#### **REVIEW ARTICLE**





# The Effect of *Helicobacter pylori* on Postoperative Outcomes in Patients Undergoing Bariatric Surgery: a Systematic Review and Meta-analysis

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#### Abstract

Helicobacter pylori (HP) occurs in 50% of people worldwide with higher rates reported in the bariatric population. HP has been associated with adverse outcomes following bariatric surgery; however, its true impact has not yet been defined. We aimed to systematically review the effect of HP on bariatric surgery outcomes. A comprehensive literature review was conducted yielding seven studies with 255,435 patients. Meta-analysis found comparable rates of bleeding, leak, hospital length of stay, and weight loss between HP-positive and HP-negative patients. HP was, however, found to be the largest independent predictor of marginal ulceration in those undergoing RYGB, with a tenfold increase versus HP-negative patients. Overall, HP is associated with increased marginal ulceration rates, but has little impact on other bariatric surgery outcomes.

Keywords Helicobacter pylori · Bariatric surgery · H. Pylori · Gastric bypass · Gastric band · Sleeve gastrectomy

# Background

*Helicobacter pylori* (HP) is a gram-negative, microaerophilic bacterium originally described in 1984 by Warren and Marshall [1, 2]. HP is prevalent in up to 50% of the population worldwide and is asymptomatic in over 80% of cases [2]. Its discovery revealed a bacterial-mediated cytokine response leading to ulcer formation, gastritis, and gastric malignancy; a process originally attributed to gastric acid hypersecretion [3]. Yet, while its correlation with gastritis and malignancy has now been well defined, its impact on patients undergoing bariatric surgery remains unclear.

Bariatric surgery has seen a rapid expansion over the last 20 years with the growing rates of severe obesity [4, 5]. Initial studies reported a greater prevalence of HP than the general population in patients undergoing bariatric surgery [6–8]. Higher HP rates were associated with increased rates of post-operative complications including increased marginal

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ulceration and leak rates [9–11]. Accordingly, some bariatric centers have adopted routine pre-operative screening and HP eradication programs [12–14].

Recent literature, however, has reported bariatric HP rates comparable to, or lower than those of the general population [8]. Prospective studies have also recently described no association between HP infection and marginal ulceration rates or adverse postoperative outcomes [15, 16]. Smoking and NSAID use have been cited as potential confounding factors regarding the effect of HP on complication rates [17]. Given the current evidence, a consensus regarding the impact of HP on bariatric surgery has not been reached.

The objective of this study was to perform a systematic review to determine the impact of *H. pylori* on patients undergoing bariatric surgery.

## Methods

## **Search Criteria**

A comprehensive search of electronic databases was performed from 1946 to July 2017. The search was conducted using the MEDLINE, EMBASE, SCOPUS, Web of Science and the Cochrane Library. Our search strategy included the following key terms: bariatric, gastric bypass, gastric band, sleeve gastrectomy, *Helicobacter pylori*, and *H. pylori*. Additional manual searches of reference lists were performed to identify potentially missed articles. Gray literature was also identified using Google.

## **Selection Criteria**

Abstracts and titles were first manually pre-screened for inclusion by two independent reviewers (VM, NS). Abstracts were screened based on the following inclusion criteria: adult patients (age  $\geq$  18 years old), patients undergoing bariatric surgery, and patients with documented *H. pylori* infection. Discrepancies were solved by consensus or through assessment by a third independent reviewer (JD). Our exclusion criteria included studies with pre-operative *H. pylori* eradication, studies with less than five patients, studies with pediatric patients, duplicate studies, kin studies, non-human, and non-English studies. Full-text articles of all selected abstracts were reviewed more thoroughly by two reviewers (VM and NS) using the same criteria and disputes were resolved with a third reviewer (JD). Studies were then assessed for methodological quality and bias using the MINORS tool [18].

## **Data Extraction**

outcomes of interest included bleeding, stricture, leak, marginal ulceration, and hospital length of stay. Secondary outcomes included type of bariatric procedure, abscess, pain, colitis, dehydration, length of stay (LOS), readmission, and percent excess weight loss (EWL) at 12 months. The following pre-operative patient characteristics were assessed: age, sex, body mass index (BMI), diabetes, hypertension, gastroesophageal reflux (GERD), peptic ulcer disease (PUD), ulcer prophylaxis, non-steroid anti-inflammatory drugs (NSAID) use, and tobacco use.

#### **Statistical Analysis**

Categorical variables were reported as frequencies and percentages while continuous data was expressed as mean  $\pm$  standard deviation. Meta-analysis was conducted where possible and appropriate. Outcomes assessed in the meta-analysis included bleeding, leak, stricture, hospital LOS, and EWL at 12 months. The estimated effects were calculated using RevMan 5.3 software obtained from the Cochrane website [19]. A random effect model was used to account for both internal and study-to-study variability. Included studies were then tested for heterogeneity using the Chi<sup>2</sup> test with significance set at P < 0.10 and the amount of heterogeneity quantified by the I<sup>2</sup> statistic: (1) low > 25%, (2) moderate > 50, and (3) high > 75% [20]. Statistical significance was set at P =0.05.

#### Results

## **Study Selection**

Preliminary database search of the literature yielded 564 articles after duplicates were removed (Fig. 1). After initial screening of titles and abstracts, 43 studies underwent full-text assessment for eligibility. Of these, seven studies met inclusion criteria and consisted of three retrospective cohort studies of prospectively collected data and four prospective cohort studies.

## **Study Characteristics**

A total of seven studies with 255,435 subjects were included [17, 21–26]. Follow-up varied from 1 to 60 months with a median of 12 months. Studies assessed a variety of both open and laparoscopic bariatric procedures including sleeve gastrectomy (SG), vertical band gastroplasty, and Roux-en-Y gastric bypass (RYGB) (Table 1). Studies were assessed for bias and methodological rigor using the MINORS tool. None of the studies met ideal scoring criteria due to limitations with loss to follow-up, lack of prospectively collected data, and failure to mention study size calculation (Table 2).

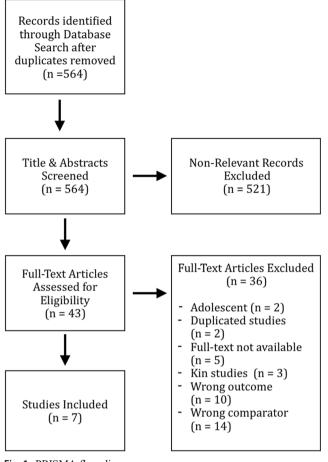


Fig. 1 PRISMA flow diagram

| Table I Baseline characteristics of included studies | Table 1 | Baseline characteristics of included studies |  |
|------------------------------------------------------|---------|----------------------------------------------|--|
|------------------------------------------------------|---------|----------------------------------------------|--|

Overall, the prevalence of *H. pylori* ranged from 0.13 to 41%. Of patients with *H. pylori*, the weighted mean age was 43.4 years, the weighted mean BMI was 45.0, and 69% were female. The prevalence of diabetes mellitus and hypertension ranged from 26 to 57%, and from 28 to 52%, respectively. The following complication rates were observed in HP patients undergoing bariatric surgery: bleeding (2.1%), stricture (2.9%), leak (0.7%), EWL at 12 months (72.3%), and hospital length of stay (4.2 days). Unadjusted marginal ulceration rate was 31% as reported by Schulman et al.

In contrast, for *H. pylori* negative patients, the weighted mean age was 51.7 years, the weighted mean BMI was 46.4, and 79% of patients were female. Rates of diabetes mellitus ranged from 26 to 58% while rates of hypertension ranged from 32 to 33%. Of patients that were negative for *H. pylori*, the following complication rates were noted: bleeding (0.7%), stricture (1.3%), leak (0.4%), EWL at 12 months (72.3%), and LOS (3.2 days). The overall rate of marginal ulceration was 3.9% [25]. No statistical significance was observed between HP and HP-negative groups for baseline patient characteristics.

#### **Meta-analysis**

There was no statistical significance between both groups for demographic characteristics including age, BMI, diabetes,

| Investigator          | Study design  | Year | n       | Surgery | Study arm   | Patients (n) | Mean Age <sup>1</sup><br>(years) | Gender<br>(% female) | Mean BMI <sup>1</sup><br>(kg/m <sup>2</sup> ) | Follow-up<br>(months) |
|-----------------------|---------------|------|---------|---------|-------------|--------------|----------------------------------|----------------------|-----------------------------------------------|-----------------------|
| Brownlee              | Retrospective | 2015 | 480     | SG      | HP positive | 52           | 40.7                             | _                    | 48.2                                          | 1                     |
|                       |               |      |         |         | HP negative | 428          | 40.2                             | -                    | 47                                            | 1                     |
| Gomberawalla          | Retrospective | 2015 | 280     | SG      | HP positive | 21           | 41.0                             | 91                   | 47.4                                          | 12                    |
|                       |               |      |         |         | HP negative | 259          | 42.0                             | 87                   | 47.6                                          | 12                    |
| Ramaswamy             | Prospective   | 2004 | 74      | RYGB    | HP positive | 21           | 39.0                             | -                    | 49                                            | 6                     |
|                       |               |      |         |         | HP negative | 10           | 40.0                             | -                    | 48                                            | 6                     |
| Rossetti              | Prospective   | 2014 | 184     | SG      | HP positive | 72           | 32.4 (4.5)                       | 71                   | 44.4 (5.2)                                    | 26                    |
|                       |               |      |         |         | HP negative | 112          | 37.3 (5.2)                       | 39                   | 47.1 (4.3)                                    | 28                    |
| Schulman <sup>2</sup> | Retrospective | 2017 | 253,765 | All     | HP positive | 340          | 54.3 (0.9)                       | 66                   | -                                             | _                     |
|                       |               |      |         |         | HP negative | 253,425      | 51.8 (0.8)                       | 79                   | -                                             | _                     |
| Shanti                | Retrospective | 2017 | 500     | SG      | HP positive | 216          | 33.3 (10.3)                      | 72                   | 45.5 (6.9)                                    | 12                    |
|                       |               |      |         |         | HP negative | 284          | 36 (10.3)                        | 73                   | 45 (6.9)                                      | 12                    |
| Wang                  | Prospective   | 2006 | 152     | VBG     | HP positive | 63           | 36.1 (9)                         | 60.3                 | 39.7 (6.2)                                    | 60                    |
|                       |               |      |         |         | HP negative | 89           | 32.4 (10.2)                      | 64                   | 42.6 (7.5)                                    | 60                    |

SG, sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; VBG, vertical banded gastroplasty; HP, Helicobacter pylori

<sup>1</sup> Reported as mean (standard deviation)

<sup>2</sup> Data extracted from NIS database

#### Table 2 MINORS assessment of included studies [17, 20–25]

| Criteria                                             | Study            |                      |                   |                  |                  |                |              |  |  |
|------------------------------------------------------|------------------|----------------------|-------------------|------------------|------------------|----------------|--------------|--|--|
|                                                      | Brownlee<br>2015 | Gomberawalla<br>2015 | Ramaswamy<br>2004 | Rossetti<br>2014 | Schulman<br>2017 | Shanti<br>2017 | Wang<br>2006 |  |  |
| A clearly stated aim                                 | 2                | 2                    | 2                 | 2                | 2                | 2              | 2            |  |  |
| Inclusion of consecutive patients                    | 0                | 2                    | 2                 | 2                | 0                | 2              | 2            |  |  |
| Prospective collection of data                       | 2                | 2                    | 2                 | 2                | 2                | 2              | 2            |  |  |
| Endpoints appropriate to the aim of the study        | 2                | 2                    | 2                 | 2                | 2                | 2              | 2            |  |  |
| Unbiased assessment of the study<br>endpoint         | 2                | 2                    | 2                 | 0                | 2                | 2              | 2            |  |  |
| Follow-up period appropriate to the aim of the study | 1                | 2                    | 2                 | 2                | 2                | 2              | 2            |  |  |
| Loss to follow-up less than 5%                       | 0                | 2                    | 2                 | 0                | 0                | 1              | 0            |  |  |
| Prospective calculation of the study size            | 0                | 0                    | 0                 | 0                | 0                | 0              | 0            |  |  |
| An adequate control group                            | 2                | 2                    | 2                 | 2                | 2                | 2              | 2            |  |  |
| Contemporary groups                                  | 2                | 2                    | 2                 | 2                | 2                | 2              | 2            |  |  |
| Baseline equivalence of groups                       | 2                | 2                    | 2                 | 1                | 2                | 2              | 2            |  |  |
| Adequate statistical analyses                        | 2                | 2                    | 1                 | 2                | 2                | 2              | 2            |  |  |
| Total*                                               | 17               | 22                   | 21                | 17               | 18               | 21             | 20           |  |  |

\*The items are scored 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate). The global ideal score being 16 for non-comparative studies and 24 for comparative studies

hypertension, and complications including bleeding (Fig. 1), leak (Fig. 2), EWL at 12 months (Fig. 3), or hospital LOS (Fig. 4). Meta-analysis could not be performed for stricture or marginal ulceration due to the paucity of studies assessing these outcomes.

Four studies [21–23, 26] examined bleeding rates (OR 3.05; CI 0.26 to 36.20; P = 0.38) and found no statistical significance between groups (Fig. 1). Likewise, five studies [17, 21–23, 26] found no statistical significance (Fig. 2) for leak rates (OR 1.72; CI 0.09 to 33.2; P = 0.72). EWL at 12 months (four studies, MD – 1.73; CI – 3.61 to 0.16; P = 0.07) was also similar between cohorts (Fig. 3) [20–22, 25]. Three studies [23, 24, 26] examined hospital LOS (MD – 0.39; CI – 1.26 to 0.47; P = 0.37), and no statistical significance was observed for HP vs. HP-negative groups. Heterogeneity was found to be significant for all of the outcomes (P < 0.05) [17, 21–26].

# Discussion

This is the first systematic review and meta-analysis to assess the impact of *H. pylori* on bariatric surgery outcomes. Overall, the unadjusted results of the systematic review were arranged into five key themes for patients with and without *H. pylori* undergoing bariatric surgery, respectively: leak (0.7 vs. 0.4%), marginal ulceration (31 vs. 4%), bleeding (2.1 vs. 0.7%), EWL at 12 months (72 vs. 72%), and hospital length of stay (4.2 days vs. 3.2 days). Meta-analysis performed for bleeding, leak, EWL, and hospital LOS revealed no statistical significance between groups. In the lone study assessing marginal ulceration, *H. pylori* infection was found to be the largest independent predictor of development of marginal ulceration with a tenfold increase compared to patients who were not infected with HP [25].

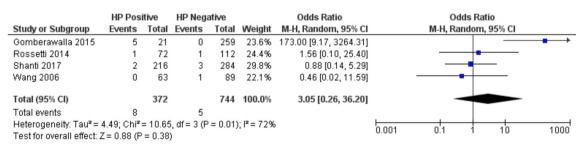


Fig. 2 Bleeding rates for HP-positive vs. HP-negative cohorts

Fig. 3 Leak rates for HP-positive vs. HP-negative cohorts

*Helicobacter pylori* is a class 1 carcinogen and is regarded as one of the most prevalent human pathogens affecting nearly 50% of the population [21–27]. Diagnosis is made through invasive and non-invasive modalities. Invasive tests are endoscopy mediated and include histology, rapid urease test, and culture. Non-invasive tests include the urea breath test, stool antigen test, and serological markers. Histologic diagnosis is considered the gold standard with a high sensitivity (97– 100%) and specificity (97–100%) [28–30]. In studies where patients underwent laparoscopic sleeve gastrectomy, the diagnosis of HP was confirmed through pathological assessment of the gastric remnant. Studies with gastric bypass and vertical banded gastroplasty utilized endoscopy to assess for the presence of HP both pre- and postoperatively.

HP infection is linked to complex hijacking of host cell signaling and a subsequent dysregulation of the inflammatory cytokine response [31, 32]. Although no clear mechanism has been defined, this pro-inflammatory response is thought to cause a myriad of complications leading some insurers to require pre-operative eradication prior to approval for bariatric surgery [12–14, 25]. One described cell signaling pathway involves the CagA effector protein. CagA, a protein translocated by HP, is described as a "master-key" involved in hijacking human gastric epithelial cell signaling cascades [31, 32]. Once bound to gastric epithelial receptor kinases, CagA, inappropriately activates phosphorylation kinase signaling leading to a dysregulation in cell proliferation, inflammation, and apoptosis. Abnormalities in these pathways lead to instability of gastric epithelial cells causing mucosal breakdown and local edema. These changes near anastomotic sites have been attributed to postoperative complications such as bleeding, leak, and marginal ulceration [22].

Pre-operative eradication of HP in bariatric surgery has been debated for several reasons. Proponents of eradication argue that it is a known carcinogen, increases the risk of cancer in the gastric remnant, and causes peptic ulcer disease [25]. Patients who undergo RYGB have an inaccessible gastric remnant making future surveillance and endoscopic evaluation for these conditions difficult. Those against eradication point to HPs are known ghrelin suppressor effects. Ghrelin drives hunger response, and eradication is thought to minimize EWL postoperatively [22].

A number of studies have demonstrated adverse outcomes in patients with HP undergoing bariatric surgery. Of those included in our review, Gomberawalla et al. looked at 280 consecutive patients undergoing SG, and found that colonization may be related to increased hospital length of stay and readmission rates. The presence of *H. pylori* was however not found to increase major complications or affect weight loss. In addition, Ramaswamy et al. looked at 99 patients undergoing bariatric surgery, 24% of which were HP positive. HP infection was found to be independently associated with an increase in postoperative foregut symptoms (OR 3.6; 95% CI 1.1–11.8) including abdominal pain, reflux, and nausea and vomiting.

Schulman et al. performed a nationwide retrospective analysis of HP and marginal ulceration using the Nationwide Inpatient Sample (NIS) database. A total of 253,765 patients who underwent bariatric surgery were assessed for marginal ulceration identified as the presence of a gastrojejunal ulcer solely using the *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) coding system.* Overall, marginal ulceration rate was found to be 3.9%. Ulceration rates in patients with HP were 31.2% compared

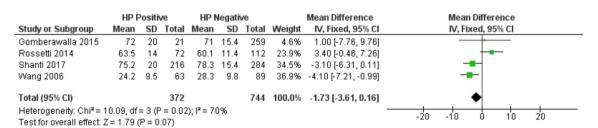


Fig. 4 EWL rates for HP-positive vs. HP-negative cohorts

to 3.9% in patients with no documented infection. After multivariate logistic regression, *H. pylori* infection was found to be the largest independent predictor for the development of marginal ulcers (OR 11.09; CI 6.5–18.9). Pathologically, marginal ulcers are thought to occur after RYGB due to high gastric pouch acidity or from small-vessel ischemia at the gastrojejunal anastomosis. HP may worsen this due to its effects on the gastric epithelium [33].

In contrast, other studies have found no association between HP and adverse surgical outcomes. Brownlee et al. looked at 480 patients who underwent SG and found no statistical significance in severe complication rates (leak, bleeding, and pain) between HP-positive and HP-negative patients. Likewise, Rossetti et al. assessed postoperative outcomes for 184 patients undergoing sleeve gastrectomy. No statistically significant difference was observed with respect to bleeding, leaks, or hospital LOS between the two groups. Wang et al. studied 152 prospective patients undergoing LVBG and similarly found no statistical difference in early (gastric stasis, band infection, and perforation) or late complications (leak, staple line disruption, and outlet obstruction) for both groups.

This systematic review is not without its limitations. Only seven non-randomized studies met our inclusion criteria and were limited by varying executional qualities. The majority were limited by sample size, surgical variability, limited follow-up, and significant heterogeneity. Only one study, an inception cohort by Ramaswamy et al., assessed the impact of *H. Pylori* on Roux-en-Y bypass anatomy. Follow-up for this study was limited to only 6 months, potentially underreporting complications associated with true bypass anatomy. Diagnosis of *H. Pylori* was also non-uniform across studies, allowing for diagnostic bias. There continues to be a paucity of studies and data surrounding *H. pylori* and its impacts on bariatric surgery. Despite these limitations, however, this review is novel in its analysis utilizing the best available literature.

Overall, no statistical significance was found for leak, bleeding, hospital length of stay, or weight loss between HPpositive and HP-negative patients undergoing bariatric surgery. HP was however found to be the single largest independent predictor for marginal ulceration in those undergoing RYGB in the lone retrospective study assessing this outcome. Together, results suggest that HP may have an association with increased marginal ulceration rates but has little impact on other bariatric surgery outcomes.

## Conclusion

*Helicobacter pylori* infection in patients undergoing bariatric surgery was not found to be adversely associated with bleeding, leak, weight loss, or hospital length of stay. It was, however, found to be an independent predictor of marginal ulceration in the single study assessing this outcome. This systematic review suggests that further research to assess the impact of H. pylori on bariatric surgery is needed, especially with a focus on marginal ulceration.

#### **Compliance with Ethical Standards**

**Ethical Approval and Consent** This article does not contain any studies with human participants or animals performed by any of the authors.

For this type of study, formal consent is not required. Informed consent does not apply.

**Conflict of Interest Statement** Authors 1, 2, 3, 4, 5, and 6—none to declare.

Author 7 is a consultant and has received educational grants from Ethicon and Covidien, educational grants from Stryker, and teaching honoraria from Cook Surgery and Bard Davol.

Author 8 is a consultant for Gore Medical and Ethicon.

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