Efficacy and safety of 7 days versus 10 days triple therapy based on levofloxacin-dexlansoprazole for eradication of Helicobacter pylori: A pilot randomized trial

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Abstract:
BACKGROUND: Levofloxacin-based triple therapies are considered the standard regimen for eradication of Helicobacter pylori (H. pylori) due to decreased sensitivity to clarithromycin and the optimal duration of therapy is still controversial. Besides, there is no complete evidence about dexlansoprazole efficacy in the eradication of H. pylori.

AIM: Our study aimed to determine the effectiveness of triple therapy based on levofloxacin-dexlansoprazole as a standard treatment for H. pylori infection and estimate the effect of H. pylori on lipid profile and hemoglobin (Hb).

MATERIALS AND METHODS: A pilot prospective randomized trial of a triple therapy based on levofloxacin-dexlansoprazole for H. pylori eradication was conducted at Damanhour Medical National Institute, Egypt; 66 participants with H. pylori infection received levofloxacin (500 mg/day) plus amoxicillin (1 g/12 h) plus dexlansoprazole (60 mg/day). All medications administrated orally for either 7 days or 10 days. Four weeks after treatment, the eradication was assessed by the stool antigen test.

RESULTS: The rate of eradication was 63.6% in levofloxacin, amoxicillin, and dexlansoprazole (LAD) 7‑day group, and 90.9% in LAD 10‑day group. In addition, laboratory test results showed a significant difference in Hb, low‑density lipoprotein, high‑density lipoprotein, triglyceride, and total cholesterol levels before and after treatment (P < 0.05).

CONCLUSION: LAD 10 days is the least duration that provides maximum efficacy for H. pylori in Egyptian participants. In addition, successful treatment of H. pylori infection may reduce the risk of anemia and dyslipidemia. Furthermore, all members of the patient’s family should be screened for H. pylori to prevent recurrent infection.

Keywords: Antibiotics, iron deficiency anemia, proton pump inhibitor, stool antigen test

Introduction

A Gram-negative bacteria, Helicobacter pylori (H. pylori) that live in an acidic environment of the gastric mucosa. Its prevalence rate is very high in developing countries. Infection with H. pylori bacteria can lead to peptic ulcers, stomach cancer, and increased the bleeding risk of the stomach, especially in patients on nonsteroidal anti-inflammatory drugs.[1]

Infection with H. pylori bacteria is asymptomatic but may result in dyspepsia,
heartburn and epigastric pain. In addition, *H. pylori* infection causes extragastric diseases like deficiency of the Vitamin B₁₂, iron-deficiency anemia (IDA) and dyslipidemia.[¹]

One of the most common public health problems is IDA that affects human health as well as economic and social development. The relation between *H. pylori* infection and IDA is still controversial.[²] *H. pylori* infection may cause IDA by several mechanisms, including decrease ascorbic acid and hyperchlorhydria secondary to chronic gastritis and the increasing depletion of the iron stores in patients with *H. pylori* infection.[³,⁴]

Another problem related to *H. pylori* infection is that *H. pylori* bacteria affect the lipid metabolism through lipoprotein lipase inhibition by cytokines, leading to efflux of lipids from tissue and decline high-density lipoprotein (HDL) levels and elevated serum triglyceride (TG).[⁵]

*H. pylori* infection can be transmitted through contaminated water, food, or interpersonally through saliva or fecal-oral route.[⁶]

A systemic review conducted in the Eastern Mediterranean Region Office noted that the prevalence of *H. pylori* infection between the healthy subclinical population was the highest in the Egyptian population.[⁷]

The *H. pylori* resistance to clarithromycin has been rising from 17.2% to 19.7% in the period between 2010 and 2017 and was found to be 30.8% particularly in Africa.[⁸] Furthermore, *H. pylori* bacteria have the lowest resistance to levofloxacin which is 14%, particularly in Egypt was found to be 2%.[⁹]

The ideal therapy of *H. pylori* infection should be of short duration, safe, simple, well-tolerated, cheap and it should reach a high cure rate of ≥90%,[¹⁰]

Recent clinical guidelines of the American College of Gastroenterology suggested the use of levofloxacin-based triple (LBT) therapy as the first-line therapy in the region with a resistance to clarithromycin is >15% with lack of evidence for the optimal duration for the treatment of *H. pylori* bacteria.[¹²]

The optimal duration of treatment for triple therapy based on levofloxacin is still controversial as several studies proved the triple therapy for 14 days is not superior to triple therapy for 7 days.[¹³]

Levofloxacin has excellent bioavailability, easy to be dosed and its broad-spectrum antimicrobial activity, making levofloxacin an attractive antibiotic for the eradication of *H. pylori* bacteria, furthermore, LBT therapy has an eradication rate of *H. pylori* from 72% to 96%.[¹¹]

All regimens for *H. pylori* eradication should include the proton pump inhibitors (PPIs), that increases the intragastric pH resulting in growth inhibition of *H. pylori* with increasing the effectiveness of antibiotics.[¹⁴]

Dexlansoprazole is a new generation of PPIs with limited data about its efficacy in *H. pylori* eradication.[¹⁵] A lansoprazole R-enantiomer, the oral bioavailability of dexlansoprazole is >80%, has three to five times higher area under the concentration-time curve of the plasma, maximum concentration and a longer half-life of elimination than the S-enantiomer.[¹⁶,¹⁷]

Dexlansoprazole 60 mg extended-release (ER) has a greater regulation of pH of the stomach than esomeprazole 40 mg, mean gastric pH values for esomeprazole and dexlansoprazole ER were 3.7 and 4.3, respectively that is suggested that nighttime pH control was effectively increased by dexlansoprazole.[¹⁸]

Dexlansoprazole ER is a PPI with a dual delayed-release dosage form that has two different drug releases to produce the duration of effective drug concentration in the plasma, so inhibiting recently activated proton pumps which stimulate after initial PPI inactivation of H⁺, K⁺-ATPase.[¹⁷]

The dual delayed-release PPI has two forms of enteric-coated granules that dissolve at different pH values to release drug initially in the proximal small intestine, at a pH 5.5, then after several hours, at a pH 6.0, in the distal small intestine another release of the drug.[¹⁵]

Another advantage of dexlansoprazole is that it is a weak inhibitor of CYP2C19, shows no drug interaction with clopidogrel, and cost-effective.[¹⁹]

*H. pylori* eradication failure can result in a low gastric pH through stimulation of gastrin secretion that may be induced by food such as spicy, salty, and fast food and caffeinated beverages. The minimal inhibitory concentrations (MIC) and low bactericidal concentrations of most antibiotics used for eradication of *H. pylori* are pH-dependent of the stomach, at pH values <7.4 the MIC increases.[²⁰,²¹] Thus, we take into consideration the effect of foods that trigger acid reflux on the efficacy of dexlansoprazole and subsequently the efficacy of levofloxacin and amoxicillin in *H. pylori* eradication.

Antibiotic resistance and poor compliance are major causes of eradication failure. However, the relation between eradication failure with other factors such as age, gender, low gastric pH, the diet that increase gastric acidities such as caffeinated beverages as coffee/tea and...
spicy food, and smoking are still controversial and need further research.\[^{[1]}\]

The increase of \(H.\) pylori resistance to clarithromycin antibiotic which is commonly used is a challenge imposing itself to treat \(H.\) pylori infection and we need extensive research to find alternative regimens for eradication of \(H.\) pylori.

Our study aimed to determine the optimal duration, safety and efficacy of triple therapy based on levofloxacin-dexlansoprazole as an alternative protocol of clarithromycin-based triple therapy for \(H.\) pylori eradication in Egyptian participants and to estimate the effect of the treatment of \(H.\) pylori infection on hemoglobin (Hb) and lipid profile.

### Materials and Methods

#### Subjects

This study was conducted at Damanhour Medical National Institute of Egypt during the period starting from November 2017 to April 2018. The study was carried out on 66 patients, aged between 17 and 65 years with \(H.\) pylori stool antigen-positive test. Patients were recruited from the gastroenterology clinic.

#### Exclusion criteria

Patients who had received triple therapy, antilipemic drugs, or iron-containing supplements, 6 months ago, children <16 years, patients with colon cancer, stomach cancer, chronic peptic ulcer, bone fracture, renal failure, nursing mothers, pregnancy or advanced liver cirrhosis.

#### Study design

This was a prospective, open-labeled, randomized, and pilot study performed to evaluate the safety and efficacy of 7-and 10-day levofloxacin-dexlansoprazole-based triple therapy as a standard treatment of \(H.\) pylori bacteria in Egyptian patients.

A total of 66 subjects consisting of 20 families were referred to a gastroenterology clinic of the Damanhour Medical National Institute and had \(H.\) pylori bacteria confirmed by \(H.\) pylori stool Ag test quantitative assay.\[^{[22]}\]

The participants were divided randomly into two groups using a table of random numbers; the group (1) received dexlansoprazole ER 60 mg every 24 h at bedtime, levofloxacin 500 mg every 24 h 1 h before breakfast, and amoxicillin 1000 mg every 12 h after meal, all medications administrated orally for 7 days, while the group (2) received the same regimen for 10 days.

Stool samples were taken from all participants before starting of the treatment and 4 weeks after the end of the treatment to analyze \(H.\) pylori bacteria by indirect enzyme-linked immunosorbent assay; \(H.\) pylori Ag positive over 40 ng/mL in the stool.

Blood samples were taken from all participants before and 4 weeks after the end of treatment to measure Hb level, total cholesterol (TC), HDL, low-density lipoprotein (LDL) and TG level. The samples were collected in a vacutainer blood collection tube, leaving the blood to sit for 30 min at room temperature to clot before spinning and then separating the centrifuged for 15 min at 2000 rpm, then the serum was stored at –20°C until time of analysis of TC, HDL, and TG. LDL levels were calculated by Friedwald equation.

Hb level was measured from whole blood by an automated cell counter from a tube of ethylenediaminetetraacetic acid-anticoagulated blood mixed well and filled to a predetermined level.

#### Follow-up protocol

The patients were requested to bring their families to ensure that all members were \(H.\) pylori-negative, in addition, patients were instructed to return all the unused and empty medication blister packs, and we assessed the compliance with therapy by pill count and history.

All patients in both groups were assessed for eradication of \(H.\) pylori by stool antigen 4 weeks after the completion of treatment.

We assessed the regimens’ safety profiles in terms of side effects using a questionnaire administered for the presence of nausea/vomiting, abdominal pain, diarrhea, headache, dizziness, palpitation, and fatigue after 3, 7, and 10 days of treatment.

Side effects, drug compliance, and food habits were assessed during phone calls and visits. We determined substantial drug compliance as the administration of > 90% of the prescribed drug and excluded patients with <90% compliance.

The study was approved by our local ethics committees (the Research Ethics Committee of Faculty of Pharmacy, Damanhour University) (Ref no: 1017PP1) and adhered to the good clinical practice guideline and the principles of the Declaration of Helsinki. All patients agreed to participate in this clinical trial and to sign informed consent.

#### Statistical analyses

SPSS for Windows ver. 23.0 software Armonk, NY: IBM Corp were used for analyzing the data. Categorical
parameters were identified as number (percentage) and continuous parameters as mean ± standard deviation. The rate of eradication was calculated with a 95% confidence interval (CI) as a percentage of all involved patients.

Categorical variables were analyzed using the Chi-square and continuous parameters were compared between groups using Student’s t-test. The risk factors affecting the rate of eradication were identified by multiple logistic regression analysis, which were expressed as the risk ratio (RR), odds ratio (OR), and 95% CIs were obtained for all comparisons. The $P < 0.05$ was considered statistically significant.

**Results**

A difference between baseline characteristics of levofloxacin, amoxicillin, and dexlansoprazole (LAD) 7 and LAD 10 groups are illustrated in Table 1. There was no statistically significant difference among two groups in demographic characteristics ($P > 0.05$) except a significant difference in the level of personal education ($P < 0.05$), therefore excluded from other tests to obtain homogeneity in the basic demographic data, that allowed the two groups to be comparable.

The age of participants ranged from 16 to 64 years. Only 11 patients (16.7%) were hypertensive, seven patients (10.6%) were HCV antibodies positive (+ve) with negative polymerase chain reaction (PCR), 12 patients (18%) were diabetic. The difference in the distribution of participants between the LAD 7 and LAD 10 groups was not statistically significant for hypertensive, HCV antibodies (+ve) with negative PCR or diabetic patients with $P = 0.74, 0.23$ and 1.0, respectively.

Forty participants (60.6%) were members of patients’ families and showed no significant difference between LAD 7 and LAD 10 groups with a $P = 0.62$.

Only six patients (9.1%) were from urban residency, without significant difference between LAD 7 and LAD 10 groups with a $P = 0.4$.

Only four participants (6%) had symptoms like heartburn, five participants (7.6%) had dyspepsia, 17 participants (25.8%) were asymptomatic and 40 participants (60.6%) were had regurgitation. The difference in the distribution of participants between the LAD 7 and LAD 10 groups showed no significant difference with a $P = 0.37$.

The laboratory changes in both LAD 7 and LAD 10 groups before and after eradication are illustrated in Table 2. Hb and HDL levels were significantly elevated after treatment of *H. pylori* bacteria in both groups ($P < 0.01$) while LDL cholesterol and TG levels were significantly decreased after treatment of *H. pylori* bacteria in both groups ($P < 0.01$).

| Table 1: Baseline characteristics of enrolled patients |
|------------------------------------------------------|
| **Characteristics** | **LAD 7** ($n=33$, $n$ (%) ) | **LAD 10** ($n=33$, $n$ (%) ) | **P** |
| Age (years) | | | |
| 16-40 | 18 (54.5) | 18 (54.5) | 1.00 |
| 41-64 | 15 (45.5) | 15 (45.5) | |
| Gender | | | |
| Male | 12 (36.4) | 19 (57.6) | 0.09 |
| Female | 21 (63.6) | 14 (42.2) | |
| HTN | | | |
| Yes | 5 (15.2) | 6 (18.2) | 0.74 |
| No | 28 (84.8) | 27 (81.8) | |
| HCV | | | |
| Positive | 2 (6.1) | 5 (15.2) | 0.23 |
| Negative | 31 (93.9) | 28 (84.8) | |
| DM | | | |
| Yes | 6 (18.2) | 6 (18.2) | 1.00 |
| No | 27 (81.8) | 27 (81.8) | |
| Family members | | | |
| Yes | 19 (57.6) | 21 (63.6) | 0.62 |
| No | 14 (42.4) | 12 (36.4) | |
| Symptoms | | | |
| Asymptomatic | 6 (18.2) | 11 (33.3) | 0.37 |
| Dyspepsia | 4 (12.1) | 1 (3) | |
| Heartburn | 2 (6.1) | 2 (6.1) | |
| Regurgitation | 21 (63.6) | 19 (57.6) | |
| Level of education | | | |
| Low | 19 (57.6) | 9 (27.3) | 0.01* |
| Intermediate | 12 (36.4) | 15 (45.5) | |
| High | 2 (6.1) | 9 (27.3) | |
| Area | | | |
| Rural | 29 (87.9) | 31 (93.9) | 0.40 |
| Urban | 4 (12.1) | 2 (6.1) | |
| Smoking | | | |
| Smoker | 8 (24.2) | 8 (24.2) | 1.00 |
| Nonsmoker | 25 (75.8) | 25 (75.8) | |
| Caffeine intake (>1 cup/day) | | | |
| Yes | 20 (60.6) | 17 (51.5) | 0.46 |
| No | 13 (39.4) | 16 (48.5) | |
| Salty food (>2 g salt/day) | | | |
| Yes | 18 (54.5) | 14 (42.4) | 0.62 |
| No | 15 (45.5) | 19 (57.6) | |
| Fast food | | | |
| Yes | 14 (42.4) | 8 (24.2) | 0.12 |
| No | 19 (57.6) | 25 (75.8) | |
| Spicy food | | | |
| Yes | 13 (39.4) | 8 (24.2) | 0.19 |
| No | 20 (60.6) | 25 (75.8) | |
| Drinking water | | | |
| Filtered | 16 (48.5) | 19 (57.6) | 0.46 |
| Tap | 17 (51.5) | 14 (42.4) | |

All data are mean±SD. *P<0.05. LAD=Levofloxacin, amoxicillin, dexlansoprazole, HTN=Hypertension, HCV=Hepatitis C virus, DM=Diabetes mellitus, SD=Standard deviation
Eradication rate
The rate of eradication was 63.6% (95% CI: 46%–81%) in LAD 7 group and 90.9% (95% CI: 81%–100%) in LAD 10 group. There was a statistically significant difference among the LAD 7 group and the LAD 10 group ($P < 0.05$) [Figure 1].

History of diabetes mellitus (DM), drinking more than one cup of coffee/tea regularly, eating salty food (>2 g of salt/day), and fast and spicy foods were demographic factors that decreased the rate of eradication in the LAD 7 group. The RR and OR were (RR: 0.11–1.63, 0.47–6.86, 0.34–4.29, 0.23–4.86, and 0.17–5.14, respectively), (OR: 14.29 [1.41–144.37], 14.67 [1.59–135.32], 12.50 [12.09–74.81], 21.25 [3.28–137.67] and 30.00 [4.73–210.66] respectively, $P < 0.05$), but did not affect the rate of eradication in the 10-day treatment group [Tables 3 and 4].

Only one participant (1.5%) from 66 participants suffered from nausea as a side effect of LAD regimen in the 10-day group.

Discussion
The treatment of $H. pylori$ infection is important due to its effects on other disorders as well as its high prevalence. Eradication rate of $H. pylori$ using clarithromycin-containing regimen was reported to be <70% in many countries all over the world.\[10\]

The increasing resistance rate to clarithromycin >15%, leading to a decrease in the efficacy of all bismuth quadruple therapies. If bismuth is unavailable in the region with the high clarithromycin resistance rate, levofloxacin, and high-dose dual PPI with amoxicillin treatment regimen can be considered.\[13\] Levofloxacin has been recommended as an alternative drug for traditional triple therapy.\[23\]

The most striking result to emerge from this study is that a 10-day LAD-based triple therapy provided an eradication rate of 90.9%. 10-day LAD-based triple therapy was well tolerated by all patients with high safety; whereas the eradication rate of LAD 7 was 63.9% [Figure 1]; this suggests the use of LAD 10 as a standard treatment for $H. pylori$ bacteria.

Dexlansoprazole has several advantages over other PPIs such as a dual release formula with a longer duration of action and it has greater acid control, so it increases the bioavailability of antibiotics. It is not affected by food, so it can be taken once daily disregarding food intake time.\[19\]

This finding is supported by a meta-analysis study that suggested the effectiveness of levofloxacin in triple therapy using a new generation of PPIs were associated with greater effectiveness.\[24\] This suggests that dexlansoprazole may provide an additional property to LBT therapy and it may have better pharmacodynamic and pharmacokinetic profiles than omeprazole and lansoprazole. The unique properties of dexlansoprazole compared with other PPIs need further research to confirm the superiority of dexlansoprazole over other PPIs in LBT therapy.

Several studies reported that the predominance of infection with $H. pylori$ was significantly higher among sexual partners participants infected with $H. pylori$ than in controls.\[25,26\] Therefore, in our study, we screened for

### Table 2: Laboratory data comparison before and after treatment

| Laboratory test | LAD 7 | LAD 10 |
|-----------------|-------|--------|
| **Before treatment, mean±SD** | **After treatment, mean±SD** | **P** |
| **Before treatment, mean±SD** | **After treatment, mean±SD** | **P** |
| Hb (g/dL)       | 11.5±1.7 | 13.2±1.4 | <0.01* | 11.8±1.5 | 12.9±1.6 | <0.01* |
| HDL (mg/dL)     | 46.8±8.77 | 50.5±7.94 | <0.01* | 49.2±16.01 | 54.5±15.02 | 0.04* |
| LDL (mg/dL)     | 147.3±39.4 | 130.9±28.4 | <0.01* | 141.6±34.35 | 123.4±25.30 | <0.01* |
| TG (mg/dL)      | 161.1±93.1 | 133.3±55.7 | 0.01* | 136±50 | 122±40 | 0.01* |
| TC (mg/dL)      | 186.5±31.3 | 136.9±43 | 0.01* | 200.7±36.6 | 184.1±28.3 | <0.01* |

Low Hb was defined as value <13 g/dL for male and <12 g/dL for female, High LDL was defined as value >140 mg/dL, Low HDL was defined as value <40 mg/dL, High TG was defined as value >160 mg/dL, High TC was defined as value >200 mg/dL. *$P$<0.05. Hb=Hemoglobin, HDL=High-density lipoprotein, LDL=Low-density lipoprotein, TG=Triglyceride, TC=Total cholesterol, SD=Standard deviation, LAD=Levofloxacin, amoxicillin, dexlansoprazole.

![Figure 1: Comparison of Helicobacter pylori Eradication Rates of 7 days and 10 days Levofloxacin-dexlansoprazole-based Triple Therapy](image-url)
**Table 3: Subgroup evaluation of eradication rate**

| Group (n) | LAD 7 Eradication rate, n (%) | LAD 7 Eradication rate, n (%) | LAD 7 RR | 95% CI | P |
|-----------|-------------------------------|-------------------------------|---------|-------|---|
| Total     | 21 (63.6)                     | 30 (90.9)                     |         |       |   |
| Age (years) |                               |                               |         |       |   |
| 16-40     | 14 (77.8)                     | 17 (94.4)                     | 2.00    | 0.85-4.71 | 0.08 |
| 41-64     | 7 (46.7)                      | 13 (86.7)                     | 0.50    | 0.24-1.03 | 0.65 |
| Gender    |                               |                               |         |       |   |
| Male      | 8 (66.7)                      | 18 (94.7)                     | 1.80    | 0.43-3.01 | 1.00 |
| Female    | 13 (61.9)                     | 12 (85.7)                     | 0.93    | 0.55-1.57 | 0.60 |
| HTN       |                               |                               |         |       |   |
| Yes       | 2 (40)                        | 5 (83.3)                      | 0.38    | 0.07-1.97 | 0.33 |
| No        | 19 (67.9)                     | 25 (92.6)                     | 1.21    | 0.55-1.72 | 0.65 |
| HCV       |                               |                               |         |       |   |
| Negative  | 20 (64.5)                     | 26 (92.9)                     | 1.04    | 0.85-1.26 | 1.00 |
| Positive  | 1 (50)                        | 4 (80)                        | 0.57    | 0.04-8.33 | 0.40 |
| DM        |                               |                               |         |       |   |
| Yes       | 1 (16.7)                      | 5 (83.3)                      | 0.11    | 0.02-0.87 | 0.02 |
| No        | 20 (74.1)                     | 25 (92.6)                     | 1.63    | 1.00-2.66 | 0.56 |
| Family member |                             |                               |         |       |   |
| Yes       | 15 (78.9)                     | 20 (95.2)                     | 2.14    | 0.92-4.99 | 0.07 |
| No        | 6 (42.9)                      | 10 (83.3)                     | 0.43    | 0.20-0.94 | 0.50 |
| Area      |                               |                               |         |       |   |
| Rural     | 18 (62.1)                     | 29 (93.5)                     | 0.94    | 0.73-1.19 | 1.00 |
| Urban     | 3 (75)                        | 1 (50)                        | 1.71    | 0.20-14.70| 0.10 |
| Smoking   |                               |                               |         |       |   |
| Smoker    | 5 (62.5)                      | 7 (87.5)                      | 0.95    | 0.28-3.30 | 1.00 |
| Nonsmoker | 16 (76.2)                     | 23 (92)                       | 1.02    | 0.68-1.52 | 1.15 |
| Caffeine intake (>1 cup/day) |                     |                               |         |       |   |
| Yes       | 9 (45)                        | 15 (88.2)                     | 0.47    | 0.28-0.79 | 0.01 |
| No        | 12 (92.3)                     | 15 (93.8)                     | 6.86    | 1.01-46.43| 1.50 |
| Salty food (>2 g salt/day) |                         |                               |         |       |   |
| Yes       | 6 (37.5)                      | 12 (85.7)                     | 0.34    | 0.17-0.71 | 0.00 |
| No        | 15 (88.2)                     | 18 (94.7)                     | 4.29    | 1.18-15.62| 1.80 |
| Fast food |                               |                               |         |       |   |
| Yes       | 4 (28.6)                      | 7 (87.5)                      | 0.23    | 0.09-0.57 | 0.00 |
| No        | 17 (89.5)                     | 23 (92)                       | 4.86    | 1.35-17.50| 1.15 |
| Spicy food |                             |                               |         |       |   |
| Yes       | 3 (23.1)                      | 6 (75)                        | 0.17    | 0.06-0.50 | 0.00 |
| No        | 18 (90)                       | 24 (96)                       | 5.14    | 1.43-18.44| 2.40 |
| Water     |                               |                               |         |       |   |
| Filtered  | 10 (62.5)                     | 18 (94.7)                     | 0.95    | 0.46-1.96 | 1.00 |
| Tap       | 11 (64.7)                     | 12 (85.7)                     | 1.05    | 0.52-2.10 | 0.60 |

*P<0.05. RR = Risk ratio, HTN = Hypertension, HCV = Hepatitis C virus, DM = Diabetes mellitus, LAD = Levofloxacin, amoxicillin, dexlansoprazole, CI = Confidence interval

**H. pylori** infection in all members of the patient’s family and infected individuals treated for the purpose of decreasing the risk of recurrent infection and decreasing rate of eradication failure.

Our results showed that Hb levels significantly elevated after **H. pylori** eradication in 7-day and 10-day regimens [Table 2]. Several studies confirmed the relation between IDA and the infection with **H. pylori** bacteria, therefore, the addition of therapy for eradication of **H. pylori** to iron therapy might be valuable in raising the levels of Hb and ferritin.[3,4]

In our study, there was a significant relationship between the treatment of **H. pylori** infection and reduction in LDL, TG, and TC with the elevation of HDL in both 7-and 10-day groups (P < 0.05).

Our results are consistent with the results of a large cohort study that carried on 13,383 patients infected with **H. pylori** which stated the successful eradication of **H. pylori** decreased the risk of dyslipidemia; this may suggest that LAD regimen effectively and safely eradicate **H. pylori** infection.[27] The relation between eradication failure of **H. pylori** and foods, caffeinated...
Table 4: Helicobacter pylori eradication-related factors of Levofloxacin, amoxicillin, dexlanzoprzole 7 and levofloxacin, amoxicillin, dexlanzoprzole 10 regimens

| Group | OR (95% CI) | P     | OR (95% CI) | P     |
|-------|-------------|-------|-------------|-------|
| LAD 7 |             |       | LAD 10      |       |
| Age (years) |         |       |             |       |
| 16-40 | 4.0 (0.89-18.01) | 0.07 | 2.6 (0.21-32.08) | 0.45 |
| 41-64 | -           |       | -           |       |
| Gender |             |       |             |       |
| Male  | 1.2 (0.28-5.55) | 0.79 | 3.0 (0.24-36.88) | 0.39 |
| Female | -          |       | -          |       |
| Smoking |            |       |             |       |
| Smoker | 1.0 (0.21-5.54) | 0.94 | 1.6 (0.13-20.94) | 0.7  |
| Nonsmoker | -      |       | -          |       |
| HTN |               |       |             |       |
| Yes  | 3.1 (0.45-22.41) | 0.25 | 2.5 (0.19-33.17) | 0.49 |
| No   | -           |       | -           |       |
| HCV |               |       |             |       |
| Negative | 1.8 (0.10-32.00) | 0.64 | 3.2 (0.24-44.69) | 0.38 |
| Positive | -       |       | -          |       |
| Diabetes |            |       |             |       |
| Yes  | 14.2 (1.41-144.37) | 0.02* | 2.5 (0.19-33.17) | 0.49 |
| No   | -           |       | -           |       |
| Salty food (>2 g salt/day) |         |       |             |       |
| Yes  | 12.5 (12.09-74.81) | 0.01* | 3.0 (0.24-36.80) | 0.39 |
| No   | -           |       | -           |       |
| Caffeine intake (>1 cup/day) |         |       |             |       |
| Yes  | 14.6 (1.59-135.32) | 0.02* | 2.0 (0.16-24.48) | 0.07 |
| No   | -           |       | -           |       |
| Family member |         |       |             |       |
| Yes  | 0.2 (0.04-0.92) | 0.04* | 0.2 (0.20-3.10) | 0.3  |
| No   | -           |       | -           |       |
| Area |               |       |             |       |
| Rural residency | 0.5 (0.55-5.92) | 0.62 | 14.5 (0.64-328.46) | 0.09 |
| Urban residency | -       |       | -          |       |
| Fast food |            |       |             |       |
| Yes  | 21.2 (3.28-137.67) | 0.001* | 1.6 (0.13-20.94) | 0.70 |
| No   | -           |       | -           |       |
| Drinking water |         |       |             |       |
| Filtered | 0.9 (0.22-3.8) | 0.9  | 3.0 (0.24-36.88) | 0.39 |
| Tap  | -           |       | -           |       |
| Spicy food |         |       |             |       |
| Yes  | 30.0 (4.73-210.66) | 0.001* | 8.0 (0.62-103.67) | 0.11 |
| No   | -           |       | -           |       |

*P<0.05. OR=Odd ratio, HTN=Hypertension, HCV=Hepatitis C virus, DM=diabetes mellitus, CI=Confidence interval, LAD=Levofloxacin, amoxicillin, dexlanzoprzole beverages as coffee/tea and smoking that lowering the pH of the stomach, is mentioning because the low pH of the stomach promotes the growth of H. pylori pathogen and decreasing efficacy of antibiotics as well.\[21\]

Smoking did not relate to eradication failure in 7- and 10-day groups. This may be a result of patient counseling to stop smoking 2 h before the administration of medication and 4 h after administration of medication.

Drinking coffee/tea >1 cup/day, eating salty food (>2 g of salt/day), fast food and spicy food were risk factors for eradication failure in the LAD 7 group while they were not in the LAD 10 group. Therefore, the 7-day regimen may be effective as a 10-day regimen, if patients are counseled to avoid eating fast, spicy and salty foods, drinking coffee/tea and smoking, that decreased pH of the stomach subsequently, decrease antibiotics and PPIs efficacy; these suggestions need further research to be confirmed.

This is a novel study because it is not only the first study that screened for H. pylori infection in all members of the patient’s family to avoid reinfection but also it takes into
consideration the effect of food that decreases the pH of the stomach on the efficacy of antibiotics and PPIs.

Our study has several limitations including the small sample size. In addition, a comparison of dexlansoprazole with other PPIs is recommended to confirm its superiority over other PPIs in the eradication of *H. pylori*.

**Conclusion**

LAD 10 days is the least duration that provides maximum safety and efficacy for *H. pylori* in Egyptian participants. In addition, successful treatment of *H. pylori* infection can be associated with reducing the risk of anemia and dyslipidemia. Furthermore, all members of the patient’s family should be screened for *H. pylori* to prevent recurrent infection.

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**Conflicts of interest**

There are no conflicts of interest.

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