Efficacy and Safety of Cinnamon Stomachic Mixture for Patients with Functional Dyspepsia

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ABSTRACT

Health care personnel at a community hospital have used cinnamon stomachic mixture for treatment of patients with functional dyspepsia for many years and they claimed that cinnamon stomachic mixture was effective without any supportive evidence.

Objective: To determine the efficacy, safety, patients' compliance and satisfaction with the treatment of cinnamon stomachic mixture.

Methods: This was a randomized controlled study in 318 adults with functional dyspepsia presenting to 6 community hospitals. The patients were randomized to receive 105 mg of simethicone three times a day or 30 ml of cinnamon stomachic mixture three times a day for 7 to 14 days. The patients were evaluated for improvement of symptoms, compliance to medication and patients' satisfaction with the treatment. The data were analysed by descriptive statistics, chi-square statistics, student t test, analysis of variance and non-parametric tests where appropriate.

Results: One hundred and fifty patients received simethicone and 168 patients received cinnamon stomachic mixture. The baseline characteristics of the patients in both groups were not significantly different. The patients' compliance to simethicone and cinnamon stomachic mixture was 82% and 89.3% respectively (p=0.09). The severity of the symptoms after treatment and the response rates were not significantly different between both groups. Side effects were observed in 9.3% and 9.5% in the simethicone group and the cinnamon stomachic mixture group respectively. Most of the patients in both groups were satisfied with the treatments they received. The cost of a 14-day course of cinnamon stomachic mixture was 36 baht compared with 84 baht for that of simethicone.

Conclusion: Cinnamon stomachic mixture is effective and safe for the treatment of the patients with functional dyspepsia similar to simethicone.

Keywords: Cinnamon stomachic mixture; functional dyspepsia; simethicone

Siriraj Med J 2006; 58: 1103-1106
E-journal: http://www.sirirajmedj.com

Dyspepsia refers to a group of upper gastrointestinal symptoms that occur commonly in adults. Dyspepsia is known to result from organic causes, but the majority of patients suffer from non-ulcer or functional dyspepsia.[1] The generally accepted definition by most clinicians includes the presence of upper abdominal pain or discomfort with or without other upper gastrointestinal symptoms, such as nausea, belching and vomiting. In studies using "upper abdominal pain" as the definition, the prevalence of uninvestigated dyspepsia has varied between 7%-34.2%.[1] Two recent randomized controlled trials revealed that simethicone was more effective than a placebo for the treatment of patients with functional dyspepsia and the response observed in the simethicone group was not significantly different from that in the cisapride

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TABLE 1. Baseline characteristics of the study patients.

Characteristic	Simethicone gr. (N=150)	Cinnamon stomachic mixture gr. (N=168)	P
Male : Female	45 : 105	44 : 124	0.53
Mean age, yr ± SD (Range)	48.6 ± 12.8 (19-80)	48.6 ± 13.3 (20-91)	0.99
Body weight, kg ± SD (Range)	57.8 ± 10.9 (35-97)	56.7 ± 13.3 (36-79)	0.2
Mean symptom score ± SD	53.7 ± 21.9	51.9 ± 19.5	0.36
Median symptom score	50	50	
Range of symptom score	20 - 100	15 - 100	

group.[2,3] The cinnamon stomachic mixture has been produced and used for the treatment of patients with functional dyspepsia at a community hospital (Uthong Hospital) in Thailand for many years. The health care providers at this community hospital claimed that most of the patients responded to cinnamon stomachic mixture and they were also satisfied with the treatment they received.

The objective of this study was to determine the efficacy and safety of cinnamon stomachic mixture for treatment of patients with functional dyspepsia.

MATERIALS AND METHODS

The study was approved by the Ethics Committee of the Department of Development of Thai Traditional Medicine and Alternative Medicine, Ministry of Public Health. This was a randomized controlled study conducted in 6 community hospitals namely Uthong Hospital, Kudchum Hospital, Bangrathum Hospital, Wangchan Hospital, Soongnern hospital and Somdej-Prayuparap-Lerng-Nok-Ta Hospitals in Thailand. The eligibility criteria for the study subjects were 1) age 20 years, 2) symptoms of dyspepsia, 3) duration of symptoms between 3 days to 30 days and 4) agreed to participate in the study and signed the written informed consent form. The exclusion criteria were 1) pregnancy, 2) had symptoms suggestive of organic diseases i.e. fever, vomiting, hematemesis, melena, diarrhea, weight loss > 3 kilograms within a month and symptoms of other organic diseases, 3) had signs suggestive of organic diseases i.e. anemia, jaundice, hepatomegaly, splenomegaly, abdominal mass, signs of chronic liver diseases, ascites, abdominal tenderness or guarding, absence of bowel sounds, signs of intestinal obstruction and signs of other organic diseases, 4) had been taking ulcerogenic drugs e.g. aspirin, NSAIDS, and 5) allergic to simethicone or any components of cinnamon stomachic mixture.

The subjects were randomized to the simethicone group or the cinnamon stomachic mixture group by block randomization. The subjects in the simethicone group received simethicone tablet of 105 mg. 3 times daily for 7 to 14 days. The subject in the cinnamon stomachic mixture group received 30 ml of cinnamon stomachic mixture 3 times daily for 7 to 14 days. Each milliliter of cinnamon stomachic contained cinnamon bark *(Cinnamomum verum)*, "samunlawaeng" bark *(Cinnamomum bejolghota)*, licorice *(Glycyrrhiza glabra)* and clove *(Syzygium aromaticum)* at the amount equivalent to 7.14 mg of each crude drug.

The cinnamon stomachic mixture was produced by boiling 50 grams of dried cinnamon, samunlawaeng, licorice and dried clove in 7,000 ml of water for 15 minutes. Then a teaspoon of camphor and 70 ml of paraben were added after leaving such a solution at room temperature for 5 minutes. The preparation was left overnight and was distilled through a clean cloth before bottling the distilled solution in 300 ml glass bottles.

A sample size of 200 per group was estimated from the following information 1) the mean difference of the symptom score at baseline and at the end of treatment was 30 (from 60 to 30) in the simethicone group and 25 (from 60 to 35) in the cinnamon stomachic mixture group, 2) the standard deviation of the mean difference in the symptom score was 20, 3) type I error was 5%, and 4) type II error was 20%.

All subjects received instructions on eating habits and avoidance of the substances that might precipitate the dyspeptic symptoms. The subject was evaluated for dyspeptic symptoms at entry and day 7 and day 14 after treatment using a visual analog scale of 0 (no symptoms) to 100 (unbearable symptoms). Any concomitant or additional treatment, compliance to the study medications, new symptom and satisfaction with the study medication received including the convenience of taking medication, taste and odor of the medications were also recorded at follow up visits. The data were analyzed by descriptive statistics, chi square statistics, student t test, analysis of variance and non-parametric test where appropriate. The p value of < 0.05 was considered statistically significant.

RESULTS

There were 318 subjects, 150 in the simethicone group and 168 in the cinnamon stomachic mixture group. The baseline characteristics of the patients are shown in Table 1. Seventy percent of the patients were females. The mean age, mean body weight and mean symptom score of the patients in both groups were not significantly

TABLE 2. Treatment responses in terms of symptom score.

	Mean symptom score ± SEM		
	Simethicone gr. (N=150)	Cinnamon stomachic mixture gr. (N=168)	P
Before treatment	53.7 ± 1.8	51.9 ± 1.5	0.36
Day 7 after treatment	32.5 ± 1.6	29.3 ± 1.6	0.17
Day 14 after treatment	16.1 ± 1.5	15.5 ± 1.2	0.76
	p<0.001	p<0.001	

TABLE 3. Treatment responses in terms of disappearance of symptoms.

	Number of patients (%) with symptom score 10		
	Simethicone gr. (N=150)	Cinnamon Stomachic Mixture gr. (N=168)	P
Before treatment	0	0	
Day 7 after treatment	22 (14.7%)	36 (21.4%)	0.15
Day 14 after treatment	99 (66%) (95% CI 58.1% - 73.1%) p<0.001	106 (63.1%) (95% CI 55.6% - 70%) p<0.001	0.67

different. Concomitant treatments such as antacid were given to 20% and 11.9% of the patients in the simethicone group and the cinnamon stomachic mixture group respectively (p=0.07). A full compliance to the medications was reported in 82% and 89.3% of the patients in the simethicone group and the cinnamon stomachic mixture group respectively (p=0.09). The mean symptom scores at the baseline and those during and at the end of treatment are shown in Table 2. The mean symptom scores at the baseline in both groups were not significantly different (p=0.14). The mean symptom score on day 7 and day 14 was significantly less than that at the baseline in both groups (p<0.001). The mean symptom scores on day 7 and day 14 in both groups were not significantly different. The treatment responses in terms of disappearance of symptoms (symptom score 10) are shown in Table 3. The response rates on day 7 and day 14 were significantly greater than those at the baseline in both groups (p<0.001). The response rates on day 7 and day 14 in both groups were not significantly different. Side effects were observed in 9.3% and 9.5% in the simethicone group and the cinnamon stomachic mixture group respectively. The common side effects were nausea, eructation, air discharge from the anus, dizziness and constipation. All side effects were mild and no medication-related serious adverse events were observed. Most of the patients in both groups were satisfied with the treatments they received i.e. 80% and 83.3% of the patients in the simethicone group and the cinnamon stomachic mixture group indicated that they would like to receive the same treatments if they had the same symptoms.

DISCUSSION

The Gastroenterological Association of Thailand reported that the prevalence of dyspepsia in Thais was 20% to 25% and the incidence of dyspepsia in Thais was 1% to 2%. A significant proportion of dyspeptic patients were functional dyspepsia cases. Therefore functional dyspepsia is one of the very common health problems in Thailand and it consumes a large amount of health care resources. A meta-analysis on psychological interventions for non-ulcer dyspepsia concluded that there was insufficient evidence to confirm the efficacy of psychological intervention in non-ulcer dyspepsia.[4] Another meta-analysis on pharmacological interventions for non-ulcer dyspepsia revealed that prokinetics, H2 receptor antagonists and proton pump inhibitors were effective in therapy of non-ulcer dyspepsia.[5] These effective medications are expensive and have side effects. Many herbal medicines were found to be effective for treatment of functional dyspepsia. They were ganaton, extracts from bitter candy tuft, matricaria flower, peppermint leaves, caraway, licorice root & lemon balm, artichoke leaf extract, iberogast, peppermint oil & caraway oil and red pepper.[6-12] However there has been no study on the efficacy and safety of cinnamon stomachic mixture for treatment of functional dyspepsia.

We conducted this randomized controlled study in 6 community hospitals where sophisticated investigations such as gastroscopic examination and urea breath test were unavailable and we needed to enroll the subjects diagnosed as having functional dyspepsia based on their clinical features. Simethicone was chosen as a comparator drug instead of placebo because there was evidence that simethicone was more effective than a placebo in treating functional dyspepsia[2,3]. Simethicone was also the medication most commonly used by health care personnel at these community hospitals for treating the patients with functional dyspepsia. We did not use cisapride in our study although it was a prokinetic drug because cisapride has many drug interactions leading to serious side effects and it is no longer a treatment option in functional dyspepsia.[13,14]

Our study found that cinnamon stomachic mixture was effective in alleviating the symptoms by 70% and had a favorable response of 63% at the end of 2 weeks, similar to that of simethicone. The use of cinnamon stomachic mixture for longer duration might increase the response rate since many clinical studies on the treatment of functional dyspepsia used the study medications for longer than 4 weeks[2, 3, 9, 12, 15-17] and they found a favorable response of up to 80%. However, we did not use a longer duration of treatment since we thought that the patients who did not respond to a 2-week course of medication should have further appropriate investigations performed to detect organic causes of their persistent dyspeptic symptoms. The side effects of cinnamon stomachic mixture were uncommon and all of them had mild severity. The patients who received cinnamon stomachic mixture showed a very good compliance to treatment and were satisfied with this treatment. Moreover the cost of a 14-day course of cinnamon stomachic mixture was 36 baht compared with 84 baht for that of simethicone.

In summary cinnamon stomachic mixture for 2 weeks is effective, safe and cheap in relieving the symptoms of 60% of the patients with a clinical diagnosis of functional dyspepsia and it should be included as a treatment option for functional dyspepsia, especially in community hospitals.

ACKNOWLEDGEMENTS

The authors thank the Department of Development of Thai Traditional Medicine and Alternative Medicine, Ministry of Public Health and the Thailand Research Fund for supporting the study. We also thank Ms Luksamee wattanamongkolsilp and Mr. Suthiphol Udompunturuk for statistical analyses.

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บทคัดย่อ

ประสิทธิผลและความปลอดภัยของยาธาตุอบเชยในการรักษาผู้ป่วย Functional Dyspepsia

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บุคลากรการแพทย์ที่ปฏิบัติงานที่โรงพยาบาลชุมชนรักษาผู้ป่วย functional dyspepsia ด้วยยาธาตุอบเชยพบว่าผู้ป่วยส่วนมากมีอาการทุเลาหรืออาการหายไป แต่ยังไม่มีการวิจัยทางคลินิกเพื่อประเมินประสิทธิผลและความปลอดภัยของยาธาตุอบเชยตำรับนี้

วัตถุประสงค์: เพื่อทราบประสิทธิผล ความปลอดภัยของการรักษาผู้ป่วย functional dyspepsia ด้วยยาธาตุอบเชย

วิธีการ: การวิจัยนี้ใช้รูปแบบ Randomized controlled study ดำเนินการที่โรงพยาบาลชุมชน 6 แห่งในผู้ใหญ่ที่ได้รับการวินิจฉัยโดยอาศัยลักษณะทางคลินิกว่าเป็น functional dyspepsia จำนวน 318 คน ผู้ป่วยถูกสุ่มให้ได้รับ simethicone ขนาด 105 มก รับประทานวันละ 3 ครั้งหลังอาหาร หรือยาธาตุอบเชย รับประทานครั้งละ 30 มล วันละ 3 ครั้งหลังอาหารติดต่อกันนาน 7-14 วัน ผู้ป่วยได้รับการประเมินผลการรักษาภายหลังการรักษานาน 7 วัน และ 14 วัน โดยประเมินอาการทั้งหมดของผู้ป่วย ความสม่ำเสมอของการรับประทานยาที่ได้รับ ผลข้างเคียงของการรักษา และความพึงพอใจของผู้ป่วยต่อการรักษาที่ได้รับ นำข้อมูลมาวิเคราะห์ด้วยสถิติเชิงพรรณนา, chi-square statistics, student t test หรือ analysis of variance หรือ non-parametric test

ผลการศึกษา: ผู้ป่วย 150 คนได้รับ simethicone และผู้ป่วย 168 คนได้รับยาธาตุอบเชย ลักษณะทั่วไปของผู้ป่วยทั้ง 2 กลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญ ผู้ป่วยร้อยละ 82 ในกลุ่ม simethicone และร้อยละ 89.3 ในกลุ่มธาตุอบเชย (p=0.09) รับประทานยาครบทุกมื้อ อาการของผู้ป่วยและความรุนแรงเฉลี่ยอาการของผู้ป่วยภายหลังการรักษาด้วย simethicone หรือยาธาตุอบเชยไม่แตกต่างกันอย่างมีนัยสำคัญ จำนวนผู้ป่วยที่อาการดีขึ้นมากหรืออาการหายไปภายหลังการรักษาด้วย simethicone หรือยาธาตุอบเชยเพิ่มขึ้นจากก่อนการรักษาอย่างมีนัยสำคัญ และจำนวนผู้ป่วยที่อาการดีขึ้นมากหรืออาการหายไปภายหลังการรักษาด้วย simethicone หรือยาธาตุอบเชยไม่แตกต่างกันอย่างมีนัยสำคัญ ผลข้างเคียงของการรักษาพบร้อยละ 9.3 ในกลุ่ม simethicone และร้อยละ 9.5 ในกลุ่มยาธาตุอบเชย และผู้ป่วยส่วนมากที่ได้รับ simethicone หรือได้รับยาธาตุอบเชยพึงพอใจต่อการรักษาที่ได้รับไม่แตกต่างกัน ค่าใช้จ่ายของยาธาตุอบเชยประมาณ 36 บาท ส่วนค่าใช้จ่ายของ simethicone ประมาณ 84 บาท

สรุป: ยาธาตุอบเชยรับประทานติดต่อกัน 14 วันมีประสิทธิผลและปลอดภัยในการรักษาผู้ป่วย functional dyspepsia ไม่แตกต่างจากการรักษาด้วย simethicone