A Systematic Review and Meta-Analysis Study to Investigate the Prevalence of Helicobacter pylori and the Sensitivity of its Diagnostic Methods in Iran

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Context: Helicobacter pylori is the most common infecting organism affecting humans, being almost half the population infected. The aim of this study was to find out the epidemiological features and the sensitivity of diagnostic methods of Helicobacter pylori infection in Iran, which can provide the logic of developing preventive approaches to control Helicobacter pylori infections and the associated diseases.

Evidence Acquisition: By reviewing the databases of SID, MAGIRAN, SCOPUS, MEDLIT, Google, ISI and PUBMED, a total of 30 papers, published from 1994 to 2011, were extracted. Summary prevalence and 95% confidence intervals (95% CI) were calculated using random-effects model. Statistical analyses were performed using STATA Ver.11.

Results: Among the 30 studies evaluated, the prevalence rate of Helicobacter pylori infections in Iran was estimated as 50.7% (95% CI: 44.4-56.9%). When the sensitivity of diagnostic methods was evaluated, ELISA, with an accuracy rate of 52.3% (95% CI: 43.8 to 60.8%) was found the most accurate diagnostic method available. The highest and the least Helicobacter pylori prevalence were 19.2% in Tehran and 74.27% in Mazandran respectively.

Conclusions: About half the population in Iran is infected with Helicobacter pylori, the pollution in different areas and preventive strategies should be carried out to control this infection. The prevalence rate of Helicobacter pylori infections in Iran showed only little changes during the years 1994 to 2011.

Keywords:Helicobacter pylori; Prevalence; Meta-analysis; Iran

1. Context

Almost half the population in the world is infected by H. pylori which is the most common infecting organism affecting humans (1, 2). Since the first experience of Helicobacter culture in 2004 by Marshall and Warren, a considerable amount of information has been acquired on clinical aspects of this infection (3). Helicobacter pylori is tightly associated with gastrointestinal disorders, some important consequences of which can be chronic gastritis, peptic ulcer leading to gastric cancer, indigestion and non-ulcer dyspepsia (4-9).

In developing countries, the prevalence of H. pylori positive serology during childhood is higher than that in developed countries. This is vice versa during adulthood (10, 11). In a Meta-analysis study, the prevalence of H. pylori infection in China was reported as 58.07% (12). In another Meta-analysis study, the association between H. pylori infection and the risk of esophageal cancer (EAC) has been suggested (13). Also, the association between H. pylori infection in diabetic and non-diabetic individuals with dyspepsia was assessed. This study showed that the prevalence of H. pylori infection was considerably higher in diabetic patients compared to non-diabetic individuals (P = 0.001). According to these results, diabetes Mellitus is one of the risk factors that need attention in the evaluation of H. pylori infections among diabetic patients with dyspepsia (14).

The prevalence of H. pylori infection was 58% among residents of two villages in Northern Italy, considerably higher than the 34% observed in an earlier similar study of adults in northern Swedish communities (mean age = 52 years). A prevalence of 60% or more was reported for groups in Albania, Egypt, Iran, Turkey, and China (15). The prevalence of H. pylori infection was 3.0% among index children at age 4 and maternal infection was the only risk factor at multivariate analysis (16).

One of the main objectives of Meta-analysis studies,
which are a combination of different studies, is to reduce the difference between parameters as a result of an increase in the number of studies involved in the process of analysis and also to reduce the confidence level of these measures/figures.

The aim of this study was to investigate the studies carried out on the prevalence of H. pylori infection in Iran and to estimate the prevalence rate of this infection according to diagnostic methods, age group of individuals infected, gender, infection age and additional parameters.

2. Evidence Acquisition

This study was a systematic review and a Meta-analysis study on the prevalence of Helicobacter in Iran. The findings of this research were based on the papers published in internal and external journals. The papers were selected from the databases of SID, MAGIRAN, SCOPUS, MEDLILIB, Google, ISI and PUBMED. Searching of the articles was carried out using the key words: Helicobacter, prevalence, and a combination of these words. To decrease bias two authors (Sayehmiri F, Darvishi Z) did search, selection of papers and extracting data of articles independently. First, all the articles related to Helicobacter pylori in Iran were collected. At this stage, the articles possessing the relevant key words in their title or abstract were entered into the list, excluding all the other articles not relevant to the prevalence of H. pylori. A check list of necessary information was included: title of the article, location of the study, location of sampling, sample volume, the methods of assessing infection, the mean age of individuals infected by H. pylori and the total prevalence of H. pylori.

According to the protocol, a total of 142 articles that were carried out from 1994 to 2011 were analyzed during the primary research. The abstracts of 94 articles, out of the 142, were then analyzed and a complete review of 45 of these papers, that included the basic information required, was then carried out. Due to unavailability of the prevalence rates, some articles were omitted and a total of 30 articles were finally entered into the process of analysis (17-46) (Figure 1 the study flowchart).

2.1. Statistical Analysis

The variance of each study was calculated according to the binomial distribution. The studies were combined together according to sample size and variance. Because of the study heterogeneity, random-effect model was used to combine the studies. To assess the heterogeneity of the studies, Cochrane Q test and the I² index were used. P-value of less than 5% was considered as significant in the heterogeneity test. To investigate the relationship between years of study and sample size meta-regression model was used.

Furthermore, considering the type of data analyzed, which were all prevalence rates, there was no need to determine the publication bias and to draw a funnel plot. The data were analyzed using STATA version 11.2.

3. Results

In the 30 papers assessed, the prevalence rate of Helicobacter pylori infection in Iran was estimated as 50.7% (95% CI: 44.4-56.9%) (Figure 2). The lowest prevalence rate (19.2%) was related to a study in Mazandaran province, the city of Sari and the highest prevalence rate (74.2%) were reported in a study in Tehran province, the city of Tehran. Details of the papers analyzed are found in Table 1.

In one classification, analysis was carried out based on the diagnostic methods. The sensitivity level of ELISA, according to this analysis, was estimated as 52.3% (95% CI: 43.8-60.8), the sensitivity of the urease method as 51.9% (95% CI: 36.9-66.9) and other diagnostic methods including touch cytology, histopathology as 45.8% (95% CI: 31.3-60.4). These results show that ELISA and urease are relatively more accurate methods to diagnose H. pylori infection (Table 2).

In another classification, the individuals under assay were divided into the two groups of symptomatic and non-symptomatic individuals. The prevalence rate of infection among individuals with digestive disease symptoms, with a sample size of 1873 individuals, was estimated as 47.6% (95% CI: 56.1-39.2) and among healthy individuals, with a sample size of 731 individuals, as 53.1% (95% CI: 45.4-60.8). Based on gender, the prevalence rate was estimated as 37.7% (95% CI: 27.5-48) in females and 35.7% (95% CI: 19.6-51.7) in males. In analysis based on the age groups, the prevalence rate among the age group below 20 years was estimated as 38.3% (95% CI: 28.1-48.5), among the age group between 20-40 years as 50.3 % (95% CI: 39.5-61) and among the age group above 40 as 60.1% (95% CI: 52.4-67.8). In this analysis, a significant difference was found among the three age groups which can be evidence to the conclusion that the rate of H. pylori infection increases as the age increases (Table 3).
Figure 2. The Prevalence Rate of *H. pylori* Infection and its 95% Confidence Interval

The Figure 3 shows the relationship between the prevalence of *H. pylori* infection and year of study, and sample size using meta regression models. In Figure 3 A the negative slope of the meta regression line showed that the prevalence of *H. pylori* infection in Iran has had a decreasing trend with a slow slope but it was not significant. In Figure 3 B the relation between sample size was compared to the prevalence rate of *H. pylori* infection and according to this figure there isn’t a significant relation between the sample size and prevalence (P = 0.06). At the following figure the circles show the weight of studies and it seems that studies with greater sample sizes are more prevalent and vice versa (Figure 3). In the Table 4, a summary of data related to meta-regression curves are shown.
### Table 1. Summary of Included Studies Evaluating the Prevalence Rate of *H. pylori* in Iran

| City            | year     | Age, y | Sample Size | Diagnostic Method | Prevalence | 95% CI | References                                           |
|-----------------|----------|--------|-------------|-------------------|------------|--------|-----------------------------------------------------|
| Kashan          | 2000     | 4.1 ± 9.9 | 39         | Urease            | 30.8       | 45.3   | 16.3 Taghavi et al. (30)                            |
| Sari            | 2000     | 7-18   | 400         | -                 | 19.2       | 23.1   | 15.3 Tergar Fakheri et al. (39)                     |
| Semnan          | 1999     | 70     | 700         | Elisa             | 48         | 57.1   | 44.3 Moradi et al. (22)                             |
| Ghazvin         | 2002     | 54.4   | 125         | Urease            | 43.7       | 52.4   | 35 Hajagamohammadi et al. (17)                      |
| Sari            | 2001     | 394    | Elisa       | 64.2              | 69.1       | 59.7   | Baba mahmoodi et al. (38)                           |
| Khorasan razavi | 2004     | 12-75  | 195         | Urease            | 62.56      | 69.4   | 55.8 Nakhaei Moghadam et al. (40)                   |
| Tehran          | 2002     | 3.065  | 120         | Urease            | 68.3       | 76.6   | 60 Faghihi et al. (23)                              |
| Yazd            | 2004     | 30-65  | 28          | -                 | 43.5       | 61.9   | 25.1 Benesh et al. (41)                             |
| Ghazvin         | 2002     | 10-60  | 240         | Elisa             | 2000.5     | 86.7   | 1993.3 Sheikholeslami et al. (18)                   |
| Tabriz          | 2009     | 3.21 ± 8.38 | 116     | Serology          | Children 60.3, Mothers 57.8, Fathers 37.9 | 61.1   | 42.9 Rafiei et al. (31)                             |
| Kerman          | 1993     | 57.05  | 513         | Urease            | 56.9       | 61.2   | 52.6 Zojajy (19)                                    |
| Tehran          | 2002     | 8.8 ± 48 | 576       | Endoscopy         | 59.7       | 63.7   | 55.7 Yasseri (24)                                   |
| Tehran          | 2004     | 2.2 ± 24 | 137       | Elisa             | 65.57      | 75.3   | 56.7 Sharifian et al. (32)                          |
| Tehran          | 2004-2006| 6-12   | 1665       | Urease            | 26         | 28.1   | 23.9 Zamani et al. (25)                             |
| Tehran          | 2003     | -      | 170        | Histopathology    | 29.4       | 36.2   | 22.6 Barati et al. (26)                             |
| Tabriz          | -        | -      | 120        | -                 | 71.6       | 2000.7 | 63.5 Rahnama et al. (43)                            |
| Tabriz          | -        | -      | 86         | -                 | 42.6       | 53.1   | 32.1 Rafeey et al. (44)                             |
| Tabriz          | 2003     | 0.03 ± 8.3 | 96      | -                 | 64.6       | 74.2   | 55 Modaresi et al. (45)                             |
| Kurdistan       | 2006     | 14.91 ± 15.32 | 1503   | Elisa             | 36.5       | 38.9   | 34.1 Yazdanpanah et al. (33)                        |
| Tehran          | 2006     | 39     | 152        | -                 | 35.52      | 43.1   | 27.9 Shokohizadeh et al. (46)                       |
| Tehran          | 2010     | 43.9   | 311        | -                 | 74.27      | 2000.1| 69.4 Neshandar et al. (34)                          |
| Kashan          | 2007     | 17.13 ± 43.3 | 100     | Elisa             | 66         | 75.3   | 56.7 Arj et al. (20)                                |
| Tehran          | 2003     | 11.67 ± 39.68 | 50     | Urease, IgG, Histology  | 70         | 2003.7 | 57.3 Baghaei et al. (42)                            |
| Isfahan         | 2010     | 16-62  | 100        | PCR               | 30         | 39     | 21 Salehi et al. (27)                               |
| Guilan          | 2004     | 11.30 ± 32.38 | 50      | Elisa             | 54         | 67.8   | 40.2 Ghanie et al. (28)                             |
| Tehran          | 2001     | 100    | Urease, Pathology | 57         | 66.7   | 47.3   | Gottaslou et al. (29)                               |
| Guilan          | 2005     | 7-11   | 961        | Elisa             | 40         | 43.1   | 36.9 Mansor et al. (35)                             |
| Tehran          | 2001     | 48.3   | 1993       | Cytology          | 58.3       | 69.7   | 46.9 Vahidi et al. (16)                             |
| Isfahan         | 2002     | 70     | Elisa      | 44.44             | 56.1       | 32.8   | Sanei et al. (21)                                   |
| Khorasan razavi | 2006     | 4.77 ± 23.50 | 187     | Elisa             | 34.7       | 41.5   | 27.9 Dolatian et al. (37)                           |
To assess publication bias we used funnel plot (Figure 4) that it showed there was a significant publication bias ($P = 0.016$). In another classification, the analysis was carried out based on the city of the study, according to which the highest prevalence rate (61.7%), with a sample size of 245 individuals, was related to Ghazvin province (95% CI: 26.6-96.8) and the lowest prevalence rate (36.5%), with a sample size of 73 individuals, was related to Kurdistan province (95% CI: 38.9-34.1) (Table 5).

4. Discussion

A data containing 9198 Helicobacter pylori-infected individuals were included in the current study. A total of 30 papers were entered into the final Meta-analysis. $I^2$ statistics showed a high variation among studies results ($I^2 = 97.4$, $P = 0.000$). In three studies, including those carried out in Gilan, Sari and Qazvin, sampling had been carried out in villages as well as in cities (17, 33, 38). The prevalence rate of $H.\ pylori$ was calculated for all the individuals in all the age groups, based on the status of the individuals, gender and age groups.

In our review, random effect models were used for meta-analysis, considering the possibility of significant heterogeneity between studies which was tested with the Q test.

### Table 2. Prevalence Rate of $H.\ pylori$ Infection in Iran According to Different Diagnostic Methods

| Diagnostic Methods          | Study, No. | $H.\ pylori$, %, 95% CI |
|-----------------------------|------------|-------------------------|
| Total Recognize group       | 30         | 50.7 (44.4-56.9)        |
| ELISA                       | 10         | 52.3 (43.8-60.8)        |
| Urease test                 | 8          | 51.9 (36.9-66.9)        |
| Other methods               | 5          | 45.8 (31.3-60.4)        |

### Table 3. Prevalence Rate of $H.\ pylori$ Infection in Iran According to Health Status, Age and Gender

| Study, No. | $H.\ pylori$, %, 95% CI |
|------------|-------------------------|
| Total      | 30                      |
| Sex        |                         |
| Women      | 5                       |
| Men        | 5                       |
| Population |                         |
| Patient    | 17                      |
| Healthy    | 13                      |
| Age, y     |                         |
| ≤ 20       | 6                       |
| 20-40      | 7                       |
| > 40       | 6                       |

![Figure 3. H. pylori Prevalence Rate According to the Year of Study and Sample Size](image)

The fitted line show meta-regression line.
Table 4. The Unadjusted and Adjusted Regression Coefficients and Corresponding P Values for Correlation Between Potential Influential Factors and H. pylori Prevalence Using meta-Regression Models

| Factors                     | Regression Coefficients | P       |
|-----------------------------|-------------------------|---------|
| Year of data collection     |                         |         |
| Unadjusted                  | -0.00332003004          | 0.707   |
| Adjusted                    | 0.0086586               | 0.21999 |
| Age group                   |                         |         |
| Unadjusted                  | 0.1077322               | 0.017   |
| Adjusted                    | 0.1222877               | 0.008   |
| Sample size                 |                         |         |
| Unadjusted                  | -0.0001338              | 0.060   |
| Adjusted                    | -0.000919               | 0.159   |

Table 5. Prevalence Rate of H. pylori in Iran According to City

| City            | Random Effects OR, 95% CI | I² , % | Sample Size | Study, No. |
|-----------------|---------------------------|-------|-------------|------------|
| Kashan          | 48.9 (14.4-2004.3)        | 93.8  | 139         | 2          |
| Sari            | 41.8 (-0.025-0.86)       | 99.5  | 20004       | 2          |
| Semnan          | 48 (44.3-51.7)           | -     | 700         | 1          |
| Ghazvin         | 61.7 (26.6-96.8)         | 97.4  | 245         | 2          |
| Khorasan Razavi | 48.6 (21.3-75.9)         | 96.9  | 32003       | 2          |
| Tehran          | 53.5 (39.3-67.8)         | 98.4  | 3295        | 10         |
| Yazd            | 43.5 (25.1-61.9)         | -     | 28          | 1          |
| Tabriz          | 57.9 (45.3-70.5)         | 86.6  | 418         | 4          |
| Kerman          | 56.9 (52.6-61.2)         | -     | 513         | 1          |
| Kurdistan       | 36.5 (34.1-38.9)         | 73    | 1503        | 1          |
| Isfahan         | 36.7 (22.6-50.8)         | 73.4  | 170         | 2          |
| Guilan          | 45.3 (32-58.6)           | 97.4  | 1011        | 2          |
| -               | 50.7 (44.4-56.9)         | -     | 9198        | 30         |

In a study carried out in Sari in 132001, a significant correlation was reported between the prevalence rate of infection and home ownership and the family size (38). In the study by Azevedo et al. the major risk factors that have been emphasized were the socioeconomic indicators (15).

Among the limitations of the current study, the following can be mentioned: 1) There was not same method to measure variables and diagnostic tests among all studies as well as, 2) The majority of the studies were carried out in a preselected population (blood donors, individuals referring to health care centers and etc.). 3) In most studies, nutritional status and life style were not considered as influencing factors. 4) The range of age groups was considerably wide among different studies.

This study aimed to determine the prevalence rate of H. pylori infection in Iran. Almost half the population in Iran is infected by H. pylori, the prevalence rate being different among different parts of the country. According to the findings of this study, it is suggested that, to prevent the spread of H. pylori, comprehensive health programs should be scheduled throughout the country. According to the results of this study, the risk of H. pylori infection significantly increases with age, and so, it is recommended that preventive procedures are more seriously followed for high risk age groups. It is also recommended that the ELISA and urease tests are used in diagnostic laboratories to increase the accuracy and perception of diagnostic methods.

Funnel plot (Figure 4) showed the effects of publication bias was significant in this study. Publication bias is very important in randomized clinical trials and case control studies, but it is not important in the meta-analysis that estimates prevalence publication bias.
Authors’ Contribution

Fatemeh Sayehmiri and Zahra Darvishi, setareh soroush: Data Collection; Kourosh Sayehmiri: Biostatistic analysis; Mohammad Emaneini and Morovat Taherikoushr: Data Collection; Kourosh Sayehmiri: Biostatistic analysis.

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