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Original Article

Global prevalence of cleft palate, cleft lip and cleft palate and lip: A comprehensive systematic review and meta-analysis

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ABSTRACT

Background: Birth defect is widely used as a term for congenital anomalies. Children with cleft lip and palate may have serious speech, hearing, nutrition, and mental and social development disorders; therefore, this study was designed to determine the overall prevalence of cleft palate, lip, and cleft palate through systematic review and meta-analysis.

Methods: In this study, systematic review and meta-analysis of data from studies on the prevalence of cleft lip and palate in Scopus, Embase, Magiran, Web of Science (WoS), PubMed and Science Direct databases were extracted between January 2000 and June 2020. In order to perform the analysis of qualified studies, the model of random effects was used and the inconsistency of studies with I^2 index was investigated. Data analysis was performed with Comprehensive Meta-Analysis software (Version 2).

Results: According to the results of the present study on cleft palate, the total number of samples entered in the study in 59 studies were 21,088,517 individuals, the prevalence of cleft palate based on the meta-analysis of the reviewed studies in every 1000 live births was obtained 0.33 (95% CI: 0.28–0.38). In the case of cleft lip, the total number of samples entered in the 57 reviewed studies were 17,907,569 individuals. The prevalence of cleft lip obtained based on the meta-analysis of the reviewed studies was 0.3 in every 1000 live births (95% CI: 0.26–0.34), and in the case of cleft lip and palate, the total number of samples entered in the 55 reviewed studies was 17,894,673. The prevalence of cleft lip and palate based on the meta-analysis of the studies reviewed in each 1000 live births was 0.45 (95% CI: 0.38–0.52).

Conclusion: Due to the high prevalence of oral clefts such as cleft palate, cleft lip, and cleft lip and palate; health system policymakers need to take precautionary measures to reduce the number of patients, as well as diagnostic and therapeutic measures to reduce the effects of this disorder in children.

1. Background

Birth defect is used for congenital anomalies. These abnormalities can be structural, morphological, metabolic, psychological, behavioural, and functional [1]. Birth defects can lead to physical, mental or even death disabilities. Decreased quality of life, life expectancy, and the imposition of exorbitant economic costs on households are among the negative effects of these anomalies [2]. With the increase in the quality of health care for children, the number of deaths due to birth defects has decreased at this age. However, birth defects are a growing problem, especially in developing countries. Studies show that more than 8 million babies are born with serious birth defects each year [3]. About 20 to 30% of these babies with birth defects have two or more birth defects [4].

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Abbreviation

WoS	web of science
PRISMA	preferred reporting items for systematic reviews and meta-analysis.
STROBE	strengthening the reporting of observational studies in epidemiology for cross- sectional study
SID	scientific information database

One of the most common birth defects around the world is oral cleft, which occurs separately or syndromically. Orofacial cleft occurs in the early stages of growth due to the failure or improper fusion of tissues [5]. Congenital cleft lip and / or palate (CLP, CL, CP) fall into the category of oral clefts. In most cases, it is multifactorial, influenced by genetic factors and exogenous factors. External factors include malnutrition, hormonal disorders, medications, toxins, and biological factors [6]. Studies have shown that cleft lip and palate can cause cleft palate [7].

According to a 2015 study in South Korea, CP, CL, and CLP prevalence were reported to be 5.57, 2.77, and 2.75 per 10,000 births, respectively [8]. A 2019 study by Rezq Alswairki et al. Showed that the prevalence of oral clefts in Egypt is 4 per 10,000 births. This study stated that cleft lip occurs more than other types of oral cleft and its main cause is maternal passive smoking [9].

Children with cleft lip and palate may have severe speech, hearing, nutrition, and mental and social developmental disorders [10]. Also, these patients are often faced with maxillary hypoplasia and oral respiration, which reduces saliva and increases periodontal problems and oral disorders that affect their quality of life [11]. Therefore, timely and early treatment of these abnormalities through surgery and their special care can play an important role in reducing some of these disabilities [12]. The importance of this has led to the collection of oral statistics in 1985 in Northern Ireland on the birth of infants with oral clefts to plan treatment needs according to a regular pattern [13].

There have been several studies on the prevalence of cleft lip and palate in the world, but these studies have reported different and heterogeneous prevalence, and the overall prevalence of these disorders is not exactly known. Therefore, the aim of the present study is to conduct a systematic review and meta-analysis to determine the overall prevalence of cleft palate, cleft lip and prevalence of cleft lip and palate in the world.

2. Methods

2.1. Search strategy and study selection

The present study was conducted to determine the prevalence of cleft lip and palate worldwide by systematic review and meta-analysis. To collect data in this study Embase, Scopus, Web of science (WoS), PubMed, Science direct, and Magiran international and Persian databases were used to collect data in this study between January 2000 and June 2020. The search process in the mentioned databases was done using Prevalence, Cleft Palate, Cleft Lip, Harelip keywords and their possible combination in international and Persian databases. For example, how to search the PubMed database is described in the box below. In order to study the Gary literature, the study of related sites was also on the agenda. In order to maximize the comprehensiveness of the search, the list of sources used in all related articles found in the above search was manually reviewed. Initially, studies that were repeated in various databases searched were removed from this study. Then, the researchers of this study prepared a list of the titles of all the remaining articles, so that we can get qualified articles by evaluating the articles in this list. In the first stage, screening, the title and abstract of the remaining articles were carefully studied and unrelated articles were removed according to the inclusion and exclusion criteria. In the second stage, i.e. the evaluation of the competence of the studies, the full text of the possible related articles remaining from the screening stage was examined based on the inclusion and exclusion criteria, and in this stage, the unrelated studies were removed. To prevent bias, all sources of resource review and data extraction were performed by two researchers independently. If the articles were not included, the reason for deleting them was mentioned. In cases where there was a disagreement between the two researchers, the third person reviewed the article. 69 studies entered the third stage, i.e. qualitative evaluation.

PubMed search strategy: (((((((((prevalence[Title/Abstract]) AND Cleft Palate[MeSH Terms]) OR Cleft Lip[MeSH Terms]) OR Harelip [Title/Abstract]) OR prevalence[Title/Abstract]) AND Cleft Palate[Title/Abstract]) OR prevalence[Title/Abstract]) AND Harelip[Title/Abstract]) OR prevalence[Title/Abstract]) AND Cleft Lip[Title/Abstract]

2.2. Inclusion and exclusion criteria

Inclusion criteria of the studies: 1- Cross sectional studies and 2- population based study and 3-studies that have examined the prevalence of cleft lip and palate. 4- Observational studies (non-interventional studies) 5- Studies in Persian language 6- Studies in English language or abstract. Exclusion criteria of the studies: 1- Case control studies 2- Case report 3- Interventional studies and 4-letter to editor and 5- Studies with no full text availability 6- Studies not related to the subject 7- Studies without sufficient data 8- Repetition of studies 9- Systematic review studies and meta-analysis.

2.3. Qualitative evaluation

In order to validate and evaluate the quality of articles (i.e., methodological validity and results), a checklist appropriate to the type of study was used. STROBE checklists are commonly used to critique and evaluate qualitative observational studies such as the present study. The STROBE checklist consists of six general scales / sections, including: title, abstract, introduction, methods, results, and discussion. Some of these scales have subscales, for a total of 32 items. In fact, these 32 items represent different methodological aspects of the study, including title, problem statement, study objectives, study type, study statistical community, sampling method, sample size determination, definition of variables and procedures, data collection tools, statistical analysis methods and findings. Accordingly, the maximum score obtained from the qualitative evaluation will be in the STROBE 32 checklist, and considering the score of 16 as the cut-off point, the articles with scores of 16 and above will be considered medium and good quality articles and the following scores will be obtained. 16 papers with poor methodological quality were considered and therefore excluded from the study.

2.4. Data extraction

Information on all final articles entered the process of statistical review and meta-analysis was extracted from a pre-prepared checklist. This checklist includes the title of the article, the name of the first author, the year of publication, the place of study, the type of oral cleft, the total volume of the community, the volume of the group with oral cleft, the number of people with cleft lip, number of people with cleft palate with cleft lip, number of people with cleft lip with or without cleft palate.

2.5. Statistical analysis

The I2 test was used to evaluate the heterogeneity of the selected studies. In order to investigate the distribution error, due to the high

volume of samples entered into the study, Egger test was used at a significance level of 0.05 and also the corresponding Funnel plot. Data analysis was performed using Comprehensive Meta-Analysis software (Version 2).

3. Results

3.1. Study selection and data extraction

This study examined the prevalence of cleft lip and palate by systematic review and meta-analysis. After searching various sites, 3072 articles were studied. 930 articles from EMBASE database, 130 articles from the Magiran database, 833 articles from PubMed database, 168 articles from science direct database, 459 articles from Scopus database, and 552 articles from Web of science database were read. No articles were included in the study after reviewing the references in other articles. Out of a total of 3072 identified studies, 1077 were duplicate and were eliminated. In the screening phase, since 1995, the remaining 1426 articles have been deleted by reading the title and abstract based on entry and exit criteria. In the competency assessment phase, out of 569 remaining studies, 298 articles were removed by studying the full text of the article based on entry and exit criteria due to un relatedness. In the qualitative evaluation stage, by reading the full text of the article based on the STROBE checklist, out of 69 remaining studies, none of the articles were deleted due to their low methodological quality.

The studies reviewed based on the four-step process of PRISMA 2009, including the identification of articles, screening, review of admission criteria, and finally the articles submitted to the meta-analysis (Fig. 1). Finally, 69 studies entered the final analysis and their information was mentioned in the tables (Tables 1 and 2).

3.2. Investigating heterogeneity and publication bias (Cleft palate)

The heterogeneity of the studies was investigated using I^2 test and based on this test, this value (I^2=99.9%) was obtained and shows high heterogeneity in the imported studies, so the model of random effects was used to combine the results of studies together. Also, the results of the study diffusion trajectory in studies with Begg and Mazumdar test were measured at a significance level of 0.1 (Fig. 2), which was not statistically significant (P = 0.101).

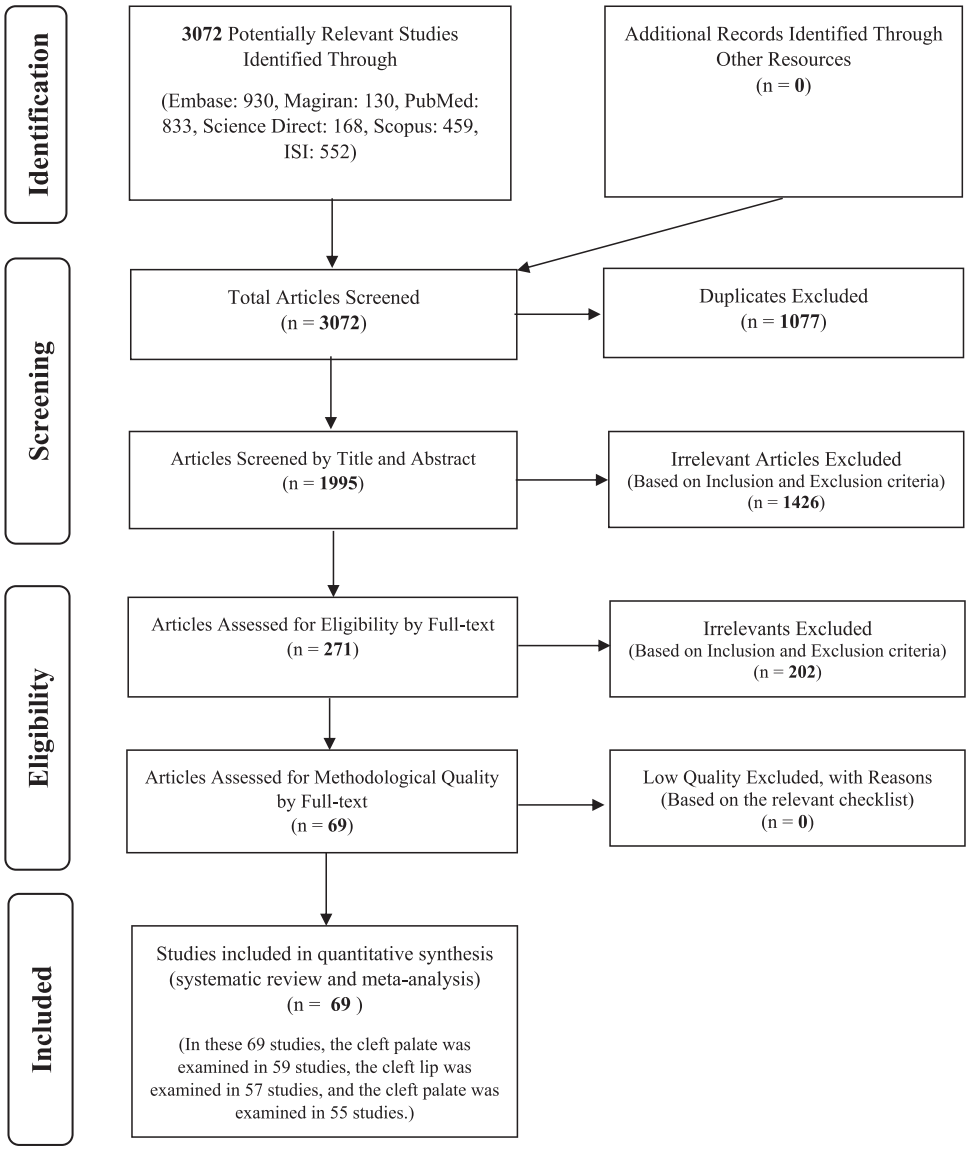


Fig. 1. The flowchart on the stages of including the studies in the systematic review and meta-analysis (PRISMA 2009).

Table 1.
The information extracted from the final studies entered the meta-analysis.

Sample number	First author	Year of publication	Research location	The average age of the sample	Total sample size
1	Abdulhameed, F. D. [14]	2014	Saudi arabia	New born	28,134
2	Aggarwal, D. [15]	2015	California	New born	2,084,386
3	Al Omari, F. [16]	2004	Jordan	New born	1,548,106
5	Alswairki, H. J. R. [17]	2019	Egypt	New born	237,783
6	Andrade, N. M. [18]	2018	Brazil	New born	206,367
7	Andrew, T. [19]	2018	California	New born	1,458,856
8	Antoszewski, B. 1 [20]	2013	Poland	New born	60,109
9	Antoszewski, B. 2 [21]	2016	Poland	New born	222,053
10	Aqrabawi, H. E. [22]	2008	Jordan	New born	25,440
11	Berg, E. [23]	2015	Norway	New born	2,449,218
12	Borno, H. T. [24]	2014	America	New born	33,969
13	Bronberg, R. [25]	2020	Argentina	New born	228,208
14	Chang, W. J. [26]	2016	Taiwan	New born	4,912,739
15	Corona-Rivera, J. R. [27]	2018	Mexico	New born	81,193
16	DeRoo, L. A. [28]	2003	America	New born	298,138
17	Dreise, M. [29]	2011	Uganada	New born	26,186
19	Fathololumi, Mr [30]	2007	Iran	New born	20,000
20	Fedeles, J., Jr. [31]	2012	Slovakia	New born	147,874
21	Figueirêdo, C. J. R. [32]	2011	Brazil	New born	318,667
22	Genisca, A. E. [33]	2009	America	New born	2,731,809
23	Golali Pour, M. J. 1 [34]	2005	Iran	New born	37,951
24	Golalipour, M. J. 2 [35]	2007	Iran	New born	37,921
25	Gregg, T. A. [13]	2008	Ireland	New born	511,693
26	Harville, E. W. [7]	2005	Norway	New born	1,800,000
27	Hashmi, S. S. [36]	2005	America	New born	1,026,868
28	Hviid, A. [37]	2011	Denmark	New born	832,636
29	Imai, Y. [38]	2019	Japan	New born	97,902
30	Jahanbin, A. [39]	2013	Iran	New born	101,435
31	Jakobsen, L. P. [40]	2003	Denmark	New born	2,806,373
32	Jalilevand, N. [41]	2015	Iran	New born	107,317
33	Jaruratanasirikul, S. [42]	2016	Thiland	New born	186,393
34	Kesande, T. [43]	2014	Uganda	New born	25,985
35	Kianifar, H. [44]	2015	Iran	New born	28,519
36	Kong, L. J. [45]	2017	China	New born	2832
37	Lee, C. W. [8]	2015	Korea	New born	883,184
38	Lei, R. L. [46]	2013	Taiwan	New born	1,705,192
39	Li, Z. [47]	2008	China	New born	25,355
40	Liu, J. [48]	2006	China	New born	99,888
41	Liu, Q. G. [49]	2016	China	New born	227,417
42	Luo, Y. L. [50]	2019	China	New born	597,306
43	Mezawa, H. [51]	2019	Japan	New born	101,825
44	Paaske, E. B. [52]	2018	Denmark	New born	182,907
45	Parker, S. E. [53]	2010	America	New born	3,120,605
46	Pavri, S. [54]	2013	Canada	New born	1,915,027
47	Pedersen, G. S. [55]	2014	Denmark	New born	1,319,426
48	Pierpaolo Mastroiacovo [56]	2011	Canada	New born	240,571
			America	New born	2,251,705
			Mexico and South America	New born	724,834
			Western Europe	New born	439,566
			Eastern Europe	New born	1,823,022
			British Isles	New born	468,112
			South-Mediterranean Europe	New born	1,135,577
			Australia-Victoria	New born	251,312
			Japan	New born	347,889
			South Africa	New born	69,321
			United Arab Emirates	New born	17,188
49	Rajabian, M. H. 1 [57]	2000	Iran	1day-18month	19,369
50	Rajabian, M. H. 2 [58]	2005	Iran	New born	147,608
51	Rakotoarison, R. A. [59]	2012	Madagascar	New born	150,973
52	Rezq Alswairki, H. J. [9]	2019	Egypt	New born	237,783
53	Rozendaal, A. M. [60]	2011	Netherlands	New born	1,970,872
54	Sabbagh, H. J. [61]	2015	Saudi arabia	New born	114,035
55	Sadri D [62]	2007	Iran	New born	147,500
56	Sarkar, S. [63]	2013	India	New born	12,896
57	Shapira, Y. [64]	2014	Israel	New born	976,578
58	Soltani, M. K. [65]	2014	Iran	New born	26,537
59	Sousa, G. F. [66]	2017	Brazil	New born	14,446,425
60	Suleiman, A. M. [67]	2005	Sudan	New born	15,890
61	Tafazzoli, H. [68]	2001	Iran	New born	6513
62	Tu, L. [1]	2012	China	New born	69,408
63	Vallino-Napoli, L. D. [69]	2006	Australia	New born	1,140,668
64	Wang, M. [10]	2018	China	New born	347,137
65	Yang, Y. [70]	2018	China	New born	50,234
66	Yassaei, S. [71]	2010	Iran	New born	65,236
67	Yazdy, M. M. [72]	2008	Georgia	New born- 1 years	760,554
68	Zandi, M. [73]	2011	Iran	New born	143,589
69	Zhou, Y. [2]	2020	China	New born	238,712

Table 2.
Abundance information based on the type of orofacial cleft studied.

Sample number	First author	Year of publication	Number of cleft palate	Number of cleft lip	The number of cleft lip and cleft palate
1	Abdulhameed, F. D.	2014	18	34	26
2	Aggarwal, D.	2015	1261	871	1189
3	Al Omari, F.	2004	477	652	1017
5	Alswairki, H. J. R.	2019	20	23	44
6	Andrade, N. M.	2018	–	–	–
7	Andrew, T.	2018	922	–	–
8	Antoszewski, B. 1	2013	31	11	28
9	Antoszewski, B. 2	2016	–	–	–
10	Aqrabawi, H. E.	2008	15	20	25
11	Berg, E.	2015	–	2890	–
12	Borno, H. T.	2014	12	5	14
13	Bronberg, R.	2020	60	54	220
14	Chang, W. J.	2016	2409	–	–
15	Corona-Rivera, J. R.	2018	51	30	146
16	DeRoo, L. A.	2003	261	–	–
17	Dreise, M.	2011	1	6	12
19	Fathololumi, Mr	2007	4	3	5
20	Fedeles, J., Jr.	2012	85	53	78
21	Figueirêdo, C. J. R.	2011	–	–	–
22	Genisca, A. E.	2009	1192	750	1395
23	Golali Pour, M. J. 1	2005	15	7	15
24	Golalipour, M. J. 2	2007	14	–	–
25	Gregg, T. A.	2008	399	117	225
26	Harville, E. W.	2005	–	1122	1572
27	Hashmi, S. S.	2005	612	281	801
28	Hviid, A.	2011	357	–	–
29	Imai, Y.	2019	51	–	–
30	Jahanbin, A.	2013	24	16	57
31	Jakobsen, L. P.	2003	1491	–	–
32	Jalilevand, N.	2015	23	10	15
33	Jaruratanasirikul, S.	2016	78	70	121
34	Kesande, T.	2014	1	7	12
35	Kianifar, H.	2015	8	19	27
36	Kong, L. J.	2017	4	8	4
37	Lee, C. W.	2015	492	245	243
38	Lei, R. L.	2013	690	–	–
39	Li, Z.	2008	6	21	44
40	Liu, J.	2006	22	68	136
41	Liu, Q. G.	2016	–	–	–
42	Luo, Y. L.	2019	177	–	–
43	Mezawa, H.	2019	83	125	208
44	Paaske, E. B.	2018	127	–	–
45	Parker, S. E.	2010	4568	–	–
46	Pavri, S.	2013	995	414	1010
47	Pedersen, G. S.	2014	1061	–	–
48	Pierpaolo Mastroiacovo	2011	–	97	179
			–	703	1594
			–	227	725
			–	186	346
			–	563	990
			–	167	266
			–	272	417
			–	92	151
			–	230	467
			–	4	16
			–	6	6
49	Rajabian, M. H. 1	2000	289	584	796
50	Rajabian, M. H. 2	2005	30	35	54
51	Rakotoarison, R. A.	2012	18	19	36
52	Rezq Alswairki, H. J.	2019	20	26	44
53	Rozendaal, A. M.	2011	1090	–	–
54	Sabbagh, H. J.	2015	32	53	48
55	Sadri D	2007	48	56	89
56	Sarkar, S.	2013	10	19	.
57	Shapira, Y.	2014	258	235	191
58	Soltani, M. K.	2014	5	8	16
59	Sousa, G. F.	2017	2931	2378	2333
60	Suleiman, A. M.	2005	3	2	8
61	Tafazzoli, H.	2001	10	6	25
62	Tu, L.	2012	9	–	.
63	Vallino-Napoli, L. D.	2006	833	–	.
64	Wang, M.	2018	37	295	118
65	Yang, Y.	2018	17	31	47
66	Yassaei, S.	2010	17	13	26
67	Yazdy, M. M.	2008	239	126	280
68	Zandi, M.	2011	23	37	69
69	Zhou, Y.	2020	3016	1759	3561

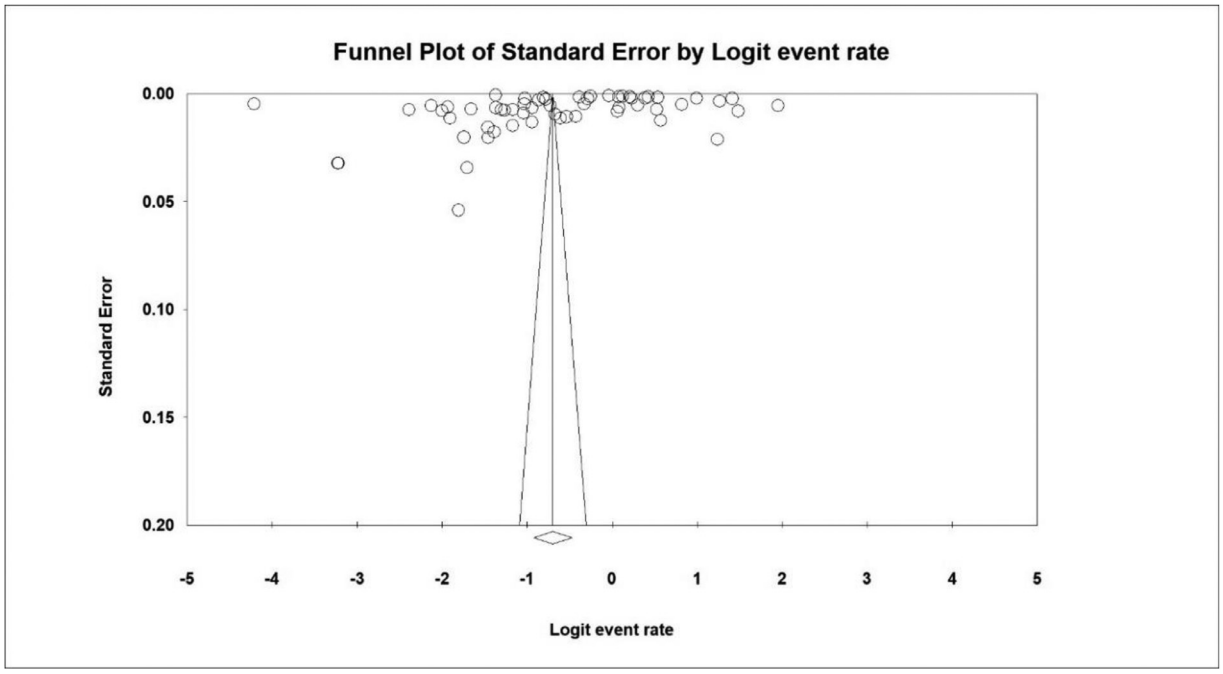


Fig. 2. Funnel Plot Results related to the prevalence of cleft palate.

3.3. Meta-analysis of the results of the cleft palate

The total number of samples included in the study was 21,088,517 peoples from 59 articles reviewed. The prevalence of cleft palate based on the meta-analysis of the studies studied in every 1000 live births was 0.33 (95% CI: 0.0–28.38). In Fig. 3, the prevalence based on the model has shown random effects in which the black square of the prevalence and the length of the line on which the square is located is 95% confidence interval in each study.

3.4. Investigating heterogeneity and publication bias (Cleft lip)

The heterogeneity of the studies was investigated using I^2 test and based on this test, this value (I^2=99.9%) was obtained and shows the high heterogeneity in the entered studies. Therefore, the model of random effects was used to combine the results of studies together. Also, the results of the study diffusion efficacy in studies with Begg and Mazumdar test were measured at a significance level of 0.1 (Fig. 4) that the efficacy was not statistically significant (P = 0.318).

3.5. Meta-analysis of the results related to the prevalence of cleft lip

The total number of samples included in the study was 17,907,569 individuals from 57 articles reviewed. The prevalence of cleft lip obtained based on the meta-analysis of the studies studied in every 1000 live births was 0.3 (95% CI: 0.26–0.34). In Fig. 5, the prevalence based on the model has shown random effects in which the black square of the prevalence and the length of the line on which the square is located is 95% confidence interval in each study.

3.6. Investigating heterogeneity and publication bias (Cleft lip and palate)

The heterogeneity of the studies was investigated using I^2 test and based on this test, this value (I^2=99.9%) was obtained and shows the high heterogeneity in the entered studies. Therefore, the model of random effects was used to combine the results of studies together. Also, the results of the study diffusion trajectory in studies with Begg and Mazumdar test were measured at a significance level of 0.1 (Fig. 6), which was not statistically significant (P = 0.214).

3.7. Meta-analysis of the results related to the prevalence of cleft lip and palate

The total number of samples included in the study was 17,894,673 individuals from 55 articles reviewed. The Prevalence of cleft lip and palate obtained based on the meta-analysis of the studies reviewed was 0.45 in every 1000 live births (95% CI: 0.38- 0.52). In Fig. 7, the prevalence based on the model has shown random effects in which the black square of the prevalence and the length of the line on which the square is located is 95% confidence interval in each study.

4. Discussion

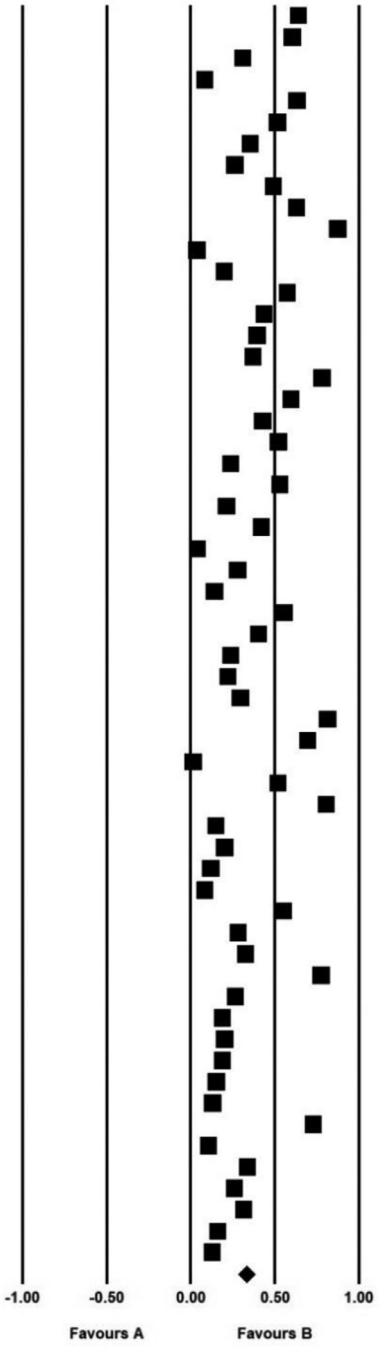
In the studies related to cleft palate, the total number of samples entered in the study in 59 reviews was 21,088,517. The prevalence of cleft palate based on meta-analysis of studies studied in every 1000 live births was 0.33 (0.28–0.38: with 95% confidence interval) was obtained.

Also in the cleft lip, the total number of samples entered in the study was 17,907,569 in 57 reviews, the prevalence of cleft lip based on meta-analysis of studies reviewed was 0.3 in every 1000 live births (0.26–0.34: with 95% confidence interval).

The total number of samples entered in the study of cleft lip and palate was 17,894,673 in 55 reviews, the prevalence of cleft lip and taste based on a meta-analysis of studies in every 1000 live births was obtained 0.45 (0.38–0.52: with 95% confidence interval).

The cleft palate prevalence in this study was 0.03 times higher than the prevalence rates reported in the Jordanian studies, which is 0.06 times higher than in China, and is 0.3 times lower than the published California rates. The prevalence of cleft lip and palate in this study was 0.11 and 0.16 less than the prevalence reported in Jordanian studies. The prevalence of cleft palate and cleft lip in this study

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Abdulhameed, F. D.	0.640	0.634	0.645	46.258	0.000
Aggarwal, D.	0.605	0.604	0.606	300.829	0.000
Al Omari, F.	0.308	0.307	0.309	-464.715	0.000
Alswairki, H. J. R.	0.084	0.083	0.085	-323.168	0.000
Andrew, T.	0.632	0.631	0.633	315.019	0.000
Antoszewski, B.	0.516	0.512	0.520	7.712	0.000
Borno, H. T.	0.353	0.348	0.358	-53.274	0.000
Bronberg, R.	0.263	0.261	0.265	-216.786	0.000
Chang, W. J.	0.490	0.490	0.491	-42.741	0.000
Corona-Rivera, J. R.	0.628	0.625	0.631	72.192	0.000
DeRoo, L. A.	0.875	0.874	0.877	351.584	0.000
Dreise, M.	0.038	0.036	0.041	-100.057	0.000
Fathololumi, Mr	0.200	0.195	0.206	-78.421	0.000
Fedeles, J., Jr.	0.575	0.572	0.577	57.321	0.000
Genisca, A. E.	0.436	0.436	0.437	-209.860	0.000
Golali Pour, M. J.	0.395	0.390	0.400	-40.508	0.000
Golalipour, M. J.	0.369	0.364	0.374	-50.343	0.000
Gregg, T. A.	0.780	0.779	0.781	374.782	0.000
Hashmi, S. S.	0.596	0.595	0.597	193.316	0.000
Hviid, A.	0.429	0.428	0.430	-129.569	0.000
Imai, Y.	0.521	0.518	0.524	13.093	0.000
Jahanbin, A.	0.237	0.234	0.239	-158.555	0.000
Jakobsen, L. P.	0.531	0.531	0.532	104.769	0.000
Jalilevand, N.	0.214	0.212	0.217	-174.633	0.000
Jaruratanasirikul, S.	0.418	0.416	0.421	-70.081	0.000
Kesande, T.	0.038	0.036	0.041	-99.793	0.000
Kianifar, H.	0.281	0.275	0.286	-71.460	0.000
Kong, L. J.	0.141	0.129	0.155	-33.454	0.000
Lee, C. W.	0.557	0.556	0.558	107.042	0.000
Lei, R. L.	0.405	0.404	0.405	-247.490	0.000
Li, Z.	0.237	0.231	0.242	-79.263	0.000
Liu, J.	0.220	0.218	0.223	-165.583	0.000
Luo, Y. L.	0.296	0.295	0.297	-305.213	0.000
Mezawa, H.	0.815	0.813	0.817	183.786	0.000
Paaske, E. B.	0.694	0.692	0.696	161.658	0.000
Parker, S. E.	0.015	0.015	0.015	-893.056	0.000
Pavri, S.	0.520	0.519	0.520	54.163	0.000
Pedersen, G. S.	0.804	0.803	0.805	643.840	0.000
Rajabian, M. H.1	0.149	0.144	0.154	-86.321	0.000
Rajabian, M. H.2	0.203	0.201	0.205	-211.215	0.000
Rakotoarison, R. A.	0.119	0.118	0.121	-251.796	0.000
Rezq Alswairki, H. J.	0.084	0.083	0.085	-323.168	0.000
Rozendaal, A. M.	0.553	0.552	0.554	148.683	0.000
Sabbagh, H. J.	0.281	0.278	0.283	-142.835	0.000
Sadri D	0.325	0.323	0.328	-131.171	0.000
Sarkar, S.	0.775	0.768	0.783	58.726	0.000
Shapira, Y.	0.264	0.263	0.265	-446.300	0.000
Soltani, M. K.	0.188	0.184	0.193	-93.026	0.000
Sousa, G. F.	0.203	0.203	0.203	-2091.524	0.000
Suleiman, A. M.	0.189	0.183	0.195	-71.918	0.000
Tafazzoli, H.	0.154	0.145	0.163	-49.667	0.000
Tu, L.	0.130	0.127	0.132	-168.503	0.000
Vallino-Napoli, L. D.	0.730	0.729	0.731	472.116	0.000
Wang, M.	0.107	0.106	0.108	-386.554	0.000
Yang, Y.	0.338	0.334	0.343	-71.093	0.000
Yassaei, S.	0.261	0.257	0.264	-116.925	0.000
Yazdy, M. M.	0.314	0.313	0.315	-315.917	0.000
Zandi, M.	0.160	0.158	0.162	-230.278	0.000
Zhou, Y.	0.126	0.125	0.128	-313.884	0.000
	0.332	0.285	0.383	-6.131	0.000



Meta Analysis

Fig. 3. The prevalence of cleft palate based on random model.

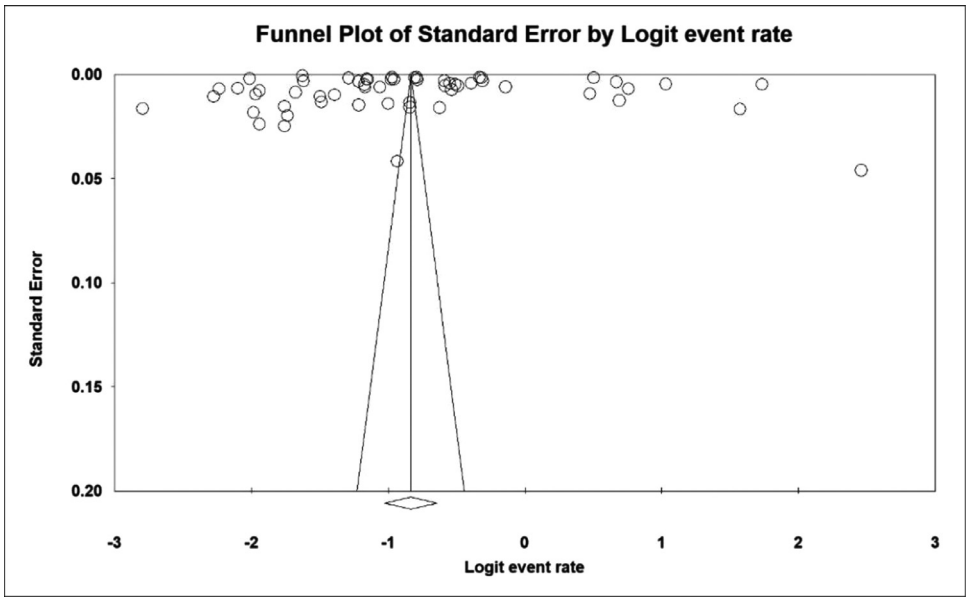
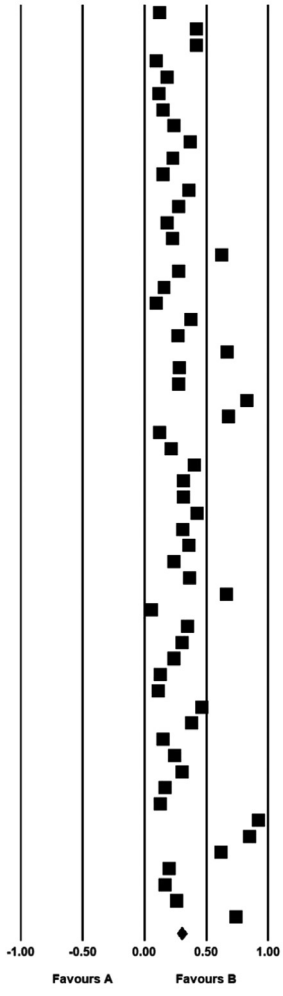


Fig. 4. Funnel Plot Results related to the prevalence of cleft lip.

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Abdulhameed, F. D.	0.121	0.117	0.125	-108.493	0.000
Aggarwal, D.	0.418	0.417	0.419	-236.069	0.000
Al Omari, F.	0.421	0.420	0.422	-195.366	0.000
Alswairki, H. J. R.	0.097	0.096	0.098	-322.020	0.000
Antoszewski, B.	0.183	0.180	0.186	-141.834	0.000
Berg, E.	0.118	0.118	0.118	-1015.575	0.000
Borno, H. T.	0.147	0.143	0.151	-114.718	0.000
Bronberg, R.	0.237	0.235	0.238	-237.805	0.000
Corona-Rivera, J. R.	0.369	0.366	0.373	-73.498	0.000
Dreise, M.	0.229	0.224	0.234	-82.511	0.000
Fathololumi, Mr	0.150	0.145	0.155	-87.593	0.000
Fedeles, J., Jr.	0.358	0.356	0.361	-107.370	0.000
Genisca, A. E.	0.275	0.274	0.275	-716.746	0.000
Golali Pour, M. J.	0.184	0.181	0.188	-112.315	0.000
Gregg, T. A.	0.229	0.228	0.230	-365.282	0.000
Harville, E. W.	0.623	0.623	0.624	327.465	0.000
Hashmi, S. S.	0.274	0.273	0.275	-441.025	0.000
Jahanbin, A.	0.158	0.156	0.160	-194.465	0.000
Jalilevand, N.	0.093	0.091	0.095	-216.678	0.000
Jaruratanasirikul, S.	0.376	0.373	0.378	-106.309	0.000
Kesande, T.	0.269	0.264	0.275	-71.353	0.000
Kianifar, H.	0.666	0.661	0.672	55.040	0.000
Kong, L. J.	0.282	0.266	0.299	-22.333	0.000
Lee, C. W.	0.277	0.276	0.278	-402.819	0.000
Li, Z.	0.828	0.824	0.833	94.483	0.000
Liu, J.	0.681	0.678	0.684	111.575	0.000
Mezawa, H.	0.123	0.121	0.125	-205.930	0.000
Pavri, S.	0.216	0.216	0.217	-733.729	0.000
Pierpaolo Mastroiacovo1	0.403	0.401	0.405	-94.344	0.000
Pierpaolo Mastroiacovo2	0.312	0.312	0.313	-549.203	0.000
Pierpaolo Mastroiacovo3	0.313	0.312	0.314	-310.085	0.000
Pierpaolo Mastroiacovo4	0.423	0.422	0.425	-101.503	0.000
Pierpaolo Mastroiacovo5	0.309	0.308	0.309	-502.539	0.000
Pierpaolo Mastroiacovo6	0.357	0.355	0.358	-193.207	0.000
Pierpaolo Mastroiacovo7	0.240	0.239	0.240	-525.429	0.000
Pierpaolo Mastroiacovo8	0.366	0.364	0.368	-132.600	0.000
Pierpaolo Mastroiacovo9	0.661	0.660	0.663	186.584	0.000
Pierpaolo Mastroiacovo10	0.058	0.056	0.059	-171.474	0.000
Pierpaolo Mastroiacovo11	0.349	0.342	0.356	-38.939	0.000
Rajabian, M. H.1	0.302	0.295	0.308	-53.656	0.000
Rajabian, M. H.2	0.237	0.235	0.239	-190.949	0.000
Rakotoarison, R. A.	0.126	0.124	0.128	-249.781	0.000
Rezq Alswairki, H. J.	0.109	0.108	0.111	-319.181	0.000
Sabbagh, H. J.	0.465	0.462	0.468	-23.774	0.000
Sadri D	0.380	0.377	0.382	-91.512	0.000
Sarkar, S.	0.147	0.141	0.154	-70.666	0.000
Shapira, Y.	0.241	0.240	0.241	-485.459	0.000
Soltani, M. K.	0.301	0.296	0.307	-62.818	0.000
Sousa, G. F.	0.165	0.164	0.165	-2289.423	0.000
Suleiman, A. M.	0.126	0.121	0.131	-81.033	0.000
Tafazzoli, H.	0.921	0.914	0.928	53.462	0.000
Wang, M.	0.850	0.849	0.851	364.802	0.000
Yang, Y.	0.617	0.613	0.621	52.001	0.000
Yassaei, S.	0.199	0.196	0.202	-141.901	0.000
Yazdy, M. M.	0.166	0.165	0.167	-524.165	0.000
Zandi, M.	0.258	0.255	0.260	-175.351	0.000
Zhou, Y.	0.737	0.735	0.739	221.543	0.000
	0.303	0.263	0.345	-8.448	0.000



Meta Analysis

Fig. 5. The prevalence of cleft lip and palate based on a random model.

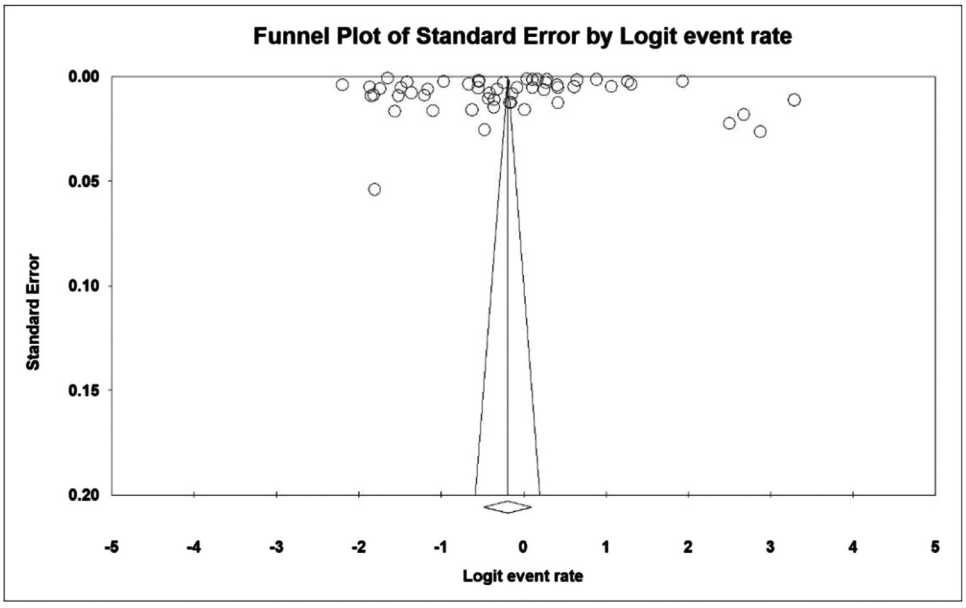


Fig. 6. Funnel Plot Results related to the prevalence of cleft lip and palate.

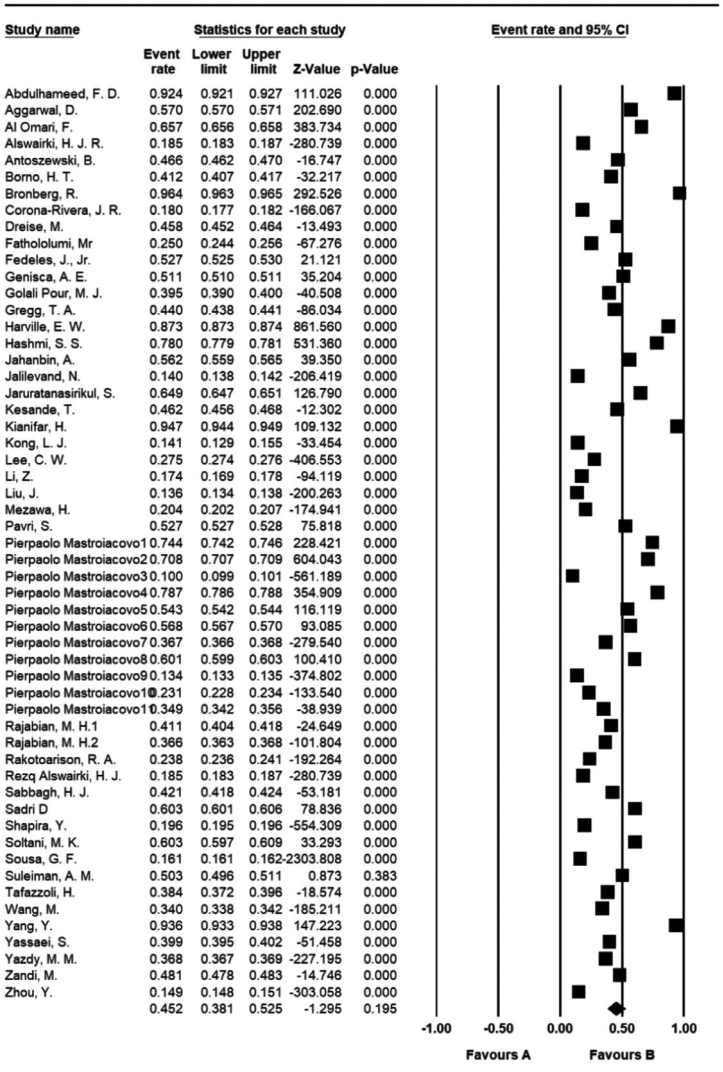


Fig. 7. The prevalence of cleft lip and palate based on a random model.

was lower than the prevalence reported in the Jordanian studies 0.21, Korea 1.36, China 0.58, California 0.76 [14–17].

In a 2018 study review conducted in Iran, it was stated that the total number of samples among the articles included in the systematic and meta-analysis review study was 1,077,537 infants, with a prevalence of cleft palate of 0.35 and a prevalence of cleft lip of 0.34 and a prevalence of cleft palate and cleft palate. 0.88 per 1000 live births were estimated to be 0.02 in cleft palate, 0.04 in cleft lip and 0.43 cleft palate, and cleft lip and palate. The study found that the low prevalence of oral clefts may be due to a lack of information in areas with a higher prevalence. According to a study by Haseli et al. and Arezoo et al., the prevalence of this disorder was higher in boys than in girls. One of the limitations of this study is the lack of information report on the prevalence of oral clefts in different regions of Iran and the lack of sufficient accuracy of the authors of the articles in reporting the prevalence of oral clefts in their regions and also the lack of access to the full text [18].

The prevalence of oral clefts varies from country to country and from region to country. This difference can be due to racial, climatic, cultural diversity, and differences in pregnant women's care programs. Some medications, such as thalidomide and aminopyrine, have been shown to have oral side effects. Also, the gaps in parents, siblings, and other relatives, injuries, radiation, and smoking can be risk factors for differences [74–77].

5. Study strengths and limitations of the study

The number of studies included in the study, as well as the diversity of the countries in which the studies were conducted, were among the strengths of the present study. The total sample size of the study was another strength of this study. Reviewers also used the best review methods in systematic review studies. However, this study's limitations should not be overlooked: (1) since only studies in English or English abstracts have been studied, it is possible to narrow the language. (2) Lack of access to the full text of the articles was another limitation of this study.

6. Conclusion

Due to the high prevalence of oral clefts such as cleft palate, cleft lip, and cleft lip and palate; Health system policymakers need to take precautionary measures to reduce the number of patients, as well as diagnostic and therapeutic tests to reduce the effects of this disorder in children.

7. Declaration

7.1. Funding

By Student Research Committee of Kermanshah University of Medical Sciences, Deputy for Research and Technology, Kermanshah University of Medical Sciences (IR) (990849). This deputy has no role in the study process.

7.2. Ethics approval

Ethics approval was received from the ethics committee of deputy of research and technology, Kermanshah University of Medical Sciences (IR.KUMS.REC.1399.764).

7.3. Consent to participate

N/A.

7.4. Consent for publication

N/A.

7.5. Availability of data and materials

Datasets are available through the corresponding author upon reasonable request.

7.6. Code availability

N/A.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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