

# Effect of Omeprazole to Dyspeptic Symptom on Ramadan Fasting Patient based on Dyspepsia Symptoms Severity Index Scores

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## ABSTRACT

**Background:** Dyspepsia is a symptoms collection of discomfort at the upper abdomen. Ramadan Fasting is a worship that must be run by all Moslems that do not eat and drink for  $\pm 12$  hours. Proton pump inhibitors are drugs commonly given to patients with dyspepsia with mechanism controlling gastric acid secretion. The aim of this study is to find the effect of omeprazole to the patient with dyspepsia and undergo Ramadan fasting.

**Method:** Using analytic study design, conducted in outpatient in Koja Hospital Jakarta from June - July 2013, for patients with dyspepsia who will undergo Ramadan fasting. Subjects are divided into 2 groups; one group was given omeprazole while others were given a placebo. Before and after 2 weeks of fasting, dyspepsia symptoms severity index scores (DSSI) was taken which assessed changes in both groups and compared using student T-test.

**Results:** DSSI scores on average before the intervention of both groups ( $n = 30$ ) was not significant ( $p = 0.9$ ). In the placebo group obtained increasing of DSSI score from  $27.7 \pm 14$  to  $36 \pm 14.8$  ( $p = 0.001$ ), whereas in the omeprazole group obtained increasing of score only from  $27.2 \pm 9.4$  to  $30 \pm 9.9$  ( $p = 0.08$ ). In the placebo group score worsened by  $8.3 \pm 7.2$  but in the omeprazole group with only  $2.7 \pm 5.7$  ( $p = 0.02$ ).

**Conclusion:** There was a significant decrease of DSSI scores in fasting patient with omeprazole. Therapy with omeprazole 20 mg twice daily during the month of fasting can reduce the abdominal complain in patient with dyspepsia.

**Keywords:** dyspepsia, DSSI, fasting, Ramadan

## ABSTRAK

**Latar belakang:** Dispepsia adalah kumpulan gejala tidak nyaman pada perut bagian atas. Puasa Ramadan merupakan ibadah wajib bagi seluruh umat muslim dengan tidak minum atau makan selama  $\pm 12$  jam. Penghambat pompa proton merupakan obat yang umum diberikan pada pasien dispepsia dengan mekanisme kerja mengontrol sekresi asam lambung. Tujuan penelitian ini adalah untuk mengetahui pengaruh omeprazole terhadap keluhan pasien dispepsia yang sedang menjalankan ibadah puasa Ramadan.

**Metode:** Penelitian ini menggunakan desain penelitian analitik, dilakukan di Rumah Sakit Koja Jakarta sejak Juni hingga Juli 2013 terhadap semua pasien dispepsia yang akan menjalankan puasa Ramadan. Subyek dibagi menjadi 2 kelompok, dimana kelompok pertama diberi omeprazol selama menjalankan puasa, sedangkan kelompok lainnya diberi plasebo. Sebelum dan sesudah 2 minggu berpuasa dilakukan skoring dengan DSSI. Dinilai perubahan skor pada kedua kelompok kemudian dibandingkan menggunakan uji student T.

**Hasil:** Skor rata-rata sebelum intervensi (pre-test) kedua kelompok ( $n = 30$ ) tidak ada perbedaan bermakna

( $p = 0,9$ ). Pada kelompok plasebo didapatkan peningkatan skor dari  $27,7 \pm 14$  menjadi  $36 \pm 14,8$  ( $p = 0,001$ ), sedangkan kelompok dengan omeprazol didapatkan skor dari  $27,2 \pm 9,4$  menjadi  $30 \pm 9,9$  ( $p = 0,08$ ). Perubahan skor rata-rata pada kelompok plasebo memburuk sebesar  $8,3 \pm 7,2$  sedangkan kelompok dengan omeprazole hanya  $2,7 \pm 5,7$  ( $p = 0,02$ ).

**Simpulan:** Terjadi penurunan skor DSSI yang bermakna pada kelompok yang menjalankan ibadah puasa dengan terapi omeprazole. Terapi omeprazole 20 mg dua kali sehari selama bulan puasa dapat mengurangi keluhan abdominal pasien dispepsia.

**Kata kunci:** dispepsia, DSSI, puasa, Ramadan

## INTRODUCTION

Dyspepsia is a collection of symptoms or signs comprises of discomfort or pain in upper abdomen which persist or recur. Most commonly encountered symptoms are epigastric pain, epigastric discomfort, early satiety, fullness, bloating, and nausea.<sup>1,2</sup> Dyspepsia is a general gastrointestinal problem worldwide with highest prevalence found in New Zealand with 34.2%.<sup>1,3,4</sup> National Health Department in the year 2004 placed dyspepsia in the 15<sup>th</sup> rank from 50 list of diseases with most number of hospitalisation with proportion of 1.3%.<sup>5</sup>

Risk factors of dyspepsia include obesity, spicy food, cigarette, stress, coffee or tea, alcohol, irregular meal times, or even medicines, such as steroid and non-steroid anti inflammatory drugs (NSAIDs).<sup>6,7,8</sup> Ramadan fasting becomes one of the risk factors because during fasting in the Ramadan month, moslems do not eat and drink for 12-13 hours starting from sunrise until sunset.<sup>9,10,11</sup> During fasting, gastrin, pepsin, and gastric acid secretion will increase.<sup>12</sup> This gastric acid change may be the basis of increasing dyspepsia complaints during Ramadan.<sup>12</sup>

Question arises, does this Ramadan fasting influence the severity of dyspepsia in patients visiting Internal Medicine Outpatient Clinic in Koja Hospital. Degree of dyspepsia is evaluated clinically based on dyspepsia symptoms severity index (DSSI).<sup>13</sup> DSSI is a questionnaire developed for screening in dyspepsia patients, which includes 20 questions comprises of dysmotility, reflux, and ulcer group of questions.<sup>13</sup> Endoscopic evaluations were not performed because in Ramadan month usually patients refuse to undergo invasive procedures.

## METHOD

This study used analytic design, which was intervention study with double blind method, performed in Internal Medicine Outpatient Clinic of Koja Hospital, Jakarta from June 2013 until July 2013, with approval

from the Ethics Committee of Health Study at Faculty of Medicine, University of Krida Wacana Christian, Jakarta. Sample collection method was non-probability sampling, which was consecutive sampling. Inclusion criteria were all patients diagnosed with dyspepsia who will perform fasting. While exclusion criteria included presence of ulcer or malignancy, dyspepsia caused by pancreatobiliary and systemic disease, patient routinely received antiaggregation medicine, NSAIDs for other diseases and pregnant patients.

All dyspepsia patients who fulfilled inclusion criteria were recorded, then they filled the DSSI questionnaire and were further divided into 2 groups through randomisation block. One of the groups was given omeprazole 20 mg twice daily during fasting, taken during the fast break and dawn, while other group was given placebo (vitamin B complex). Before and after fasting for two weeks, DSSI scoring evaluation was performed. DSSI score changes in both groups were assessed and compared using T-test with significant p value  $< 0.05$  using SPSS version 21.0.

## RESULTS

During 35 days of study, 30 patients with clinical complaints of dyspepsia who fulfilled inclusion criteria were chosen as study participants. Characteristics of chosen subjects were shown in Table 1.

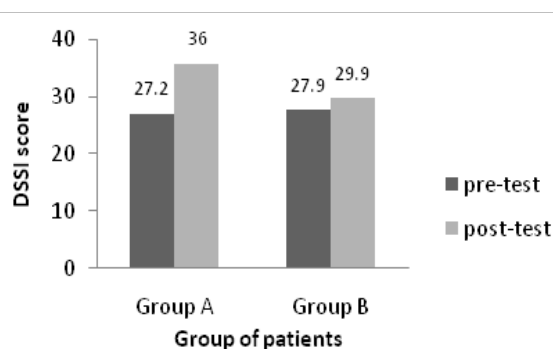
To all subjects, DSSI score analysis was performed. Average of DSSI score before intervention (pre-test) in group A (without omeprazole) was  $27.7 \pm 14$  while in group B  $27.2 \pm 9.4$  ( $p = 0.9$ ). In group A to which omeprazole was not given during Ramadan fasting, worsening of DSSI score was obtained from  $27.7 \pm 14$  to  $36 \pm 14.8$  ( $p = 0.001$ ), while in group B to which omeprazole was given during Ramadan fasting, changes of DSSI score from  $27.2 \pm 9.4$  to  $30.9.9$  ( $p = 0.08$ ) (Figure 1). Worsening of DSSI score after performing Ramadan fasting for 2 weeks was statistically significant with  $p = 0.001$ . On the other

hand, in group receiving omeprazole for prevention of dyspepsia, it was obtained that there was minor worsening, however not statistically significant.

**Table 1. Dyspepsia patients characteristics (n = 30)**

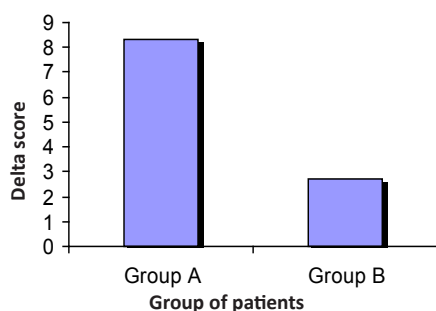
Characteristic	Group A n (%)	Group B n (%)
<b>Risk factors</b>		
Drugs	0 (0)	2 (13.3)
Irregular meal times	13 (86.7)	9 (60)
Alcohol	2 (13.3)	2 (13.3)
Coffee or tea	9 (60)	10 (66.7)
Stress	9 (60)	10 (66.7)
Cigarette	1 (6.7)	1 (6.7)
Spicy food	11 (73.3)	10 (66.66)
<b>BMI (kg/m<sup>2</sup>)</b>		
< 18.5 (underweight)	1 (6.7)	0 (0)
18.5 – 22.9 (normal)	6 (40)	7 (46.7)
23 – 24.9 (overweight)	3 (20)	1 (6.7)
25.0 – 29.9 (obese)	4 (26.7)	7 (46.7)
≥ 30 (very obese)	1 (6.7)	0 (0)
<b>Clinical symptoms</b>		
Epigastric pain syndrome	3 (20)	3 (20)
Fullness/bloating (PDS)	1 (6.6)	3 (20)
Both	11 (73.7)	9 (60)

PDS: postprandial distress syndrome; Categorical data are presented in n (%) and numeric data are presented in mean [SD]



**Figure 1. Mean of DSSI score pre-test and post-test in group A and B**

Additionally, average score changes (delta score) between pre-test and post-test was calculated in group A and B. In group A score worsened  $8.3 \pm 7.2$  and in group B  $2.7 \pm 5.7$  ( $p = 0.02$ ). This difference was statistically significant.



**Figure 2. Average score changes between pre-test and post-test in group A and B**

## DISCUSSION

In the study performed to 30 patients diagnosed with dyspepsia in Internal Medicine Outpatient Clinic Koja Hospital, it was obtained that based on sex, number of female (73.33%) was greater compared to male (26.66%) in both groups. Most population studies revealed that there were no difference in the prevalence of dyspepsia based on sex, however some studies exhibited that the prevalence of dyspepsia was higher in female.<sup>14</sup> Similarly, in the study conducted by Marwaha et al, it was reported that the prevalence of dyspepsia was higher in female.<sup>15</sup> This might happen due to difference in nutrition, culture, socioeconomic, and hormonal.

Based on complaints from patients' history taking, it was recorded that 6 (20%) patients complained of epigastric pain syndrome (EPS), 4 (13.33%) patients complained of postprandial distress syndrome (PDS), and 20 (66.66%) patients complained of both (EPS + PDS). This result differed from that of the study performed by Nwokediuko et al in Nigeria which obtained results of EPS, PDS, and EPS + PDS with presentation of 79.2%, 62.5% and 50%.<sup>16</sup> This difference may be caused by ethnical difference or methods in data collection.

In the study performed by Li et al in China, highest prevalence of dyspepsia was the age group of 41–50 year old<sup>17</sup> and in the study in Japan, highest prevalence was in the age group of 50–59 year old.<sup>14</sup> In this study, highest prevalence was in the age group of 51–60 year old (30% patients) where it was in concordance with the study in Japan. Variations of age group in different studies might be caused by environmental and nutritional factors, or even in drugs consumed.

Many risk factors influence the presence of dyspepsia complaints. Every patient may has more than one risk factor. In this study, most risk factors obtained was irregular meal as much as 73.33%. This study agreed with the study performed by Annisa, where there was relationship between meals irregularity with dyspepsia syndrome.<sup>18</sup>

Average of DSSI score in pre-test and post-test in both groups showed increased score in group A (as much as 8.4) which was much higher compared to group B (as much as 2.7). This result showed that there was increase of gastric acid which happened during fasting in Ramadan month and influenced the presence of worsening in dyspepsia complaints. In accordance to the study performed by Iraki et al which studied the decrease of gastric pH during fasting in Ramadan month, it was known that gastric

pH decreased significantly after day-10 of Ramadan fasting compared to the gastric acid level before fasting.<sup>9</sup>

The difference of DSSI score in group A compared to group B after intervention and Ramadan fasting for 2 weeks revealed higher score improvement in group B compared to group A. This difference was statistically significant, because obtained  $p = 0.02$ . This result showed that administration of omeprazole 20 mg twice daily to dyspepsia patients who will do fasting is beneficial in preventing worsening of dyspepsia complaints.

Limitations of this study mainly were small sample size and short duration of data collection. Limited sample size was caused by difficulty in collecting samples and number of dropouts due to several factors, such as menstruation in female, not performing fasting completely during the period of the study; hence, those samples were not included in the study.

## CONCLUSION

From the study which has been performed, it was found that dyspepsia patients were mostly females, most notable complaints were combination of epigastric pain and fullness/bloating (EPS + PDS), and most frequent risk factor of dyspepsia was irregular meal timings. There was significant decrease of DSSI score in study subjects who performed fasting and consumed omeprazole.

Similar study could be done better by collecting more samples to obtain optimal results and it was expected that this study can be applied in medical practice as part of management in dyspepsia patients who will perform Ramadan fasting.

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