Special Article

Global Birth Prevalence of Orofacial Clefts: A Systematic Review

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Background: *A birth prevalence of orofacial clefts (OFCs) worldwide has been documented to vary. However, a systematic assessment is lacking.*
Objective: *To assess the evidence in the literature for the birth prevalence of OFCs.*
Material and Method: *A systematic literature search was conducted using electronic databases through PubMed between 1950 and June 2015 using key words and search terms of cleft lip palate OR orofacial cleft AND prevalence.*
Results: *There were 45,193 patients with OFCs found in a study population of 30,665,615 live births. According to continents, the OFC birth prevalence (95% confidence interval) from Asia, North America, Europe, Oceania, South America, and Africa were 1.57 (1.54-1.60), 1.56 (1.53-1.59), 1.55 (1.52-1.58), 1.33 (1.30-1.36), 0.99 (0.96-1.02), and 0.57 (0.54-0.60) per 1,000 live births, respectively. The American Indians had the highest prevalence rates of 2.62 per 1,000 live births, followed by the Japanese, the Chinese, and the Whites of 1.73, 1.56, and 1.55 per 1,000 live births, respectively. The Blacks had the lowest rate of 0.58 per 1,000 live births.*
Conclusion: *Observed differences may also be of ethnic origin, genetic, environmental factors, and methods of ascertainment. Further investigations are needed to manage this global health problem.*

Keywords: *Orofacial clefts, Cleft lip, Cleft palate, Cleft lip and palate, Birth prevalence*

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Orofacial clefts (OFCs), including cleft lip (CL) or cleft lip with cleft palate (CLP) and isolated cleft palate (CP), are common birth defects of the head and neck and have complex etiologies with environmental and genetic factors[1,2]. Reports on the birth prevalence of OFC varied widely among studies worldwide[1,2]. The generally accepted estimation of OFC occurrence is one in 700 live births[1].

Patients with OFCs need multidisciplinary care from birth until adult lives and generally have higher morbidity and mortality than normal populations[1-4]. Many studies have shown an increased frequency of associated abnormalities[1-3]. Although multidisciplinary care teams can be effective in many places, OFCs inevitably pose global health problems around the world, particularly to the low-income populations[1-5].

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It is crucial to have precise data about worldwide OFC birth prevalence because this may guide to better understanding of its etiology and to manage public health resources and strategies. The purpose of this study is to systematically evaluate the birth prevalence of OFCs around the world.

Material and Method

Data sources

A systematic literature search was conducted using electronic databases through the PubMed between 1950 and June 2015 using key words and search terms of cleft lip palate OR orofacial clefts and birth prevalence OR incidence. The eligible papers in all languages were included and screened. The titles and abstracts of the 605 relevant articles were screened independently by two authors (VP and MP) to identify potentially relevant articles for which full text publications were retrieved. Duplicated papers were removed. Reference lists of included papers were screened for additional relevant papers that may have been missed in the database search.

Definitions

The birth prevalence rate in this review was expressed by dividing the number of orofacial cleft cases (numerator) by the number of live birth infant (denominator) multiplied by 1,000.

Orofacial clefts included cleft lip or cleft lip with cleft palate and isolated cleft palate.

Study selection

The studies included reports on prevalence of orofacial clefts, prevalence of congenital birth defects including orofacial clefts, those that presented adequate information on the methodology of study, and studies on orofacial cleft cases that presented for treatment with a defined sample population. The authors excluded studies limited to clinical features and cleft patterns without a mention of the prevalence rate, reports on the etiology, social impact and clinical studies without a mention of prevalence rate of orofacial clefts, and studies that did not include data for the calculations of the prevalence rates. Two authors (VP and MP) performed the search independently using these inclusion and exclusion criteria. Disagreements were resolved by discussion.

When a study was eligible for inclusion, two authors (VP and MP) independently verified the numerator and denominator and recalculated the estimated birth prevalence to check accuracy. Studies with incorrect or missing numerators or denominators were excluded.

Data extraction and quality assessment

Using a standardized data extraction form, data on locations, ethnics, types of study, number of OFC cases, and number of live birth infants were extracted. Studies were assessed on completeness of data and origins of the data.

Statistical analysis

Total OFC birth prevalence rates were presented with average values (95% confidence interval).

Results

The search combination in the databases identified 605 relevant articles. A thorough evaluation of these articles using the inclusion and exclusion criteria led to the exclusion of 555 articles leaving 50 papers that met the inclusion criteria. Of the 50 papers remaining, after critical review of the full text, four papers were excluded due to incomplete data in three papers and duplicated data in one paper. After the full paper review, 46 papers containing relevant data. Of these papers, there were two additional papers found after reference checks were performed. These two additional papers were not initially retrieved by the original search because they were not indexed in the searched database. Thus, 48 papers were eligible for the inclusion into this systematic review (Fig. 1).

There were 45,193 patients with OFC found in a study population of 30,665,615 live births. According to continents, the OFC birth prevalence (95% confidence interval [CI]) from Asia, North America, Europe, Oceania, South America, and Africa were 1.57 (1.54-1.60), 1.56 (1.53-1.59), 1.55 (1.52-1.58), 1.33 (1.30-1.36), 0.99 (0.96-1.02), and 0.57 (0.54-0.60) per 1,000 live births, respectively. Significant geographical differences were documented (Tables 1-7). The differences might be attributed to ethnic differences (Table 8).

Asia

Fourteen studies conducted in different places of Asia reported the prevalence rates for Asians from 1.05 to 2.36 per 1,000 live births (Table 2).

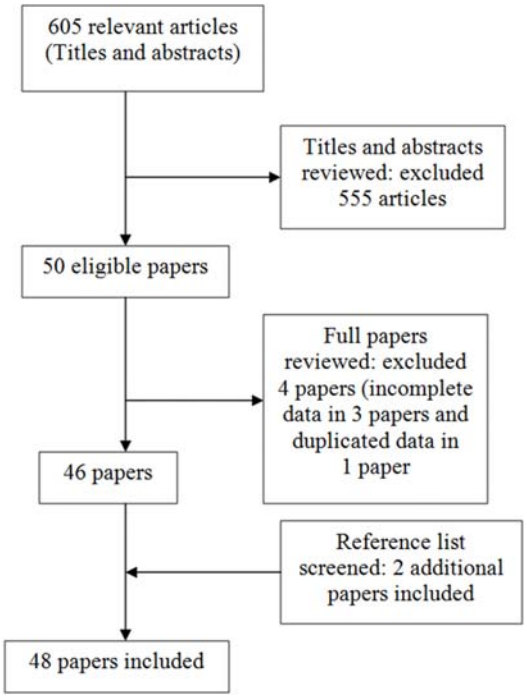

Fig. 1 Flow diagram of paper search and papers included into this systematic review.

Table 1. Geographical variation in birth prevalence of orofacial clefts according to continents

Continent (Location)	Numbers of orofacial clefts	Numbers of live births	Birth prevalence (per 1,000 live births)	95% Confidence Interval
Asia	15,646	9,965,084	1.57	1.54-1.60
North America	18,276	11,728,914	1.56	1.53-1.59
Europe	5,028	3,236,253	1.55	1.52-1.58
Oceania	2,822	2,125,912	1.33	1.30-1.36
South America	3,205	3,229,179	0.99	0.96-1.02
Africa	216	380,273	0.57	0.54-0.60
Total	45,193	30,665,615	1.47	1.44-1.50

North America

Twelve studies conducted in different places in North America reported the prevalence rates for Whites, Blacks, Hispanics, and American Indians ranged from 0.6 to 3.92 per 1,000 live births (Table 3).

Europe

Six studies conducted in different places in Europe reported the prevalence rates for Whites, and Arabs ranged from 1.02 to 1.94 per 1,000 live births (Table 4).

Oceania

Four studies conducted in different places of Oceania reported the prevalence rates for Whites ranged from 1.21 to 1.73 per 1,000 live births (Table 5).

South America

Two studies conducted in different places in the South America reported the prevalence rates for Whites and Hispanics ranged from 0.99 to 1.00 per 1,000 live births (Table 6).

Africa

Ten studies conducted in different places in the Africa reported the prevalence rates for Blacks and Whites ranged from 0.3 to 1.65 per 1,000 live births (Table 7).

Birth prevalence rates among races

There were differences in the birth prevalence of OFC clefts among races. The American Indians had the highest prevalence rates, followed by the Japanese, the Chinese, and the Whites whilst the Blacks had the lowest rate (Table 8).

Discussion

Although this study had information from differences in sample sources, method of ascertainments and ethnic groups, the important geographical differences were found. Asia documented the highest birth prevalence and Africa had the lowest prevalence. The present study revealed ethnic variation in the birth prevalence rates of OFC clefts. It has been documented that populations of Native North American Indians had the highest prevalence, followed by the Japanese and the Chinese. The Caucasian or White populations had intermediate prevalence whilst the African or Black populations had the lowest prevalence[1,2]. The present study confirmed those previous documents[47] (Table 8).

Our results show that the prevalence rate of cases per live births is lower than the rate of World Health Organization registry and many studies reported of all cases from all births or all pregnancies. All births include live births and stillbirths. Stillbirths have greater risks of associated malformations or syndromes accompanying OFC clefts[2]. Infants with stillbirths have approximately three times higher prevalence rates of OFC clefts than infants with live births[2]. Thus, the prevalence rate of cases per live births is generally lower than the prevalence rate per all births or per all pregnancies[2].

Ascertainment may be difficult in low income countries where a high proportion of births may occur in remote areas far from healthcare delivery systems, resulting in incomplete records. This factor may have contributed to lower estimates in some low-income countries. Although hospital-based estimates give a precision of rates, they are subjected to biases and resulted in uncomparable with those where complete ascertainment is achieved.

Study limitations

The present study has three comparative limitations: (1) case finding using data sources such

Table 2. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) in Asia

Author/year	Period (year)	Location	Ethnics	Types of study	Live births (N)	OFC cases (N)	OFC prevalence (N per 1,000 live births)
Kobayasi (1958)[6]	1940-1956	Tokyo	Japanese	R	46,651	97	2.08
Tanaka et al (1972)[7]	1965-1967	Hokkaido	Japanese	R	105,462	189	1.79
Cooper et al (2006)[8]	1953-2004	China	Chinese	R	5,003,592	7,640	1.53
Cooper et al (2006)[8]	1953-2004	Japan	Japanese	R	1,077,006	1,780	1.65
Cooper et al (2006)[8]	1953-2004	Asia	Asians	R	944,574	1,719	1.82
Jamilian et al (2007)[9]	1998-2005	Iran	Arabs	R	11,651	25	2.14
Alwis et al (2007)[10]	2002-2003	Sri Lanka	Arayan	P	9,105	20	2.19
Tan et al (2008)[11]	1993-2002	Singapore	Chinese	P	460,532	859	1.87
Aqrabawi HE (2008)[12]	2000-2005	Jordan	Arabs	P	25,440	60	2.36
Sabbagh et al (2011)[13]	1982-2009	Saudi Arabia, Oman, Jordan	Arabs	R	1,985,663	2,846	1.43
Silberstein et al (2012)[14]	1996-2006	Israel	Jews	R	131,218	140	1.07
Jalili et al (2012)[15]	2004-2008	Iran	Arabs	R	57,526	103	1.79
Singh et al (2012)[16]	2005-2010	Nepal	Arayan	R	30,952	51	1.65
Hoang et al (2013)[17]	2010	Vietnam	Vietnamese	R	13,954	28	2.01
Borno et al (2014)[18]	1986-1995	Jerusalem	Palestinian	R	33,239	35	1.05
Kianifar et al (2015)[19]	1982-2011	Iran	Arabs	R	28,519	54	1.89
Total	1953-2011	Asia	Asians	R, P	9,965,084	15,646	1.57

R = retrospective study; P = prospective study; OFCs = orofacial clefts; N = number

Table 3. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) in the North America

Author/ year	Period (year)	Location	Ethnics	Types of study	Live births (N)	OFC cases (N)	OFC prevalence (N per 1,000 live births)
Loretz et al (1961)[20]	1955	California	Blacks	R	21,532	13	0.60
Tretsven (1965)[21]	1955-1961	Montana	American Indians	R	7,461	27	3.62
Gilmore et al (1966)[22]	1943-1962	Wisconcin	Whites	R	1,670,400	1,740	1.04
Niswander et al (1967)[23]	1963-1968	USA.	American Indians	R	25,341	50	1.97
Emanuel et al (1973)[24]	1956-1965	Washington DC	Blacks	R	8,708	11	1.26
Emanuel et al (1973)[24]	1956-1965	Washington DC	Whites	R	189,096	311	1.75
Emanuel et al (1973)[24]	1956-1965	Washington DC	American Indians	R	1,764	6	3.40
Ching et al (1974)[25]	1948-1986	Hawaii	Whites	R	77,013	123	1.60
Ching et al (1974)[25]	1948-1986	Hawaii	Japanese	R	67,068	178	2.65
Lowry et al (1977)[26]	1952-1971	British Columbia	Whites	R	713,316	1,409	1.97
Lowry et al (1977)[26]	1952-1971	British Columbia	American Indians	R	30,532	114	3.74
Lowry et al (1977)[26]	1952-1971	British Columbia	Chinese	R	12,430	22	1.76
Shaw et al (2004)[27]	1983-1997	Califonia	Whites	R	3,548,991	6,415	1.81
Contreras et al (2012)[28]	2008-2010	Mexico	Hispanics, Whites	R	24,043	24	1.00
Matthews et al (2015)[29]	1998-2007	Canada	Whites	R	3,015,325	4,221	1.40
Wang et al (2015)[30]	1998-2007	USA.	Whites, Hispanics, Blacks	P	231,508	291	1.26
Aggarwal et al (2015)[31]	1983-2010	Califonia	Whites	R	2,044,118	3242	1.59
Aggarwal et al (2015)[31]	1983-2010	Califonia	American Indian	R	40,268	79	3.92
Total	1943-2010	North America	Whites, Blacks, Hispanics, and American Indians	R,P	11,728,914	18,276	1.56

R = retrospective study; P = prospective study; OFCs = orofacial clefts; N = number

Table 4. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) in Europe

Authors/year	Period (year)	Location	Ethnics	Types of study	Live births (N)	OFC cases (N)	OFC prevalence (N per 1,000 live births)
Moller et al (1965)[32]	1956-1962	Reykjavik, Iceland	Whites	R	32,979	64	1.94
Saxen et al (1975)[33]	1972-1973	Finland	Whites	P	116,407	190	1.63
Bille et al (2005)[34]	1988-2001)	Denmark	Whites	P	992,727	1,332	1.34
Tomatir et al (2009)[35]	2000-2004	Turkey	Arabs, Whites	R	63,159	64	1.02
Rozendaal et al (2011)[36]	1997-2006	Netherlands	Whites	P	1,970,872	3,308	1.68
Antoszewski et al (2013)[37]	2001-2010	Poland	Whites	P	60,109	70	1.16
Total	1956-2010	Europe	Whites, Arabs	R, P	3,236,253	5,028	1.55

R = retrospective study; P = prospective study; OFCs = orofacial clefts; N = number

Table 5. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) in Oceania

Author/year	Period (year)	Location	Ethnics	Type of study	Live births (N)	OFC cases (N)	OFC prevaence (N per 1,000 live births)
Chi et al (1970)[38]	1964-1966	Australia	Whites	R	143,948	174	1.21
Brogan et al (1974)[39]	1963-1972	Australia	Whites	R	193,520	332	1.73
Spry et al (1975)[40]	1949-1968	South Australia	Whites	R	392,228	559	1.41
Bell et al (2013)[41]	1980-2009	Australia	Whites	R	1,396,216	1,757	1.26
Total	1963-2009	Oceania	Whites	R	2,125,912	2,822	1.33

R = retrospective study; P = prospective study; OFCs = orofacial clefts; N = number

Table 6. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) in South America

Author/year	Period (year)	Location	Ethnics	Types of study	Live births (N)	OFC cases (N)	OFC prevalence (N per 1,000 live births)
Menegoto et al (1991)[42]	1967-1981	Brazil	Whites, Hispanics	R	849,381	849	1.00
Souza et al (2013)[43]	2002-2008	Brazil	Whites, Hispanics	R	2,379,798	2,356	0.99
Total	South America	Brazil	Whites, Hispanics	R	3,229,179	3,205	0.99

R = retrospective study; P = prospective study; OFCs = orofacial clefts; N = number

Table 7. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) in Africa

Author/year	Period (year)	Location	Ethnics	Types of study	Live births (N)	OFC cases (N)	OFC prevalence (N per 1,000 live births)
Khan (1965)[44]	1963-1964	Kenya	Black	R	3,016	5	1.65
Gupta (1969)[45]	1964	Nigeria	Black	P	4,066	4	0.95
Robinson et al (1970)[46]	1968	Uganda	Black	P	67,143	47	0.75
Iregbulem (1982)[47]	1976-1980	Nigeria	Black	P	21,624	8	0.30
Morrison et al (1985)[48]	1983-1984	South Africa	Black, Whites	R	9,377	3	0.33
Ogle OE (1993)[49]	1977-1979	Zaire	Black	R	56,637	26	0.46
Msamati et al (2000)[50]	1988-1999	Malawi	Black	R	25,562	17	0.67
Sulaiman et al (2005)[51]	1997-2000	Sudan	Black	R	15,890	13	0.90
Rakotoarison et al (2012)[52]	1998-2007	Madagascar	Black	R	150,973	73	0.48
Kesande et al (2014)[53]	2005-2010	Uganda	Black	R	25,985	20	0.77
Total	1963-2010	Africa	Black	R,P	380,273	216	0.57

R = retrospective study, P = prospective study, OFCs = orofacial clefts, N=number.

Table 8. The birth prevalence of Clefts (Lip, Lip and Palate, and Palate) among races

Ethnics	Numbers of orofacial clefts	Numbers of live births	Birth prevalence (per 1,000 live births)
American Indians	276	105,366	2.62
Japanese	2,244	1,296,187	1.73
Chinese	8,521	5,476,554	1.56
Whites	22,489	14,494,512	1.55
Blacks	240	410,513	0.58

as birth registries, hospital records, and survey can produce ascertainment bias, selection bias or both, (2) the reported prevalence rates from studies with incomplete data collection, and (3) data from different geographic areas and ethnic groups.

Conclusion

Many of the low-income countries do not have surveillance systems for birth defects and OFC clefts. Therefore, the reported birth prevalence rates are not accurate in some of these regions. The WHO International Collaborative Research on Craniofacial Anomalies project including OFC clefts registry is currently initiating in birth defects surveillance, particularly in low-income countries. The international collaboration in this task is needed.

What is already known on this topic ?

Global prevalence data on orofacial clefts have been incomplete for live births and international prevalence rates have not been established.

What this study adds ?

The global prevalence rates on orofacial clefts would have implications for healthcare and policy makers, as evidence-based data. The international collaboration and national registry of this birth defect is needed.

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Potential conflicts of interest

None.

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ความชุกแต่กำเนิดของผู้ป่วยปากแหว่งเพดานโหว่ทั่วโลก: การศึกษาทบทวนอย่างเป็นระบบ

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ภูมิหลัง: *ความชุกแต่กำเนิดของผู้ป่วยปากแหว่งเพดานโหว่ทั่วโลกยังไม่มีการศึกษาอย่างเป็นระบบ*

วัตถุประสงค์: *เพื่อศึกษาความชุกแต่กำเนิดของผู้ป่วยปากแหว่งเพดานโหว่ทั่วโลก*

วัสดุและวิธีการ: *ศึกษาความชุกแต่กำเนิดของผู้ป่วยปากแหว่งเพดานโหว่ทั่วโลกจากรายงานต่างในฐานข้อมูล PubMed ตั้งแต่ปี พ.ศ. 2493 ถึง มิถุนายน พ.ศ. 2558*

ผลการศึกษา: *ผู้ป่วยมีจำนวน 45,193 ราย จากจำนวนเด็กแรกเกิดมีชีพจำนวน 30,665,615 ราย ความชุกแต่กำเนิดของปากแหว่งเพดานโหว่ (ความเชื่อมั่นในระดับร้อยละ 95) แยกตามรายทวีปได้แก่ เอเชีย อเมริกาเหนือ ยุโรป โอเชียนเนีย อเมริกาใต้ และแอฟริกามีดังนี้ 1.57 (1.54-1.60), 1.56 (1.53-1.59), 1.55 (1.52-1.58), 1.33 (1.30-1.36), 0.99 (0.96-1.02), and 0.57 (0.54-0.60) ต่อทารกแรกเกิดมีชีพ 1,000 คน ชนเผ่าอินเดียนชาวพื้นเมือง ในอเมริกาเหนือมีความชุกแต่กำเนิดสูงสุดคือ 2.62 ต่อทารกแรกเกิดมีชีพ 1,000 คน รองลงมาเป็นคนญี่ปุ่น คนจีน และคนผิวขาว คือ 1.73, 1.56 และ 1.55 ต่อทารกแรกเกิดมีชีพ 1,000 คนตามลำดับ ประชากรผิวดำ มีความชุกต่ำสุด คือ 0.58 ต่อทารกแรกเกิดมีชีพ 1,000 คน*

สรุป: *ความชุกแต่กำเนิดของผู้ป่วยปากแหว่งเพดานโหว่ที่แตกต่างกันในรายทวีปเป็นผลมาจากมีความแตกต่าง เผ่าพันธุ์ของประชากรที่อาศัยอยู่ในแต่ละทวีป ทำให้มีความแตกต่างกันทางกรรมพันธุ์และอาจมีปัจจัยของสิ่งแวดล้อมด้วย*