].

The implementation of a registry requires the cooperation of various scientific and executive departments, and each of them cannot achieve the goals of a registry plan separately[12].

As mentioned in the result section, hospital files, due to their clinical nature, lack the necessary features to record the data required for research projects and do not provide researchers with more data except for demographic data. Thus, running a registry system for cleft lip and palate patients in Hazrat Fatemeh Hospital as a reference hospital in this field, is an important and valuable measure, however it should be noted that a registry program can achieve its goals if all or the majority of patients are covered in a specific geographical area, otherwise the obtained information cannot be considered as a source for health policy[12].

As the first and scientific stage of the program, we designed 14 forms containing 790 variables in cooperation with the professors of the Maxillofacial Surgery Department, Orthodontics Department, and Speech Therapy Department of the center. The variables are based on the research objectives proposed by academic staff of Hazrat Fatemeh Plastic Surgery Center, and were validated by experts in the field of cleft lip and palate.

CONCLUSION

Hazrat Fatemeh Plastic Surgery Hospital as one of the biggest centers for cleft lip and palate patients, does not record required data for medical research purposes, and to conduct studies on the data of these patients, we need an independent registration system. However, in order to obtain the maximum coverage of these patients, we need extensive cooperation from other referral cleft lip and palate centers in other parts of the country.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interests.

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