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Original article

Nonsteroid anti-inflammatory drugs and the risk of peptic ulcers after gastric bypass and sleeve gastrectomy

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Abstract

Background: Pharmacologic pain treatment is common among bariatric patients. Nonsteroid anti-inflammatory drugs (NSAID) are not recommended after Roux-en-Y gastric bypass (RYGB) because of the increased risk of marginal ulceration, but the connection with NSAID is not unambiguous.
Objectives: Examine the association between NSAID exposure and peptic ulcers after primary laparoscopic RYGB and sleeve gastrectomy (SG) respectively.
Setting: University Hospital, Sweden.
Methods: Cross-matched data from 3 national registers were used in this retrospective, population-based cohort study of all primary laparoscopic RYGB and SG in Sweden within the period from 2010–2015. NSAID exposure was analyzed with individual data of dispensed daily defined doses (DDD) of NSAID after surgery. Multivariate logistic regression estimated the association between NSAID exposure and peptic ulcers, expressed as odds ratios with 95% confidence intervals adjusted for confounding.
Results: Of the 41,380 patients (37,913 RYGB, 3467 SG), 1.8% were diagnosed with peptic ulcers after surgery (RYGB 1.9%, SG .2%). In total, 60% of the patients had been prescribed NSAID during a follow-up period of 4.1 (1.0–7.0) years in median. The adjusted risk odds ratios for NSAID exposure were 1.10 (.88–1.38), 1.43 (1.16–1.76), and 1.52 (1.25–1.84) for >0–30 DDD, >30–100 DDD, and >100 DDD, respectively. In subanalysis, the association was similar for RYGB alone, whereas no association was found for SG.
Conclusion: The results of the present study support the notion that continuous NSAID use of ≥30 days is a significant risk factor for the development of peptic ulcers after RYGB, whereas temporary use (<30 days) is not. No association between NSAID exposure and the development of peptic ulcers after SG was identified. (Surg Obes Relat Dis 2022;18:888–893.) © 2022 American Society for Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Key words: Gastric bypass; Sleeve gastrectomy; Bariatric surgery; Peptic ulcer; nonsteroid anti-inflammatory drugs; NSAID

As clinical syndromes, pain and obesity are significantly associated with each other and likely mediated by various factors [1]. Obesity is a risk factor for musculoskeletal pain such as osteoarthritis [2], rheumatic diseases [3], and low back pain [4] because of the increased biomechanic stress on weight bearing joints and systemic inflammatory changes [5]. The substantial weight loss achieved by bariatric surgery improves many obesity-related co-morbidities [6–8], including joint pain, although conclusive evidence is lacking [9]. On the other hand, some patients develop chronic abdominal pain after Roux-en-Y gastric bypass (RYGB) [10]. Altogether, this makes different types of pain-related pharmacologic treatments common among

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bariatric patients. We have recently reported that preoperative opioid use is a risk factor for severe complications after bariatric surgery [11] and Raebel et al. [12] found an increased use of opioids after bariatric surgery. Treatment of chronic pain with opioids is controversial because of addiction as well as a significant number of side effects [13].

Nonsteroid anti-inflammatory drugs (NSAID) have potent anti-inflammatory and analgesic effects and are among the most widely used drugs worldwide, however, also associated with an increased risk for adverse gastrointestinal, renal, and cardiovascular effects [14]. Hakkarainen et al. [15] found that NSAID administration was associated with an increased risk of anastomotic leaks among patients undergoing nonelective colorectal surgery, but no effect was identified among patients undergoing bariatric surgery. Long-term use of NSAID is not recommended after bariatric surgery [16], because of the increased risk of marginal ulceration (MU) after RYGB [17,18], but the connection is not unambiguous [19]. Smoking, diabetes, immunosuppressive medication, and increased gastric acid exposure due to a long gastric pouch as well as peptic ulcer history have also been associated with an increased risk of MU [19–21]. Whether NSAID use is associated with increased risk of adverse gastrointestinal effects after sleeve gastrectomy (SG), has not been studied.

The aim of this registry-based study is to examine the association between NSAID exposure and peptic ulcers after primary laparoscopic RYGB and SG respectively.

Methods

Study design

This retrospective population-based cohort study included all primary laparoscopic RYGB and SG operated in Sweden between January 1, 2010, and December 31, 2015, according to the Scandinavian Obesity Surgery Register (SOReg). Since the start in 2007, SOReg has included 97.4% all bariatric procedures performed in Sweden and has a 99% internal validity [22]. Data on the studied covariates including sex, age, body mass index (BMI), year of surgery, smoking status, and 4 obesity-related co-morbidities, i.e., diabetes, hypertension, depression, and sleep apnea, were obtained from SOReg.

The outcome variable, a diagnosis of peptic ulcer, was obtained from the Swedish Patient Registry data which we had access to until December 31, 2016. This register provides data on all inpatient care and outpatient visits at specialized clinics (i.e., hospital-based clinics, endoscopic units, and emergency departments). Diagnoses are recorded and coded by the International Classification of Diseases (ICD) with a validity of 85%–95% in general [23]. The definition of peptic ulcer was based on the ICD codes K25 (gastric ulcer), K26 (duodenal ulcer), K27 (peptic ulcer, site unspecified), and K28 (gastrojejunal/marginal ulcer). It was possible to classify whether peptic ulcer disease had been present before, or developed after surgery, via the date of surgery from SOReg and date of diagnosis from the Swedish Patient Registry.

The exposure, prescribed NSAID use, was obtained from the Swedish Prescribed Drug Registry which records all prescribed and dispensed drugs in Sweden. The register captures drug names, based on the Anatomical Therapeutic Chemical Classification system (ATC), and individual data on dispensed drug-specific daily defined dose (DDD). NSAID use was defined by dispensed prescription of drugs with ATC code M01A up until December 31, 2016. NSAID exposure was categorized into 4 groups: (1) none; (2) low (>0–30 DDD); (3) middle (>30–100 DDD); and (4) high (>100 DDD). In addition, prescribed proton pump inhibitors (PPI) and other antacids (ATC code A02B) were captured from the registry.

The personal identity number, assigned to all Swedish residents, enabled linkage of all individual data in the 3 registers. The study was approved by the Reginal Ethical Review Board (Dnr: 2013/535-31/5 and 2017/857-32).

Statistical analysis

Independent sample t test and χ^2 test were used as univariate analyses for continuous and categorical variables, respectively. Multivariate logistic regression was used to estimate association between NSAID exposure and postoperative development of peptic ulcer disease (ICD codes K25–K28), presented as odds ratio (OR) with 95% confidence intervals (CIs). The model adjusted for differences in age, sex, BMI, year of operation, smoking status, ulcer history, and the co-morbidities (diabetes, hypertension, depression [dichotomized, on medication or not], and sleep apnea [use of continuous airway positive pressure]). All P values were 2-sided and $P < .05$ was considered statistically significant. All analyses were done using IBM SPSS Statistics version 28.

Results

In total 41,380 patients were included in the study and the median follow-up time was 4.1 years (range 1.0–7.0 years). Primary laparoscopic RYGB and SG constituted 91.6% (n = 37,913) and 8.4% (n = 3467), respectively, of the study cohort. Overall, 1.8% (n = 728) of the patients were diagnosed with a peptic ulcer, in median 16 months after surgery. The incidence of peptic ulcer was 429/100,000 person-years. This group consisted of more men, more smokers, and had a higher prevalence of co-morbid condition as well as a higher prescription of NSAID (Table 1).

NSAID and peptic ulcers

In total, 60% of the patients had been prescribed NSAID during the study period, with a higher proportion in RYGB

Table 1
Characteristics of the study cohort (n = 41,380), with all patients undergoing primary laparoscopic RYGB or SG in Sweden between 2010 and 2015

	Patients developing peptic ulcers			Total		
	Mean	N	%	Mean	N	%
Age, yr	42			41		
BMI, kg/m^2	41.9			41.9		
Sex						
Female		456	62.6%		31,483	76.1%
Male		272	37.4%		9897	23.9%
Operation						
RYGB		722	99.2%		37,913	91.6%
SG		6	.8%		3467	8.4%
Yr of surgery						
2010		162	22.3%		6754	16.3%
2011		183	25.1%		7769	18.8%
2012		132	18.1%		7117	17.2%
2013		127	17.4%		7270	17.6%
2014		79	10.9%		6497	15.7%
2015		45	6.2%		5973	14.4%
Smoking						
Yes		122	16.8%		4912	11.9%
Missing data		272	37.4%		12,496	30.2%
Sleep apnea*		112	15.4%		4128	10.0%
Hypertension†		270	37.1%		10,520	25.4%
Depression†		131	18.0%		6294	15.2%
Diabetes†		138	19.0%		5743	13.9%
Ulcer history‡		10	1.4%		116	.3%
NSAID use§						
None		226	31.0%		16,566	40.0%
>0–30 DDD		114	15.7%		7308	17.7%
>30–100 DDD		152	20.9%		7329	17.7%
>100 DDD		236	32.4%		10,177	24.6%

RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; BMI = body mass index; NSAID = nonsteroid anti-inflammatory drug; DDD = dispensed daily defined dose.

* Use of continuous airway positive pressure.

† On medication.

‡ Previous diagnosis of peptic ulcer disease (K25–K28) before surgery.

§ Prescribed and dispensed NSAID (M01A) after surgery.

than SG ($P < .001$) (Table 2). The mean annual prescription rate was 764 prescriptions/1000 individuals and year. A peptic ulcer was diagnosed in 1.4%, 1.6%, 2.1%, and 2.4% of the patients with none, low (>0–30 DDD), middle (>30–100 DDD), and high (>100 DDD) NSAID exposure. More than 30 dispensed DDD was associated with an increased risk of having a peptic ulcer, as demonstrated in Table 3.

Table 2
The proportion of patients with dispensed NSAID after RYGB and SG

	RYGB		SG	
	Number	%	Number	%
NSAID use				
None	14,877	39.2%	1689	48.7%
>0–30 DDD	6704	17.7%	604	17.4%
>30–100 DDD	6795	17.9%	534	15.4%
>100 DDD	9537	25.2%	640	18.5%

NSAID = nonsteroid anti-inflammatory drug; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; DDD = dispensed daily defined dose.

In subgroup analysis of RYGB, the prevalence of peptic ulcers was 1.9% and an increased risk was observed for NSAID exposure >30–100 DDD (OR = 1.44 [1.17–1.78]) and >100 DDD (OR = 1.52 [1.26–1.84]). No such association was found for the 6 patients (.2%) with peptic ulcers in SG, nor did the prevalence of peptic ulcers after SG differ from that of the whole cohort before surgery (.3%, $P = .308$).

Smoking and peptic ulcers

The prevalence of peptic ulcers was 2.5% among smokers versus 1.4% among nonsmokers ($P < .001$) with an adjusted risk OR of 1.73 (1.40–2.15).

Table 3
Unadjusted and adjusted risk ratios of dispensed NSAID in the whole cohort of 41,380 patients (37,913 RYGB and 3467 SG)

	Unadjusted		Adjusted*	
	OR	95% CI	OR	95% CI
NSAID use				
None	1.00	Reference	1.00	Reference
>0–30 DDD	1.45	.91–1.44	1.10	.88–1.38
>30–100 DDD	1.53	1.24–1.88	1.43	1.16–1.76
>100 DDD	1.72	1.43–2.06	1.52	1.25–1.84

NSAID = nonsteroid anti-inflammatory drug; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; OR = odds ratio; CI = confidence interval.

* Adjusted for age, body mass index, sex, operation, smoking, sleep apnea, hypertension, depression, diabetes, ulcer history, and year of surgery.

PPI and peptic ulcers

Prescribed PPI were found in 62.2 % (n = 25,729) of patients, whereof 38.6% (n = 15,961) had repeated prescriptions (≥2). When comparing RYGB and SG, 60.9% (n = 23, 084) of RYGB and 76.3% (n = 2645) of SG ($P < .001$) had at least 1 prescription of PPI after surgery, while repeated prescriptions (≥2) were found in 37.8% (n = 14, 337) of RYGB and 46.8% (n = 1624) of SG ($P < .001$).

Of the 728 patients diagnosed with a peptic ulcer, 724 (99.5%) had prescribed PPI and 699 (96%) had repeated prescriptions.

Discussion

In this nationwide cohort study of 41,380 individuals having had primary laparoscopic RYGB or SG, 60% of the patients had been dispensed NSAID after surgery. Higher exposure of NSAID (>30 DDD) was associated with increased risk for development of peptic ulcers for RYGB, but not for SG. The prevalence of peptic ulcer was 1.9% (n = 722) and .2% (n = 6) after RYGB and SG, respectively.

The mean annual prescription rate of 764 prescriptions/1000 operated individuals and year is 3 times higher than in a corresponding age group (20–59 years) of the Swedish population, as reported by the Swedish Prescribed Drug Registry (231 prescriptions/1000 individuals and year during 2010–2015) [24]. An overall similar prescription rate has been seen in the United Kingdom [25] and the United States (200–240 prescriptions/1000 individuals and year) [26].

According to our internal guidelines, we do not prescribe NSAIDs to bariatric patients. However, our patients are in contact with other specialties e.g., orthopedic surgeons or rheumatologists for joint diseases. The surprisingly high proportion of patients (25.2%) with >100 DDD of prescribed NSAIDs suggests that the awareness of the increased risks of marginal ulcers after RYGB among other physicians is deficient.

MU is a well-known late complication after RYGB, ranging from .6%–25% [18]. According to the same systematic review, time between surgery and presentation with MU varies from 1 month–6 years, depending on definition, screening method, and follow-up time. In the present study, 1.9% of the RYGB patients were diagnosed with peptic ulcer after 16 months in median. Using the same definition (ICD codes K25–K28), a higher incidence (3.3%) has previously been reported in 20,924 Swedish RYGB [19], however, these operations were performed between 2006–2011 and included 14% open surgery, which per se is associated with a higher incidence of peptic ulcers. In the above-mentioned age-matched cohort of the Swedish population, incidence of peptic ulcers (K25–K28) was 22.3/100 000 individuals and year, thus markedly lower than the present 429/100,000 in our postoperative bariatric patients. There is, however, contradicting results whether NSAID is a risk factor for MU after RYGB, as some studies have reported an increased risk [17,27] while other studies contradict this [19,20]. The results of the present study support the notion that continuous NSAID use (>30 DDD) is a significant risk factor, while temporary use is not.

Wilson et al. [17] found a protective effect of concomitant use of PPI with NSAID. However, postoperative PPI prophylaxis has not been effective; there is 7.6% MU after RYGB with PPI prophylaxis [28] and no difference in incidence of MU in patients negative for *Helicobacter pylori* regardless of PPI treatment [29]. In the present retrospective registry-based study we were not able to study the effect of PPI because of confounding by indication, as explained by others [19].

To the best of our knowledge, this is the first study exploring NSAID exposure and peptic ulcer disease in SG. We speculate that the low prevalence in SG (.2% versus 1.9% in RYGB) is a result of the preserved anatomical passage through the pylorus, utilizing the large buffering capacity of the duodenal bulb, as earlier demonstrated by our group [30]. The absence of association between NSAID exposure and development of peptic ulcers after SG is an important factor to consider when choosing bariatric procedure for patients with an expected need of NSAIDs after surgery (e.g., inflammatory joint diseases).

Strengths and limitations

The large sample size from a nation-wide cohort of primary laparoscopic RYGB and SG, completeness of follow-up and access to valid data from 3 national registers are among the strengths of the present study. Previously identified risk factors such as smoking [18], hypertension [31], diabetes [20], and peptic ulcer history [19] were adjusted for in the multivariate logistic regression model, in addition to differences in age, sex, BMI, year of operation, depression, and sleep apnea. However, as in any

registry-based study, there is an inherent risk of residual confounding factors not adjusted for. More important, there are several specific limiting factors that need to be considered. Firstly, the exposure, NSAID use could be influenced by over-the-counter NSAID which is not accounted for in this study. Long-term use is typically based on prescriptions, but some patients might be misclassified as nonusers or as having a lower exposure than they actually have because of over-the-counter purchase. This source of error is most likely random between groups and has only minor influence on the risk estimates. Secondly, *H. pylori* is a well-known risk factor for peptic ulcer disease and may potentiate MU formation [32], but data on *H. pylori* status was not available in any of the registers. It was, however, possible to adjust for previous history of peptic ulcer disease before bariatric surgery, based on former ICD diagnoses. Thirdly, the definition of peptic ulcers was based on ICD codes (K25–K28) obtained from the Swedish Patient Registry, which does not include diagnoses from primary care. However, most symptomatic patients undergo endoscopic examination and the vast majority of endoscopic units in Sweden are connected to the patient registry. Fourthly, concerning smoking status, missing data were about 30%. However, worth noting is that having missing data on smoking status was associated with a similar increased adjusted risk ratio as being an active smoker.

Conclusion

The results of the present study support the notion that continuous NSAID use $\geq$30 days is a strong risk factor for the development of peptic ulcers after RYGB, while temporary use ($<$30 days) is not. No association between NSAID exposure and the development of peptic ulcers after SG was identified.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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