ORIGINAL ARTICLE

Prevalence and Incidence of Insulin Dependent Diabetes Mellitus (IDDM) in Fars province in the South of Iran, 2016-17: An Insurance Archived-Prescription-based Study

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Abstract

Background: Insulin-dependent diabetes mellitus (IDDM) or type 1 diabetes mellitus (T1DM) is known as a chronic autoimmune disease with an increasing prevalence and incidence. This study was conducted to determine the incidence rate and prevalence of insulin-dependent diabetes in Iran in 2016 and 2017.

Methods: In this cross-sectional study, the prevalence of IDDM in insured subjects under the age of 19 was measured through the prescribed insulin in two consecutive years. In this study, we assumed that IDDM patients are those who receive at least one prescription containing any insulin over 2 years in insurance databases. This study was carried out on 98% of patients under age 19, and the prevalence and incidence of IDDM were calculated. Finally, the result of this method was compared with Integrated Health System (IHS) databases.

Results: In general, 1,135,105 insured persons under 19 years of age were enrolled in this study, and the prevalence rates of IDDM in subjects under 19 were 117.6 (111.5-124.2) and 136.8 (130.1-143.8) per 100,000 in 2016 and 2017, respectively. The incidence rate of this disease was 27.4 (24.6-30.8) per 100,000. The highest incidence and prevalence were significantly observed in the age group of 14-19 years. The prevalence of IDDM was not significantly different between boys and girls.

Conclusion: The results of this study showed that the method of prescription follow up was appropriate, acceptable, convenient, and accurate. Our findings showed that the incidence and prevalence of IDDM in this method were in line with other worldwide reliable and accurate reports, even in the developed countries. The results of the present study showed that the prevalence and incidence rate of IDDM in Iran (Fars province) is at an intermediate level.

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Introduction

Diabetes mellitus (DM) is a metabolic disease caused by increased blood glucose due to impaired insulin secretion or insulin function, or both.[1] The incidence rate and prevalence of DM are on the rise worldwide, and studies have shown that the prevalence of type 2 diabetes mellitus (T2DM) has almost doubled during the

last three decades.[2 3] In 2013, about 381.8 million people were diagnosed with DM and estimated to increase to 591.9 million until 2035.[3] Most people with DM live in low or middle-income countries, and the most frequent occurrence is observed in these nations.[4]

Type 1 diabetes mellitus (T1DM) occurs because of very low or lack of insulin production. It affects about 5-10% of all diabetes cases, and is most commonly seen in children.[5, 6] T1DM might occur at any age, but it is rare at the age below one. The disease has a stormy onset, unknowns are rare, and it is diagnosed shortly after onset. The incidence of T1DM increases with age until adolescence.[7] It is estimated that around 40 million people in the world are affected by this disease, and 78,000 are added each year.[8] It is predicted that the number of people with T1DM under the age of 15 in Europe will be rising from 94,000 in 2005 to 160,000 in 2020.[9] The highest incidence rate of T1DM in the world was amongst people under the age of 14 in Finland and the lowest in China and Venezuela with 40 and 0.1 per 100,000, respectively.[7] The incidence rate of T1DM in Macedonia was 3.6, Sudan 30,[9-11] New Zealand and Australia 25,[7] and the United States 24.3 per 100,000.[12]

However, there is no accurate information on the incidence and prevalence of T1DM in Iran. A study in Fars province, Iran, 1991-1996 showed that the incidence rate in women was 4.37 and in men 3.14 per 100,000 per year.[13] IDDM includes mostly T1DM and some cases of T2DM who require using insulin.[14]

Almost, all studies that estimated the incidence and prevalence of T1DM mellitus used screening tests, or surveillance system information.[15] However, today, there is a different and newer method for examining the incidence and prevalence of some chronic diseases in special circumstances, and the mentioned method is based on prescriptions records. If prescription database is available, this method can be economical, easier and more accurate.

To conduct this method, the following conditions are required:[16]

It is better to be a chronic disease, the disease has an accurate and accepted definition, the disease has very short asymptomatic period, there are certain drugs or medications, medications are specific for the disease, the patients do not get medicine free, and finally prescriptions are recorded in a database.

In different countries, this method has been used to estimate the prevalence of eligible diseases. In 2010, this method was used to assess the prevalence of epilepsy in people over 18 years of age in Ireland, and the prevalence was estimated at 10 per 100,000 people.[17] In 2016, health information records were used to investigate the prevalence of multiple sclerosis (MS) in Italy, and the researchers found the prevalence of MS to be 13.5 per 100,000.[18] In 2016, the prescriptions information was utilized to measure the diabetes prevalence and pattern of treatment in Greece; it was concluded that 7% of all Greek people are diabetic and 3.4% of all patients with diabetes have type 1 diabetes.[19]

However, there is no accurate information on the prevalence of IDDM in Iran. Measuring the incidence and prevalence of IDDM through blood sample is very difficult, costly and time-consuming. Therefore, we decided to determine the prevalence and incidence of IDDM in the age group under 19 by reviewing prescriptions in Iran.

Methods

In this cross-sectional study, we measured the prevalence of IDDM in subjects under the age of 19 through the prescribed insulin in two consecutive years. The reason for choosing this age group was the increased incidence of type 2 diabetes after the age of 20.[20] In this study, we assumed that IDDM patients are those who receive at least one prescription containing no insulin over a year.

The study inclusion criteria were:

being under 19 years of age, living in Fars province, being covered by the Iranian health insurance (IHI) or social security insurance (SSI), and the individual information being available in 2016 and 2017.

The study exclusion criteria were:

living in Fars Province during these two years (2016-17) and dying within these two years (2016-17), and they immigrating to the Province in 2017.

In this study, we reviewed all registered IHI and SSI prescriptions (covering 98% of the total population) of people under the age of 19 in 2016-17. Other insurance agencies included the army insurance, banks insurance, teachers insurance, and people with no insurance. Based on Iran insurance rules, everyone for getting insulin at the first time needs to create an account in insurance centers; to create an account, he/she needs HBA1C test and a specialist doctor's approval. After that, each time the patient needs a new prescription to receive insulin. Therefore, insulin drug in Iran has a strong registration system.

In this study, based on the national ID number, we collected every person's prescriptions over the mentioned 2 years using the KU-TOOLS in Excel software (Microsoft Excel, 2013; Microsoft, Redmond, Washington, USA). For each individual, the type of drugs and their doses were calculated over a year. The family physician database was used to obtain information on the age and gender for all individuals under the age of 19 years; accordingly, there were 1,135,105 insured people under the age of

19 years. The family physician information and drug information based on the national ID number were integrated using Excel software and the VLOOKUP command. To ensure that the estimation of Insulin-containing prescription was accurate, we confirmed all people who had insulin prescription over the mentioned two years and also 200 people who had no history of receiving insulin by telephone; Kappa was high and equal to 96.2% (95.8% - 96.5%). In this study, 95 people had received insulin in 2016, but there was no evidence of insulin record in 2017, and we could not get any information in this regard, despite several phone calls. To overcome the uncertainty in people who received insulin in 2016 and had not received any insulin in 2017 and to eliminate the gestational diabetes cases, we used one-way sensitivity analysis.

For estimation of gestational diabetes and the rates of marriage under 19 years, we extracted the rate of pregnancy under 19 years and the incidence rate of gestational diabetes in people under 19 years from various articles.[21-26] Then, we used the following equation to calculate the prevalence of IDDM in the best and worst scenarios:

Probability of female without gestational diabetes = *[1 - (Proportion of female × Proportion of age 15-19 × Probability of marriage × rate of pregnancy × rate of gestational diabetes)]*

To calculate the probability of gestational diabetes, we multiplied the maximum and minimum of all of mentioned factors (proportion of female, proportion of age 15-19, probability of marriage, rate of pregnancy and rate of gestational diabetes), and an upper and lower limit was determined for gestational diabetes. An upper and lower limit for gestational diabetes determined the prevalence of gestational diabetes in the best and worst conditions. Finally, the determined limits were subtracted from the calculated prevalence of IDDM.

With respect to uncertainty, 95 patients who had received insulin in 2016 and had not received any insulin in 2017, but we could not get in touch with them, the incidence and prevalence rates of IDDM in the best (all 95 were assumed as healthy people) and the worst scenarios (all 95 people were considered as ill) were calculated. 95% confidence interval (CI) for the incidence and prevalence rates of IDDM with parametric Wald interval and nonparametric Bootstrap method were calculated using the R software version 3-0-2 (The R Project for Statistical Computing).[27] There was negligible difference between CI estimations in the two mentioned methods. Finally, we compared prescription-based method findings with those of Integrated Health System (IHS) database.

Results

In general, 1,135,105 insured persons under 19 enrolled in this study. Their demographic characteristics are shown in Table 1.

According to the prescribed insulin, the prevalence of IDDM in people under 19 was 117.6 and 136.8 per 100,000 in 2016 and 2017, respectively. The incidence rate of this disease was 27.4 per 100,000. (Table 2)

Sensitivity analysis results illustrate that the prevalence of IDDM considering the gestational diabetes mellitus can vary from 116.3 to 117.7 per 100.000 in 2016, and 135.5 to 136.8 per 100.000 in 2017, and prevalence of IDDM with regarding unknown cases can vary from 136.8 to 145.3 per 100.000 in 2017.

According to age, gender and insurance type, we conducted sub-group analysis and the highest incidence and prevalence were significant in the age group of 14-19. The prevalence of IDDM was not significantly different between boys and girls (Table 3).

Prevalence of IDDM in people under 19 that lived in cities was significantly higher than those who lived in rural areas (P<0.001). Hence, living in cities increased the risk of insulin-dependent diabetes by 57%.

According to the insurance records, there was uncertainty regarding two factors namely gestational

Table 1: Demographic characteristics of the participants

Variable	Frequency	Percent
Gender		
Male	582,122	51.3
Female	552,983	48.7
Age group(years)		
<2	135,203	11.9
2-7	395,499	34.8
8-13	351,314	30.9
14-<19	253,089	22.3
Type of Insurance		
SSI [a]	571,939	50.4
IHI [b](Urban)	312,509	27.5
IHI (Rural)	250,657	22.1

[a]Social security insurance; [b]Iranians health insurance

Table 2: Annual incidence and prevalence (%) of IDDM in 2016 and 2017

Year 2016 \ Year 2017		Insulin		Total
		Yes	No	
Insulin	Yes	1,241 (0.109)	95 (0.008) [a]	1,336 (0.117%) [b]
	No	312 (0.027%) [c]	1,133,457 (99.900%)	1,133,769 (99.9%)
Total		1,553 (0.136%) [d]	1,133,552 (99.900%)	1,135,105 (100%)

[a]Cases that consider as IDDM in 2016 but she/he had no any medication in prescription in 2017; [b]Prevalence of IDDM in 2016; [c]Incidence of IDDM; [d]Prevalence of IDDM in 2017; IDDM =Insulin-dependent diabetes mellitus

Table 3: The prevalence and incidence of IDDM by age, gender and insurance groups

Demographic Characteristics		Prevalence and 95% CI (per 100,000)				Annual Incidence	
		N	2016	N	2017	N	(per 100,00)
Age group (years)	<2 (N=135,203)	1	0.7 (0.1-4)	9	6.6 (3.5-12)	8	5.9 (2.9-11.6)
	2-7 (N=395,499)	173	43.7 (37.7-50)	229	57.9 (50.9-65.9)	77	19.5 (15.6-24.3)
	8-13 (N=351,314)	537	152.9 (140.5-166.3)	630	179.3 (165.9-193.9)	124	35.3 (29.6-42.1)
	14-<19 (N=253,089)	625	246.9 (228.4-267.1)	685	270.7 (251.2-291.7)	103	40.7 (33.6-49.3)
Gender	Male (N=582,122)	653	112.2 (104-121.1)	747	128.3 (119.5-138)	145	25 (21.2-29.3)
	Female (N=552,983)	683	123.5 (114.6-133.1)	806	145.8 (136-156.2)	167	30.2 (26-35.1)
Location	Urban (N=884,448)	1132	128 (120-135)	1308	148 (140-156)	246	27 (24.5-31.5)
	Rural (N=250,657)	204	81.4 (71-93.3)	245	97.7 (86.3-111)	66	35.1 (28.5-43.2)
Insurance	SSI [a] (urban) (N=571,939)	702	122.7 (114-132.2)	826	144.4 (144.4-154.6)	149	26.1 (22.2-30.6)
	IHI [b](urban) (N=312,509)	430	137.6 (125.2-151.2)	482	154.2 (141.1-168.6)	97	31 (25.4-37.8)
	IHI (rural) (N=250,657)	204	81.4 (71-93.3)	245	97.7 (86.3-110.8)	66	35.1 (28.5-43.2)
Total (N=1,135,105)		1336	117.7 (111.5-124.2)	1553	136.8 (130.1-143.8)	312	27.5 (24.6-30.8)
Sensitivity analysis (scenarios)	Best	1,320	116.3	1,538	135.5	218	19.2
Worst	1,336	117.7	1,649	145.3	312	27.5	

[a]Social security insurance; [b]Iranians health insurance

diabetes and persons who received insulin in 2016, but did not receive it in 2017. To overcome uncertainty, we used sensitivity analysis and the prevalence changed from 116.3 in 2016 to 145.3 per 100,000 in 2017 between the best and worst scenarios, respectively.

The prevalence of IDDM in people under 19 was calculated based on three methods including follow up prescription method, the number of registered patients with type 1 diabetes and those using insulin in the IHS in 2017. This comparison was used to evaluate Integrated Health System (IHS). IHS is a care system affiliated with medical universities in which the individuals' health information is recorded. This system has been used since 2014. The prevalence of IDDM estimated based on prescription method was higher than IHS databases (Table 4).

The result of this comparison showed that IHS system did not recognize and register all the patients and prevalence of IDDM based on prescription-based method was higher than HIS (Table 5).

Discussion

Diabetes is a major public health challenge in the twenty first century.[28] Insulin-dependent diabetes mellitus or T1DM is a type of diabetes, known as a chronic autoimmune disease,[29] with an increasing prevalence.[30, 31] A problem with IDDM is the method used to measure its incidence and prevalence because it is a rare disease and screening methods are not cost-effective to estimate the burden of the disease. Several studies used the method of tracking the prescriptions for estimating the prevalence and incidence of different diseases.[17-19, 32, 33] In this study, we also selected the method of using insulin-prescribed prescriptions as an alternative method to measure the prevalence and incidence of IDDM. The reasons for selecting this method was that insulin is the only drug for IDDM, and it is not used to treat any other illnesses at the age below 19, and IDDM has no other treatment. In addition, because of the complete and accurate pharmacological registration system of insulin delivery in Iran, which was approved by a specialist physician at first, all prescriptions containing

Table 4: Comparison of the prevalence of Insulin-dependent diabetes mellitus (IDDM), by age, gender and insurance groups in prescription-based method in the insurance records with registered diabetic patients and those using insulin in the integrated health system (IHS) in 2017

Measurements \ Databases		Prescription-based (N)	Integrated Health System (IHS) databases	
			Cases identification (N)	Insulin consumption (N)
Total Number of cases (N=1,135,105)		1553	557	485
Total prevalence (*100,000) (N=1,135,105)		136.8	49	42.7
Gender	Prevalence in male (N=582,122)	128.3	48.9	41.4
	Prevalence in female (N=552,983)	145.8	52.6	44.1
Age groups	<2 (N=135,203)	6.6	1.4	2.9
	2-7 (N=395,499)	57.9	17.1	15.2
	8-13 (N=351,314)	179.3	65.1	56.3
	14-<19 (N=253,089)	270.7	109.8	88.1

Table 5: Insulin dose changes based on prescribed prescriptions in the insurance archive

Types of insulin	Doses (vial)		
	2016	2017	Change rate (%)
Novo rapid	24,810	32,442	30.8
Lantus	21,559	27,309	26.7
Regular	1391	1045	-24.9
NPH	1953	1526	-21.8
Novo mix	432	447	3.5
Apidra	143	738	416.1
Levemir	90	587	552.2
Biphasic Isophane	1	3	200.0

insulin are registered at the databases of pharmacies before delivery to the patients. Therefore, we assume that IDDM has all the necessary criteria to be used. A study compared the prevalence and incidence of chronic diseases in two methods, routine cross-sectional vs. prescription; it was found that prescription-based method like the routine cross-section could provide precise and accurate estimation of the burden of chronic diseases in a general population.[34] A study that had assessed the prevalence of Parkinson's disease showed that this method was very good and could be used to estimate the prevalence of some diseases in large populations.[33]

Our findings showed that the prevalence of IDDM was 117.7 and 136.8 per 100,000 people in 2016-17, respectively. The incidence and prevalence of the disease in men and women did not differ significantly, but increased with age, and was consistent with the results of a similar study.[7] A population based study in the US showed that the prevalence of IDDM was 228 per 100,000.[35] A study conducted in 2008 in the United States also illustrated that the prevalence of IDDM in people younger than 19 years old was 193 per 100,000.[36] In African American youth, the prevalence of IDDM was 261 per 100,000.[37] In another study in Sydney, the prevalence of IDDM in people under the age 19 was estimated at 80 per 100,000 people,[38] which was in line with our study findings.

Most studies reported incidence rates rather than the prevalence. Our results showed that the annual incidence of IDDM was 27.4 per 100,000 people. The range of reported incidence in the world was wide from 0.1-36.8 per 100,000.[11] The results of our study is similar to those of other studies; the incidence of IDDM was reported 31in Saudi Arabia and 22in Kuwait per 100,000 people.[39] A study in the United States showed that the incidence of IDDM in people younger than 20 was 24.3 and in Finland 27 per 100,000.[40, 41] In two separate studies conducted to estimate IDDM in northern Europe and Australia, the incidence of IDDM was estimated 13-16 and 21-22.1 per 100,000, respectively.[42, 43]

According to the current classification, the incidence of more than 20 per 100,000 is considered as a very high incidence region.[11] Therefore, according to our findings, Iran is amongst the countries with very high incidence of IDDM. Of course, presence of differences between our findings and this study could be due to different methods of collecting data and different target age groups.

Strengths

Since a specialist physician should approve a case of

IDDM as a new case, validity of our study is acceptable because all IDDM cases are listed in insurance database, and pharmacies should register all types of insulin in computer before delivering. The comparison of our findings with the recorded information in integrated health system (IHS) showed that IHS had no acceptable sensitivity and cannot provide accurate information about IDDM. As shown in Table 4, IDDM patients registered in the surveillance system related to IHS are one third of real patients, and those who received insulin were less than a third of the known patients. Therefore, the current diabetes surveillance system that comes from IHS database cannot cover all IDDM cases or those who received insulin. Finally, we covered 98% of the total population aged under 19 in Fars province; hence, the incidence and prevalence of IDDM could be generalized to the whole population.

Limitations

As mentioned, prescription-based method requires several assumptions or conditions to operate. This is a convenient and low cost method, if all disease and medication assumptions exist and there is an updated and complete computerized database. In this study, some people who had received insulin, but we could not obtain their disease-related information or contact them. To solve this problem, we conducted sensitivity analysis. As another limitation, precise date on prescription was not available. If we had the exact prescription date, we could make a better decision and estimation on insulin-contained prescriptions as IDDM case. Consequently, we had to label anyone as IDDM who received even only one prescription-containing insulin. Finally, it would be better to estimate the prevalence and incidence of IDDM in people under the age of 30, but due to the possibility of T2DM in ages 19-30 years,[20] we preferred to conduct this study in the age under 19. It was better if we had removed those who were taking the oral anti-hyperglycemic drugs from the study.

Conclusion

The results of this study showed that the method of prescription tracing is appropriate, acceptable, convenience, low cost, and accurate. This method needs to record all prescriptions in a comprehensive and updated database; in this case, we could estimate the incidence and prevalence of most chronic diseases. Our findings showed that the incidence and prevalence of IDDM in this method were moderately high and in line with other worldwide reliable and accurate reports, even in the developed countries.

Recommendation

Finally, we suggest that this method and its prerequisites should be considered as a standard method for estimation of burden of diseases.

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Conflict of Interest: None declared.

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