Original Research

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Does administration of proton pump inhibitors for 3 days decrease the complaints related to gastroscopic biopsy in patients with dyspepsia?

Dispepsili hastalarda gastroskopik biyopsi ile ilişkili şikayetler, 3 gün proton pompa inhibitörü uygulanmasıyla azalır mı?

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Background/aims: *The aim of this study was to evaluate whether administration of single-dose proton pump inhibitor for 3 days to patients undergoing upper gastrointestinal endoscopy with biopsy decreases the complaints related to the procedure using a severity scale and to investigate whether the procedure has any negative impact on quality of life.* ***Methods:*** *Sixty patients were enrolled in the study. Before the procedure, patients were queried using the complaint severity scale. Following the endoscopy, patients were randomized into two groups: Group A was given pantoprazole 40 mg 1x1, while Group B received placebo 1x1 for 3 days. After 3 days, patients were queried again using the same scale.* ***Results:*** *In Group A, all scores had decreased 3 days after the procedure, but only the decrease in the score for the complaint of bloating was significant. In Group B, the scores for epigastric pain, bloating and nausea had increased, and the increases in the scores for epigastric pain and bloating were statistically significant.* ***Conclusions:*** *Administration of proton pump inhibitor for a short period after the procedure will not only decrease the present complaints but also prevent the negative impacts of the procedure, even if only partially.*

Key words: *Proton pump inhibitors, gastroscopy, pain*

Giriş ve Amaç: *Amacımız üst GİS endoskopisi yapılan ve biyopsi alınan hastalara işlem sonrası günde tek doz 3 gün boyunca proton pompa inhibitörü vererek; işlem ile ilgili olabilecek şiakayetlerde azalma olup olmayacağını bir skala üzerinden değerlendirmek ve işlemin günlük yaşam kalitesi üzerine etkisi olup olmadığını araştırmaktır.* ***Gereç ve Yöntem:*** *Çalışmaya 60 hasta alındı. İşlemden önce hastalar bir ankete tabi tutuldu ve endoskopi sonrası 2 gruba ayrıldı. Grup A'ya 40 mg pantoprazol 1x1 verilirken, Grup B'ye 1x1 plasebo verildi. 3. günün sonunda, hastalara aynı anket uygulandı.* ***Bulgular:*** *Grup A'da işlem sonrası tüm skorlar düşerken, şişkinlik şikayetindeki düşüş anlamlıydı. Grup B'de ise epigastrik ağrı, şişkinlik ve bulantı skorlarında artış görülürken, epigastrik ağrı ve şişkinlik skorlarındaki artış anlamlıydı.* ***Sonuç:*** *Endoskopiden sonra kısa süreli proton pompa inhibitörü verilmesi sadece şikayetleri azaltmakla kalmayıp, hastalarda işlemle ilgili negatif etki oluşmasını da kısmen önlemektedir.*

Anahtar kelimeler: *Proton pompa inhibitörleri, gastroskopi, ağrı*

INTRODUCTION

At present, upper gastrointestinal (GI) system endoscopy is a frequently performed procedure for the diagnosis and treatment of GI disorders. Although complications that may develop during and after the procedure can be minimized in experienced hands, some complications independent of the endoscopist, which may be due to the procedure itself, may occur commonly. The procedure alone is stressful for the patient. Furthermore, the development of post-endoscopy complaints is possibly related to the duration and type of the procedure and tissue sampling. After the procedure, patients frequently develop some complaints such as pain, bloating and flatulence. These complaints are usually disregarded by physicians, and treatment is usually initiated after biopsy results are obtained. In the period between the end of endoscopy and biopsy results, patients are left with their complaints. The complaints that occur due to the procedure may influence the patient's quality of life.

The aim of this study was to administer single-dose proton pump inhibitor (PPI) for 3 days to patients undergoing upper GI endoscopy with biopsy for indications other than ulcer, bleeding and tumor, etc., in order to evaluate complaints (such as epigastric pain, bloating, vomiting, and fatigue) prior to and 3 days after the procedure, using a complaint severity scale. We also investigated whether the procedure had any negative impact on patient quality of life.

MATERIALS AND METHODS

Sixty patients biopsied due to indications other than ulcer, polyp and tumor, etc. among patients who underwent upper GI endoscopy for dyspeptic symptoms in the endoscopy unit of our hospital between April-May 2009 were included in the present study. The procedure was carried out by a single endoscopist, and biopsies were obtained from both the corpus and antrum from two sites.

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As there were no similar studies in the literature at the time the study was planned, we developed a scale for complaints. As a pilot study, 200 similar patients over approximately three months were queried about dyspeptic complaints that could be caused by the procedure, and all complaints were recorded. A scale comprising the most frequent complaints, epigastric pain, bloating, nausea, and fatigue, was developed and scored between 0-5 according to the severity of the complaints (Table 1). Before the procedure, patients were questioned using the scale. Following the endoscopy procedure, patients who met the eligibility criteria of the study were consecutively randomized into two groups regardless of the severity of their complaints. One group was given pantoprazole (40 mg once per day, Group A), while the other group was given placebo (once per day, Group B) for 3 days. All patients were asked to not take any other drug except for those they received routinely. When they were questioned again after 3 days, those who had used other drugs were excluded from the study. After 3 days, patients were queried again regarding the complaints using the same scale. In addition, patients were asked if the endoscopy procedure hindered their daily activities. Endoscopic and histopathological diagnoses of the patients were also recorded.

Patients with marked gross pathology in their endoscopy, history of PPI, steroidal or non-steroidal anti-inflammatory drug use within the last 1 week, cholelithiasis or other diseases that delay gastric emptying, or a history of smoking and alcohol use were excluded from the study.

In the analysis of the data, chi-square ($\chi 2$) independence test and Fisher's exact $\chi 2$ were used.

RESULTS

Overall, 60 patients were included in the study (30 in Group A, 30 in Group B). Group A included patients given PPI, while Group B included those given placebo. Age and sex distribution was similar between the groups (Table 2).

The PPI and placebo groups were evaluated with respect to their complaints, including epigastric pain, bloating, nausea, and fatigue, according to the scale scored from 0 to 5, at baseline and on the 3rd day. It was seen that all scores had decreased 3 days after the procedure in Group A, while only the decrease in the score regarding bloating was significantly different. In Group B, the scores for epigastric pain, bloating and nausea had increased, and the increases in the scores for epigastric pain and bloating were statistically significant (Table 3).

When the mean scores of complaints were evaluated, it was seen that the mean score decreased in Group A after the administration of the drug (8.23±4.00 on the 1st day vs

Tablo 1. A scale evaluating the complaints related to upper GI endoscopy and gastric biopsy

			BEFORE	AFTER
Epigastric pain (a)	0	absent	☐	☐
	1	mild, does not disturb	☐	☐
	2	mild, disturbs	☐	☐
	3	moderate, disturbs	☐	☐
	4	severe, I can fulfill daily activities	☐	☐
	5	severe, I cannot fulfill daily activities	☐	☐
Bloating (b)	0	absent	☐	☐
	1	very mild, does not disturb	☐	☐
	2	very mild, disturbs	☐	☐
	3	moderate, disturbs	☐	☐
	4	severe, I can fulfill daily activities	☐	☐
	5	severe, I cannot fulfill daily activities	☐	☐
Nausea (c)	0	absent	☐	☐
	1	very mild, does not disturb	☐	☐
	2	very mild, disturbs	☐	☐
	3	moderate, disturbs	☐	☐
	4	severe, I can fulfill daily activities	☐	☐
	5	severe, I cannot fulfill daily activities	☐	☐
Fatigue (d)	0	absent	☐	☐
	1	very mild, does not disturb	☐	☐
	2	very mild, disturbs	☐	☐
	3	moderate, disturbs	☐	☐
	4	severe, I can fulfill my daily activities	☐	☐
	5	severe, I cannot fulfill my daily activities	☐	☐

Tablo 2. Demographic characteristics of the patients

	Sex	Age
Group A (n:30)	11 ♂ 19 ♀	44.46±11.7 (♂:46±11.58 ♀:44.6±12)
Group B (n:30)	8 ♂ 22 ♀	44.03±10.46 (♂:48.25±11.47 ♀:41.95±9.91)

Tablo 3. Comparison of the means scores of complaints in Groups A and B at baseline and on the 3rd day

	Group A	*p*	Group B	*p*
a1 / a2	2.53±1.38 / 2.03±1.47	0.096	1.30±1.17/ 2.03±1.18	0.001
b1 / b2	2.43±1.33 / 1.93±1.46	0.045	1.63±1.40/ 2.20±1.49	0.024
c1 / c2	1.33±1.37 / 1.00±1.36	0.224	1.23±1.25/ 1.53±1.40	0.153
d1 / d2	1.93±1.48 / 1.83±1.53	0.717	1.97±1.35 / 1.83±1.31	0.354
The sum of baseline complaints/3rd day complaints sum	8.23±4.00 / 6.80±4.42	0.075	6.13±3.91 / 7.60±3.80	0.010

a: epigastric pain, b: bloating c: nausea, d: fatigue 1: prior to the procedure, 2: at the end of 3rd day

6.80±4.42 on the 3rd day), but the difference was not statistically significant (p=0.075). In Group B, mean scores significantly increased (6.13±3.91 on the 1st day vs 7.60±3.80 on the 3rd day) (p=0.010) (Table 3).

In Group A, the number of cases who responded "no" to the question 'Did the procedure have any negative impact on your quality of life?" was 26 (86.6%), while it was 17 (56.6%) in Group B, with a statistically significant difference between groups (p=0.036) (Table 4).

Results with respect to the endoscopic and histopathological diagnoses are summarized in Tables 5 and 6. Endoscopic and histopathological diagnoses were similar between the two groups. The frequency of *Helicobacter pylori* positivity was also equal between groups.

DISCUSSION

Although there are scales measuring functional dyspeptic complaints in the literature (1,2) as we could not find any scale evaluating post-endoscopic complaints, we developed the scale ourselves with a pilot study and applied it to our patients. When we divided the patients into two groups irrespective of their complaints at baseline and queried them about their complaints after 3 days using the same scale, we established that complaints increased in the group given placebo, with the increases in epigastric pain and bloating being significant. In the group given PPI, there was a marked decrease in post-endoscopy complaints. In the comparison of the scores of the complaints according to the scale, a substantial reduction was seen in the PPI group, while the scores increased in the placebo group. Even more striking was the finding that the majority of the patients given PPI stated that the procedure had no negative impact on their life quality (89%), while in the group given placebo, the corresponding rate was lower. In the group given PPI, the mean rate of complaints was lower at baseline than in the group given placebo (8.23±4.00 in Group A vs 6.13±3.91 in Group B). As the patients were given placebo in a double-blind manner irrespective of their complaints according to the scale at baseline, it was impossible to have equal mean values in both groups. However, the complaints decreased markedly in Group A, while they increased in Group B.

Tablo 4. The rates of the response 'no' to the question 'Did the procedure have any negative impact on your life quality?' in both groups

	Group A	Group B	*p*
No negative impact on quality of life (n / %)	26/86.6%	17/56.6%	0.036

Tablo 5. Comparison of the patients according to endoscopic diagnosis

Endoscopic diagnosis	Group A (n)	Group B (n)	p
Esophagitis	5	5	>0.05
Endoscopic antral gastropathy	21	22	>0.05
Endoscopic pangastropathy	6	5	>0.05

Tablo 6. Comparison of the patients according to histopathologic diagnosis

Pathological diagnosis	Group A (n)	Group B (n)	p
Normal	3	4	>0.05
Chronic inactive superficial gastritis	16	14	>0.05
Chronic inactive atrophic gastritis	2	4	>0.05
Chronic active superficial gastritis	9	8	>0.05
H. pylori positivity	11	11	>0.05

Dyspepsia is a symptom encountered frequently in general practice and occurs in 5-15% of the patients referring to internal medicine clinics and in 40-60% of those referring to gastroenterology clinics (3). As is known, dyspepsia is defined as episodic or persistent occurrence of symptoms, such as epigastric pain, discomfort, early satiety, bloating, nausea, retching, and flatulence, thought to be associated with the upper GI system (4). In daily clinical practice, upper GI endoscopy is considered for the evaluation of patients with the above- mentioned symptoms. However, it is stated by the patients that this diagnostic procedure sometimes enhances these complaints, even though there are no such scientific data. Biopsy obtained during upper GI endoscopy leads to mucosal damage. Yet, there is no scientific data showing that this damage gives rise to dyspeptic complaints such as pain and bloating, etc. in the area involved. In addition, air given during the procedure may cause complaints such as bloating and flatulence. These complaints increase the dyspeptic complaints already present and decrease the life quality. Based upon these observations, we observed that PPIs given after the procedure relieved our patients' complaints.

Endoscopic diagnosis of the patients was similar between groups. As both groups comprised patients with non-ulcer dyspepsia and without marked gross pathology, the similarity of histopathological findings is expected. Therefore, when the histopathological diagnoses of the two groups were compared, similar diagnoses and equal numbers of H. pylori-positive cases were established. There is no doubt that a randomization that was not predicted at the onset of the study took place. This even distribution will render the results of our study more reliable for comparing the groups in terms of complaints that may develop after the procedure. However, this even distribution prevented us from determining the relationship between endoscopic and histopathological diagnosis and complaints. The results of the studies investigating the relationship between histopathological and endoscopic diagnosis and the severity of dyspeptic symptoms are conflicting. Some studies have found a relationship between histopathological and endoscopic diagnosis and dyspeptic complaints, while others did not (5,6).

It is no doubt impossible to predict the pain threshold of the patients and their reactions to any invasive procedure beforehand and to randomize them accordingly. However, as can be seen from our findings, randomization of both groups was satisfactory in terms of both endoscopic and microscopic findings.

In the present study, sex and age were adjusted in both groups. Similarly, Talley et al. (7) found no statistically significant relationship between dyspeptic symptoms and sex, age, education, or marital status in their study, with the aim of determining risk factors in patients with dyspepsia.

A marked decrease in complaints and minimal negative impact on life quality in the group given PPI when compared to the other group are striking. PPIs may have caused the improvement in symptoms both by inhibiting acid secretion, hence accelerating mucosal healing, and by its effect on H. pylori, albeit partially.

To the best of our knowledge, there is no publication in the literature on the complaints that may occur after endoscopy, which may be due to the fact that the majority of the studies focus on diseases rather than the patients.

In daily clinical practice, we may withhold treatment from patients whom we diagnose as non-ulcer dyspepsia until pathology results are obtained, as we focus generally on their endoscopic findings. While evaluating the post-endoscopic process, we recommend PPIs according to the presence of complaints prior to the procedure. As can be seen from the results of the present study, routine administration of PPIs for a short period after the procedure will not only decrease the present complaints but also prevent the negative impacts of the procedure, even if only partially. If the patient feels well during the evaluation period, it will strengthen his relation with his physician and increase the efficacy of treatment by increasing the trust of the patient in his physician, hence enhancing patient compliance to the treatment.

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