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DISEASES  
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VOLUME 16 ISSUE 4 (VER. 1.0)

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## Prevalence of Helicobacter Pylori Infection among the Whole Spectrum of Age and the Performance of the Different Diagnostic Tests

By Awad Magbri, Eussera El-Magbri, Mariam El-Magbri & Fiona Stevens

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**Abstract- Design, setting, participants & measurements:** Three hundred and thirty eight patients were included in the study. They presented to the endoscopy suite at University College Hospital Galway, Ireland (UCHG) with upper gastrointestinal symptoms. The age range is 21-90 years with a median age of 52 years, 62% females, and 24% diabetics. They were divided into 3 groups 18-30 years, 31-60 years, and 61-90 years. The prevalence of H. pylori among the different spectrum of age is calculated using different methods of diagnosing H. pylori.

**Reliabilities of the diagnostic tests:** The sensitivity, specificity, positive and negative predictive values for (i) Rapid urease test (RUT), (ii) ELISA, (iii) Histology and (iv) Culture. The rapid urease test was found to have a high sensitivity and specificity (89.5% and 96.8%), respectively. Although estimation of serum IgG H. pylori antibody by ELISA is relatively non-invasive procedure, unfortunately, it lacks sufficient sensitivity (63%) to be used as a sole diagnostic test for H. pylori infection. Histology on the other hand is widely available in most hospitals and has a relatively high sensitivity (77.4%) and specificity (75%).

**Keywords:** helicobacter pylori, sensitivity, specificity, rapid urease test, gastric cancer, ELISA test, IgG to H. pylori.

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PREVALENCE OF HELICOBACTER PYLORI INFECTION AMONG THE WHOLE SPECTRUM OF AGE AND THE PERFORMANCE OF THE DIFFERENT DIAGNOSTIC TESTS

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# Prevalence of Helicobacter Pylori Infection among the Whole Spectrum of Age and the Performance of the Different Diagnostic Tests

Awad Magbri <sup>α</sup>, Eussera El-Magbri <sup>σ</sup>, Mariam El-Magbri <sup>ρ</sup> & Fiona Stevens <sup>ω</sup>

**Abstract- Design, setting, participants & measurements:** Three hundred and thirty eight patients were included in the study. They presented to the endoscopy suite at University College Hospital Galway, Ireland (UCHG) with upper gastrointestinal symptoms. The age range is 21-90 years with a median age of 52 years, 62% females, and 24% diabetics. They were divided into 3 groups 18-30 years, 31-60 years, and 61-90 years. The prevalence of H. pylori among the different spectrum of age is calculated using different methods of diagnosing H. pylori.

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**Prevalence of H. pylori infection:** The prevalence of H. pylori is assessed in the different age groups. There was a substantial increase in the prevalence of H. pylori infection with increasing age up to the age 61 years. In this study the highest prevalence of infection was found in the age group 31-60 years. The overall prevalence of H. pylori infection in patients with upper gastrointestinal symptoms as assessed by histology (73%), culture (53%), serum IgG ELISA (56%), and rapid urease test (65%).

**Conclusion:** The prevalent of Helicobacter pylori infection are worldwide and the infection rate is intimately related to age, ethnicity, and socio-economic factors. The sensitivity and specificity of the different methods used to detect H. pylori infection vary considerably and depends on the inherent characteristics of the test used. A test with high sensitivity and specificity is needed to capture the majority of patients with infection so they can be treated early and cured of the bacteria this will prevent the development of gastric and duodenal ulcer and the late consequences of gastric malignancy.

**Keywords:** helicobacter pylori, sensitivity, specificity, rapid urease test, gastric cancer, ELISA test, IgG to H. pylori.

## I. INTRODUCTION

Studies from Western Europe, New Zealand, Australia, and United States have shown that the prevalence of H. pylori infection in symptomatic patients undergoing endoscopy is very high. The rate of H. pylori infection in patients with upper gastro-intestinal symptoms ranges from 40-60%. In benign gastric ulcer the organism is found in about 70% (1). No the other hand, the rate of infection in duodenal ulcer patients is 85-95% (2, 3). The rate of infection of H. pylori related to several factors, for example the rate of infection increases with age (1, 4-8). The prevalence in children was found to range between 20-68% (9-15). The rate of infection also correlate to underlying disease process; in duodenal ulcer and duodenitis the rate of H. pylori infection may be as high as 95%, and in gastritis the rate of infection ranged from 62-97% (16-30). The sensitivity and specificity of the various tests used to diagnose H. pylori infection have wide variation ranging from (63% to 89.5% for sensitivity) and (41.7% to 100% for specificity). The prevalence of H. pylori infection in different age groups was carried out in this study and was found to be highly variable in different age groups. The highest prevalence was found in the age group of 31-60 years.

## II. SUBJECTS AND METHODS

Three hundred and thirty eight patients were included in the study. They presented to the endoscopy suite at University College Hospital Galway, Ireland (UCHG) with upper gastrointestinal symptoms. The age range is 21-90 years with a median age of 52 years, 62% females, and 24% diabetics. They were divided into 3 groups 18-30 years, 31-60 years, and 61-90 years. The prevalence of H. pylori among the different spectrum of age is calculated using different methods of diagnosing H. pylori, table 3.2.

Formal written consent was obtained and the procedure was explained to each patient included in the study.

Blood was collected in a plain tube before endoscopy for estimation of serum IgG antibodies to H. pylori using ELISA test (Biometra, Germany).

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Specimens were taken from antrum and duodenum from each patient enrolled in the study, for histological examination and culture. They were forwarded to the bacteriology laboratory in a separate containers containing a transport medium (Nutrient Broth Code: CMI oxide) for direct smear and culture on Colombia blood agar base (code: CM331) containing cefoperazone selective supplement (code: SR125) mixed together into sterile Petri dishes prepared according to the specifications of the supplier (Oxide, Ireland).

The specimens for the histological examination were labeled with reference numbers, and were formalin fixed and prepared according to the standard methods. Sections 5  $\mu$ m thin and stained with haematoxylin and eosin (H&E) or modified Giemsa stain and read by an experienced pathologist (RS) without previous knowledge of clinical or microbiological information.

A biopsy specimen was examined by commercially available rapid urease test kindly provided by (Jatrox HP-Test, Rohm Pharma Waterston, Germany).

The performance of the different tests used to diagnose H. pylori was outlined in table 3.1.

### III. RESULTS

*Reliabilities of the diagnostic tests:* The sensitivity, specificity, positive and negative predictive values for (i) Rapid urease test, (ii) ELISA, (iii) Histology and (iv) Culture are shown in table 3.1.

The rapid urease test (RUT) was found to have a high sensitivity and specificity (89.5% and 96.8%) respectively. However, it needs an endoscopic procedure to obtain an antral biopsy for the assay which is not available in all hospitals. Endoscopy is an invasive and expensive procedure.

Although estimation of serum IgG H. pylori antibody by ELISA is relatively non-invasive procedure, unfortunately, it lacks sufficient sensitivity (63%) to be used as a sole diagnostic test for H. pylori infection, table – 3.1.

Histology on the other hand is widely available in most hospitals and has a relatively high sensitivity (77.4%) and specificity (75%), table 3.1. It is relatively quick, cheap and easy to perform but it requires endoscopic examination which is an invasive technique and needs a well trained histological expertise and therefore, it cannot be utilized as a screening test for H. pylori diagnosis.

Culture of H. pylori was found to be highly specific (100%) and sufficiently sensitive (86.2%), table – 3.1. However, it takes a few days for the results to come through and it cannot be used for quick diagnosis of H. pylori infection. Culture of H. pylori is, however, needed to determine the sensitivity of the bacterium to the antimicrobial agents, especially to metronidazole. Obtaining the biopsy for culture is an invasive procedure.

*Prevalence of H. pylori infection:* The prevalence of H. pylori is assessed in the different age groups, table – 3.2. There was a substantial increase in the prevalence of H. pylori infection with increasing age up to the age 61 years. This result agrees with the results of previous workers. However, in the age group 18-30 years the prevalence of H. pylori infection in patients with dyspepsia ranges from 45-53% depending on the mode used for diagnosis.

In this study the highest prevalence of infection was found in the age group 31-60 years, table-3.2. Usually the colonization of the bacteria is most prevalent in the elderly. The reason for this finding is not entirely clear. However, the frequent use of drugs like NSAIDS, and corticosteroids could contribute to the relatively low prevalence in this age group.

The overall prevalence of H. pylori infection in patients with upper gastrointestinal symptoms as assessed by histology (73%), culture (53%), serum IgG ELISA (56%), and rapid urease test (65%) table-3.2 agree with the previous studies from the developed countries (31-33).

### IV. DISCUSSION

Infection with H. pylori is rampant and worldwide. The rate of infection is influenced by age, race, geographical and socio-economic factors, as well as dietary practices (34-44). The rate of infection is found to be higher in China and India than in North America. On the other hand, the infection rate is similar in Mexico and the United States (37, 45). It has been revealed that the rate of infection of H. pylori in the United States is influenced by many factors like social-economic, ethnicity, age, and gender. These findings suggest that the rate of H. pylori infection is modified by geographical and host factors. The type and severity of gastritis associated with H. pylori colonization are also influenced the rate of infection.

The epidemiology of H. pylori infection has been extensively studied and was found to be closely correlated with superficial type-B gastritis. Infection with H. pylori is associated with active and chronic inflammation of gastric mucosa (32, 46). The density of the bacteria in the tissue is also correlated to the severity of inflammation and the local and systemic immune response mounted against the bacteria (32, 46-48).

H. pylori infection can be detected with various methods e. g histological examination and culture of the gastric biopsy specimens which takes several days, serology, rapid urease test etc. Serum IgG/IgA ELISA and Rapid Urease test were compared to the gold standard tests (histology and culture) and evaluated in this study. The organism was detected in 76 of 107 dyspeptic patients attending GI unit at UCHG. We found a relatively good correlation between serology and histological findings in the antral biopsies despite the

low sensitivity (63%) of our ELISA test compared to histology and culture, table-3.1. Our results of high sensitivity and specificity (89.5% and 96.8%) of rapid urease test agreed with Carvalho and others (15, 49-56), but disagreed with the results of Nichols and others (23, 57). The advantages of quick test e.g. RUT is that treatment can be given to the patients within one hour of their endoscopic procedures. In the Amsterdam study (15) the results of culture and histology were analogous to ours.

We found that, histological examination, culture, ELISA and RUT revealed an increased prevalence of *H. pylori* infection and the rate of infection are rising with increasing age up to the age of 61 years. This is in parallel with the findings that the prevalence of infection is related to the prevalence of gastritis (6, 31-33). However, the prevalence of *H. pylori* in the elderly age group is lower than the reported prevalence from Western countries, table-3.2. We noted that the prevalence of *H. pylori* infection in the age group 61-90 years was below that of 30-60 years. This agreed with the findings of Newell et al (57).

Previously, it has been suggested that the age discrepancy is due to progressive atrophic gastritis with hypochlorhydria in the body and fundus of the stomach of the elderly patients. This environment is hostile to the existence of the organism. Another possible explanation to the low infection rate in the elderly could be related to the increased use of the antibiotics in this age group which may clear the organism. The histological sections from the mucosa of the 25 patients from the group 61-90 years old were reviewed, none were taken NSAIDs concurrently. We found 14(56%) of these patients had either normal or mild inflammation and of them 6(43%) were *H. pylori* positive. Moderate inflammation was present in 9(36%) all were *H. pylori* positive. Only 2(8%) had severe inflammation and both were *H. pylori* positive. Atrophy of specialized cells in the fundus and body of the stomach cannot be inferred from examination of antral biopsies. Thus in this study we have no evidence to support the notion that atrophic gastritis is associated with a decreased prevalence of *H. pylori* in the elderly. We concluded that the majority if the elderly (>61 years) had a prevalence of *H. pylori* ranging from (45-64%), table-3.2, depending on the mode used for detection of *H. pylori* infection. More than 50% of them had only mild inflammation; in these group *H. pylori* was isolated in 43%. However, moderate to severe degree of inflammation was present in 44% of them and *H. pylori* were always associated with gastritis.

## V. CONCLUSION

The prevalent of *Helicobacter pylori* infection are worldwide and the infection rate is intimately related to age, ethnicity, and socio-economic factors. The sensitivity and specificity of the different methods used

to detect *H. pylori* infection vary considerably and depends on the inherent characteristics of the test used. A test with high sensitivity and specificity is needed to capture the majority of patients with infection so they can be treated early and cured of the bacteria this will prevent the development of gastric and duodenal ulcer and the late consequences of gastric malignancy.

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*Table – 3.1* : The reliabilities of the various diagnostic tests for H. pylori infection.

| Test        | Sensitivity | Specificity | PP value | NP value |
|-------------|-------------|-------------|----------|----------|
| Histology   | 77.4%       | 75%         | 83.7%    | 66.7%    |
| Culture     | 86.2%       | 100%        | 100%     | 76.5%    |
| Serum IgG   | 63%         | 97%         | 98%      | 51%      |
| Local IgA   | 79.2%       | 41.7%       | 57.6%    | 66.7%    |
| Urease test | 89.5%       | 96.8%       | 98.6%    | 78.9%    |

*Table 3.2* : The prevalence of H. pylori infection: age difference.

|                   | 18-30 years | 31-60 years | 61-90 years | Overall |
|-------------------|-------------|-------------|-------------|---------|
| Histology         | 52.9%       | 85.3%       | 56%         | 72.8%   |
| Culture           | 47.1%       | 57.4%       | 45.5%       | 53%     |
| ELISA             | 45.8%       | 61.2%       | 52.6%       | 55.8%   |
| Rapid Urease test | 47.06%      | 69.8%       | 64%         | 64.8%   |

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## The Prevalence and Risk Factors of Cardiovascular Comorbidity in Patients with Severe and Very Severe COPD

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**Abstract-** Cardiovascular comorbidities are most frequent comorbidities in COPD and are responsible for many deaths in those patients. The aim of the study was to investigate the prevalence and the risk factors of these comorbidities. In the survey 114 COPD patients were included with severe and very severe stage of the disease, FEV1 < 50%, which were stable. Cardiovascular comorbidity was detected in 92 (80.7%) respondents, 61.9 % with severe and 38.1 % with very severe COPD. Blood sugar ( $p=0.023^*$ ), CRP ( $p=0.00007^{**}$ ), CAT score ( $p<0.0006^{**}$ ) and number of exacerbations ( $p<0.0001$ ) were significantly higher in patients with cardiovascular comorbidity. We can conclude that cardiovascular comorbidities are frequent in COPD patients with severe and very severe stage. They have a great impact in this patients.

**Keywords:** *severe COPD, very severe COPD, risk factors, cardiovascular comorbidity.*

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# The Prevalence and Risk Factors of Cardiovascular Comorbidity in Patients with Severe and Very Severe COPD

Jagoda Stojkovicj <sup>α</sup>, Beti Ivanovska-Zafirovska <sup>σ</sup>, Irina Angelovska <sup>ρ</sup>, Angela Debreslioska <sup>ω</sup>, Sead Zejnel <sup>¥</sup>, Smiljko Jovanovski <sup>§</sup>, Dragana Stojkovicj <sup>χ</sup>, Sasha Anastasova <sup>ν</sup> & Ivana Jovanovska <sup>θ</sup>

**Abstract-** Cardiovascular comorbidities are most frequent comorbidities in COPD and are responsible for many deaths in those patients. The aim of the study was to investigate the prevalence and the risk factors of these comorbidities. In the survey 114 COPD patients were included with severe and very severe stage of the disease, FEV1 < 50%, which were stable. Cardiovascular comorbidity was detected in 92 (80.7%) respondents, 61.9 % with severe and 38.1 % with very severe COPD. Blood sugar (p=0.023\*), CRP (p=0.00007\*\*), CAT score (p<0.0006\*\*) and number of exacerbations (p<0.0001) were significantly higher in patients with cardiovascular comorbidity. We can conclude that cardiovascular comorbidities are frequent in COPD patients with severe and very severe stage. They have a great impact in this patients.

**Keywords:** severe COPD, very severe COPD, risk factors, cardiovascular comorbidity.

## I. INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is defined as a systemic disease, and is a major cause of morbidity and mortality throughout the world and continues to cause a heavy health and economic burden. (1,2) Understanding of the pathophysiology of COPD, focused on the concept of systemic inflammation, has also helped to explain the high comorbidities frequency in these patients. Comorbidities affect seriously health status and influence the prognosis of these patients (1,3). Cardiovascular comorbidities are responsible for many deaths in COPD patients. The risk of cardiovascular morbidity and mortality is two to three times higher in patients with COPD in comparison to an age-matched and gender-matched population without COPD. (1,4,5) Probably due to shared pathophysiological mechanisms; cardiovascular comorbidities often remain unrecognized in patients with COPD. Great number of severe even very severe cases of COPD first has been diagnosed in the Cardiovascular Intensive Care Units during myocardial infarction or some other cardiovascular disease. (6,7,8) Longitudinal population-

based studies show that low lung function, measured by forced expiratory volume in 1 second (FEV1), is associated with cardiovascular mortality. Participants in the National Health and Nutrition Examination Survey (NHANES) Epidemiologic Follow-up Study with the lowest levels of FEV1 showed 5 times higher risk of death by ischemic heart disease. (9,10,11) In recent years, a hypothesis has been generated that a systemic inflammatory process, present in COPD patients, could be the link between this disease and different comorbidities. Inflammatory cytokines, including tumor necrosis factor- $\alpha$ , interleukin-6, C-reactive protein (CRP) and fibrinogen, are increased within the circulation of patients with COPD, particularly during exacerbation when this inflammation significantly increase, probably representing an overflow of inflammatory mediators from the peripheral lung. These cytokines are common to many inflammatory diseases, and could explain their association with COPD. (4,12,13.) Risk factors, however, can also explain this association. Tobacco is a most common risk factor implicated in the genesis of COPD, remain as well as cardiovascular disease. In addition, the reduced physical activity due to reduced exercise tolerance first of all as a result of dyspnea, which is a primary clinical feature of chronic obstructive pulmonary disease (COPD). (1,2,14,15) The increase of vascular disease can be due to the higher prevalence of classic risk factors. Thus, in the recently published Cardiovascular Risk Factors in COPD study (4), it was observed that COPD patients presented high prevalence of hypertension, diabetes, and dyslipidemia, which were related with an increased risk for ischemic heart disease. The pathophysiological mechanisms underlying the vascular alterations in COPD are mainly mediated by endothelial dysfunction and coagulopathy. The systemic inflammation observed in COPD seems to be the key determinant for the development of pulmonary and systemic endothelial dysfunction. (1) Low body mass index (BMI) and weight loss is common in many chronic diseases; however, in COPD the picture is more complex, as low weight is due to a disproportionate loss of fat-free tissue, especially muscle mass increase death risk. (15,16) The mechanisms explaining cachexia in COPD are still

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unclear,(16) but go beyond the classic explanation of an increase in the oxygen cost of breathing, or the pro-inflammatory effect of hypoxemia. (16, 17)Physical inactivity and smoking were more strongly associated with the presence of comorbidities compared with airflow obstruction. (17)

## II. MATERIAL AND METHODS

The aim of the study was to investigate the prevalence and risk factors of cardiovascular comorbidities in patients diagnosed COPD patients with severe and very severe stage of the disease, which were stable. For that we investigated 114 subjects, all of them current smokers, with smoking status >10 years. According Global Initiative for Chronic Obstructive Lung Disease the patients with severe stage of the disease were with: 50% >FEV1>30%, FEV1/FVC <0,70, and with very severe stage of the disease: FEV1<30%, FEV1/FVC <0,70. Then they were divided in two groups: 92 subjects with and 22 without cardiovascular comorbidities. It was cross sectional study. Besides demographic parameters (age, gender), body mass index (BMI), level of cholesterol, LDL and HDL, CRP, mMRC dyspnea scale, we use CAT score, according to the: 2011 Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy document which recommends assessment of chronic obstructive pulmonary disease (COPD) using symptoms and future exacerbation risk, employing two score cut-points: COPD Assessment Test (CAT) score ≥10 or modified Medical Research Council dyspnea scale (mMRC) grade and exacerbations number (18,19). Also the number of

exacerbations and number of cardiovascular comorbidities were calculated.

### a) Statistical analysis

Statistical analysis: Statistical analysis of the data base was made in the program SPSS for Windows 17, 0. Testing of the distribution of the data was done with Kolmogorov-Smirnov and Shapiro-Wilk's test. Categorical variables were presented with absolute and relative numbers, numeric variables were shown with descriptive statistics (mean, median, rank values). For comparing of respondents with and without cardiovascular comorbidities were used parametric and nonparametric methods for independent samples (Chi-square test, Student t-test, Mann-Whitney U test). The correlation between the number of cardiovascular comorbidities and both (mMRC dyspnea scale and CAT test) was analyzed with Spearman's rho correlation. For independent significant factors associated with cardiovascular comorbidity, Binary Logistic Regression analysis was used. For statistically significant values was taken  $p < 0,05$ .

## III. RESULTS

In the research participated 114 subjects, COPD patients. Cardiovascular comorbidity was detected in 92 (80.7%) respondents, 61.9 % with severe and 38.1 % with very severe COPD.

Sex, age and body mass index of patients with severe and very severe COPD had not significant effect on the occurrence of cardiovascular comorbidity ( $p=0.9$ ,  $p=0.98$  and  $p=0.19$  consequently)

Table 1 : The age, gender and BMI in patients

| variable             | noCVS<br>N=22 | yesCVS<br>N=92 | p value  |
|----------------------|---------------|----------------|----------|
| <b>gender (%)</b>    |               |                |          |
| Female 40            | 8 (20)        | 32 (80)        | $p=0.9$  |
| Male 74              | 14 (18.92)    | 60 (81.08)     |          |
| <b>age (mean±SD)</b> |               |                |          |
|                      | 62,44 ± 6,4   | 62,34 ± 10,7   | $p=0.98$ |
| <b>BMI (mean±SD)</b> |               |                |          |
|                      | 22.4 ± 6.6    | 24.87 ± 5.3    | $p=0.19$ |

<sup>a</sup>(Student-t test) <sup>c</sup> (Chi-square)

The values of cholesterol, LDL and HDL insignificantly differ between patients studied with and without cardiovascular comorbidity.

Elevated blood sugar significantly more often was registered in the group of patients with cardiovascular comorbidity compared with patients without cardiovascular comorbidity (25% vs 0%).

In group with cardiovascular comorbidity were measured significantly higher values of glucose ( $p = 0.023$ ).

More than 50% of subjects with cardiovascular comorbidity present or 54.35% had values of CRP higher than 6 mg/l.

Significantly higher values of CRP were observed in the group of patients with cardiovascular comorbidities ( $p = 0.00007$ ).

Table 2 : The level of cholesterol, LDL, HDL, glycaemia and CRP in patients

| variable                                  | noCVS<br>N=22   | yasCVS<br>N=92  | p value                  |
|---|-----------------|-----------------|--------------------------|
| <b>cholesteroln (%)</b>                   |                 |                 |                          |
| 0 – 5.51                                  | 14 (63.64)      | 41 (44.56)      | <sup>c</sup> p=0.1       |
| > 5.51                                    | 8 (36.36)       | 51 (55.44)      |                          |
| <b>cholesterol (mean±SD) median (IQR)</b> |                 |                 |                          |
|   | 5.74 ± 1.2      | 6.17 ± 1.5      | <sup>b</sup> p=0.51      |
|   | 5.6 (4.7 – 6.6) | 5.6 (4.9 – 6.1) |                          |
| <b>LDL n (%)</b>                          |                 |                 |                          |
| 0 – 2.2                                   | 5 (22.73)       | 24 (26.09)      | <sup>c</sup> p=0.89      |
| 2.3 – 3.7                                 | 11 (50)         | 36 (39.13)      |                          |
| > 3.7                                     | 6 (27.27)       | 32 (34.78)      |                          |
| <b>LDL (mean±SD) median (IQR)</b>         |                 |                 |                          |
|   | 3.13 ± 1.4      | 3.58 ± 1.1      | <sup>b</sup> p=0.21      |
|   | 2.7 (1.9 – 4.2) | 3.8 (2.2 – 3.9) |                          |
| <b>HDL n (%)</b>                          |                 |                 |                          |
| 0.9 - 2                                   | 6 (27.27)       | 45 (48.91)      | <sup>c</sup> p=0.09      |
| > 2                                       | 6 (27.27)       | 11 (11.96)      |                          |
| < 0.9                                     | 10 (45.45)      | 36 (39.13)      |                          |
| <b>HDL (mean±SD) median (IQR)</b>         |                 |                 |                          |
|   | 1.26 ± 0.7      | 1.25 ± 0.6      | <sup>b</sup> p=0.94      |
|   | 1.2 (0.8 – 2.1) | 1.2 (0.7 – 1.8) |                          |
| <b>glycemia n (%)</b>                     |                 |                 |                          |
| 3.5 – 6.1                                 | 22 (100)        | 69 (75)         | <sup>c</sup> p=0.02      |
| > 6.1                                     | 0               | 23 (25)         |                          |
| <b>glycemia (mean±SD) median (IQR)</b>    |                 |                 |                          |
|   | 5.09 ± 0.4      | 6.44 ± 2.5      | <sup>b</sup> p=0.023*    |
|   | 5 (4.9 – 5)     | 5.7 (5 – 6.4)   |                          |
| <b>CRP n (%)</b>                          |                 |                 |                          |
| < 6                                       | 22 (100)        | 42 (45.65)      | <sup>c</sup> p=0.00004** |
| > 6                                       | 0               | 50 (54.35)      |                          |
| <b>CRP (mean±SD) median (IQR)</b>         |                 |                 |                          |
|   | 4.22 ± 0.4      | 7.15 ± 2.8      | <sup>b</sup> p=0.00007** |
|   | 4 (4 – 4)       | 7 (5 – 9)       |                          |

<sup>b</sup>(Mann-Whitney test) <sup>c</sup>(Chi-square) \*p<0.05 \*\*p<0.01

Respondents with and without cardiovascular comorbidity scores had insignificantly different mMRC, while significantly differed in terms of CAT score (p <0.0006). CAT average score in the group, with and without cardiovascular comorbidity was 9.56 ± 0.5 and 15.54 ± 5.0 consequently, while the median score was 10 (range 9-100 ) and 17 (range 10-20 ) consequently.

Values of CAT score higher than 10 were significantly more likely registered only in group with cardiovascular comorbidities (67.39 %).

COPD patients with and without cardiovascular comorbidity significantly differ in the number of exacerbations in addition to patients with cardiovascular comorbidity (p <0.0001).



**Table 3 :** The level of mMRC dyspnea scale, CAT test score and exacerbation number in patients

| variable                          | noCVS<br>N=22              | yesCVS<br>N=92              | p value                 |
|-----------------------------------|----------------------------|-----------------------------|-------------------------|
| <b>mMRC n (%)</b>                 |                            |                             |                         |
| 1                                 | 0                          | 2 (2.17)                    | <sup>b</sup> p=0.09     |
| 2                                 | 17 (77.27)                 | 40 (43.48)                  |                         |
| 3                                 | 5 (22.73)                  | 40 (43.48)                  |                         |
| 4                                 | 0                          | 8 (8.69)                    |                         |
| 5                                 | 0                          | 2 (2.17)                    |                         |
| <b>CAT n (%)</b>                  |                            |                             |                         |
| < 10                              | 22 (100)                   | 30 (32.61)                  | <sup>c</sup> p<0.0001   |
| > 10                              | 0                          | 62 (67.39)                  |                         |
| <b>CAT (mean±SD) median (IQR)</b> |                            |                             |                         |
|                                   | 9.56 ± 0.5<br>10 (9 – 100) | 15.54 ± 5.0<br>17 (10 – 20) | <sup>b</sup> p=0.0006** |
| <b>egzacerbation number n (%)</b> |                            |                             |                         |
| 0                                 | 9 (40.91)                  | 2 (2.17)                    | <sup>c</sup> p<0.0001   |
| 1                                 | 10 (45.45)                 | 33 (35.87)                  |                         |
| 2                                 | 3 (13.64)                  | 17 (18.48)                  |                         |
| 3                                 | 0                          | 25 (27.17)                  |                         |
| 4                                 | 0                          | 9 (9.78)                    |                         |
| 5                                 | 0                          | 6 (6.52)                    |                         |
| <b>egzacerbation number n (%)</b> |                            |                             |                         |
| 0                                 | 9 (40.91)                  | 2 (2.17)                    | <sup>c</sup> p<0.0001   |
| 1-2                               | 13 (59.09)                 | 50 (54.35)                  |                         |
| 2>                                | 0                          | 40 (43.48)                  |                         |

<sup>b</sup>(Mann-Whitney test) <sup>c</sup>(Chi-square) \*p<0.05 \*\*p<0.01

As an independent predictor of cardiovascular comorbidity regression analysis confirmed serum marker CRP (p = 0.013). Increasing the values of CRP in serum 1mg/l in patients with severe and very severe COPD increases chance to 7.92 (95 % CI 1.545 - 14.607) times for cardiovascular comorbidity.

**Table 4 :** Binary Logistic Regression independent predictors of cardiovascular comorbidities in patients with severe and very severe HOBB

|                     | B       | S.E    | Wald  | df | Sig. | Exp(B) | 95,0% C.I. for EXP (B) |        |
|---------------------|---------|--------|-------|----|------|--------|------------------------|--------|
|                     |         |        |       |    |      |        | Lower                  | Upper  |
| Step 1 <sup>a</sup> |         |        |       |    |      |        |                        |        |
| glycaemia           | 1,028   | 1,053  | ,952  | 1  | ,329 | 2,794  | ,355                   | 22,005 |
| CRP                 | 2,069   | ,834   | 6,158 | 1  | ,013 | 7,920  | 1,545                  | 14,607 |
| CAT                 | 1,661   | ,986   | 2,837 | 1  | ,092 | 5,267  | ,762                   | 36,401 |
| Constant            | -30,152 | 12,614 | 5,713 | 1  | ,017 | ,000   |                        |        |

a. Variable(s) entered on step 1: glikemijam CRP, CAT.

Patients with CRP values greater than 6 mg/l were more significant in the register group 3 or 4 cardiovascular comorbidities as compared with the group with one or two cardiovascular comorbidities (88.46 % vs. 42.42% p = 0.00006).

CAT score significantly differed in patients with different number of cardiovascular disease (p<0.0001).

**Table 5 :** The association of CRP and CAT score with number of comorbidities in patients

| variable                          | number of CVS (1-2)<br>N=66 | number of CVS (3-4)<br>N=26 | p value                  |
|-----------------------------------|-----------------------------|-----------------------------|--------------------------|
| <b>CRPn (%)</b>                   |                             |                             |                          |
| < 6                               | 38 (57.57)                  | 3 (11.54)                   | <sup>c</sup> p=0.00006** |
| > 6                               | 28 (42.42)                  | 23 (88.46)                  |                          |
| <b>CAT (mean±SD) median (IQR)</b> |                             |                             |                          |
|                                   | 6.12± 1.7<br>6 (5 – 7)      | 9.61 ± 3.3<br>9 (8 – 11)    | <sup>b</sup> p<0.0001**  |

<sup>b</sup>(Mann-Whitney test) <sup>c</sup>(Chi-square) \*\*p<0.01

The number of cardiovascular comorbidities in patients with severe and very severe COPD significantly

positively correlated with mMRC and CAT score ( $R = 0.423$  and  $R = 0.637$  accordingly) Fig.1 and Fig.2.

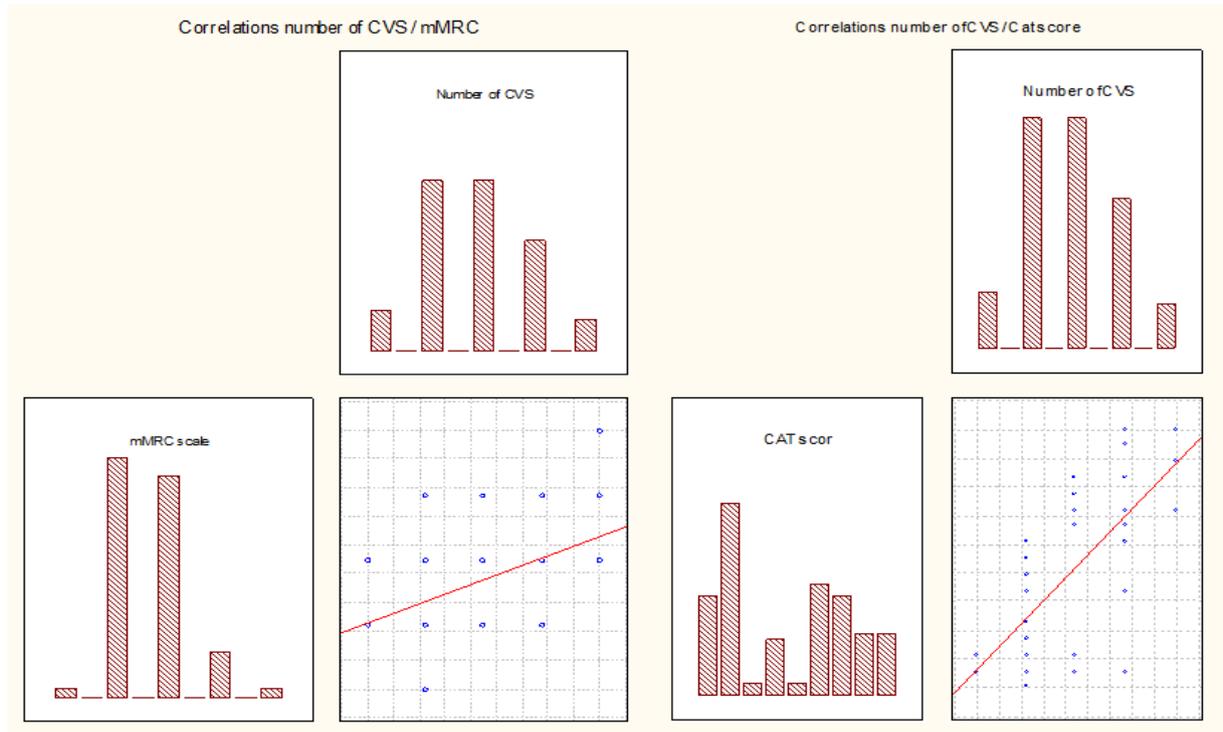


Fig. 1

Fig. 2

#### IV. DISCUSSION

COPD is primarily characterized by the presence of airflow limitation resulting from inflammation and remodeling of small airways and is often associated with lung parenchymal destruction or emphysema. It is increasingly recognized that COPD extends beyond the lung and that many patients have several systemic manifestations that can further destruction or emphysema. It is increasingly impair functional capacity and health-related quality of life [11,20,21]. In addition, COPD is associated with several other diseases.

Rover L. in a systematic literature review concluded that FEV1 is a risk factor for cardiovascular mortality in patients of COPD, 10% decrease in FEV1 increases all-cause mortality by 14%, cardiovascular mortality by 28%, and nonfatal coronary event by almost 20%. (22)

The leading causes of hospitalizations and mortality among COPD patients are cardiovascular events. In the Lung Health Study, over 5 800 patients with mild to moderate COPD were studied. Forty-two to 48% of all hospitalizations that occurred over the study's 5-year follow-up period were related to cardiovascular complications.

Various population-based studies suggest that independent of smoking, age, and gender, COPD

increases the risk of cardiovascular morbidity and mortality twofold. (11)

In our survey from 114 COPD patients which were included, 92 (80,7%) had cardiovascular comorbidity. Sex, age and body mass index of patients with severe and very severe HOB had not significant effect on the occurrence of these comorbidity ( $p=0.9$ ,  $p=0.98$  and  $p=0.19$ ).

It is very alarmingly that the use of bronchodilators, which are commonly used to treat symptoms in COPD, may increase the risk of cardiovascular morbidity and even mortality among COPD patients. Some dates discuss the epidemiologic evidence linking COPD and cardiovascular events as well as the potential mechanism(s) which may be responsible for this association. A pooled analysis of similar longitudinal studies determined that for every 10% decline in FEV1, cardiovascular mortality increases by 28% showing a clear relation between overall cardiovascular death and low lung function.(9,23) A similar gradient exists if the analysis is limited to those fulfilling the diagnosis of COPD. Data from more than 5,000 participants in 2 cohorts (the Atherosclerosis Risk in Communities Study and the Cardiovascular Health Study) showed that while the odds ratio (OR) of having cardiovascular disease is 1.7 (95% confidence interval [CI] 1.5-1.9) for those in the Global Initiative for chronic Obstructive Lung Disease (GOLD) spirometry category

1, it increased to 2.2(95% CI 1.9-2.5) for those in GOLD 2, and 2.4(95% CI 1.9-3.0) in GOLD spirometry stage 3-4.(6,9,24)

Chen et al. identified 18,176 unique references and included 29 datasets in the meta-analyses. Compared with the non-COPD population, patients with COPD were more likely to be diagnosed with cardiovascular disease (odds ratio [OR] 2.46; 95% CI 2.02-3.00;  $p < 0.0001$ ), including a two to five times higher risk of ischemic heart disease, cardiac dysrhythmia, heart failure, diseases of the pulmonary circulation, and diseases of the arteries. Additionally, patients with COPD reported hypertension more often (OR 1.33, 95% CI 1.13-1.56;  $p = 0.0007$ ), diabetes (1.36, 1.21-1.53;  $p < 0.0001$ ), and ever smoking (4.25, 3.23-5.60;  $p < 0.0001$ ). The associations between COPD and these cardiovascular disease types and cardiovascular disease risk factors were consistent and valid across studies. (21,24)Metabolic syndrome also is one of the comorbidity in COPD patients. It is one of the risk factor for cardiovascular comorbidity. (25,26,27,28)

In our group of patients the values of cholesterol, LDL and HDL insignificantly differ between patients with and without cardiovascular comorbidity, but in this group were measured significantly higher values of glucose ( $p = 0.023$ ).

Systemic inflammation that occurs in COPD is considered one of main risk factors for cardiovascular comorbidities in these patients. (30,31)The chronic inflammatory process in the lung contributes to the extrapulmonary manifestations of COPD which are predominantly cardiovascular in nature. Same dates review the significant burden of cardiovascular disease in COPD and discuss the clinical and pathological links between acute exacerbations of COPD and cardiovascular disease. The exacerbations increase the inflammation. (29) CAT test (25,26,27) is designed as a simple tool to assist patient's health status, and for identification of patients at increased risk of exacerbations. (32,33)

More than 50% of subjects in our survey with cardiovascular comorbidity is present or 54.35% had values of CRP higher than 6 mg/l. Significantly higher values of CRP were observed in the group of patients with cardiovascular comorbidities ( $p = 0.00007$ ). And as an independent predictor of cardiovascular comorbidity regression analysis confirmed serum marker CRP ( $p = 0.013$ ). Also our patients with and without cardiovascular comorbidity significantly differ in the number of exacerbations in addition to patients with cardiovascular comorbidity ( $p < 0.0001$ ). The number of cardiovascular comorbidities in patients with severe and very severe COPD significantly positively correlated with mMRC and CAT score ( $R = 0.423$  and  $R = 0.637$  accordingly). Values of CAT score higher than 10 were significantly more likely registered only in group with cardiovascular comorbidities (67.39 %).

## V. CONCLUSION

Chronic obstructive pulmonary disease (COPD) is a growing global epidemic that is particularly important in developing countries. Comorbidities, especially cardiovascular are frequent occurrence in these patients, and significantly influence the treatments and prognosis of the disease. Common risk factors in these patients are age, smoking, physical inactivity and systemic inflammation and treatment with corticosteroids. Lower FEV1-severe COPD, increases cardiovascular mortality and all-cause mortality.

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## Testosterone and Vitamin D Deficiency as Risk Factors for Hip Fracture Elderly Male Patients: Time for Vitamin D and Testosterone Replacement

By Awad Magbri MD, Gussail MA, Eussera El-Magbri, Smew MA, Mariam El-Magbri, Taha El-Magbri, H. Grimes & J Kelly

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**Abstract-** Twenty eight male patients with non-pathological fracture neck of femur (FNOF), age range 61-89 years, mean age 74.4 years, presented for surgery for fracture neck of femur to Merlin Park Regional Hospital, Galway Ireland and 28 age and sex matched control patients, age range 60-85 years, mean age 72.4 years who were admitted to the medical ward for chest pain were included in the study. Following a formal written consent blood were collected for CBC, CMP, and total and free testosterone levels, LH, Estradiol, total 25OHD and 1,25(OH)<sub>2</sub>D, and PTH levels pre-operatively. Bone mineral density was done within 7 days of the incident fracture on the patients and the control groups. The study is approved by the local IRB.

The results were analyzed using T-test for paired data and Chi-square test for the dichotomous data when applicable. The levels of free and total testosterone (<0.001), LH (<0.001), total protein (<0.001), albumin (<0.001), PTH (<0.001), and free estradiol levels (<0.04) were significantly low in patients with hip fracture compared to controls.

**Keywords:** *osteoporosis, fracture neck of femur, hip fracture, testosterone, bone mineral density, vitamin D, 25(OH)D, 1, 25(OH)<sub>2</sub>D. secondary hyperparathyroidism.*

**GJMR-F Classification :** *NLMC Code: WE 855*



*Strictly as per the compliance and regulations of:*



# Testosterone and Vitamin D Deficiency as Risk Factors for Hip Fracture Elderly Male Patients: Time for Vitamin D and Testosterone Replacement

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The results were analyzed using T-test for paired data and Chi-square test for the dichotomous data when applicable. The levels of free and total testosterone (<0.001), LH (<0.001), total protein (<0.001), albumin (<0.001), PTH (<0.001), and free estradiol levels (<0.04) were significantly low in patients with hip fracture compared to controls. The BMD of the femoral neck in g/cm<sup>2</sup> were also significantly lower in the patient compared to controls (P<0.001).

**Conclusions:** testosterone and vitamin D deficiency are potentially preventable risk factors in elderly male patients with non-pathological hip fracture. Vitamin D deficiency might also be implicated for the rise in PTH levels, secondary hyperparathyroidism and bone mineral disorders. Hormonal treatment may be potential option to prevent osteoporosis and decrease the risk of hip fracture in elderly male patients.

**Keywords:** osteoporosis, fracture neck of femur, hip fracture, testosterone, bone mineral density, vitamin D, 25(OH)D, 1, 25(OH)<sub>2</sub>D. secondary hyperparathyroidism.

## I. INTRODUCTION

Vitamin D and hormonal deficiency are well recognized disorders in elderly women. However, there has been insufficient awareness in the medical profession or the public arena that these disorders are leading secondary causes for osteoporosis in elderly males. Osteoporotic fractures are public health problems and any measures to curtail their frequency will have a great impact on the health

delivery and expenditure. Trauma in the form of falls, reduced bone density and impaired bone quality all contribute to fracture risks. The incidence of hip fracture increases sharply after 75 years of age. It is also greater at higher latitude. There is encouraging data from Canada and elsewhere that the age-standard rate decline in hip fracture in both females and males is occurring (1). However, the one year mortality and the need for institutional care after hip fracture are higher in men than women. On the other hand, men are less likely to be investigated and treated for secondary causes of osteoporosis excluding age (2). How common is osteoporosis in men? Has not unfortunately, been answered clearly and sufficiently as the case in women. Even though, the definition of osteoporosis in men is ambiguous (-2.5 T-score below the normal young males), It is estimated that 3-6% of males >50 years of age are osteoporotic, compared to 22% in women (3).

Between 28-60% of fractures in elderly females >80 yrs are attributed to osteoporosis (3, 4). Bone quantity and quality as well as the extent of trauma are important determinants of hip fracture in this age group (5-7).

Androgen deficiency and advanced age have been associated with increased parathyroid hormone (PTH) level (8,9). Reduced levels of 25-hydroxycholecalciferol [25(OH)D] and 1,25-dihydroxycholecalciferol [1,25(OH)<sub>2</sub>D] (10-13) may have contributed to the frequent occurrence of hip fracture in elderly male patients.

## II. PARTICIPANTS AND METHODS

This study included 28 elderly male patients with fracture neck of femur who were admitted to the orthopedic ward for surgery. The age range of these patients was 61-89 years, mean age 74.4 years. A 28 age and sex matched elderly male patients (age range 60-85 years, mean age 72.4 years) admitted to the medical ward for various medical problems, including chest pain, gastroenteritis, or upper respiratory tract infection were included. Informed consent was obtained from each participant in the study and the study is

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approved by the local IRB. The 2 groups are well balanced as far as age, weight and height, tobacco and alcohol consumption.

The eligibility criteria are age >60 years, participants should have no previous fracture, no use of steroids or vitamin D supplements. Patients had to be ambulatory and have suffered a fracture neck of femur due to minor trauma (fall). All blood samples were taken from the patients within 24 hours to minimize the effect of trauma on the biochemical parameters.

The exclusion criteria include: i) pathological fracture ii) previous fracture or fractures of femurs secondary to trauma other than falls iii) thyroid diseases iv) alcohol abuse v) use of calcium or vitamin D supplements vi) use of thiazide, bisphosphonate, calcitonin or corticosteroids medications for more than 3 months.

Blood was drawn from each participant including the control group for estimations of parathyroid hormone (PTH), vitamin D levels, CBC, complete metabolic panel, luteinizing hormone (LH), testosterone, and estradiol levels. Bone mineral density scan were done within one week from the patients and controls using dual-energy X-ray absorptiometry (DXA). Area bone mineral density (BMD) was used measured using Lunar DPX-L scanner (Lunar Corp., Madison, WI, USA) according to the manufacture specification.

#### a) Statistical analysis

All statistical analysis was done using the SAS (Statistical analysis systems Inc. NC, USA). P value of 0.05 or less is taken as significant results. Student T-test is used for continuous data and all p value is reported as two-sided. Dichotomous data are analyzed using the chi-square test whenever applicable.

### III. RESULTS

Serum vitamin D levels below the reference range were found in 19/28(68%) of patients with hip fracture compared to 3/28(10.7%) in control subjects. Both 25(OH)D 23/28(82%) Vs 4/28(14.3%) and 1, 25(OH)<sub>2</sub> D levels were significantly lower in patients compared to controls. This may explain the significant higher levels of PTH and evidence of compensatory secondary hyperparathyroidism in patients compared to control subjects. The PTH levels were higher in patients compared to control 16/28(57.1%) vs 2/28(7.1%).

Total protein and albumin levels were significantly lower in patients compared to control subjects. The trauma incurred during fall with fractures could have been contributing factors to low levels of proteins and albumin in patients compared to control subjects.

Calcium, phosphorus, and creatinine levels are similar in the 2 groups.

No significant difference observed between the 2 groups as far as age, height, tobacco habits, and

alcohol consumption. However, the BMI was significantly lower in patients compared to control subjects' table-1.

Serum total and free testosterone levels less than the reference value were found in 24/28(85.7%) and 26/28(92.9%) of patients compared to 5/28(17.9%) and 3/28(10.7%) in controls, respectively. As a results of low androgen levels secondary to primary gonad insufficiency the LH is significantly higher in patients compared to controls.

Bone mineral density were lower in patients compared to controls, denoting evidence of osteoporosis probably secondary to testosterone and vitamin D deficiencies in patients compared to controls table-1.

### IV. DISCUSSION

Low vitamin D with secondary hyperparathyroidism (SHPT) and decreased radial bone density in elderly men was illustrated in Baltimore Longitudinal Study of aging and others (14,15). In a study involving 133 community based elderly men the inverse relationship between high level of PTH after adjusting for BMI and low level of BMD of multiple femoral sites have supporting the notion that SHPT may contribute to bone loss in elderly men with increased incidence of hip fracture. The high levels of PTH coupled with low levels of 25(OH)D in patients with hip fracture is in agreement with our study (16-18). Even after adjusting for protein binding, the low level s of 25(OH) D in patient s with hip fracture is well demonstrated. These findings are concurring with our results (18). The levels of 1,25(OH)2D showed no difference between the patients and the controls denoting that the activity of 1  $\alpha$ -hydroxylase enzyme is sensitive to PTH levels even in elderly men (19). The normal levels of 1,25(OH)D in patients with hip fracture may explain the low incidence of osteomalacia in cases of hip fracture (20,21). Moreover, the increased activity of 1 $\alpha$ -hydroxylase brings about normalization of 1,25(OH)D at the expense of low levels of 25(OH)D3. This effect is mediated by high levels of PTH.

The androgen deficiencies in hip fracture patients along with high levels of LH are consistent with primary gonadal failure (22). Androgens are indeed essential for the maintenance of bone mass; especially if we believe that hypogonadism in adult men is associated with osteopenia (23-25). There have been reports that treatment with testosterone in hypogonadal adults could result in high BMD with reversal of bone loss (26,27). Androgen and vitamin D deficiencies in elderly men with hip fracture have additive but not synergistic effect.

This study and others have shed light on how common androgen and vitamin D deficiencies in elderly male patients with osteoporotic hip fractures. This study

also showed that (68% and 92.9%) of elderly male patients with hip fracture had vitamin D and testosterone deficiencies, respectively, while 57.1% had increased levels of PTH as a compensatory SHPT from low 25(OH)D levels. These staggering numbers call for further studies to evaluate the importance of vitamin D and testosterone supplementation to prevent osteoporotic hip fractures in this section of population.

The limitation of this study is that markers of bone resorption were not done. The small sample size and effects of other cofounders like trauma on the levels of protein, albumin, and testosterone in these patients could not be entirely dismissed. A cross-sectional study like this can not suggest cause and effect relationships

between androgen and vitamin D and bone resorption. Our study also was not design to study the effects of hormone replacement therapy on the quality and quantities of underlying bone fracture.

### V. CONCLUSION

Testosterone and vitamin D deficiency are potentially preventable risk factors in elderly male patients with non-pathological hip fracture. Vitamin D deficiency might also be implicated for the rise in PTH levels, secondary hyperparathyroidism and bone mineral disorders. Hormonal treatment may be potential option to prevent osteoporosis and decrease the risk of hip fracture in elderly male patients.

Table-1 : Clinical and biochemical data for fracture neck of femur patients and controls.

|                                       | Controls (n = 28) |       | Patients (n = 28) |       | (p value) |
|---------------------------------------|-------------------|-------|-------------------|-------|-----------|
|                                       | Mean              | SD    | Mean              | SD    |           |
| Age (years)                           | 74.4              | 4.3   | 72.4              | 4.7   | 0.12      |
| BMI (kg/m <sup>2</sup> )              | 27.3              | 2.8   | 24.9              | 5.1   | 0.005     |
| Phosphorus (mg/dl)                    | 3.1               | 0.6   | 3.0               | 0.7   | 0.87      |
| Calcium (mg/dl)                       | 9.5               | 0.4   | 9.3               | 0.5   | 0.10      |
| Total Protein (g/dl)                  | 7.3               | 0.3   | 6.2               | 0.2   | 0.001     |
| Albumin (g/dl)                        | 4.3               | 0.4   | 3.5               | 0.3   | 0.001     |
| Creatinine (mg/dl)                    | 1.05              | 0.14  | 1.08              | 0.18  | 0.18      |
| Total 25(OH)D (ng/ml)                 | 18.9              | 7.3   | 11.2              | 8.5   | <0.001    |
| Total 1,25(OH) <sub>2</sub> D pg/ml)  | 47.9              | 8.9   | 35.6              | 14.9  | <0.001    |
| PTH (pg/ml)                           | 15.3              | 7.2   | 44.5              | 26.8  | <0.001    |
| LH $\mu$ IU/ml)                       | 7.0               | 4.6   | 13.8              | 8.7   | <0.001    |
| Total testosterone (ng/dl)            | 435.8             | 178.4 | 169.3             | 81.3  | <0.001    |
| Total estradiol (pg/ml)               | 25.7              | 6.4   | 23.2              | 14.6  | 0.21      |
| Free testosterone index               | 8.3               | 2.8   | 3.2               | 1.3   | <0.001    |
| Free estradiol index                  | 1.6               | 0.3   | 1.2               | 0.7   | 0.04      |
| Femoral neck BMD (g/cm <sup>2</sup> ) | 0.952             | 0.128 | 0.615             | 0.103 | <0.001    |

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## The Prevalence of Hearing Loss in Chronic Kidney Disease Bangladeshi Patients Undergoing Dialysis

By Rezwanur Rahman & Nayareen Akhtar

*Delta Medical College*

**Abstract- Objectives:** End stage renal failure patients, face multiple complications. One of them is the involvement of auditory system. The aim of this study was to determine the prevalence and degree of hearing loss in CKD patients on haemodialysis.

**Methods and Results:** This cross sectional study was conducted from July 2014 to June 2015. The subjects consist of 50 CKD patients on haemodialysis. The patients were from a tertiary care teaching hospital. The baseline characteristics and risk factors such as age, sex, exposure to ototoxic drugs, diabetes, hypertension, renal functions, electrolytes and duration of dialysis were recorded for all patients. The patients were evaluated for their hearing function using pure tone audiometry. Association of CKD patients with haemodialysis for hearing loss was compared with duration of dialysis. The prevalence of hearing loss in CKD patients on dialysis was found to be 42%. Prevalence of hearing loss based on duration of dialysis is 52.4% in patient who got HD < 1 month, 23.8. % who got HD for 1-6 months and 23.8% in >6 months group.

**Conclusion:** Mild sensorineural hearing loss was seen to be relatively prevalent in patients with CKD on haemodialysis. Hearing loss was seen to be inversely associated with duration of dialysis.

**Keywords:** CKD, hearing loss, haemodialysis.

**GJMR-F Classification :** NLMC Code: WJ 300



THE PREVALENCE OF HEARING LOSS IN CHRONIC KIDNEY DISEASE BANGLADESHI PATIENTS UNDERGOING DIALYSIS

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RESEARCH | DIVERSITY | ETHICS

# The Prevalence of Hearing Loss in Chronic Kidney Disease Bangladeshi Patients Undergoing Dialysis

Rezwanur Rahman <sup>α</sup> & Nayareen Akhtar <sup>σ</sup>

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## I. INTRODUCTION

The kidney and the Cochlea are closely linked together. Antigenic similarity between basement membranes of glomeruli and stria vascularis of the inner ear may explain this association to some extent.<sup>1</sup> It has been suggested that common physiologic mechanisms involving fluid and electrolyte shifts in stria vascularis of cochlea and glomerulus might explain the association between hearing loss and CKD.<sup>2</sup> The aetiopathogenetic mechanisms reported included osmotic alteration resulting in loss of hair cells, collapse of the endolymphatic space, oedema and atrophy of specialized auditory cells in some, complications of haemodialysis have been hypothesized.<sup>3</sup> The prevalence of end-stage renal disease is increasing worldwide. Several small studies have indicated an increased prevalence of high-frequency hearing loss in

patients with CKD or those with end-stage kidney disease who are on dialysis Therapy.<sup>4, 5, 6</sup> As the disease progresses, hemodialysis and renal transplants are almost always required, both of which induce electrolytic, osmotic and immunological alterations at the inner ear level, resulting in tinnitus, vertigo and hearing loss.<sup>7</sup> Effect of duration of dialysis and type of dialysate used, on hearing impairment is still under debate. Sensorineural hearing impairment following single session of dialysis has been reported.<sup>8</sup>

## II. METHODS

This was a cross sectional study conducted in Department of Nephrology, Bangabandhu Sheikh Mujib Medical University, Dhaka. The participants comprised of 50 hemodialysis CKD patients. Subjects with audiometric evidence of conductive hearing loss & past medical or surgical treatment of otologic conditions were excluded from the study. Detailed general and systemic examinations as age, gender, and risk factors, such as diabetes, hypertension, and history of ototoxic drug use were assessed. Blood parameters haemoglobin, serum creatinine, calcium & phosphate were also obtained. A prescribed data collection sheet was used for this purpose. Duration of haemodialysis was documented. All CKD patients were evaluated for their hearing function using standard pure tone audiometry. Prevalence and degree of hearing loss was determined in CKD patients undergoing haemodialysis. Sensorineural hearing impairment were also compared with regard to duration of haemodialysis. Written informed consent was obtained from CKD patients. Permission was taken from the departments concerned for this study. The study was conducted after due ethical approval which was subjected to the hospital administrations.

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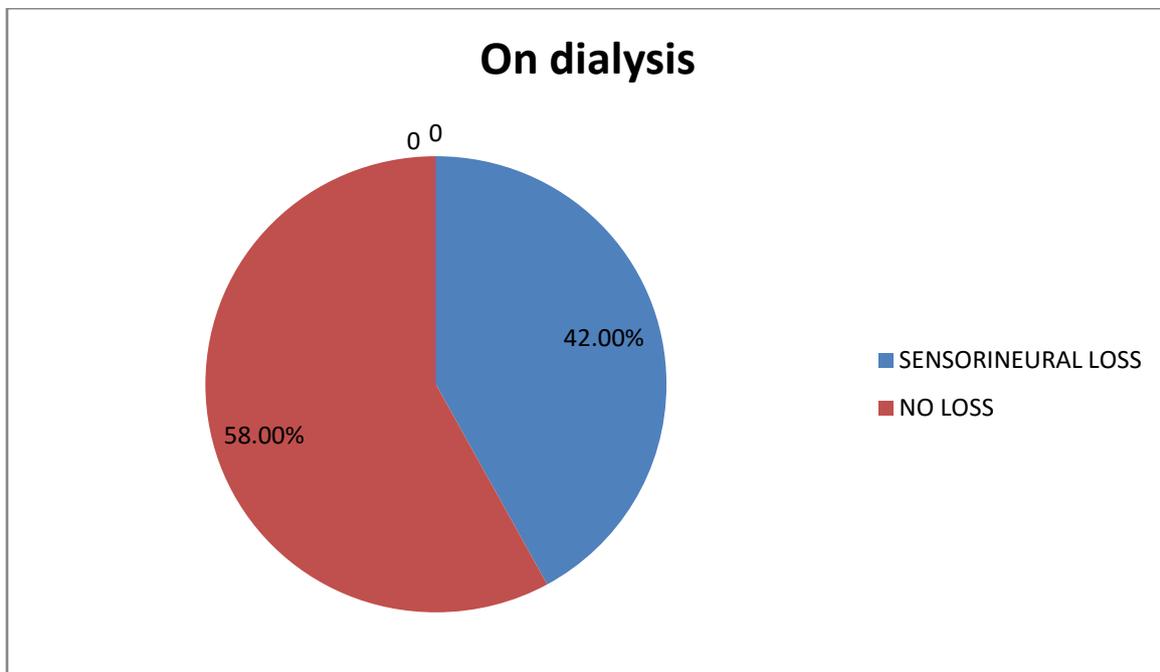
### III. RESULTS

Case group consist of 50 CKD patients undergoing haemodialysis. Data obtained are summarized in Table 1

*Table 1* : Different baseline clinical characters of patients with chronic kidney disease

| Baseline characteristics             | CKD group (n=50) |
|--------------------------------------|------------------|
| Age,y Mean± SD                       | 39.4±12.5        |
| Sex(male/female)                     | 30/20            |
| Diabetes mellitus                    | 16               |
| Hypertension                         | 34               |
| Duration of CKD (in Months) Mean± SD | 18.7±17.1        |
| BMI (kg/m <sup>2</sup> ) Mean± SD    | 19.6±3.83        |
| Systolic BP(mm Hg) Mean± SD          | 149±18           |
| Diastolic BP(mm Hg) Mean± SD         | 85.3±7.6         |
| Hb % (gm/dl) Mean± SD                | 8.5±1.75         |
| Serum creatinine(mg/dl) Mean± SD     | 6.1±3.8          |
| Serum Calcium (mmol/l) Mean± SD      | 1.72±0.12        |
| Serum Phosphate (mmol/l) Mean± SD    | 1.93±0.2         |

Fig 1 shows total 50 patients were on haemodialysis. Among them 21 patients (42%) showed evidence of sensorineural hearing loss and 29 patients (58%) had normal hearing function.



*Figure 1* : Prevalence of hearing loss in patient undergoing dialysis (n=50)

Figure 2 shows prevalence of hearing loss based on duration of dialysis. Total 21 patients on haemodialysis had sensorineural hearing loss. Among those 11 patients (52%) were getting dialysis for less than 1 month, 5 (24%) patients were getting dialysis for 1-6 months and another 5 (24%) patients were getting dialysis for more than 6 months.

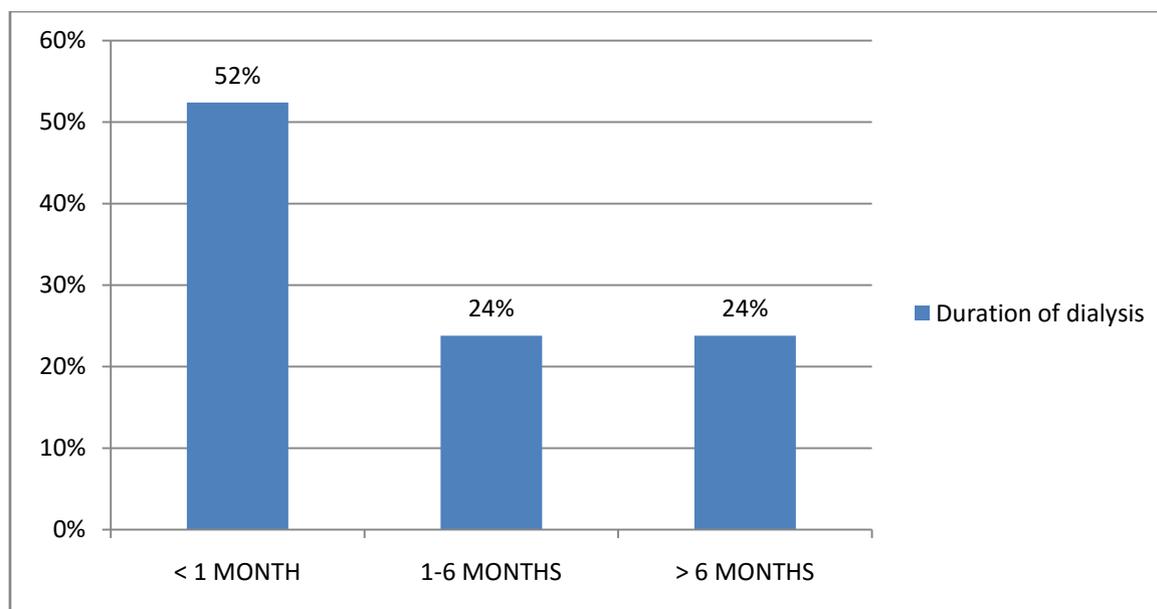


Figure 2 : Prevalence of hearing loss based on duration of dialysis (n=21)

#### IV. DISCUSSION

This study was conducted to evaluate the prevalence of hearing loss in patients undergoing haemodialysis.

Many similarities, anatomical, physiological, pharmacological and pathological, exist between the nephron and the stria vascularis of the cochlea, and hearing loss has been reported in patients with renal failure.<sup>9,10,11</sup> The fact that the cochlea is susceptible to a wide variety of metabolic, hydroelectrolytic and hormonal imbalances is already widely known and these imbalances are systemic alterations usually found in patients who have compromised renal function. Therefore, it is expected that subjects with CRF develop cochlear dysfunction, clinically manifested by sensorineural hearing loss.<sup>12, 13,14,15</sup>

This study found that 42 per cent of CKD patients on haemodialysis had hearing loss. Our study result almost matches with Jishana et al. (2015).<sup>16</sup> Effects of both a single session of hemodialysis<sup>17</sup> and long-term hemodialysis<sup>18</sup> therapy have been studied in several small studies. Bazzi et al. (1995) performed an audiometric evaluation of 91 patients on hemodialysis therapy and found a very high prevalence (77%) of slight to moderate sensorineural hearing loss. Ozturan and Lam (1998) found a moderate to severe hearing loss in 46% of the tested patients.<sup>19</sup> Result of prevalence of hearing loss in dialysis patient in our study is more consistent with Ozturan and Lam (1998).<sup>19</sup> Bergstrom suggested that before the advent of haemodialysis and renal transplantation uraemic patients had no higher incidence of hearing loss than the general population.<sup>10</sup> A possible explanation of this statistic may be that the demise of the patient occurred before they developed a

hearing loss. Mathog and Johnson described fluctuation of hearing in patients undergoing haemodialysis.<sup>20</sup> Impairment of hearing with haemodialysis has been reported by Rizvil and Mitschke.<sup>21, 22</sup>

We found that hearing loss is more prevalent in patients who are getting haemodialysis for < 1 months (52%) compared to those who are getting haemodialysis between 1-6 months (24%) and > 6 months (24%).

Our finding that hearing loss is more prevalent in patients who are getting haemodialysis for < 1 months (52%) is interesting as it suggests a possible beneficial association between increasing number of dialysis sessions and hearing loss. Gartland et al. (1991) recorded pure tone thresholds on 31 patients before and after a session of haemodialysis and documented a low frequency hearing loss, which improved significantly on one-third of the patients after dialysis.<sup>23</sup>

#### V. CONCLUSION

Sensorineural hearing loss was seen to develop in CKD patients undergoing haemodialysis. However, there may be an ameliorative effect of haemodialysis on hearing loss in CKD, an association that needs to be tested further. So, we recommend closely monitoring of hearing levels in dialysis patients.

Hemodialysis may have an important role in occurrence of hearing loss in CRF.

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## Medico Social Study of Aged Persons: A Case Study from Serampore City

By Partha Talukdar

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**Abstract-** Ageing is a biological process, experienced by mankind. Ageing is a dynamic process, determined by the relative size of the younger and older. However, concern for Ageing of population is a relatively new phenomenon, which has raised due to significantly large increase in the number and proportion of aged persons in the society. The phenomenon of population Ageing is becoming a major concern for the policy makers all over the world during the last two decades. Ageing of population is affected due to downward trends in fertility and mortality i.e. due to low birth rates with long life expectancies. Life expectancy at birth is projected to continue to rise in the coming years all over the world. The aged population has specific health problems that are basically different from those of adults or young persons. Most diseases in the aged are chronic in nature-cardiovascular, arthritis, stroke, cataract, deafness, chronic infections, cancer. Disease process is usually multiple. Availability and utilization of health services is an important determinant of the health status of population. The needs for health services tend to vary directly with the age of the individuals. The older the one gets, the more health care he needs. Although the aged people face multiple health problems, even then, they do not consider seeking medical aid and as a result, many conditions remain unreported and untreated till they become complicated.

**Keywords:** morbidity, elderly population, ageing, physical disabilities.

**GJMR-F Classification :** NLMC Code: W 322



*Strictly as per the compliance and regulations of:*



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Partha Talukdar

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**Keywords:** morbidity, elderly population, ageing, physical disabilities.

## I. INTRODUCTION

It is difficult to define the onset of old age. Biologically, Ageing begins as early as puberty and is a continuous process throughout adult life. Socially, the characteristics of members of society who are perceived as being old vary with the cultural settings and from generation to generation. Economically, the elderly are sometimes defined in terms of retirement from the work force. Chronologically, age has long been used as an indicator of expected residual life span. Recent changes in mortality rate have changed the predictive significance of chronological age and refined health care has shifted the emphasis from prolonging life expectancy to increasing the expectancy free of disability.

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Ageing is generally defined as a process of deterioration in the functional capacity of an individual that results from structural changes, with advancement of age. High fertility and declining mortality are the major factors responsible for population increase in most countries of the world, especially the developing ones. Longevity has increased significantly in the last few decades mainly due to the socio-economic and health care developments. These factors are responsible for higher numerical presence of elderly people leading to higher dependency ratio. Demographers, researchers and responsible citizens have started to think about the aged population and its problems because of the demographic transition in many countries of the third world now taking place in a much shorter period of time. Ageing of the population will be one of the major challenges of the near future.

In USA, UK and other western countries, the attainment of the age of 65 years has been considered for the purpose of classifying aged persons, whereas in India, it is from 60 years (Vijaykumar S et al, 1999). The elderly sub-population referred to as the "young old" (60-74), the "old" (75-84), and the "old-old" (above 85) (Swash Michael, 1995).

## II. MATERIAL AND METHODS

Serampore is an important city of Hooghly district, state of West Bengal, India. At the time of 2011 census, the population within the Municipal area of Serampore was 181,842. Study was conducted in randomly selected 32 areas distributed in Serampore city including Urban and Slum areas. List of zones and wards including Slum and Urban areas were obtained from Municipality of Serampore. From eight zones of Serampore city by simple random technique, four zones were selected. Out of the four zones, four wards were selected by simple random technique. From each ward, one slum area and one urban area were included in the study using simple random technique. A total of 32 areas were included in this study. Door to door survey was conducted. From each area, 20 elderly were included in study.

**Sampling method:** Multi stage simple random sampling technique.

**Sample size:** 640

Sample size was calculated by using statistical formula,  $n = Z^2 I-a/2 P (I-P)/d$

P = Morbidity Problems (50%), d= Absolute Precision (4%), Confidence level= 95%

As there was no baseline study in Serampore, Chhattisgarh, therefore it was not possible to estimate 'P', so a figure of 0.5(50%) was used. This is the 'safest' choice for the population proportion, since the sample size required is largest when P = 0.5(50%) [128].

A total of 600 figures come using statistical formula. For making uniformity, 20 subjects from each of 32 areas were selected that comes 640. Therefore, a total 640 subjects were included in the study.

### III. OBJECTIVES OF THE STUDY

- 1) To study morbidity pattern in elderly population of Serampore city.
- 2) To determine the pattern of morbidity in elderly population of Serampore city.
- 3) To study the health-care seeking behaviour of elderly population.

- 4) To make suitable recommendations on the basis of the study.

### IV. OBSERVATIONS AND DISCUSSION

Descriptive cross-sectional observational study was undertaken among the elderly population in Serampore city during the period July 2015 to June 2016. Information was collected from 640 elderly persons. The findings of the present study is an attempt to explore the morbidity pattern and health-care seeking behaviour among elderly population.

The findings of the study are discussed under following headings:

- (A) Socio-demographic characteristics.
- (B) Physical activity and substance abuse.
- (C) Morbidity Profile.
- (D) Health-care seeking behaviour.

Table – 1 : Age and sex wise distribution of morbidity in elderly population

| Age groups (years) | Male        |        |       | Female      |        |       | Total       |        |       |
|--------------------|-------------|--------|-------|-------------|--------|-------|-------------|--------|-------|
|                    | No examined | Morbid | %     | No Examined | Morbid | %     | No examined | Morbid | %     |
| 60-74              | 200         | 176    | 88    | 323         | 319    | 98.76 | 523         | 495    | 94.64 |
| 75-84              | 67          | 65     | 97.01 | 47          | 47     | 100   | 114         | 112    | 98.24 |
| >85                | 0           | 0      | 0     | 3           | 3      | 100   | 3           | 3      | 100   |
| Total              | 267         | 241    | 90.26 | 373         | 369    | 98.92 | 640         | 610    | 95.31 |

Chi-Square = 21.282 (df = 2, p < 0.0001)

Above table-1 shows, out of total study population (640 elderly) prevalence of morbidity was 95.31% (610). Prevalence among females was 98.92%, whereas among males was 90.26%. Morbidity was statistically positively associated with advancement of age. Among females, 98.76% in young old, 100% in both old and very old age group were morbid; whereas in males, 88% young old, and 97.01% of old were morbid. There was no one in very old age group in male elderly population. Present study shows that prevalence of morbidity was more in females than males. In all age

groups, prevalence of morbidity among females was more in comparison to males. A community based study from rural area of West Bengal observed that almost all the elderly (96.95% males and 98.15% females) were suffering from one or more diseases at the time of study. The difference was small and statistically not significant (z=0.54, P>0.05). All elderly aged 70 years and above were found to be diseased. Only five elderly (2.45%) were well at the time of study in the age group of 60-69 years. All elderly in more than 80 years age group were suffering from some disease.

Table-2 : Distribution of morbidity according to system of involvement

| System of involvement          | Male (n= 241) |       | Female (n= =369) |       | Total n=610) |       |
|--------------------------------|---------------|-------|------------------|-------|--------------|-------|
|                                | No            | %     | No               | %     | No           | %     |
| GIS                            | 211           | 87.55 | 293              | 79.40 | 504          | 82.62 |
| Eye                            | 192           | 79.66 | 295              | 79.94 | 487          | 79.83 |
| CVS                            | 113           | 46.88 | 207              | 56.09 | 320          | 52.45 |
| Locomotor                      | 71            | 29.46 | 174              | 47.15 | 245          | 40.16 |
| Ear                            | 83            | 13.60 | 128              | 34.68 | 211          | 34.59 |
| Metabolic and Endocrine system | 57            | 23.65 | 111              | 30.08 | 168          | 27.54 |

|                            |     |       |      |       |      |       |
|----------------------------|-----|-------|------|-------|------|-------|
| Respiratory system         | 32  | 13.27 | 70   | 18.97 | 102  | 16.72 |
| Nervous system             | 35  | 14.52 | 38   | 10.29 | 73   | 11.96 |
| Skin & subcutaneous tissue | 18  | 7.46  | 28   | 7.58  | 46   | 7.54  |
| Genito urinary system      | 29  | 12.03 | 16   | 4.33  | 45   | 7.37  |
| Others                     | 5   | 2.07  | 12   | 3.25  | 20   | 3.27  |
| Total                      | 852 | -     | 1398 | -     | 2250 | -     |

Note : Multiple system involvement was observed in many subjects.

Above Table-2 shows, out of total morbid subjects (n=610), many elderly had multiple system involvement and many had more than one disease in a particular system. Most common system involvement were Gastro intestinal system (GIS) (82.62%), Eye (79.83%), Cardiovascular system (52.45%), Locomotor system (40.16%), Ear 34.59%), Metabolic & Endocrine system (27.54%), Respiratory system (16.72%), Nervous system (11.96%). Skin & Subcutaneous tissue involvement in (7.54%), Genito urinary system (7.37%), and others (3.27%). Others included Anaemia, Enteric fever, Malaria, Generalized weakness. In most of the systems, prevalence of morbidity was more in female elderly than male elderly, except Gastro-intestinal system, Nervous system, and Genito-urinary system, where prevalence was more in males than in females. P Ray et al (2013) reported that 67.2% elderly had GIS disorder, followed by involvement of eye, cardiovascular and musculoskeletal system in 49.5%, 46.1% and 29.9% elderly respectively.

Respiratory system was also involved in 29.2% study population. In 15.7% elderly there was Skin and subcutaneous tissue disease. Genito-urinary system, nervous system and ENT problem was seen in 9.8%, 5.4% and 4.9% study population. In 24% elderly, there were other diseases. Shradha K et al (2012) studied that most common disorder reported among elderly was eye diseases (51.7%) followed by endocrine, nutritional and metabolic diseases (38.4%), diseases of circulatory system (33.1%), disorders of oral cavity (32.3%), musculoskeletal disorders (30.2%) and diseases of respiratory and digestive system was reported about 10% by the geriatric people. Rahul Prakash et al (2004) in a study in urban area of Udaipur, Rajasthan India observed that major health problem as per diagnostic group was Eye problem (70%), Hypertension (48%), Psycho-social problems (42%), Respiratory problems (36%), and rest others were Musculoskeletal disorders in 14.6%, Nervous system disorders 8.6% .

Table-3 : Distribution of diseases of gastrointestinal system including oral cavity

| Diseases               | Male (n=241) | %      | Female (n=369) | %      | Total (n=610) | %      |
|------------------------|--------------|--------|----------------|--------|---------------|--------|
| Haemorrhoids           | 3            | 1.24%  | 3              | 0.81%  | 6             | 0.98%  |
| Acute hepatitis        | 1            | 0.41%  | 0              | 0      | 1             | 0.16%  |
| Inguinal hernia        | 3            | 1.24%  | 0              | 0      | 3             | 0.49%  |
| Constipation           | 12           | 4.97%  | 19             | 5.14%  | 31            | 5.08%  |
| Acute Gastro Enteritis | 0            | 0      | 7              | 1.89%  | 7             | 1.14%  |
| Peptic Ulcer Disease   | 4            | 1.65%  | 10             | 2.71%  | 14            | 2.29%  |
| Gingivitis             | 2            | 0.82%  | 2              | 0.54%  | 4             | 0.65%  |
| Hydrocele              | 2            | 0.82%  | 0              | 0      | 2             | 0.32%  |
| Attrition of tooth     | 158          | 65.56% | 173            | 46.88% | 331           | 54.26% |
| Enteric Fever          | 0            | 0      | 1              | 0.27%  | 1             | 0.16%  |
| Partial Edentulous     | 44           | 18.25% | 94             | 25.74% | 138           | 22.62% |
| GERD                   | 7            | 2.90%  | 2              | 0.54%  | 9             | 1.47%  |
| Carries tooth          | 0            | 0      | 3              | 0.81%  | 3             | 0.49%  |
| Submucosal fibrosis    | 1            | 0.41%  | 0              | 0      | 1             | 0.16%  |
| Aphthous ulcer         | 3            | 1.24%  | 1              | 0.27%  | 4             | 0.65%  |
| Others (Macroglossia)  | 0            | 0      | 2              | 0.54%  | 2             | 0.32%  |
| Total                  | 240          |        | 317            |        | 557           |        |

Note: Multiple illnesses were observed in many subjects.



Above table-3 shows, out of all 610 morbid elderly, 82.62% had morbidity related with Gastro intestinal system. Prevalence among the elderly males was 87.55% whereas in females, 79.40%. Of all the illnesses related to Gastro intestinal system and oral cavity, majority had Attrition of tooth (54.26%), Partial edentulous (22.62%), Constipation (5.08%), Peptic Ulcer disease (2.29%), Gastro oesophageal reflux disease (1.14%), Acute gastro enteritis (1.14%). Most of the illnesses were prevalent among females than males except, Haemorrhoids and Gastro oesophageal reflux disease (GERD), which was prevalent among males.

This is comparable to P Roy et al (2012) who reported 67.2% of gastrointestinal disorder in rural area of West Bengal .In another study done by Shradha K et al

(2012) ,prevalence was less, reported 10.8% only;in females 11.3% whereas in males 10.1%. Aggrawal Anupam (1992) reported only 44.28% in their study.Another study done by Kulkarni and Niyogi (1974) reported 35.6% in a study at Baroda. Shradha K et al (2012) reported commonest disease was Gastritis (2.9%), Constipation (4.4%), and others.P Ray Karmakar et al (2012) reported Periodontal disease was most common followed by Dental caries , Constipation, Glossitis and others.Purohit and Sharma (1976) observed a much higher prevalence of Periodontitis (38.23%) and Raj and Prasad (1970) reported Dental caries in 7.90% of the elderly. Raj (1971) observed stomatitis in 4.0% elderly people.

Table-4 : Distribution of diseases of cardio vascular system

| Diseases                    | Male (n=241) | %     | Female (n=369) | %     | Total (610) | %     |
|-----------------------------|--------------|-------|----------------|-------|-------------|-------|
| Hypertension                | 113          | 46.88 | 207            | 56.09 | 320         | 52.45 |
| Acute Myocardial Infarction | 0            |       | 1              | 0.27  | 1           | 0.16  |
| Congestive Cardiac Failure  | 2            | 0.82  | 3              | 0.81  | 5           | 0.81  |
| Total                       | 115          | -     | 211            | -     | 326         | -     |

Chi-square = 0.594 (df = 2 , p = 0.743)

Above Table-4 shows, among total morbid elderly, prevalence of Cardio vascular system morbidity was 52.45%; prevalence was more in females (56.09%) than males (46.88%). Out of total morbidity related with Cardio vascular system, 52.45% had Hypertension, 0.81% had Congestive cardiac failure, and 0.16% had acute myocardial infarction. Prevalence of Hypertension was more in females (56.09%) than males (46.88%). There was positive association with advancement of age, 27.87% in young old to 100% in very old age group. Shradha K et al (2012), in their study in urban elderly at Mysore, Karnataka, India observed that 33.1% had morbidity of Cardio vascular system, more in males (34.3%) than females (32.3%). Of all the Cardio vascular morbidity, 29.3% had Hypertension, 30.45% in males whereas 28.55% in females. In present study, prevalence is higher than the observation made by Shradha K et al (2012), and it may be due to the absence of Class I socio-economic group in Shradha K et al (2012). Prakash Rahul et al (2004), in their study in urban area of Udaipur, Rajasthan India observed that 48% elderly had Hypertension; more in females (54.5%) than males (44.2%).Out of total 640 examined study population 320 (50%) had Hypertension. Out of the total hypertensives, 42.18% were newly diagnosed during the study and 57.81% were Known Hypertensives. Of the known hypertensive cases, 60% were females and 40% were males. Of the known hypertensives, 82.70% were receiving anti-hypertensive treatment; out of which 58.16% were females and 41.83% were males. Statistically significant difference was observed between

those adequately treated (41.17%) and inadequately treated (58.82%). Females (76.19%) were more adequately treated than males (23.80%). Out of the total hypertensive population, 35.93% had family history of Hypertension. Out of total female hypertensives, 36.71% had family history of Hypertension whereas among male hypertensives, 34.51% had family history of Hypertension. Sulakshna et al (2013) found that 52% were hypertensive, 134 (39.8%) were males and 202 (60.1%) were females. Of the 174 hypertensives, 28 (16.09%) were newly diagnosed during the study and 146 were known hypertensives. Out of the 146 known hypertensives , 49 (33.5%) were males and 97 (66.43%) were females. Out of the 146 hypertensives, only 41 (28%) took regular anti-hypertensive treatment and 105 (72%) did not seek treatment regularly.

Table-5 : Distribution of Hypertension with alcohol status

| Alcohol Status    | Hypertension    |         |                |         | Total(n=640) | %     |
|-------------------|-----------------|---------|----------------|---------|--------------|-------|
|                   | Present (n=320) | %       | Absent (n=320) | %       |              |       |
| Current alcoholic | 28              | (43.07) | 37             | (56.92) | 65           | 10.15 |
| Ex-alcoholic      | 0               | 0       | 23             | (100)   | 23           | 3.59  |
| Non-alcoholic     | 292             | (52.89) | 260            | (47.10) | 552          | 86.25 |
| Total             | 320             | (50)    | 320            | (50)    | 640          | (100) |

Chi-square = 26.101 (df = 2, p = < 0.0001)

Above Table-5 shows that 43.07% of current alcoholic were hypertensives, whereas 52.89% among non-alcoholic were hypertensives. Among ex-alcoholics, none was hypertensive. The relation between alcohol and Hypertension was found to be statistically significant.

In another study by Anupam Prakash (1992) in rural area in Delhi, it was observed that 5.23% persons were presently taking alcohol while 6.04% were ex-alcoholic. The relation between alcohol and Hypertension

was found to be statically significant (Chi square cal > Chi square tab). Out of 54 hypertensives, 16.67% were current alcoholics as compared to 558 non-hypertensives, amongst whom 4.13% were consuming alcohol presently.

In present study, finding was different from study done by Anupam Prakash (1992), there was negative association of hypertension with alcohol, may be due to more number of females who were mostly non-drinker in comparison to males.

Table-6 : Distribution of Hypertension with Smoking status

| Smoking Status | Hypertension   |         |               |         | Total(n=640) | %       |
|----------------|----------------|---------|---------------|---------|--------------|---------|
|                | Present(n=320) | %       | Absent(n=320) | %       |              |         |
| Current Smoker | 60             | (49.58) | 61            | (50.41) | 121          | (18.90) |
| Ex-smoker      | 29             | (33.33) | 58            | (66.66) | 87           | (13.59) |
| Non-smoker     | 231            | (53.47) | 201           | (46.52) | 432          | (67.50) |
| Total          | 320            | 50      | 320           | 50      | 640          | 100     |

Chi-square = 11.758 (df = 2, p = 0.0028)

Above Table-6 shows that there was a total of 18.90% current smokers; out of which, 18.75% were hypertensives. 13.59% were ex-smokers, out of which 33.33% were hypertensives. A large number of elderly were non-smoker (67.50%), out of which 53.47% were hypertensives. Anupam Prakash et al (1992) observed that there was statistically negative association of hypertension with smoking. Out of total current smokers,

57.41% were hypertensive current smokers, whereas 12.96% ex-smokers were hypertensives, and 29.63% of non-smokers were hypertensives though smoking is a known risk factor for hypertension, but in present study negative association of hypertension with smoking was statistically significant. This indicates that there are some additional factors too responsible for hypertension.

Table-7 : Distribution of diseases of locomotor system

| Diseases             | Male(n=241) |        | Female(n=369) |        | Total(n=610) |        |
|----------------------|-------------|--------|---------------|--------|--------------|--------|
|                      | No          | %      | No            | %      | No           | %      |
| Fracture Forearm     | 2           | 0.82%  | 0             |        | 2            | 0.32%  |
| Lumbar Disc Disease  | 21          | 8.71%  | 59            | 15.98% | 80           | 13.11% |
| Osteo- Arthritis     | 45          | 18.67% | 121           | 32.79% | 166          | 27.21% |
| Frozen Shoulder      | 3           | 1.24%  | 15            | 4.06%  | 18           | 2.95%  |
| Rheumatoid Arthritis | 1           | 0.41%  | 2             | 0.54%  | 3            | 0.49%  |
| Psoriatic Arthritis  | 0           | 0      | 1             | 0.27%  | 1            | 0.16%  |
| Cervical Spondylitis | 0           | 0      | 4             | 1.08%  | 4            | 0.65%  |
| Total                | 72          | -      | 202           | -      | 274          | -      |

Note: Multiple illnesses were observed in many subjects.

Chi-square = 8.388 (df = 6, p= 0.211)

Above Table-7 shows, the prevalence of Locomotor system disorder was found in 40.16% of the elderly. Prevalence was more in females (47.15%) than males (29.46%). The most common condition observed was Osteoarthritis (27.21%) which was more common in females (32.79%). The next common condition was Lumber Disc Disease (13.11%) which was also more common in females (15.98%). 2.95% elderly had Frozen shoulder; it was also more common in females (4.06%) than males (1.24%). The least common condition was Cervical Spondilitis (0.65%), Rheumatoid arthritis (0.49%), and Psoriatic arthritis (0.16%). There was an increase in the prevalence of Osteoarthritis with age which can be explained on the basis of degenerative nature of the disorder and its cumulation with age. In present study, prevalence of Osteoarthritis among morbid population was, from 27.87% in young old, to 22.32% in old and 100% in very old age group.

P Ray Karmakar et al (2012), reported Locomotor system disorders in 29.90% of elderly. Out of the aged males, 23.7% and out of aged females, 35.5%

had disease of Musculoskeletal system. Osteoarthritis was the most common manifestation (22.54%) in both sexes together. Hanger et al (1990) in their Christchurch study observed that 33.80% of the elderly had Locomotor system involvement, of which Osteoarthritis was in 14.20% of the elderly which is almost comparable to the figure in the present study (14.71%). Mc Donnel et al (1979) reported involvement of Musculoskeletal system in 19.0% of elderly in Leeds Metropolitan District.

In present study prevalence of Locomotor system was almost comparable to other study, especially Osteoarthritis which is almost comparable. One case of fracture forearm was observed. The overall prevalence of Rheumatoid arthritis was very low (0.46%) in the present study, which was found to be lower than that reported by P Ray Karmakar et al (2012), Raj (1971), and could be due to the fact that in present study proportion of very old population was very low. While Ehrlich et al (1970) had shown that this disease commenced after 60 years of age and flourishes as age advances.

Table-8 : Distribution of diseases of metabolic and endocrine system

| Diseases          | Male(n=241) | %      | Female(n=369) | %      | Total(n=610) | %      |
|-------------------|-------------|--------|---------------|--------|--------------|--------|
| Diabetes Mellitus | 52          | 21.57% | 96            | 26.01% | 148          | 24.26% |
| Hypothyroidism    | 3           | 1.24%  | 9             | 2.43%  | 12           | 1.96%  |
| Gout              | 2           | 0.82%  | 6             | 1.62%  | 8            | 1.31%  |
| Total             | 57          | -      | 111           | -      | 168          |        |

Chi-square = 0.807 (df 2, p = 0.667)

In present study, prevalence of metabolic and endocrine system disorders was 27.54%, among females 30.08% whereas in males 23.65%. Above table shows that, common metabolic disorder was Diabetes mellitus (24.26%), prevalence among females (26.01%) was more than males (21.57%), followed by Hypothyroidism (1.96%), more in females (2.43%) than males (1.24%). Prevalence of gout was 1.31%, more in females (1.62%) than in males (0.82%). Most common illness was Diabetes mellitus (23.12%), followed by Hypothyroidism (1.87%) and Gout (1.25%). Hypothyroidism was more

common in female elderly (2.41%) than male elderly (1.12%). In other study done by Prakash R et al (2004), observed that 3.33% of total elderly population had metabolic and endocrine disorders. All male elderly were affected. Anupam Prakash et al (1992), in a study in rural area in Delhi, observed that Thyrotoxicosis was present in 0.33% of total elderly population. In present study, a significant number of cases of Hypothyroidism may be due to iodine deficiency which is common in Chhattisgarh state.

Table-9 : Distribution of diseases of respiratory system

| Diseases          | Male (n=241) |       | Female (n=369) |       | Total (n=610) |       |
|-------------------|--------------|-------|----------------|-------|---------------|-------|
|                   | No           | %     | No             | %     | No            | %     |
| Acute Pharyngitis | 3            | 1.24% | 35             | 9.48% | 38            | 6.22% |
| LRTI              | 1            | 0.41% | 3              | 0.81% | 4             | 0.65% |
| Asthma            | 2            | 0.82% | 20             | 5.42% | 22            | 3.6%  |
| COPD              | 18           | 7.46% | 13             | 3.52% | 31            | 5.08% |
| Tuberculosis      | 0            |       | 1              | 0.27% | 1             | 0.16% |
| Pneumonia         | 7            | 2.90% | 1              | 0.27% | 8             | 1.31% |
| Laryngitis        | 1            | 0.41% | 5              | 1.35% | 6             | 0.98% |

Chi-square = 39.281 (df = 6, p < 0.0001)

In present study, prevalence of Respiratory system disorders was 16.72%; among females prevalence was 18.97% whereas in males, 13.27%. Out of total Respiratory system disorders, common disorder was Acute Pharyngitis (6.22%), Chronic Obstructive Pulmonary Disease (COPD) 5.08%, Asthma (3.6%), Pneumonia (1.31%). Asthma was more common in females (5.42%) than males (0.82%). COPD and Pneumonia were more common in males than females. COPD among males was 7.46% whereas in females was 3.52%. Pneumonia among males was 2.90% whereas among females was 0.27%. One case of tuberculosis was reported. In another study,

Rahul et al (2004) reported that 36% had respiratory diseases, more in males (41%) than females (27.3%). In present study, prevalence is more than the observation made by Rahul et al (2004). This may be due to more number of current male smokers than female smokers.

In another study by Prakash R et al (2004), reported that Asthma was the leading respiratory problem among both males and females followed by Coryza, Chronic bronchitis, Upper Respiratory Tract Infection (URTI) and Tuberculosis. Shradha et al (2012) observed that URTI, Acute Bronchitis, Bronchial Asthma were the major respiratory diseases.

Table-10 : Distribution of diseases of nervous system

| Disease                                   | Male(n=241) | %    | Female(n=369) | %    | Total(n=610) | %    |
|---|-------------|------|---------------|------|--------------|------|
| TTH                                       | 1           | 0.41 | 0             |      | 1            | 0.16 |
| Migraine                                  | 1           | 0.41 | 10            | 2.71 | 11           | 1.80 |
| Hemiparesis                               | 7           | 2.90 | 1             | 0.27 | 8            | 1.31 |
| Peripheral Neuritis                       | 12          | 4.97 | 1             | 0.27 | 13           | 2.13 |
| Post op case of frontal lobe brain tumour | 1           | 0.41 | 0             |      | 1            | 0.16 |
| Hemiplegia                                | 5           | 2.07 | 0             |      | 5            | 0.81 |
| Anxiety                                   | 9           | 3.73 | 30            | 8.13 | 39           | 6.39 |
| Depression                                | 9           | 3.73 | 30            | 8.13 | 39           | 6.39 |
| Total                                     | 45          |      | 72            | -    | 117          |      |

Note: Multiple illnesses were observed in many subjects.

Chi-square = 47.062 (df = 7, p < 0.0001)

Present study shows that, prevalence of Nervous system disorders including Mental illness disorder was 11.96%; among males 14.52% whereas in females 10.29%. Out of total morbidity among nervous system including Mental illness, majority had Anxiety (6.39%) and Depression (6.39%), followed by Peripheral Neuritis (2.13%). The least common conditions were Migraine (1.80%), Tension type headache (TTH) 0.16%, Hemiparesis (1.31%), Hemiplegia (0.81%), one post op case of frontal lobe brain tumour. Prevalence of Anxiety and Depression was more in females than in males. In another study conducted by Rahul Prakash et al (2004), reported that prevalence of Nervous system disorder was 8.5%.

## V. CONCLUSION

The present study is an endeavour to find out the morbidity pattern among elderly in Serampore city on a small scale of young growing state of West Bengal, along with the existing health practices and finally to suggest a pattern of health services suitable for the elderly population in the city. The study was conducted in 640 elderly subjects selected randomly from 32 areas including urban and slum areas from 8 zones and 77 wards of Serampore city. Elderly persons in the age group, 60 years and above were 63635 (6.3% of total population in Serampore city), out of which only 640

persons (267 males and 373 females) were included in the study. Elderly females 373 (58.28%) out-numbered elderly males 267 (41.71%). Majority of the elderly persons (81.71%) belonged to “young old” age group. Bulk 40.15% of the elderly persons received education upto higher secondary. Graduates and above was only 15.78%, out of which 83.16% were in urban whereas 16.83% were from slum areas.

36.40% of the elderly population belonged to socio-economic Class IV, followed by Class II. A large proportion (84.07%) was living in joint families and 15.93% in nuclear family settings. Only 5.93% were living alone. 51.09% of the elderly were themselves heading the family with males predominating. A large proportion 42.03% of elderly population was unemployed. The principle occupation of the persons who were currently employed in some gainful occupation was agriculture/ shop owner/clerical 11.25%, while 18.12% were professional including retired persons. A large proportion 48.28% was financially dependent on others. Only 14.84% were receiving old age pension. Out of total dependent, 66.66% were dependent on their children, 13.26% on grand children and 1.29% on spouse, 14.56% on others. A small proportion 33.59% was aware about various Government welfare schemes for the elderly. The geriatric population is a dependent population. Hence, health care delivery system should

reorganize their timing other than routine schedule. Periodic comprehensive health check up, preferably twice a year must be carried out and primary health care delivery must be ensured to geriatric population.

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## *Helicobacter Pylori* and Steps for its Elimination: A Review

By Sangita Boro & Manash Pratim Sarma

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**Abstract-** The only host for *H. pylori* is human and it is found to be present in stomach, duodenum, oesophagus and rectum. *H. pylorus* is responsible for causing chronic infections and therefore its complete eradication from the society is very much essential. This article therefore aims to review the recent treatment options prevalent for the eradication of this dreadful disease.

**Keywords:** *helicobacter pylori, antimicrobial resistance, eradication, therapy.*

**GJMR-F Classification :** *NLMC Code: WI 387*



*Strictly as per the compliance and regulations of:*



# Helicobacter Pylori and Steps for its Elimination: A Review

Sangita Boro <sup>α</sup> & Manash Pratim Sarma <sup>σ</sup>

**Abstract-** The only host for *H. pylori* is human and it is found to be present in stomach, duodenum, oesophagus and rectum. *H. pylorus* is responsible for causing chronic infections and therefore its complete eradication from the society is very much essential. This article therefore aims to review the recent treatment options prevalent for the eradication of this dreadful disease.

**Keywords:** *helicobacter pylori*, antimicrobial resistance, eradication, therapy.

## I. INTRODUCTION

**H**elicobacter pylorus (*H. pylori*) is a microbial species that specifically colonizes the gastric epithelium. *Helicobacter pylori*, is a gram-negative, spiral bacterium situated on the epithelial surface of the stomach. It is thought to be the most common bacterial infection worldwide. Virtually, all

persons infected by this organism develop gastritis, a signature feature of which is the capacity to persist for decades leading to chronic inflammation of the underlying mucosa. It has been recognized to be associated with increased risk of chronic gastritis, peptic ulcer disease (PUD) (gastric and duodenal), gastric mucosal-associated lymphoid tissue (MALT) lymphoma, gastric adenocarcinoma, World Health Organisation (WHO) has described *H. pylori* as a class 1 carcinogen for gastric carcinoma. *H. pylori* infection also induces insulin resistance and has been defined as a predisposing factor to T2D development. Gastric and fecal microbiota may have been changed in *H. pylori*-infected persons and mice to promote gastric inflammation and specific diseases [1].

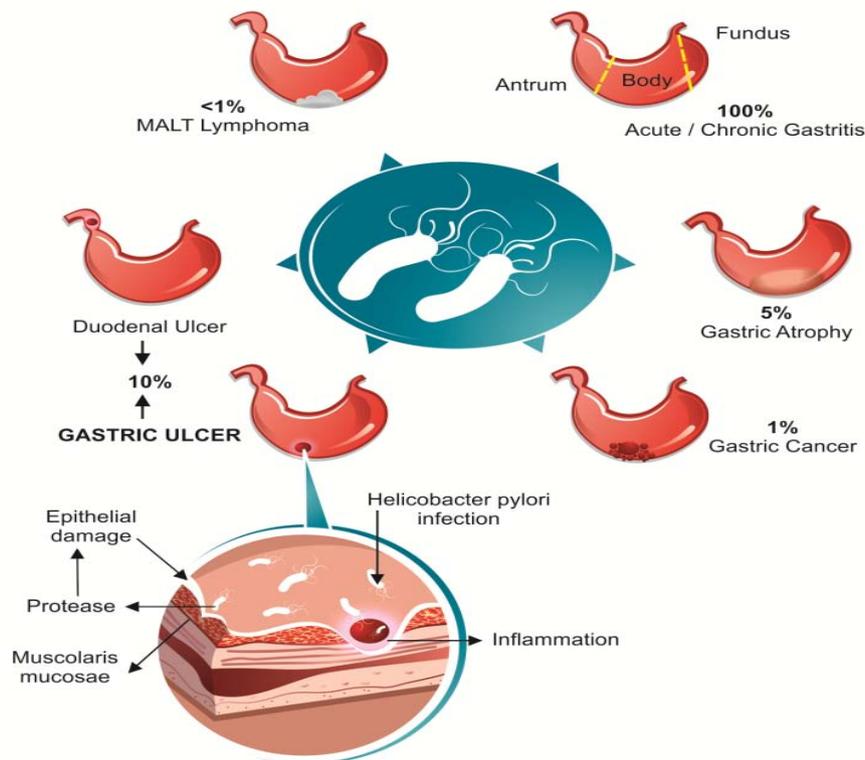


Figure 1 : A pictorial representation of the diseases involving *H. pylori*

Source: *The Mechanisms of Action and Resistance to Fluoroquinolone in Helicobacter pylori Infection*, Carolina Negrei and Daniel Boda, *INTECH*. **13**; 349-378

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Although the incidence varies by geographic location and socioeconomic conditions, *H. pylori* remains one of the most common bacterial infections in the world [2]. Therefore this review aims to find the most prevalent treatment options throughout world in order to eliminate *H. pylori*.

## II. ANTIMICROBIAL RESISTANCE

The main reason behind failure of treatment is antibiotic resistance. The prevalence of antimicrobial resistance has been found to have regional variance both within countries and outside countries. Studies done in India found that drug resistance in *H. pylori* was more for metronidazole, tinidazole and clarithromycin [36]. Clarithromycin resistance was also found to be prevalent in many western countries like USA, Canada, Northern, Southern and Eastern Europe [4]. The high prevalence of resistance in the developing countries compared to the industrialised countries is the high rate of antibiotic misuse. Metronidazole is more commonly used in developing countries for the treatment of parasitic infections whereas in developed countries it is more frequently used for dental and gynaecological infections (53). Patients who had had a failed case of *H. pylori* eradication have been found to be more prone to multi resistant *H.pylori* than untreated cases [65].

### a) Diagnosis

The diagnostic tests for *H.pylori* infection include endoscopic and non endoscopic methods. The techniques used may be direct (culture, microscopic demonstration of the organism) or indirect (using urease, stool antigen or an antibody response as a marker of disease). The choice of test depend on factors like the cost and the requirement of the test i.e. whether it is for establishing the diagnosis of infection or for the eradication of the disease [7]. Successful eradication should always be confirmed by urea breath test (UBT) or an endoscopy based test. If UBT is not available then Stool Antigen Test (SAT) should be the alternative [8].

### b) Treatment

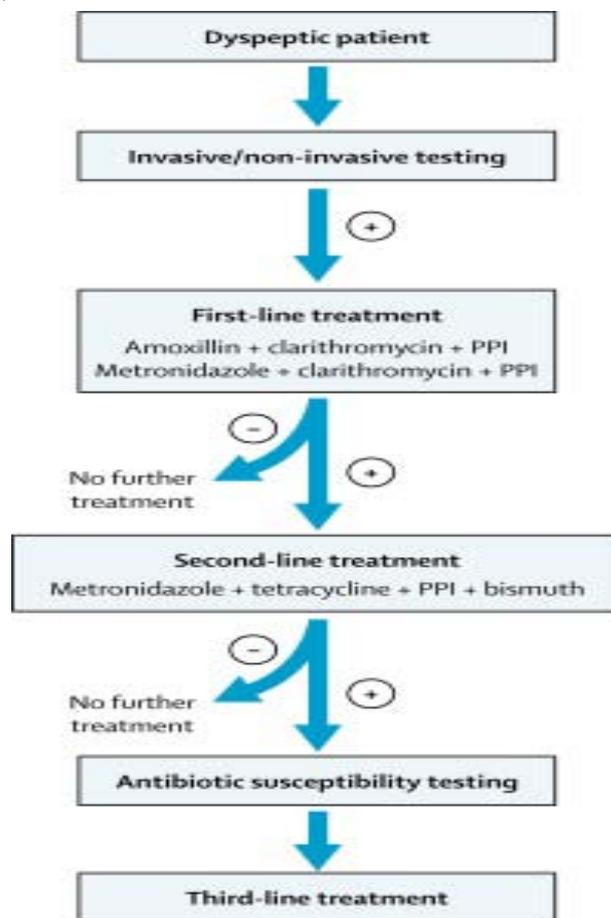


Figure 2 : A flowchart of the prevailing treatment regime

Source: <http://www.clinsci.org/content/110330>

### c) Sequential Therapy

Since there has been tremendous decline in the cure rate of *H. pylori* hence sequential therapy was introduced. The sequential therapy in which PPI plus amoxicillin are given for 5 days followed by PPI plus clarithromycin and tinidazole also for 5 days has been found to have eradication rates close to or greater than 90%. In a number of Italian studies this sequential therapy has proved to be superior than the standard triple therapy in eradicating both susceptible and resistant *H. pylori* strains [8]. The incidence of side-effects was similar with both regimes in these trials. This treatment regimen appeared to overcome clarithromycin resistance. [9]

### d) First Line Treatment

For over a decade the proton pump inhibitor (PPI) - based triple therapy has been used as the first line treatment of choice [10]. The currently approved regimen i.e. (a triple therapy consisting of a proton pump inhibitor, amoxicillin and clarithromycin) has been recommended by the European Helicobacter Study Group [11]. The currently approved regimen now been proven to be relatively ineffective because of the high

rate of clarithromycin resistance [12-16]. In many countries this therapy has been considered to be obsolete but since this is the only approved therapy by the government insurance the doctors are still in a dilemma. In the United States four drugs combinations therapy has been used (e.g., 14 day therapy with a proton pump inhibitor, clarithromycin, metronidazole, and amoxicillin or concomitant therapy which is effective except in the presence of clarithromycin-metronidazole dual resistance) or the combination of a bismuth, tetracycline, metronidazole and a proton pump inhibitor which is generally effective despite metronidazole resistance provided it is given a full dose and for 14 days [17, 18]. The combination of a high dose proton pump inhibitor and amoxicillin such as 20 mg of rabeprazole and 500 to 750 mg of amoxicillin every 6 hours for 14 days appears to be effective in Asia [19]. No single therapy can be recommended for any area as there are wide variations in the resistance patterns in different parts of the world.

Factors influencing outcome:

| Treatment:   | Strains:   | Patients:                                     |
|--|--|---|
| Increasing the dose of clarithromycin to 1-1.5 mg per day improves cure rates  | Resistance of <i>H.pylori</i> to antimicrobial agents. | Depending on geographical region of patients. |
| The optimal duration of treatment has been found that better cure rates have been found for longer treatment duration. | Strain type.   | Patient compliance.                           |

Since so many factors has to be considered, therefore it is very essential to have an organized program to identify the resistance pattern in order to define highly effective regimes.

*e) Quadruple*

Bismuth quadruple therapy entails: bismuth 525 mg four times daily, metronidazole 250 mg four times daily, tetracycline 500 mg four times daily and a standard dose PPI for a total of 7-14 days. On seeing there ported eradication rate of 87%, some authors advocate bismuth based quadruple therapy as first line therapy for *H pylori* [20-22]. In areas of high clarithromycin resistance (> 15 percent) or in patients with a documented penicillin allergy the clinicians may consider Bismuth based quadruple therapy as first line treatment. [23,24]. The side effect profile of standard triple therapy versus quadruple therapy is almost equivalent as the overall adverse event rate in the quadruple therapy treatment arm was 58.5% compared to 59.0% in the triple therapy arm [25,26]. Symptoms included: diarrhea, dyspepsia, nausea, abdominal pain, and taste perversion, changes in stool colour or firmness and headache.

*f) Second-Line Therapy*

*H. pylori* may develop resistance to the prescribed antibiotics used for the first-line therapy. The resistance may be acquired by acquisition and recombination of genes from other bacteria and chromosomic mutations [27, 28]. Clarithromycin and Metronidazole appear to be the two antibiotics noted for resistance and most of *H. pylori* isolates after two eradication failures are resistant to the two drugs [29]. Subsequently, quadruple therapy which consists of PPI, bismuth, metronidazole and tetracycline is a recommended alternative to first-line treatment, which may be advocated in areas of high antibiotic resistance. In any case if bismuth is not available, second-line therapy may be with PPI-based triple therapy. [10]

*g) Third-Line (Rescue/Salvage) Therapy*

On multiple (at least two) treatment failures with different regimes the third line therapy is applied. Ideally, it would be chosen based on the results of antimicrobial susceptibility testing. Since it was noted that most of *H. pylori* isolates after two eradication failures are resistant to metronidazole and clarithromycin therefore, has been recommended to exclude the two drugs from the third-linetherapy. As a result, the third-line therapy is now being applied in some countries. These third-line therapies are the new emerging therapies. [8]



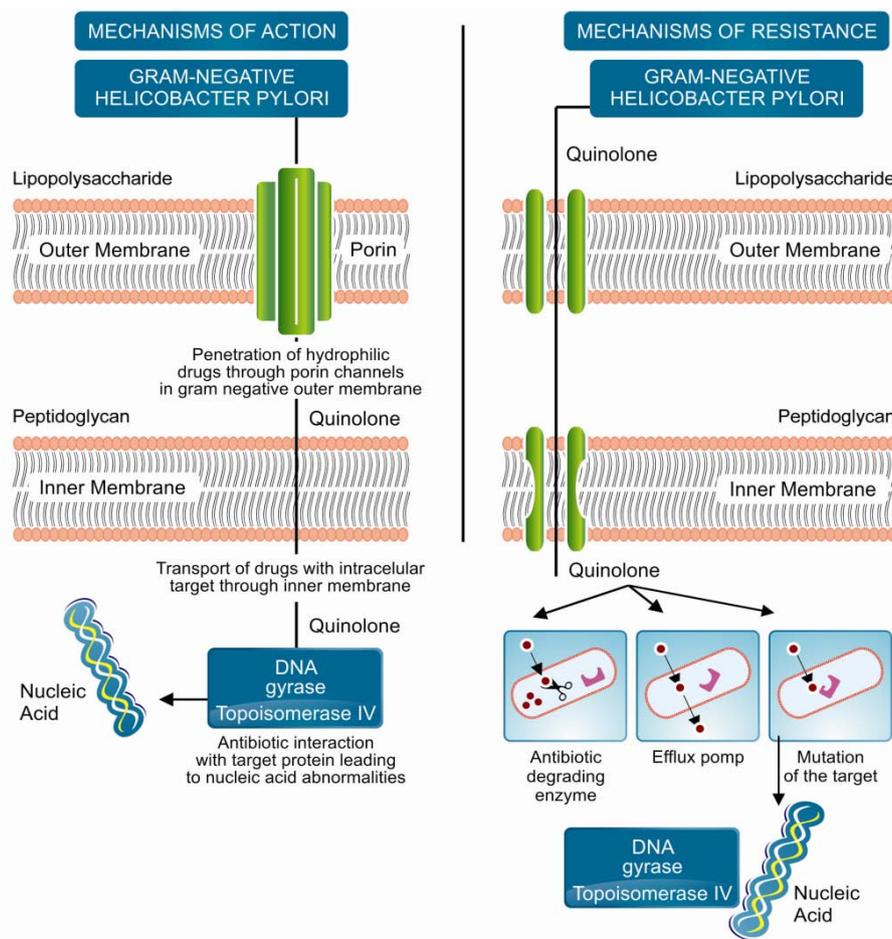


Figure 3 : Mechanism of action/ Mechanism of resistance

Source: *The Mechanisms of Action and Resistance to Fluoroquinolone in Helicobacter pylori Infection*, Carolina Negrei and Daniel Boda, *INTECH*. **13**; 349-378

*h) Concomitant Therapy*

Concomitant therapy entails: Standard dose PPI, Amoxicillin 1000mg twice daily, Clarithromycin 50mg twice daily and Metronidazole 500 mg twice daily for 10-14 days. In terms of eradication it is similar to sequential therapy with an eradication rate of 94% and maybe a simple regimen when compared to sequential therapy as all antibiotics are given at once. A randomized trial comparing sequential and concomitant therapy, demonstrated comparable eradication rates (92.3% versus 93%, respectively) and similar adverse event rates (30.7% versus 26.9%). A regimen consisting of: esomeprazole and amoxicillin for seven days then esomeprazole, amoxicillin, clarithromycin, and metronidazole for 7 seven days (sequential-concomitant hybrid therapy) generated a 99.1% eradication rate in 117 patients [2].

*i) Emerging Therapies*

*i. Fluoroquinolone based therapies*

Levofloxacin-based triple therapies are now becoming the second-line treatment of choice in some European countries. It has proven very effective in the

treatment of *H. pylori* infection in a study carried out in Italy. In a comparative study in Italy, the eradication rate achieved with levofloxacin-based triple therapy as a first-line treatment was significantly higher than that with standard therapies. Levofloxacin has been advocated for use in second- and third-line "rescue" regimens. Levofloxacin may thus represent a reasonable treatment regimen in the setting of Clarithromycin resistance [8]

*ii. Lactoferrin*

Lactoferrin is a natural antibiotic which is found in bovine milk. It has been found to be bacteriostatic to *H. pylori* both *in vivo* and *in vitro*. It is a milk protein that binds iron and its addition to the regular treatment regimen for *H. pylori* may improve eradication rates. Studies have been carried out to determine its use in combination with PPI and other antibiotics with varying efficacies. This modality of treatment has not been universally accepted [8].

*iii. Levofloxacin and rifaximin-based quadruple therapy*

Levofloxacin and rifaximin-based quadruple regimen as first line treatment for *H. pylori* infection has

been studied by Choi *et al.* but has limited efficacy in a Korean cohort [30]. Further multi-centred studies may be required in other countries.

### III. CONCLUSION

Despite the introduction of various treatment regimens, *H. pylori* infection is still a major problem of concern. Though the clinicians have many different treatment regimens within them but standard PPI based triple therapy and bismuth based quadruple therapy remain in first line as the eradication rates remain relatively high (70-80%). The increased resistance of drugs and non compliance, due to complexity of regime and associated side effects has led to the investigation of many other therapeutic options which is necessary for the complete eradication of *H. pylori*. Hence from this review we can conclude that further many more trials are necessary to get a complete eradication of *H. pylori*.

### IV. FUTURE TREATMENT MODULE

The next generation of *H. pylori* therapeutic regimens should be simpler, novel and specific. There are some novel approaches available to achieve this goal, such as-

- 1) Development of therapeutic vaccine
- 2) Genome based drug discovery
- 3) Pathogen –host tissue adhesion inhibitor
- 4) Novel site specific drug delivery at specific site of *H. pylori* infection.

Although combination therapies have been found to have high rates of eradication, therapies that would be preferred are the ones which use a low dose of single drug with a short duration treatment and without any adverse effect.

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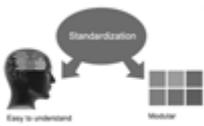
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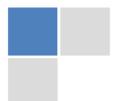
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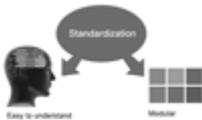


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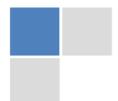
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- Simplify - details how procedures were completed not how they were exclusively performed on a particular day.
- If well known procedures were used, account the procedure by name, possibly with reference, and that's all.

#### **Approach:**

- It is embarrassed or not possible to use vigorous voice when documenting methods with no using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result when script up the methods most authors use third person passive voice.
- Use standard style in this and in every other part of the paper - avoid familiar lists, and use full sentences.

#### **What to keep away from**

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings - save it for the argument.
- Leave out information that is immaterial to a third party.

#### **Results:**

The principle of a results segment is to present and demonstrate your conclusion. Create this part a entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Carry on to be to the point, by means of statistics and tables, if suitable, to present consequences most efficiently. You must obviously differentiate material that would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matter should not be submitted at all except requested by the instructor.



## Content

- Sum up your conclusion in text and demonstrate them, if suitable, with figures and tables.
- In manuscript, explain each of your consequences, point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation an exacting study.
- Explain results of control experiments and comprise remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or in manuscript form.

### What to stay away from

- Do not discuss or infer your outcome, report surroundings information, or try to explain anything.
- Not at all, take in raw data or intermediate calculations in a research manuscript.
- Do not present the similar data more than once.
- Manuscript should complement any figures or tables, not duplicate the identical information.
- Never confuse figures with tables - there is a difference.

### Approach

- As forever, use past tense when you submit to your results, and put the whole thing in a reasonable order.
- Put figures and tables, appropriately numbered, in order at the end of the report
- If you desire, you may place your figures and tables properly within the text of your results part.

### Figures and tables

- If you put figures and tables at the end of the details, make certain that they are visibly distinguished from any attach appendix materials, such as raw facts
- Despite of position, each figure must be numbered one after the other and complete with subtitle
- In spite of position, each table must be titled, numbered one after the other and complete with heading
- All figure and table must be adequately complete that it could situate on its own, divide from text

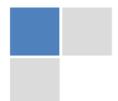
### Discussion:

The Discussion is expected the trickiest segment to write and describe. A lot of papers submitted for journal are discarded based on problems with the Discussion. There is no head of state for how long a argument should be. Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implication of the study. The purpose here is to offer an understanding of your results and hold up for all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of result should be visibly described. Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved with prospect, and let it drop at that.

- Make a decision if each premise is supported, discarded, or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."
- Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work
- You may propose future guidelines, such as how the experiment might be personalized to accomplish a new idea.
- Give details all of your remarks as much as possible, focus on mechanisms.
- Make a decision if the tentative design sufficiently addressed the theory, and whether or not it was correctly restricted.
- Try to present substitute explanations if sensible alternatives be present.
- One research will not counter an overall question, so maintain the large picture in mind, where do you go next? The best studies unlock new avenues of study. What questions remain?
- Recommendations for detailed papers will offer supplementary suggestions.

### Approach:

- When you refer to information, differentiate data generated by your own studies from available information
- Submit to work done by specific persons (including you) in past tense.
- Submit to generally acknowledged facts and main beliefs in present tense.



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| <i>References</i>             | Complete and correct format, well organized  | Beside the point, Incomplete  | Wrong format and structuring                                       |



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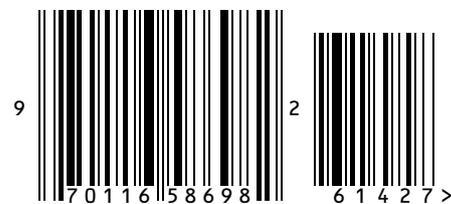
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