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Original Article

Time Series Analysis of Cutaneous Leishmaniasis in Sabzevar Northeastern Iran Using Segmented Regression Model

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Abstract

Background and aims: Cutaneous leishmaniasis (CL) is one of the most important parasitic diseases in the world. Sabzevar city is endemic area for CL in the north east of Iran. The aim of this study was to evaluate the time distribution of cutaneous leishmaniasis (CL) in Sabzevar County using the segmented regression model.

Methods: This ecological study used the existing data related to the rural districts of Sabzevar County that were obtained from the Health Deputy of this county during 2011-2017. In addition, the segmented regression model was applied to evaluate the time trend of CLs. Finally, Joinpoint software was used for time series analysis.

Results: A total of 1912 CL cases occurred in Sabzevar County from 2011 to 2017, with an incidence rate of 93.61 per 100 000. The highest and lowest observed incidence rates were in 2011 (25 per 10 000 persons) and 2015 (3.24 per 10 000 persons), respectively. Based on the results, the annual incidence of CL in the intended region decreased and the annual percent change was equal to -22.40. Further, the time series analysis using segmented regression by rural districts showed a change point in the trend of the incidence of leishmaniasis in three rural districts (Pain Joveyn and Joghatai in 2014 and Qasabeh-ye Sharqi in 2013). In other words, the trend was different before and after the change point in the mentioned districts.

Conclusion: In general, the results indicated that interventional, preventive, and therapeutic measures for breaking the *chain* of CL *transmission* in Sabzevar have been desirable in recent years. Eventually, it is suggested that further time-series studies be conducted at the level of the month or a longer interval in order to better evaluate the period effect and secular trend.

Keywords: Cutaneous leishmaniasis, Segmented regression model, Sabzevar

Introduction

Cutaneous leishmaniasis (CL), as a neglected disease, is one of the most important parasitic diseases in the world.[1] There is no determined treatment for leishmaniasis, and several issues are frequently reported in this regard, including inappropriate treatment, failure to treat, and disease relapse.[2] Nearly 90% of cases occur in Afghanistan, Algeria, Iran, Iraq, Saudi Arabia, Syria, Brazil, and Peru.[3]

Iran is regarded as one of the main foci of Leishmaniosis in the world. The annual frequency of leishmaniasis in Iran is more than 20 000 cases,[4] and its prevalence is increasing due to environmental changes (caused by crises, travel, and migration) and malnutrition.. The epidemiological pattern of CL has changed in recent years and has led to an increase in the incidence of disease in non-endemic areas and the emergence of new foci of the disease in some places.[6] Therefore, the investigation of the epidemiological aspects of CL can play an important role in its reduction. More precisely, monitoring the leishmaniasis and its reservoirs in different regions, especially in indigenous areas, is extremely necessary for preventing the occurrence of the disease, its complications, and the high cost of treatment.[7-10]

The determination of its incidence pattern over time is one of the important determinants of surveillance, monitoring, and health planning. It is believed that providing epidemiological data on the trend of incidence, mortality, or the risk factors of the disease plays an important role in preventing adverse outcomes. In other words, providing evidence and information about the trend of a disease over time can have an essential role in evaluating the health plans and development of the indicators of a community.[11,12]

The segmented regression model is one of the appropriate methods for evaluating the incidence of a disease, which allows determining the number and location of changes in the incidence of a given disease over a period of time.[13-15] The estimation of the annual percentage changes (APC) and the average of annual changes is possible by using this regression model. These two indexes indicate the trend of incidence. The segmented linear regression is a useful instrument for describing the trend of data changes, particularly data on the incidence of disease or mortality. Therefore, the present study applied the segmented regression model to evaluate the time distribution of CL in Sabzevar County so that the results can be used to promote prevention and control programs in this county.

Materials and Methods

Study Site

The present ecological study used the existing data related to the rural districts of Sabzevar county. The geographical units of the study were 24 villages in this county. It should be noted that Sabzevar is located in the northeast of Iran with about 57° 67’ N latitude and 36° 20’ E longitude.

Data Collection

The data of people suffering from CL and treated in the health care centers of Sabsevar during 2011-2017 were collected from the Health Deputy of this county. Data were collected on a monthly basis and classified according to age, gender, and the rural district, and the incidence of the disease was calculated by year.

Statistical Analysis

In this study, a segmented linear regression was used to identify the time pattern of leishmaniasis. It is a method for the segmentation of the nonlinear regression model into separate linear fragments. These fragments are separated by the change point. The optimal number and location of the change-point were estimated using the grid search method.

For each geographic unit *i*, the mean of the regression function is equal to

$$E\left(y|x\right)=\beta_0+\beta_{i,1}x+\delta_{i,1}\left(x-\tau_{i,1}\right)^{+}+\cdots+\delta_{i,k_i}\left(x-\tau_{i,k_i}\right)^{+}$$

where *ki* and τ represent the number of unknown change-points and the change-points, respectively, and β and δ denote the parameters of regression. In this study, the natural logarithm of the annual incidence of CL and the intended years (2011-2017) were considered as dependent and independent variables, respectively.

The Estimation of Annual Percent Changes and Average Annual Percent Changes (AAPC)

APC is used to describe the incidence of a disease over time, considering the assumption that the incidence of years x to year x-1 is constant.

The following regression model was used to estimate of APC for a series of data.

$\text{Log}(R_X) = b_0 + b_{1X}$

Where log (Rx) is the natural logarithm of the rate in year x. The APC estimation from year x to year x+1 is equal to

$$X+1=\left[\frac{R_{X+1}-R_X}{R_X}\right]\times 100=\frac{\left[e^{b_0+b_1(X+1)}-e^{b_0+b_1(X)}\right]}{e^{b_0+b_1(X)}}\times 100=\left(e^{b_1}-1\right)\times 100$$

In addition, AAPC is applied to provide a summary of the time trend and a single index for the time trend. This index is a weighted average of the APC obtained from the regression model corresponding to each segment. Weights are equal to the APC time interval.

The following formula was used to estimate the AAPC.

$$AAPC=\left\{\left\{Exp\left(\frac{\Sigma w_i b_i}{\Sigma w_i}\right)-1\right\}\times 100\right.$$

The b_is value represents the slope of the line (regression coefficient) for each section over a period of time and *wis* is the length of each segment over a period of time. Further, the confidence interval for AAPC and APC is based on the normal distribution and the t distribution, respectively. Joinpoint software was used for time series analysis. The random error variable in the segment regression model is homoscedastic if the variance of the errors is constant. Otherwise, the error is heteroscedastic. The assumption of homoscedasticity does not frequently exist, especially when the variance of the error varies greatly over time. Considering the changes in the frequency of the leishmaniasis over time in the intended population and for having a more conservative state in the analyses, the random variable error was considered heteroscedastic. In Joinpoint software, the inequality of variance was checked in several ways. Regarding the nature of the dependent variable, which is the type of count, the variance of the random variable was determined using the Poisson variance option, and the parameters of the segmented regression model were estimated as well. The *P* value of the test was estimated applying the permutation distribution of the test statistic and obtained through 4499 permutations.

Results

In general, 1912 cases of CL (93.61 per 10 000) were observed in the whole region under study during 2011-2017. The largest number of CL cases (511) occurred in 2011 with an incidence rate of 25 per 10 000 persons whereas the least number was found in 2015 with an incidence rate of 3.30 per 10 000 persons in the entire region under investigation. Figure 1 displays the time trend related to the annual incidence of the total cases of

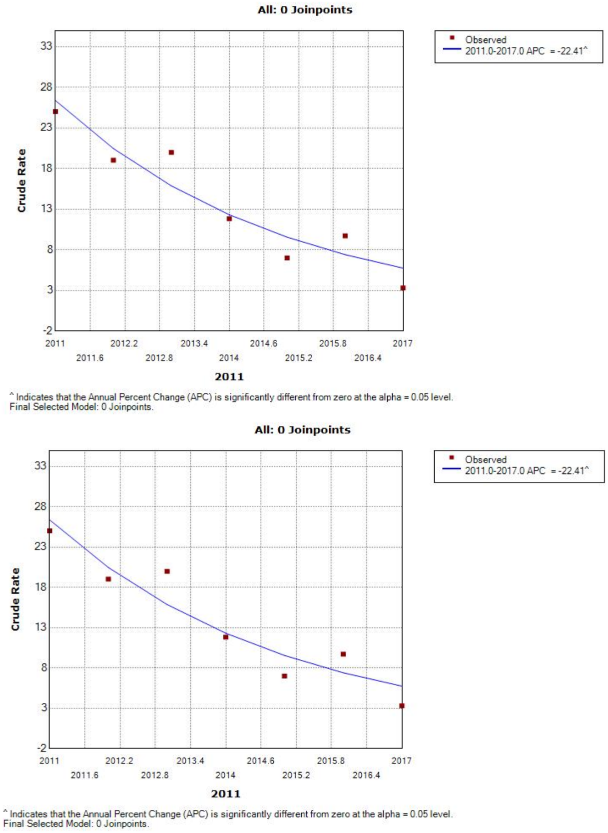

Figure 1. The Time Trend Related to the Annual Incidence of the Total Cases of Leishmaniasis Based on the Segmented Regression Analysis in Sabzevar County during 2011-2017

leishmaniasis based on the segmented regression analysis in the intended region for the period from 2011 to 2017.

The fitting of the model to the applied data showed that there was no break or change-point during the period. Regarding the formula:

Log-linear model:

Rate=Exp(β_0) × Exp(β_1X)

ln(rate)= β_0 + β_1X

The joinpoint regression mean response function for the incidence of the CL was equal to

358.18-0.25x=(x|y)E

Furthermore, APC in the incidence of the disease was estimated -22.40 (95% confidence interval of -11.99--31.6). In other words, it is expected that the incidence of CL decreases by about 22.40%.

The time trend of the annual incidence of total leishmaniasis based on the regression analysis in the intended region during 2011-2017 by the rural districts is shown in Supplementary.

Moreover, Tables 1 and 2 present the estimation of the regression coefficient β_i, the regression coefficients δi segments, APC, and AAPC by the rural districts.

The results showed that the trend of the incidence of CL in some villages differs, and change points were observable. For example, in Pain Joveyn, Joghatai, and Qasabeh-ye Sharqi villages, there was a change point at different times. In other words, in the mentioned districts, the trend was different before and after the change point. Additionally, there was no change point for other villages, indicating a constant trend in the incidence of the disease. However, for Miyan Joveyn, Bashtin, Robat, Bala Jowayin, and Hokmabad villages, the trends were statistically significant (P<0.05).

The joinpoint regression mean response function for the incidence rate in the rural district where the change point has occurred in the trend is as follows.

For example, for a Joghatai rural district with a change point , the regression coefficients are as follows:

$$E\left(y|x\right)=\beta_0+\beta_1 x+\delta_1\left(x-\tau_1\right)^+ +\cdots+\delta_k\left(x-\tau_k\right)^+$$

+(2014-x)21 /1-0.51x +721.80 - = (x|y)E

Regarding the Joghatai rural district, the trend increased from 2011 to 2014 while decreasing from 2014 to 2017. Given the following function, the APC was as follows:

$$\log\left(R_y\right)=b_0+b_1 x$$

where log(Rx) is the natural log of the rate in year x. The APC from year x to year is expressed as

$$x+1+\left[\frac{R_{X=1}-R_X}{R_X}\right]\times 100=\frac{\left\lfloor e^{b_0+b_1(X+1)}-e^{b_0+b_1(X)}\right\rfloor}{e^{b_0+b_1(X)}}\times 100=\left(e^{b_1}-1\right)\times 100.$$

As regards the Joghatai rural district, the APC of the incidence of the disease was estimated to be 68.1 with a 95% confidence interval (-58.8-586.4) during 2011-2014 and 49.5 with a 95% confidence interval (191.9-91.3) during 2014-2017. In other words, it is expected that the incidence of CL has increased 68.1 for each year during 2011-2014 while it has decreased by 49.5% after 2014. The AAPC index for the Joghatai rural district as the average of the two APC was estimated -7.9. Although it was not statistically significant, it could generally indicate a decreasing trend of the disease during 2011-2017.

Discussion

In the present study, the annual incidence of CL was 93.61 per 10 000 persons, which is consistent with the findings of previous reports in Iran.[8,16,17] The highest and lowest observed incidence rates were in 2011 (25 per 10 000 persons) and 2015 (3.24 per 10 000 persons), respectively. In a study conducted by Ayubi et al. during 2005-2017, the highest incidence (212.86 per 10 000 persons) of the disease was observed in 2011 (2011-2012) while the least incidence (2.47 per 10 000 persons) was related to 2015 (2015-2016) all over the country.[18] In addition, 2676 new cases of CL were reported in another study conducted in Kashan[19] during 2009-2016. The highest and the least incidence was reported in 2009 (21%) and 2016 (6.6%) with an incidence of 182 per 100 000 and 47 per 100 000 persons, respectively. Accordingly, there have been common reasons that led to an increase in the incidence of

Table 1. Estimation of the Regression Coefficient and Significant Level for the Correlation Between Time Period and the Incidence of Cutaneous Leishmaniasis in the Rural District

District	Parameter*	Parameter Estimate	Standard Error	*P* Value
Pain Joveyn	Intercept 1	74.21	145.21	0.66
	Slope 1	-0.05	0.10	0.67
	Slope 2 - Slope 1	-0.93	0.33	0.10
Joghatai	Intercept 1	-721.80	454.92	0.25
	Slope 1	0.51	0.32	0.25
	Slope 2 - Slope 1	-1.20	0.52	0.14
Miyan joveyn	Intercept 1	358.31	132.65	0.04
	Slope 1	-0.25	0.09	0.04
Bashtin	Intercept 1	-1278.51	443.7	0.03
	Slope 1	0.91	0.31	0.03
Kah	Intercept 1	-647.06	376.97	0.14
	Slope 1	0.46	0.27	0.14
Mazinan	Intercept 1	168.79	256.34	0.53
	Slope 1	-0.12	0.18	0.54
Takab-e Kuhmish	Intercept 1	88.77	817.04	0.91
	Slope 1	-0.06	0.58	0.91
Rob-e Shamat	Intercept 1	-90.59	96.22	0.38
	Slope 1	0.06	0.06	0.38
Shamkan	Intercept 1	-60.04	100.27	0.57
	Slope 1	0.04	0.07	0.57
Beyhaq	Intercept 1	85.55	95.49	0.41
	Slope 1	-0.06	0.06	0.41
Qasabeh-ye Gharbi	Intercept 1	-288.57	256.44	0.31
	Slope 1	0.20	0.18	0.31
Qasabeh-ye Sharqi	Intercept 1	-1190.08	960.42	0.34
	Slope 1	0.85	0.60	0.34
	Slope 2 - Slope 1	-1.72	0.73	0.14
Robat	Intercept 1	315.70	101.03	0.02
	Slope 1	-0.22	0.07	0.02
Khavashod	Intercept 1	-16.07	95.76	0.87
	Slope 1	0.01	0.06	0.87
Frughan	Intercept 1	-26.088	204.73	0.25
	Slope 1	0.19	0.14	0.25
Kuh Hamayi	Intercept 1	-14.04	81.97	0.87
	Slope 1	0.01	0.05	0.85
Bala Jowayin	Intercept 1	522.60	91.75	0.002
	Slope 1	-0.37	0.06	0.002
Pirakuh	Intercept 1	1.87	258.94	0.99
	Slope 1	-0.000049	0.18	0.99
Hokmabad	Intercept 1	602.56	59.53	< 0.001
	Slope 1	-0.42	0.04	< 0.001
Darreh Yam	Intercept 1	190.09	168.65	0.31
	Slope 1	-0.13	0.12	0.31
Soltanabad	Intercept 1	121.23	193.73	0.55
	Slope 1	-0.08	0.14	0.56
Tabas	Intercept 1	598.10	381.04	0.17
	Slope 1	-0.42	0.27	0.17
Dasturan	Intercept 1	-50.41	264.92	0.85
	Slope 1	0.03	0.19	0.85
Robat-e-jaz	Intercept 1	455.49	179.09	0.05
	Slope 1	-0.32	0.12	0.05

Table 2. The Estimation of APC and AAPC by the Rural District

Rural District	Change Point	APC	CI (95%)	*P* Value	AAPC	CI (95%)	*P* Value
Pain Joveyn		-4.9	-39.3 - 49	0.7	-40.5	-57.2 – 17.3	< 0.001
		-62.8	-90.6 – 47.4	0.1			
Joghatai		68.1	-58.8 – 586.4	0.3	-7.9	-44.8 – 53.8	0.8
		-49.5	-91.3 – 191.9	0.2			
Miyan joveyn		-22.5	-39.3 - 1	< 0.001			
Bashtin		150.8	10.7 – 468.3	< 0.001			
kah		59.4	-20.4 – 219.3	0.1			
mazinan		-11.3	-44.8 – 42.3	0.5			
Takab-e Kuhmish		-6.0	-79.2 – 324.5	0.9			
Rob-e Shamat		6.7	-10.6 – 27.5	0.40			
Shamkan		4.4	13.2 – 25.6	0.60			
Beyhaq		-5.9	-21.1 – 12.2	0.40			
Qasabeh-ye Gharbi		23.1	-23.3 – 97.5	0.3			
Qasabeh-ye Sharqi		135.5	-87.9 – 4500.5	0.30	-25.4	-57.3 – 30.5	0.3
		-58.0	-85.8 – 24.3	0.1			
Robat		-20.3	-33.9 - -3.9	< -0.001			
Khavashod		1.2	-15.2 – 20.7	0.9			
Frughan		20.9	-17.1 – 76.4	0.3			
Kuh Hamayi		1.1	-13.1 – 17.6	1.1			
Bala Jowayin		-31.1	-41.9 - -18.4	< 0.001			
Pirakuh		0	-38 – 61.3	1			
Hokmabad		-34.9	-41.7 - -27.4	< 0.001			
Darreh Yam		-12.8	-36.1 – 19.1	0.30			
Soltanabad		-8.3	-35.9 – 31.1	0.60			
Tabas		-34.8	-67.7 – 31.7	0.20			
Dasturan		3.8	-36.4 – 69.2	0.90			
Robat-e-jaz		0.10	-48.2 – 0.50	0.10			

Note. APC: Annual percent changes; AAPC: Average annual percent changes; CI: Confidence interval.

the disease in the two populations. The results of Pakzad et al[8] regarding the spatiotemporal of CL in Iran showed that there was a fluctuation in the incidence of the disease throughout the country and there was no linear trend. Some studies reviewed the trend and time series of CL in Iran and the world.

For instance, Sharafi et al[20] predicted the trend of CL and assessed the relationship between disease trend and climate variables in the south of the province using the autoregressive integrated moving average model during 2010-2016. They concluded that the descending trend of the disease was because of drought condition continuation.

In another study in Iran, the trend and time series of CL were decreasing in a way that for each year, the incidence of CL decreased by 3.6%.[18] The results of the present study demonstrated that the time trend for the annual incidence of leishmaniasis in the region under study was decreasing, and APC was equal to -22.40. This means that the incidence of CL decreased by 22.40% for every year increase. Time series analysis using segmented regression by the rural district revealed that there was a change point in the trend of the incidence of leishmaniasis in three villages (i.e., Pain Joveyn and Joghatai in 2014 and Qasabeh-ye Sharqi in 2013), implying that there was increasing and decreasing trends before and after the change point. Such a trend was observed in a study conducted during 2005-2017.[18] In this study, the results of the time series indicated an increase in the disease during this period so that it reached its peak in 2013 (An incidence of 74 per 10 000 persons) and then represented a decline although this change point was not statistically significant. This non-significant result may be due to the lack of study points. The results of a study in the general population of Khuzestan Province during 2010-2014 indicated a decrease in the incidence of the disease[21] in a way that it decreased from 1166 cases in 2010 to 420 cases in 2014. The changes in climate are most likely to be the cause of these changes in the incidence of the disease.

Limitations of the Study

Like any other studies based on existing data and registration systems, this study had some limitations such as the lack of age and gender information, misclassification, mistreatment, missing data, and underestimation or overestimation that should be considered in the interpretation of the results of our study.

Conclusion

Based on the results of the time series analysis, there has been a significant decrease in CL in Sabzevar in recent years. However, the pattern of the disease over time in some rural areas is different from the observed pattern in the county. Considering that the incidence of CL depends on the month, season, and some climatic variables, it is suggested that further time-series studies be conducted at the level of the month or a longer interval for better investigation of the period effect and secular trend. The effects of climate variables on the incidence of the disease over time should be evaluated as well.

Thus, the results of this study indicate that in recent years, interventional, preventive, and therapeutic measures have been desirable for breaking the *chain* of CL *transmission* in the county of Sabzevar.

Conflict of Interest Disclosures

The authors declare no conflicts of interest.

Ethical Approval

This research was approved by the Ethics Committee of Sabzevar University of Medical Sciences (Ethic No. IR.MEDSAB.REC.1396.17) in accordance with the Helsinki Declaration and Guidelines.

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