Treatment of Laryngopharyngeal Reflux: A Comparison between Domperidone Plus Omeprazole and Omeprazole Alone

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Objective: *To evaluate the efficacy of domperidone in combination with omeprazole in the treatment of laryngopharyngeal reflux (LPR) compare to omeprazole alone.*
Material and Method: *A prospective and randomized study included seventy patients with a reflux symptom index (RSI) 13 or more. They received either domperidone 10 mg thrice daily plus omeprazole 20 mg twice daily or omeprazole alone for three months. RSI was assessed at baseline and after three months of treatment.*
Results: *Total RSI as well as several subscores were comparable between groups before the treatment. After three months of the treatment, moderate improvement of total RSI was shown in both groups (72.7%, 67.5%). The reduction of total RSI and individual subscores were statistically significant within each group ($p < 0.001$ each). Comparing between each treatment group, the mean difference of total RSI and individual subscores did not shown any statistically differences ($p > 0.05$ each) at the end of the study period.*
Conclusion: *Domperidone in combination with omeprazole is not superior to omeprazole alone in the treatment of LPR.*

Keywords: *Domperidone, Prokinetic, Omeprazole, Proton pump inhibitor, Laryngopharyngeal reflux*

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Laryngopharyngeal reflux (LPR) is the result of retrograde flow of gastric contents up into the laryngopharynx or the hypopharynx, where it comes in contact with mucosa of the pharynx and the larynx. Refluxed contents from the stomach, including acid and pepsin, may lead to direct chemical injuries and inflammation of the mucosa of the laryngopharyngeal structures, or may indirectly stimulate vagal reflex in this area. It has been reported in up to 10% of patients presenting to an otolaryngologist's office[1]. Many symptoms associate with LPR, such as, lump in throat, throat clearing, excessive throat mucus, chronic sore throat, chronic cough, hoarseness, dryness of throat, dysphagia, and odynophagia[1-3]. Belafsky et al[4] have developed a self-assessment tool, the Reflux Symptom Index (RSI), which could help clinicians assess the relative degree of LPR symptoms during initial evaluation and after treatment. Patients are asked to use a 0- to 5-point scale to grade the 9-item symptoms (Table 1). From the present study, RSI correlated well with LPR and the RSI score greater than 13 is suggestive of LPR. Diagnosis of LPR was best achieved by demonstration of reflux events with ambulatory 24-hour double-probe pH monitoring[5]. The treatments of LPR are lifestyle and dietary modification, medical and surgical treatments. The recommended medical treatment is twice-daily-dose proton pump inhibitor (PPI) for three to six months[6,7]. Many PPI were used for treatment, such as, omeprazole, esomeprazole, pantoprazole, lansoprazole and rabeprazole.

However, there is some controversy regarding the adequate PPI dosage and even, the efficacy of these drugs for LPR treatment[7-9]. Prokinetic drugs, such as, metoclopramide, domperidone and cisapride, are theoretically useful in LPR because of their effects in increasing gastrointestinal motility and lower esophageal sphincter pressure. Cisapride has been discontinued due to serious adverse effects of ventricular arrhythmias and diarrhea[10]. Metoclopramide also had adverse effects of central nervous systems and extrapyramidal tract symptoms[11]. Domperidone is

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Table 1. The reflux symptom index

Within the last month, how did the following problems affect you? Circle the appropriate response	0 = No problem 5 = Severe problem					
1. Hoarseness or a problem with your voice	0	1	2	3	4	5
2. Clearing your throat	0	1	2	3	4	5
3. Excess throat mucus or postnasal drip	0	1	2	3	4	5
4. Difficulty swallowing food, liquids, or pills	0	1	2	3	4	5
5. Coughing after you ate or lying down	0	1	2	3	4	5
6. Breathing difficulties or choking episodes	0	1	2	3	4	5
7. Troublesome or annoying cough	0	1	2	3	4	5
8. Lump in throat sensations	0	1	2	3	4	5
9. Heartburn, dyspepsia, or stomach acid coming up	0	1	2	3	4	5

Adapted from Belafsky et al[4]

a prokinetic drug that acts by peripheral dopamine antagonist without crossing blood-brain barrier, thus avoiding central nervous system adverse symptoms[12,13]. Systematic review had revealed the efficacy of domperidone in reducing the symptoms of GERD in children[14]. Combination of PPI and prokinetic drugs had been used for the treatment of patients with GERD or LPR in many studies. Some studies showed effectiveness in the treatment[15,16] but some studies did not[17,18]. Therefore, the objective of the present study was to evaluate the efficacy of empiric treatment of LPR with combination of domperidone and omeprazole compared to omeprazole alone.

Material and Method

Between January 2009 and July 2010, a randomized, prospective controlled trial was performed in the patients with LPR who met the following criteria (Table 2). A total of seventy patients were enrolled into the present study. The present study was approved by the Ethic Review Boards of the Faculty of Medicine, Srinakharinwirot University.

Study procedures

Patients passing all inclusion and exclusion criterias were randomized to receive either domperidone 10 mg thrice daily plus omeprazole 20 mg twice daily or omeprazole twice daily alone for three months. All included subjects were instructed to take the medication at about 30-60 minutes before meals. Enrolled patients were advised to follow lifestyle modifications as instructional papers to reduce acid reflux, such as, avoidance of fatty meals, spicy food, caffeine, alcohol, smoking, too tight clothing and avoid lying down within 3 hours after meals. The primary objective of the study was to compare the total RSI and individual subscores after the treatment period of three months. Four categories of the interpretation of the study were divided by comparing total RSI before and after the treatment. These four categories were recovery, moderate improvement, mild improvement and no improvement according to percentages of improvement, 80 or more, 50-79, 10-49 and less than 10, respectively.

Statistical analysis

Baseline characteristics of both groups were reported as mean values and standard deviations (SD) and were compared using the t-test and the Chi-square test for categorical variables (Table 3). Differences in mean changes between two groups were additionally tested using independent and paired t-test (Table 4, 5). A p-value < 0.05 was considered statistically significant.

Table 2. Criteria of the study

Inclusion criteria
1. Patient's age 18 years or more
2. Reflux symptoms index (RSI) 13 or more

Exclusion criteria
1. History of allergy to domperidone
2. Patients who had laryngeal malignancy or vocal fold mass, or history of previous gastrointestinal tract surgery
3. Patients with history of cardiac arrhythmias
4. Pregnant patients or on breast feeding
5. Psychiatric patients

Discontinuation criteria
1. Allergy or adversed effects to drugs
2. Patients who not willing to continue in the study

Results

Sixty-five patients completed the present study. Thirty-two patients who received omeprazole plus domperidone were the study group and thirty-three patients who received omeprazole alone were the control group. Baseline characteristics between the two study groups were comparable (Table 3). Age and gender were not statistically different between the two groups (p = 0.414, 0.948). LPR was more common in female than male in both groups (ratio 3.6-3.7:1). Total RSI before treatment did not show significant difference in both groups (p = 0.154) (Table 3). When considering the 9-item symptoms of RSI, item 8 (Lump in throat sensations) and item 9 (Heartburn, dyspepsia)

Table 3. Comparison of baseline characteristics of LPR patients

Characteristic	Omeprazole plus domperidone	Omeprazole alone	p-value
Age (yr)			
Mean ± SD	45.84 ± 1.61	47.00 ± 2.26	0.414*
Range	21-70	23-69	
Gender			
Male:Female	7:25	7:26	0.948+
Total RSI before treatment (mean ± SD)	19.67 ± 6.11	22.09 ± 5.62	0.154*

LPR = laryngopharyngeal reflux; RSI = reflux symptom index; SD = standard deviation
+ Chi-square test, * t-test

Table 4. Change of RSI after three months of treatment

RSI	Before	After	Difference	p-value+
Study group	19.67 ± 1.18	5.37 ± 0.92	14.30 ± 1.28	<0.001
Control group	22.09 ± 1.17	7.17 ± 1.16	14.91 ± 1.06	<0.001
p-value*	0.154	0.223	0.718	

Data are given as mean differences ± standard error of the mean (SEM), RSI = reflux symptom index
+ p-value in each group = paired t-test, * p-value when comparison between both group = independent t-test

Table 5. Change of RSI within each group after three months

RSI	Study group			Control group			p-value^
	Pre	Post	Diff (p)	Pre	Post	Diff (p)	
Hoarseness	1.70	0.78	0.93 ± 0.22*	1.83	0.70	1.13 ± 0.20*	0.502
Clearing throat	2.07	0.59	1.48 ± 0.27*	2.78	1.00	1.78 ± 0.23*	0.411
Throat mucus	2.33	0.70	1.63 ± 0.25*	2.91	1.17	1.74 ± 0.22*	0.745
Difficulty swallowing	2.07	0.52	1.56 ± 0.31*	2.26	0.43	1.83 ± 0.30*	0.535
Coughing after eating	1.59	0.33	1.26 ± 0.28*	1.78	0.61	1.17 ± 0.26*	0.826
Breathing difficulties	1.81	0.56	1.26 ± 0.30*	2.35	0.65	1.70 ± 0.28*	0.302
Annoying cough	1.48	0.11	1.37 ± 0.29*	1.57	0.52	1.04 ± 0.23*	0.392
Lump in throat sensations	3.41	0.96	2.44 ± 0.30*	3.13	0.83	2.30 ± 0.29*	0.741
Heartburn, dyspepsia	3.19	0.81	2.37 ± 0.35*	3.48	1.26	2.22 ± 0.28*	0.739

RSI = reflux symptom index; Pre = before treatment; Post = after treatment; Diff = mean difference ± standard error of mean
p-values are from paired t test
* p < 0.001, ^ p-values comparison between two groups

were the two most common presenting symptoms in both groups. The improvements of total RSI in the present study and control groups were moderate (72.7% and 67.5% respectively). The reduction was statistically significant in both groups ($p < 0.001$) (Table 4). This was also true for all respective subscores of RSI compared to before the treatment ($p < 0.001$) (Table 5). However, differences in total RSI and individual subscores between the study and the control group were not statistically significant ($p > 0.05$) (Table 4, 5).

Discussion

The present study could not demonstrate any additional benefits of domperidone in the treatment of LPR patients. This result is comparable to some previous reports that showed ineffectiveness of prokinetic drugs combined with PPI for treating patients with LPR or GERD[17,18]. On the other hand, some reports demonstrated the benefits of prokinetic drug, either alone or combined with PPI, in the treatment of patients with LPR or GERD[15,19,20]. Smythe et al[17] investigated two groups of patients with Barrett's esophagus on PPI therapy, one group combined with prokinetic (cisapride, n = 12) and another group received placebo (n = 11). The results showed no significant difference between the two groups with respect to Duodenogastro-esophageal reflux (DGER), DGER characteristics, or the percentage of peristalsis and simultaneous waves and their characteristics. They concluded that addition of cisapride to PPI treatment did not appear to improve esophageal motility or reduce DGER in patients with Barrett's esophagus. The limitation of the present study was the small number of studied population that may question on reliability of the outcome. Van Rensberg et al[18] performed a study that recruited rather a large number of the population. They investigated whether pantoprazole plus cisapride leads to an additional benefit in treatment of GERD compared to pantoprazole alone. They conducted a randomized double-blind prospective multicentre study of thirty-three hospitals in Ireland, South Africa and the UK. Three hundred and fifty patients aged eighteen years or older with GERD were included in the present study. Patients received either pantoprazole 40 mg once daily or pantoprazole 40 mg once daily plus cisapride 20 mg twice daily. After four weeks of treatment 81% and 82%, and after eight weeks 89% and 90%, of patients treated with pantoprazole or pantoprazole plus cisapride were healed, respectively. They concluded that the addition of cisapride to pantoprazole provided no further benefit in the treatment of GERD. However, this conclusion came from high success rates of treatment with pantoprazole in both groups, which might cause such a result. The difference between the present study and the two studies above is that the previous studies used cisapride as a prokinetic drug and all the patients were GERD, not LPR. Nonetheless, the result was similar.

On the contrary, Ishoo[15] reported a significant effectiveness of tegaserod, a prokinetic drug, in the treatment of patients with LPR and concurrent Irritable Bowel Syndrome with Constipation (IBS-C). He performed a retrospective cohort analysis of twenty-two female patients. The patients were placed on tegaserod for symptomatic IBS-C while being followed for LPR unresponsive to lifestyle changes and twice-daily maximal dose PPI therapy for a minimum of twelve weeks. At the end of the present study period, marked improvements were noted in patients' RSI and RFS in 82% and 77%, respectively. He concluded that tegaserod might have a role in the treatment of LPR due to gastroesophageal dysmotility causing acidic or non-acidic extraesophageal gastric reflux. These results might differ from the present study because of a different kind of prokinetic drug and a rather small sample sizes. The other study by Sharma B et al[19] had revealed the role of domperidone plus omeprazole in the treatment of GERD in adult asthmatic patients. They treated one hundred and ninety-eight asthmatics with GERD diagnosed by 24-h esophageal pH monitoring. One group received omeprazole 20 mg twice daily and domperidone 10 mg three times daily while the other group received placebo for sixteen weeks. After the treatment period, significant reduction in daytime asthma symptom score, nighttime asthma symptom score, reflux symptom score and rescue medication use were revealed. This trial was different from the present study in that they conducted it in patients with GERD, not LPR, and they did not compare between omeprazole combined with domperidone and omeprazole alone so those results might come from omeprazole alone.

Another study from Karhilas et al[20] also demonstrated roles of tegaserod, alone, in treating GERD. They evaluated the efficacy of tegaserod compared to placebo in nineteen patients. They found that tegaserod in a dose of 1 mg/day causes a significant decrease in postprandial esophageal acid exposure which might result from enhanced esophageal acid clearance, improved gastric emptying and/or reduced transient lower esophageal sphincter relaxations. The

differences of this article from the present report were the type of prokinetic drug used, no combined PPI and all cases were GERD instead of LPR. Tegaserod were shown effective for treating LPR or GERD in the above two studies[15,20]. However, further studies are needed to confirm this result.

Comparison between PPI and prokinetic drugs for LPR patients has been studied by Chung et al[21]. Sixty-two patients were randomly allocated either to the four weeks of prokinetics (n = 31) or PPI (n = 31) medication. They founded that short-term PPI therapy was more highly effective than prokinetics in selected LPR patients. This research compared the efficacy of PPI and prokinetic drug as a single treatment unlike the present report demonstrating that domperidone gives no additional benefits for the treatment of LPR.

The efficacy of omeprazole from the present study was statistically significant in both groups. This favorable result of PPI for treatment patients with LPR corresponds well with the latest report from Lam et al[22]. The total reflux symptom index score decreased significantly in the rabeprazole group, compared to the placebo group, at weeks sixth and twelfth, but not at week eighteenth. However, there were no significant differences in reflux finding scores between the rabeprazole and placebo groups at any of the time points. They concluded that twelve weeks of treatment with rabeprazole significantly improved reflux symptoms, compared with placebo, in patients with LPR. Nonetheless, relapses of symptoms were observed six weeks after stopping PPI therapy, indicating the requirement for longer treatment duration in patients with LPR.

Another study from Richel et al[23] also demonstrated effectiveness of another PPI for LPR treatment. They conducted a prospective, double-blind, randomized, placebo-controlled study. Sixty-two patients with a reflux finding score (RFS) > 7 and a reflux symptom index (RSI) > 13 were enrolled and received either esomeprazole 20 mg twice daily or placebo for three months. They found reductions of total RSI and RFS as well as of several subscores that were significantly higher in the treatment group compared to placebo.

A controversy about the efficacy of PPI in treatment for patients with LPR remains. Reimer et al[9] reviewed on the topic of management of LPR with PPI. Seven placebo-controlled trials[24-30] were identified and included in their review. All studies evaluated the effect of a PPI on symptoms and objective laryngoscopic findings in suspected LPR. Data from these trials showed that PPI therapy was not more effective than placebo in producing symptom relief in patients suspected of LPR. They found high placebo response levels that suggested a much more complex and multifactorial pathophysiology of LPR than simple acid reflux. They proposed further studies to characterize subgroups of LPR patients that might benefit from treatment with PPI. However, this review did not mention about prokinetic drugs.

Some critical aspects of this trial might be the fact that the present study did not use reflux finding scores (RFS) and a 24-hour double-probe pH monitoring as the measured outcomes. The reason was RFS might be subject to examiners' bias and the preliminary report of Belafsky et al[31] showed that the physical findings of LPR resolved more slowly than the symptoms. Evidence showed that only a small proportion of their patients undergoing pH monitoring had documented pharyngeal acid exposure despite typical LPR symptoms and laryngoscopic signs[29]. The sensitivity of pH monitoring for the detection of proximal esophageal or hypopharyngeal reflux episodes might not be more than 50%[29]. Another argument against performing pH monitoring before inclusions is the fact that more and more authors doubt that 24-hour pH monitoring, although supposed to be the gold-standard test for LPR, is the preferable initial step in the work-up of most patients with LPR[27,29,32]. According to the reports of other authors, patients tolerance is poor for this procedure[28]. A third limitation of the present study might be the short follow-up of twelve weeks so that recurrence rate cannot be evaluated.

Although the present study could not demonstrate any additional benefits of domperidone in LPR treatment, significantly high response rates were obtained from both treatment groups. One reason was the efficacy of omeprazole in both groups. Another reason for this could be the positive influence of dietary and lifestyle modifications on symptoms improvements in these patients. This result might confirm the opinion of many authors; not to underestimate the impact of dietary and lifestyle modifications[1,6]. To assess the influence of a possible placebo effect in these patients, a blinded study with a separate control population would have been necessary.

Conclusion

The present study could not demonstrate any additional benefit of domperidone for the treatment of

patients with LPR. However, the total RSI and all subscores were significantly reduced in both groups after a treatment period of three months. This result showed the high success of treatment in both groups, which might be from the effect of omeprazole itself or combined with the effect of dietary and lifestyle modifications.

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Potential conflicts of interest

None.

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การประเมินผลการใช้ยา domperidone ร่วมกับ omeprazole ในการรักษาผู้ป่วยกรดไหลย้อนเข้าคอ

นิรันดร์ หุ่นฉายศรี

วัตถุประสงค์: *เพื่อประเมินประสิทธิภาพของยา domperidone ร่วมกับ omeprazole เปรียบเทียบกับยา omeprazole เพียงอย่างเดียวในการรักษาโรคกรดไหลย้อนเข้าคอหรือ laryngopharyngeal reflux (LPR)*

วัสดุและวิธีการ: *เป็นการศึกษาแบบ prospective, randomized ทำในผู้ป่วยจำนวน 70 รายที่มีค่า reflux symptom index (RSI) เท่ากับ 13 หรือมากกว่า โดยแบ่งผู้ป่วยเป็น 2 กลุ่ม ๆ หนึ่งได้รับยา domperidone ขนาด 10 มก. วันละ 3 เวลาร่วมกับยา omeprazole ขนาด 20 มก. วันละ 2 เวลาและอีกกลุ่มหนึ่งได้รับยา omeprazole ขนาด 20 มก. วันละ 2 เวลาอย่างเดียว โดยให้ยานาน 3 เดือน การประเมินผลการศึกษาดูจากค่า RSI ก่อนการรักษาและหลังการรักษาครบ 3 เดือน*

ผลการศึกษา: *ก่อนศึกษาไม่พบความแตกต่างของค่า RSI รวมและค่าย่อยในระหว่างผู้ป่วยทั้ง 2 กลุ่ม หลังการรักษาครบ 3 เดือน พบ moderate improvement ของค่า RSI รวมในผู้ป่วยทั้ง 2 กลุ่ม (72.7%, 67.5%) หลังการรักษาพบการลดลงของค่า RSI รวมและค่าย่อยภายในกลุ่มผู้ป่วยเดียวกันมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p < 0.001$ ในแต่ละค่า) เมื่อเปรียบเทียบค่า RSI รวมและค่าย่อยในระหว่างผู้ป่วยทั้ง 2 กลุ่ม หลังการรักษาครบไม่พบว่ามีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p > 0.05$ ในแต่ละค่า)*

สรุป: *การให้ยา domperidone ร่วมกับ omeprazole มีประสิทธิภาพไม่ดีกว่าการให้ยา omeprazole เพียงอย่างเดียวในการรักษาโรคกรดไหลย้อนเข้าคอ*