

## Accepted Manuscript

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PII: S2095-4964(18)30023-2  
DOI: <https://doi.org/10.1016/j.joim.2018.02.008>  
Reference: JOIM 23

To appear in: *Journal of Integrative Medicine*

Received Date: 29 October 2017  
Accepted Date: 6 January 2018

Please cite this article as: S.K. Varnosfaderani, F. Hashem-Dabaghian, G. Amin, M. Bozorgi, G. Heydarirad, E. Nazem, M.N. Toosi, S.H. Mosavat, Efficacy and safety of Amla (*Phyllanthus emblica* L.) in non-erosive reflux disease: a double-blind, randomized, placebo-controlled clinical trial, *Journal of Integrative Medicine* (2018), doi: <https://doi.org/10.1016/j.joim.2018.02.008>

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## Efficacy and safety of Amla (*Phyllanthus emblica* L.) in non-erosive reflux disease: a double-blind, randomized, placebo-controlled clinical trial

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### ABSTRACT

**BACKGROUND:** Gastroesophageal reflux disease (GERD) is one of the most common gastrointestinal complaints. GERD, caused by the reflux of stomach contents into the esophagus, leads to troublesome symptoms such as heartburn and regurgitation. It is classified into two types: erosive esophagitis, characterized by visible esophageal mucosa erosion in endoscopy, and non-erosive reflux disease (NERD). GERD is a chronic and recurrent disease that impairs the quality of life and imposes socioeconomic and therapeutic burdens to both patients and society.

**OBJECTIVE:** Due to the failure of the conventional treatments for GERD and to the traditional use of Amla (*Phyllanthus emblica* L.), in addition to beneficial effects shown in recent studies, we evaluated the safety and efficacy of Amla tablet for improvement of symptoms of patients with NERD.

**DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS:** We designed a double arm, randomized, double blind, placebo-controlled clinical trial. Sixty-eight patients who had classic symptoms of GERD (heartburn, regurgitation and epigastralgia) for at least three months before the start of the trial were randomized in two parallel groups. Patients in the Amla group received two 500 mg Amla tablets twice a day, after meals, for 4 weeks. In the control group, patients received placebo tablets similar to the Amla prescription.

**MAIN OUTCOME MEASURES:** The patients were visited at baseline, and at the end of the 2nd and 4th weeks of intervention; their symptoms were measured on a frequency and severity scale for the symptoms of NERD, according to the quality of life in reflux-associated disease questionnaire.

**RESULTS:** Frequencies of heartburn and regurgitation in both groups of the study were significantly reduced after intervention ( $P < 0.001$ ). Repeated measures logistic regression analysis showed that, in the Amla group, there was a more significant reduction in regurgitation frequency, heartburn frequency, regurgitation severity and heartburn severity during the study period, compared with the placebo group ( $P < 0.001$ ).

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