

EFFECTIVENESS OMEPRAZOLE AND LANSOPRAZOLE IN DYSPEPSIA PATIENT WITH NEPEAN DYSPEPSIA INDEX

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ABSTRAK

Pada pasien dengan dispepsia, strategi manajemen umum awal dalam perawatan primer adalah untuk meresepkan program terapi antisekresi empiris. Lansoprazole dan omeprazole sebagai agen antisekresi telah terbukti efektif untuk pengobatan dispepsia. Penelitian ini bertujuan untuk membandingkan efek Omeprazol (1 x 20 mg) dan lansoprazole (1x 30 mg) kepada pasien rawat jalan dispepsia dengan menggunakan kuesioner kualitas hidup Nepean Indeks Dispepsia (NDI) di RSUD. Prof Dr Margono Soekardjo Purwokerto Juni sampai Agustus 2009. Indeks dispepsia (NDI) yang diterjemahkan dan divalidasi dalam bahasa Indonesia. Sejumlah 79 subyek dengan diagnosis klinis dispepsia sesuai dengan kriteria inklusi direkrut dan acak untuk menerima Omeprazole 20 mg sekali sehari dan lansoprazole 30 mg sekali sehari. Gejala dispepsia dievaluasi dengan menggunakan NDII pada awal satu minggu setelah pengobatan. Hasil dari Omeprazole dan lansoprazole dievaluasi dengan membandingkan peningkatan skor NDII dalam 5 domain (ketegangan, kegiatan, makan/minum, pengetahuan/kontrol dan kerja/belajar). Setelah satu pengobatan minggu, pasien dispepsia NDI skor dalam kelompok lansoprazole diperlakukan sangat berbeda dari yang dalam kelompok Omeprazol diperlakukan dalam kegiatan domain dan makan/minum. Kesimpulannya, efek lansoprazole adalah lebih baik daripada Omeprazol ketika diberikan sebagai pengobatan empiris untuk dispepsia pasien.

ABSTRACT

In patients with dyspepsia, a common initial management strategy in primary care is to prescribe a course of empiric antisecretory therapy. Lansoprazole and omeprazole as antisecretory agents have been proven effective for treatment of dyspepsia. This study was aimed is to compare the effect of Omeprazole (1 x 20 mg) and Lansoprazole (1x 30 mg) to ambulatory dyspepsia patient by using questionnaire quality of life Nepean Dyspepsia Index (NDI) in RSUD. Prof. Dr. Margono Soekardjo Purwokerto Juny until August 2009. Dyspepsia Index (NDI) which was translated and validated in Indonesian language. A number of 79 subjects with a clinical diagnosis of dyspepsia according to the inclusion criteria were recruited and randomized to receive Omeprazole 20 mg once daily and Lansoprazole 30 mg once daily. Symptoms of dyspepsia were evaluated by using NDII at baseline one week after treatment. The outcomes of Omeprazole and Lansoprazole were evaluated by comparing improved NDII score in 5 domains (tension, activities, eating/drinking, knowledge/control and work/study). After one week treatment, the NDII dyspepsia patients score in Lansoprazole treated group was significantly different from that in Omeprazole treated group in domains activities and eating/drinking. In conclusion, the effect of Lansoprazole was better than Omeprazole when it was given as empirical treatment for dyspepsia patients.

Keywords: Dyspepsia, NDI, Lansoprazole, Omeprazole

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INTRODUCTION

Dyspepsia is a collection of complaints/clinical symptoms consisting of malaise/upper abdominal pain that persisted or have a relapse. Based on Rome II criteria in 2000 dyspepsia is defined as dyspepsia refers to pain or discomfort centered in upper abdomen (Talley et al. 2000). Various epidemiological studies have been conducted and found the prevalence varies between 15-40% of adults had experienced dyspeptic symptoms or relapse (Tack et al. 2004, Talley et al. 2002). Prevalence in SMF. Internal Medicine General Regional Hospital Prof. dr. Margono Soekardjo Navan, in the period from

January - December 2005 obtained by 29% (Arinton 2008).

Dyspepsia is common in the community and is an important health problem particularly in relation to the economic and clinical aspects (Moayyedi & Mason 2002). Improved quality of life need to be considered because it is one measure of therapeutic outcome and disease symptoms include the loss as a measure of objectivity penurunan therapy-related morbidity and mortality (Talley et al. 2001). Problems associated with the absence of treatment guidelines that are universal in the response to dyspepsia. Various guidelines have been

proposed in which empirically with antisecretory treatment of the most widely used, especially in primary health care (Talley & Vakil 2005).

American Gastroenterological Association (AGA) offers four strategies in the management of uninvestigated dyspepsia in primary health care (Brennan et al. 2002). Two such strategies is through testing and eradication of *H. pylori* as the initial action and therapy. According to Talley, when *H. pylori* positive > 10% then it should be testing and eradication of *H. pylori* (Talley & Vakil 2005). However, studies that have been reported in Indonesia the prevalence of *H. pylori* between 7 to 10.2% (Sham et al. 2006). Therefore, empiric therapy with antisecretory is an economical choice.

Based on the above condition then the emergence of data supporting the use of Proton Pump Inhibitor (PPI) on dyspepsia. Three factors support the strategy of PPI use in dyspepsia are: (1) PPI may improve symptoms of non ulcer dyspepsia, (2) empirical PPI therapy is effective in many cases Gastroesophageal reflux disease (GERD), (3) PPI may accelerate the reduction of symptoms of peptic ulcer disease (Brennan et al. 2002). According to the Cochrane review that Antacids, H₂ blockers Sukralfat and no better than PPI in addressing cases of dyspepsia (Moayyedi et al. 2003)

Nepean dyspepsia index (NDI) was first developed in Sydney, was a questionnaire instrument used to measure symptoms and quality of life of patients with dyspepsia. Selection of NDI in this study because it is one specific quality of life questionnaire in dyspepsia, which is divided into 5 domains with 10 pieces of questions involves the ability to eat & drink, tension, knowledge or control, work or study and restriction of daily activities (Talley 2002).

This study used the NDI has been translated into Indonesian (NDII). The NDII used has been through a validation test with a correlation coefficient > 0.27 and internal consistency values > 0.7 (Arinton et al. 2006). Therefore the background above then designed a test of the effectiveness of Omeprazole and Lansoprazol in patients with dyspepsia using NDII.

MATERIALS AND METHODS

The study was conducted at the Poli Prof Medicine Hospital. Margono Soekardjo Navan and an experimental research (true experimental), with a

research design "The two-group pretest-posttest design" using the tools of validated questionnaires and rehabilitasi NDII. The division of the group performed "Simple Random Sampling" by using a lottery. The study was conducted during June-August 2009 and obtained a sample of 89 patients with dyspepsia who came to Poly Margono Medicine Hospital, met the inclusion criteria as many as 79 patients. There were 10 patients out of the study (drop outs) on the grounds of 3 patients drank alcohol, smoked 5 people and 2 on the third day endoscopy study. Before it is taken as a sample, patients were given education about dyspepsia, research SOPs and sign a consent form the patient. In this case there is no compulsion for patients to participate in the study. Furthermore, patients filled out questionnaires NDII assisted by investigators. In the analysis of each data domain of each group on NDI conducted Wilcoxon test and each domain group Lansoprazol Omeprazole and analyzed using the Mann-Whitney test.

RESULTS

Most dyspeptic patients are women (93.7%) with status does not work (housewives) (78.5%) and the last is elementary school education (49.4%). While the sample age range was 18-45 years with an average age of 34 years of age and most up was 39 years (11.4%). Results showed that demographic data from both groups had no significant difference ($P > 0.05$) or demographic data from both groups were homogeneous. Wilcoxon nonparametric statistical test on the domain NDII (tension, daily activities, eating & drinking abilities, knowledge and work/study) for the two treatment groups and Lansoprazol Omeprazole showed no difference in effectiveness between the pre and post therapy in NDII domains ($p < 0.05$) (Table 1)

Table 1. Wilcoxon test results of data pre and post Omeprazole and Lansoprazol

NDI Domain	Omeprazol	Lansoprazol
	P value (n=40)	P value (n= 39)
Tension	0	0
Daily activities	0	0
Eating and drinking	0	0
Knowledge	0	0
Working/studying	0	0

Table 2. Data from Maan-Whitney test and Lansoprazol Omeprazole group

Domains	P value n= 79
Tension	0.105
Daily activities	0.019
Eating and drinking	0.02
Knowledge	0.309
Working/studying	0.057

Table 3. Data on the number of patients who experienced the effectiveness of pre and post differences

Domain	Omeprazol			Lansoprazol		
	Effect <i>post</i> > <i>pre</i>	Effect <i>post</i> < <i>pre</i>	Effect <i>post</i> = <i>pre</i>	Effect <i>post</i> > <i>pre</i>	Effect <i>post</i> < <i>pre</i>	Effect <i>post</i> = <i>pre</i>
	n	n	n	n	n	n
Tension	28	1	11	32	1	6
Daily activities	31 (77.5%)	1	8	36 (92.3%)	1	2
Eating and drinking	30 (75%)	1	9	35 (89.9%)	1	3
Knowledge	29	0	11	30	1	8
Working/studying	30	1	9	35	1	3

After doing the Wilcoxon test in each treatment group, followed by a nonparametric Mann-Whitney test between groups Omeprazole and Lansoprazol on NDII domain (Table 2). There were significant differences ($p < 0.05$) in the domain daily activities and ability to eat and drink. To find more effective therapies on the domain daily activities and ability to eat & drink, do the calculation the percentage of patients in the Omeprazole and Lansoprazol. Percentage calculation based on the number of patients who experienced improvement effectiveness of pre and post drug treatment (Table 3).

In the domain daily activities and ability to eat and drink, there is an increase in effectiveness after therapy than before (the effects of $\text{post} > \text{pre}$). Percentage increase in effectiveness Lansoprazol higher than Omeprazole.

DISCUSSION

The research was conducted during June - August 2009 and found 79 patients who entered dyspepsia in the inclusion criteria. From the results of demographic analysis, most samples with the status of female sex does not work (housewives) and the last primary school education. This is probably because women tend to not be able to withstand the pain than men. Status as a housewife may influence the therapy because of the level of stress that arises when a woman has to take care

of children, husbands and psychosocial relationships (McDonough & Walters. 2001).

Despite the pressure of stress faced by each individual is different, it is known that stress can affect individual etiopatogenesis as digestive disorders, although through mechanisms that are not clear. This statement is dikemukakan also by Richard in his study with a sample of 70% of women concluded that women average age 33 years with the status of marriage would be susceptible to stress and significantly affect the impairment of GI function (Richard L et al. 2004). It resembles the results of research conducted by researchers with the number of samples of women (93.7%) and the average age of 34 years.

In the study 10 people found the exclusion was due to smoking, drinking alcohol. Cigarettes and alcohol will stimulate the nerves secrete HCl via impulses in the hypothalamus which was subsequently accepted by the vagus nerves. This led to increased production of hormones that affect the secretion of HCl include gastrin, histamine and acetylcholine (Mejia & Kraft 2009). Excessive secretion of HCl will cause digestive disorders like dyspepsia. So that researchers categorize smoking and drinking alcohol as a confounding variable that must be excluded. The effect of pain does not decrease after 3 days of drug use may be due to patients suffering from organic dyspepsia. For that we need to do further tests.

Nonparametric test used was Wilcoxon to distinguish the effectiveness of pre and post therapy in each treatment group and the domain Mann-Whitney to distinguish the therapeutic effectiveness of each domain in both treatment groups. According to the Wilcoxon test, no significant differences between pre and post therapy each domain in the Omeprazole and Lansoprazol with $P < 0.05$. These results are similar to other studies which concluded that Omeprazole and Lansoprazol effective in patients with dyspepsia (Philip et al. 2003).

Subsequent data analysis to detect differences in the effectiveness of each domain between groups Omeprazole and Lansoprazol through Mann-Whitney nonparametric test. Table 2 looks at price $P < 0.05$ for the domain daily activities and ability to eat & drink. So based on these data concluded no significant differences between groups of Omeprazole and Lansoprazol in both domains. To find a more effective drug therapies performed calculations on the percentage of both domains. Domain everyday activities Omeprazole group of 77.5% (31 patients) said there was improvement between pre and post therapy while in the group Lansoprazol of 92.3% (36 patients) who said something similar. For the domain the ability to eat and drink in the Omeprazole group contained 75% (30 patients) said there was improvement between pre and post therapy while in the group Lansoprazol of 89.9% (35 patients) say the same thing. The results of these calculations can be concluded Lansoprazol more effective in reducing symptoms of dyspepsia in the domain daily activities and ability to eat & drink.

This is probably caused by differences in pharmacokinetics and pharmacodynamics Omeprazole and Lansoprazol. Omeprazole has a bioavailability 35-60% while Lansoprazol about 80%. Asian nations will experience a "poor metabolizer" by 20% due to the racemic form of Omeprazole. This leads to an increase in AUC and plasma drug levels. Lansoprazol while not having "poor metabolizer" (Mejia & Kraft 2009). In theory Lansoprazol more effective in reducing symptoms of dyspepsia and the theory is consistent with the results of this study.

CONCLUSION

In this study concluded that the effectiveness of therapy is indicated from NDII showed no significant difference in patient quality of life between pre-and post-therapy with Omeprazole and Lansoprazol $P < 0.05$ (Wilcoxon test) and $P < 0.05$ (Mann-Whitney test) domain restrictions on daily activities- day and ate and drank. The results of the percentage of domain restriction of

daily activities showed Omeprazole group (77.5%) and Lansoprazol (92.3%) while the ability to eat and drink Omeprazole group (75%) and Lansoprazol (89.9%). Use of Lansoprazol (1x30 mg) is more effective than Omeprazole (1x20 mg) in the case of dyspepsia measured by NDII.

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