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A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF COMPARATIVE EFFICACY AMONG VONOPRAZAN AND PROTON PUMP INHIBITORS FOR HEALING OF REFLEX ESOPHAGITIS

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Objective: To evaluate the comparative efficacy among vonoprazan, a potassium-competitive acid blocker, and proton pump inhibitors (PPIs) for healing of reflux esophagitis. Methods: MEDLINE and Cochrane Central Register of Controlled Trials (CENTRAL) were used to search literatures. Selected articles were double-blind randomized controlled trials (RCTs) written in English or Japanese of vonoprazan and/or PPIs and/or placebo for healing of adult reflux esophagitis patients. Eligible studies were those conducted using recommended dosage(s) and administration, and which included information about healing rate. Number of all patients randomized (intent-to-treat population), and those who achieved treatment success were extracted from the studies. Bayesian network meta-analyses were carried out using White et al. (2011)’s consistency models where the consistency assumption among studies was assessed via a Wald-like test statistic in fitted inconsistency models and deviance informative criterion. WinBUGS were used to analyze data in this study. Results: Of 4,001 articles identified in the database search, 42 RCTs were eligible. One study described in a package insert was also included from a manual search. A total of 14 drugs including placebo were extracted; and the direct comparison network diagram was created as shown in Figure 1. The consistency hypothesis was not rejected. Odds ratios of vonoprazan (20 mg) to esomeprazole (20 mg), rabeprazole (20 mg), lansoprazole (30 mg), and omeprazole (20 mg) were 5.28 (95% credible interval [CI], 1.01-38.7), 12.19 (95% CI, 2.23-100), 5.36 (95% CI, 1.14-38.7), and 6.31 (95% CI, 1.26-44.5), respectively. Limitations: Differences of attribute of each patient group (mean age, sex ratio, severity, etc.) and treatment period in each RCT may affect the analysis. Study for vonoprazan was only one, which may affect the analysis as well. Conclusion: Healing effect of vonoprazan for reflux esophagitis is likely to be greater than PPIs which are prescribed in Japan according to our network meta-analysis. It is desirable to conduct direct comparison studies between vonoprazan and these drugs to confirm this result. Systematic Review Registration Number PROSPERO registry CRD42015024880

WinBUGS were used to analyze data in this study. Results: Of 4,001 articles identified in the database search, 28 RCTs were eligible. A total of 14 drugs including placebo were extracted; and the diagram was created as shown in Figure 1. As the result of inconsistency test, consistency hypothesis was not rejected. Odds ratios of vonoprazan (10 mg) to esomeprazole (20 mg), rabeprazole (10 mg), lansoprazole (15 mg), and omeprazole (20 mg) were 2.57 (95% credible interval [CI], 0.68-9.52), 6.04 (95% CI, 1.43-25), 7.83 (95% CI, 1.72-34.3), and 8.01 (95% CI, 0.96-81.6), respectively. Limitations: Differences of attribute of each patient group (mean age, sex ratio, severity, etc.) and treatment period in each RCT may affect the analysis. For many treatment dosages only one trial arm was available for analysis. Conclusions: It is suggested that the maintenance effect of vonoprazan for reflux esophagitis was on the same or higher level than PPIs based on the network meta-analysis. Direct comparison studies between vonoprazan and these drugs should be conducted to confirm this result. Systematic Review Registration Number PROSPERO registry CRD42015024880

Figure 1. The direct comparison network diagram of maintenance treatment of included studies. TD, twice daily; 3TD, 3 times daily, number of studies are shown as numerical values.

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A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF COMPARATIVE EFFICACY AMONG VONOPRAZAN AND PROTON PUMP INHIBITORS FOR MAINTENANCE TREATMENT OF REFLEX ESOPHAGITIS

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Objective: To evaluate the comparative efficacy among vonoprazan, a potassium-competitive acid blocker, and proton pump inhibitors (PPIs) for healing of reflux esophagitis. Methods: MEDLINE and Cochrane Central Register of Controlled Trials (CENTRAL) were used to search literatures. Selected articles were double-blind randomized controlled trials (RCTs) written in English or Japanese of vonoprazan and/or PPIs and/or placebo for healing of adult reflux esophagitis patients. Eligible studies were those conducted using recommended dosage(s) and administration, and which included information about healing rate. Number of all patients randomized (intent-to-treat population), and those who achieved treatment success were extracted from the studies. Bayesian network meta-analyses were carried out using White et al. (2011)’s consistency models where the consistency assumption among studies was assessed via a Wald-like test statistic in fitted inconsistency models and deviance informative criterion. WinBUGS were used to analyze data in this study. Results: Of 4,001 articles identified in the database search, 42 RCTs were eligible. One study described in a package insert was also included from a manual search. A total of 14 drugs including placebo were extracted; and the direct comparison network diagram was created as shown in Figure 1. The consistency hypothesis was not rejected. Odds ratios of vonoprazan (20 mg) to esomeprazole (20 mg), rabeprazole (20 mg), lansoprazole (30 mg), and omeprazole (20 mg) were 2.58 (95% credible interval [CI], 1.01-38.7), 12.19 (95% CI, 2.23-100), 5.36 (95% CI, 1.14-38.7), and 6.31 (95% CI, 1.26-44.5), respectively. Limitations: Differences of attribute of each patient group (mean age, sex ratio, severity, etc.) and treatment period in each RCT may affect the analysis. Study for vonoprazan was only one, which may affect the analysis as well. Conclusion: Healing effect of vonoprazan for reflux esophagitis is likely to be greater than PPIs which are prescribed in Japan according to our network meta-analysis. It is desirable to conduct direct comparison studies between vonoprazan and these drugs to confirm this result. Systematic Review Registration Number PROSPERO registry CRD42015024880

Figure 1. The direct comparison network diagram of healing treatment of included studies. TD, twice daily, 3TD, 3 times daily, number of studies are shown as numerical values.

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TO COMPARE THE EFFICACY AND SAFETY OF ALBIS D® WITH PROTON PUMP INHIBITOR AS THE TREATMENT FOR RELIEVING SYMPTOMS IN NON-EROSSIVE GASTRO-OESOPHAGEAL REFLUX DISEASE: A RANDOMIZED, PROSPECTIVE, MULTI-CENTER, NON-INFERIORITY STUDY

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Background: About half to one-third of patients with typical GERD symptoms, such as heartburn, belching, cough, nausea, have no erosive changes on upper gastrointestinal endoscopic evaluation so called non-erosive gastro-oesophageal reflux disease (NERD). Proton pump inhibitor (PPI) has been widely used for treatment of NERD. But the effectiveness of symptoms relief in NERD patients was not enough. Moreover recently, there are many studies that long term PPI therapy can induce several medical problems such as infection diseases including pneumonia, C. difficile associated diarrhea, bone fracture and vitamin B12-deficiency. So alternative treatment drug for PPI in NERD was on the rise. Albis D® (comprised of ranitidine 168mg, bismuth 200mg, sucralfate 600mg, Daewoong Pharmaceuti-

cal Co., Ltd) is a developed drug compound of ranitidine, bismuth and sucralfate. AIM: To compare the non-inferiority of Albis D® with PPI, (omeprazole 20mg) as therapy for relieving symptoms associated with NERD. Methods: This is a multi-center, prospective, randomized, active-controlled, open-label trial of 4 weeks regular therapy with Albis D® (group A) vs omeprazole (group B). Total 113 adult patients (age 20-80 years old) diagnosed as NERD were enrolled. All patients have been experienced typical heartburn symptoms within 6 months and no Z-line mucosal break observed on gastroendoscopy at screening. Group A (N=57) were taken Albis D® twice a day and Group B (N=56) omeprazole once a day. Patients recorded daily symptoms diary at baseline and after 4 weeks treatment. The primary end point is no day and night time heartburn symptom during 7 continuous days after 4 weeks treatment. RESULTS: 59 patients A and 52 group B patients finished all scheduled study. After 4 weeks treatment, there was no significant difference in no day and night time heartburn symptom for 7 days between Albis D® group and omeprazole group (35.09% vs 32.14%, respectively; P=0.54). And there was no significant difference in acid reflux symptom for 7 days between Albis D® group and omeprazole group (27.27% vs 51.92%, respectively; P=0.63). Additionally, we also compared the efficacy of relief in both heartburn and acid reflux symptom during 7 days after 44 weeks treatment, defined as complete response. There was no significant difference between Albis D® group and omeprazole group (30.91% vs 28.85%, respectively; P=0.81). And also there was no significa-
tant difference in less than two days heartburn and acid reflux symptoms between two groups (36.36% vs 42.31%, respectively; P=0.52). No significant side effect was reported during study in both groups. Conclusion: Albis D® has a comparable efficacy compared to omeprazole when given twice daily for 4 weeks in treatment of NERD and is also safe.

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GERD PREVALENCE AND TREATMENT IN PRIMARY CARE PATIENTS IN RUSSIA: PRELIMINARY DATA OF THE MULTICENTER STUDY

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Background: Population-based MEGRE study (7812 subjects in 6 cities of Russia) performed in 2005-2006 showed that the average prevalence of GERD according to Mayo Clinic Questionnaire proved to be 13.3%. The aim of our study was to determine the current...