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
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), samunlaweng 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, samunlaweng, 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 different.

### TABLE 1. Baseline characteristics of the study patients.

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

### TABLE 2. Treatment responses in terms of symptom score.

<table>
<thead>
<tr>
<th>Mean symptom score ± SEM</th>
<th>Simethicone gr. (N=150)</th>
<th>Cinnamon stomachic mixture gr. (N=168)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>53.7 ± 1.8</td>
<td>51.9 ± 1.5</td>
<td>0.36</td>
</tr>
<tr>
<td>Day 7 after treatment</td>
<td>32.5 ± 1.6</td>
<td>29.3 ± 1.6</td>
<td>0.17</td>
</tr>
<tr>
<td>Day 14 after treatment</td>
<td>16.1 ± 1.5</td>
<td>15.5 ± 1.2</td>
<td>0.76</td>
</tr>
<tr>
<td>p&lt;0.0001</td>
<td>p&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 84% 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=0.15). 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 0) 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. Another meta-analysis on pharmaceutical interventions for non-ulcer dyspepsia revealed that prokinetics, H2 receptor antagonists and proton pump inhibitors were effective in therapy of non-ulcer dyspepsia. 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. 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. 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.

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 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**

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

<table>
<thead>
<tr>
<th></th>
<th>Number of patients (%) with symptom score 10</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Simethicone gr. (N=150)</td>
<td>Cinnamon Stomachic Mixture gr. (N=168)</td>
</tr>
<tr>
<td>Before treatment</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Day 7 after treatment</td>
<td>22 (14.7%)</td>
<td>36 (21.4%)</td>
</tr>
<tr>
<td>Day 14 after treatment</td>
<td>99 (66%)</td>
<td>106 (63.1%)</td>
</tr>
</tbody>
</table>

(95% CI 58.1% - 73.1%) (95% CI 55.6% - 70%) p<0.001 p<0.001
REFERENCES

บทคัดย่อ
ประสิทธิภาพและความปลอดภัยของการใช้ยาคุณภาพผู้ป่วย functional Dyspepsia คือการคุณภาพผู้ป่วยที่มีความเป็นอยู่ของการรักษาการ หายไป แต่ยังไม่มีการจัดการเทคนิคเพื่อประเมินประสิทธิภาพและความปลอดภัยของการคุณภาพผู้ป่วยที่มีการรักษาดังนี้

วัตถุประสงค์: เพื่อทราบประสิทธิภาพ ความปลอดภัยของการรักษาผู้ป่วย functional dyspepsia ด้วยยาคุณภาพผู้ป่วยที่มีความเป็นอยู่ของการรักษา

วิธีการ: การวิจัยใช้แบบ Randomized controlled study ดำเนินการที่ประเทศไทย 6 แห่งในศูนย์ที่ได้รับการวินิจฉัยโดยองค์การหลักระดับโลก จำนวน 318 คน ผู้ป่วยที่ได้รับ simethicone แบ่งออกเป็น 3 กลุ่ม คือ 1. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วย simethicone 2. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 3. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 4. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 5. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 6. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone

ผลการสังเคราะห์: ผู้ป่วย 150 คนได้รับ simethicone และผู้ป่วย 168 คนได้รับยาคุณภาพผู้ป่วยที่มีความเป็นอยู่ของการโรคอุจจการที่มีการรักษาด้วย simethicone 3. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 4. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 5. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone 6. ยาคุณภาพผู้ป่วยที่มีการรักษาด้วยยาที่มีผลต่อระบบทางเดินอาหารในผู้ป่วยที่มีการรักษาด้วย simethicone

Sriraj Med J, Volume 58, Number 11, November 2006 1106