Experimental Comparative Study of the Efficacy and Side Effects of *Cissus quadrangularis* L. (Vitaceae) to Daflon (Servier) and Placebo in the Treatment of Acute Hemorrhoids

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Objective: *To investigate efficacy and side effects of Cissus quadrangularis L. and micronised purified flavanoid fraction (MPFF) in treatment of hemorrhoids.*
Material and Method: *A prospective double blind randomized study was designed in acute hemorrhoidal patients from three hospitals. In each hospital, eighty patients received the flavanoid mixture, C. quadrangularis, or placebo (3 x 2 p.c. for 4 days and then 2 x 2 p.c. for 3 days). Patients were evaluated on bleeding, pain, discharge, pruritis, erythema, and direct patient interviews. Each symptom was scored on a graded severity scale from 0 to 3 on the first day and the seventh day. Blood tests and monitoring of treatment-related side effects were conducted.*
Results: *Five hundred seventy patients (299 females, 271 males) were enrolled. No significant difference regarding age, gender, occupation, and history of disease was recorded. Mostly acute bleeding ceased at the second day in all groups. Analysis on all groups revealed improvement in all symptoms with non-significant difference. No adverse events, no blood chemistry changes were reported.*
Conclusion: *The therapeutic efficacy of flavanoid mixture, C. quadrangularis L. and placebo are not different indicating that they play no role in improving early hemorrhoidal symptoms. Long-term studies should be conducted for effects in preventive and curative action.*

Keywords: *Cissus quadrangularis L., Flavanoid mixture, Hemorrhoids references*

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Hemorrhoids disease is a common anorectal condition affecting 5% of individuals worldwide. Hemorrhoids can occur for everyone, but mostly with increasing age and particularly after 50 years. Dietary habits such as low fiber food, low liquid intake, and less exercise and movement are associated with rising Hemorrhoids. The common symptoms of hemorrhoids normally depend on the areas of condition. Painless bleeding during bowel movement found inside the rectal canal indicates internal hemorrhoids and as a result, there is a small amount of red blood in faeces. External hemorrhoids are found under skin near the anus. Occasionally painful swelling is found there. Irritation, itching and bleeding are other common symptoms resulting in pain, swelling and inflammation.

There are many treatment options available depending on the degree of the hemorrhoidal disorder such as surgical and non-surgical treatment. In the early stage, provision of a medical treatment with modern medicine and herbal products might be an option.

A medicinal plant, *Cissus quadrangularis* L.; VITACEAE, veld grape vine, known in Thailand as Phet Sang Khat, Kun Koat, San Cha Koat and

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Sam Roi Tow. In India, liquid from crushed fresh vine was used to treat scurvy, dysmenorrheal, and stomachache. A decoction of *C. quadrangularis* injected intramuscularly into mice significantly increased the rate of healing[1-4]. In Thailand, the active ingredients of *C. quadrangularis* by decoction with petroleum ether were investigated. There were three types of triterpene (lupenone, epifriedelinol, isoarborenol) and a type of Phytosterol (β-sitosterol)[5]. No acute or a little toxic effect of *C. quadrangularis* in mice, rat and rabbit[6,7]. It has been used to treat early hemorrhoid by fresh ingestion of one septum of vine daily for three days. It was sliced and covered with ripe tamarind pulp or banana for swallowing. Because of throat irritant due to crystal of calcium oxalate in the fresh vine, The *C. quadrangularis* was heat dried, grounded and filled in capsules. *C. quadrangularis* is currently marketed in Thailand as an herbal product. The studies were conducted on limited subjects and by non-clinician practitioners. Therefore, the role of *C. quadrangularis* in the treatment of patients with hemorrhoids needs to be further analyzed in a large population.

Daflon 500 mg (Servier), micronised purified flavanoid fraction (MPFF) is a flavonoid vasoprotector venotonic agent that has been used in reducing symptoms of acute hemorrhoids[5-7]. The purpose of the present study was to investigate the efficacy and side effects of *C. quadrangularis* compared with micronised purified flavanoid fraction (MPFF) in the treatment of hemorrhoid as a feasible herbal product for replacement of an imported drug.

Material and Method

Patients

All 720 male and female patients included in the studies were under 50 years of age and suffered from acute symptomatic Hemorrhoid within the last five days. Each of the 240 outpatients from three hospitals (Rajavithi, Cholburi and Somdej Sriracha) was diagnosed with hemorrhoid by clinical examination, including proctoscopy. The inclusion criteria were acute rectal bleeding within five days, understanding, and ability to comply with protocol requirements concomitant with the present study and gave written informed consent. Exclusion criteria were previous hemorrhoidectomy, treatment with anticoagulant or ASA, taking other antihemorrhoid drugs at that time, permanent prolapsed internal hemorrhoid requiring surgery, patients suffering from moderate to severe hypertension; cardiovascular diseases; renal failure, cirrhosis, pregnancy and lactation. Discontinuation criteria were severe side effects and life threatening situations. The present study was approved by the institutional ethics committee and was conducted according to good clinical practice. Patients were not allowed to take any other medical treatment during the present study.

Study design

A double-blind randomized controlled study was conducted to investigate the efficacy and side effect of *C. quadrangularis* compared with micronised purified flavanoid fraction (MPFF) in the treatment of hemorrhoid. About 80 patients from each hospital received C. *quadrangularis*, the flavanoid mixture, or the placebo at the dosage of three tablets twice a day p.c. for 4 days and then two tablets twice a day p.c. for 3 days. The investigational drugs (*C. quadrangularis* powder 500 mg dry weight) and placebo were prepared with similar appearance of the flavonoid mixture tablets. On the first day, blood tests and medical examination including proctoscopy were conducted to assess the degree of hemorrhoid (grade 1, only bleeding with no prolapse; grade 2, bleeding and prolapse which reduced spontaneously; grade 3, Prolapse required manual reduction. Direct patient interviews were performed to establish the patients' age, gender, occupation, history of diseases and self-assessed symptom scoring. Patients were evaluated on bleeding, pain, discharge, pruritis and erythema on examination. Each symptom was scored on a graded severity scale from 0 to 3 (0 = absent, 1 = mild, 2 = moderate, 3 = severe). A second clinical examination, blood test, questions regarding to symptoms to score their severity and other treatment-related side effects was performed on the seventh day after treatment.

Statistical analysis

The statistical analyses were carried out using number and percentage for comparing group difference and patient history. Percent difference in response and Mc Nemar Chi-square were used for comparing efficacy of drug before and after treatment. Significant differences were defined as $p < 0.05$. Pearson Chi-square for comparative clinical symptom before treatment and efficacy of symptomatic improvement after treatment in each group was applied. ANOVA for quantitative variables from blood test for investigation of liver and kidney function was used in the present study. Odd ratio and 95% confidence interval (95% CI) were presented for self-

assessment and investigators assessment on efficacy of treatment.

Results

Five hundred seventy of 720 patients were enrolled into the present study. Forty-one patients withdrew from the treatment before finishing the protocol due to dissatisfaction with the therapeutic results. At baseline, *C. quadrangularis*, the flavanoid mixture, and placebo groups were compared with respect to age, gender, occupation, work task and history of diseases (Table 1, 2). Of the 570 patients, 191, 189, and 190 patients were in *C. quadrangularis* L., MPFF, and placebo groups, respectively. The majority of patients were females. Most patients were categorized in the age group of between 25 and 40 years for all groups (more than 50%). For all three groups, the majority of occupations were laborers, whereas the work task was mainly indicated as normal task. There was no significant difference between the three groups in age, gender, occupation, and work task. When comparing each symptom before treatment such as rectal bleeding, pain, discharge, anal purities and degree of prolapsed at the score levels on severe-moderate and mild-none, there was no significant difference between groups in baseline self-assessed symptom scores ($p > 0.05$). Based on physical examination before treatment, comparison in all three groups showed similar symptoms except proctoscopic findings (Table 3). The number of grade 3 degree in the placebo group was greater than that of other groups (p-value = 0.021).

There was significant overall improvement in self-assessed symptoms ($p < 0.001$) in all treatment groups except symptom of prolapse. Odds ratios were calculated but there was no statistic significance overall improvement in self-assessed symptoms in all treatment groups (Table 4).

The effect of treatment was not improved in proctoscopic findings while the clinical symptoms, which respond to all treatments, were significantly improved. The acceptability by clinicians in all treatments was good acceptable with no significant difference between groups (p-value > 0.05) (Table 5). Two patients in the placebo group and one patient in

Table 1. Baseline characteristics

Characteristics	*C.quadrangularis* L. (n = 191) n (%)	MPFF[a] (n = 189) n (%)	Placebo (n = 190) n (%)	p-value
Gender				0.539
Male	97 (50.8)	86 (45.5)	88 (46.3)	
Female	94 (49.2)	103 (54.5)	102 (53.7)	
Age (years)				0.225
< 25 years	30 (16.0)	28 (15.5)	20 (10.9)	
25-40 years	98 (52.1)	98 (54.1)	116 (63.4)	
> 40 years	60 (31.9)	55 (30.4)	47 (25.7)	
Missing	3	8	7	
Occupation				0.120
Labourers	88 (47.8)	104 (56.5)	114 (61.0)	
Farmer	1 (0.5)	6 (3.3)	3 (1.6)	
Retail	26 (14.1)	13 (7.1)	18 (9.6)	
Employee	21 (11.4)	20 (10.9)	6 (3.2)	
Civil servant	16 (8.7)	15 (8.2)	21 (11.2)	
House wife	16 (8.7)	15 (8.2)	18 (9.6)	
Student	16 (8.7)	11 (6.0)	7 (3.7)	
Missing	7	5	3	
Work task				0.753
Heavy lifting	30 (17.9)	36 (21.2)	40 (22.5)	
Prolong standing	20 (11.9)	15 (8.8)	19 (10.7)	
Normal task	118 (70.2)	119 (70.0)	119 (66.8)	
Missing	23	19	12	

[a] Micronised purified flavanoid fraction

* Significant at $p < 0.05$

Table 2. Patients history of symptoms and treatment

Characteristics	*C.quadrangularis* L. (n = 191) n (%)	MPFF[a] (n = 189) n (%)	Placebo (n = 190) n (%)	p-value
History				
Alcoholic drinking	20 (10.5)	15 (7.9)	20 (10.5)	0.621
Chronic cough	4 (2.1)	4 (2.1)	4 (2.0)	0.996
Forced defecate	13 (6.8)	15 (7.9)	10 (5.3)	0.578
Drug allergy	22 (11.5)	22 (11.6)	20 (10.5)	0.931
Defecation				0.244
Constipation	78 (41.1)	91 (49.2)	89 (47.6)	
Frequent diarrhea	11 (5.8)	16 (8.7)	14 (7.5)	
Normal	73 (38.4)	52 (28.1)	66 (35.3)	
Forced defecate	28 (14.7)	26 (14.1)	18 (9.6)	
Missing	1	4	3	
Bleeding	134 ((70.2)	130 (68.8)	133 (70.0)	0.951
Once	79 (59.0)	77 (59.2)	85 (63.2)	
Twice	10 (7.5)	14 (10.8)	21 (15.8)	
Three times	23 (17.2)	21 (16.2)	16 (12.0)	
Four times	12 (9.0)	11 (8.5)	7 (5.3)	
Five times	3 (2.2)	2 (1.5)	2 (1.5)	
Six times	1 (0.8)	1 (0.8)	2 (1.5)	
Ten times	6 (4.5)	3 (2.3)	0 (0.0)	
Eleven times	0 (0.0)	1 (0.8)	0 (0.0)	
Previous treatment (2)				0.860
Modern medicine	43 (22.8)	47 (25.3)	46 (25.0)	
Herbal product	17 (9.0)	14 (7.5)	10 (5.4)	
On the counter drug	24 (12.7)	19 (10.2)	20 (10.9)	
No treatment	50 (26.5)	51 (27.4)	59 (32.1)	
First time visit	55 (29.1)	55 (29.6)	49 (26.6)	
Missing	2	3	6	
Precipitated symptom (2)				0.860
Constipation	43 (22.8)	47 (25.3)	46 (25.0)	
Diarrhea	17 (9.0)	14 (7.5)	10 (5.4)	
Alcoholic drinking	24 (12.7)	19 (10.3)	20 (10.9)	
Hot spicy food	50 (26.5)	51 (27.4)	59 (32.1)	
Others	55 (29.1)	55 (29.6)	49 (26.6)	
Missing	2	3	6	

[a] Micronised purified flavanoid fraction

* Significant at $p < 0.05$

the *C. quadrangularis* group had to be withdrawn owing to headache, drowsiness, and gastritis. No other side-effects were reported.

Blood testing data before and after treatment in all groups were not significantly altered, indicating that all investigation drugs had no effect on standard biological data of patients.

Discussion

This double-blind randomized controlled study of efficacy and side effects of investigational drugs in the treatment of acute symptoms were performed according to good clinical practice. The present study of 570 patients in the three hospitals could be accepted for statistical analysis of efficacy even though some patients did not finish the trial in Somdej Sriracha hospital and 34 patients were withdrawn due to failure to follow-up in the second visit in Rajavithi hospital. According to some ethical issues limited to clinical study of herbal products, the very strict criteria of patient age, history of diseases, and duration of symptoms, which must be in early

Table 3. Physical history before treatment

Characteristics	*C.quadrangularis* L. (n = 191) n (%)	MPFF[a] (n = 189) n (%)	Placebo (n = 190) n (%)	p-value
Proctoscopy				0.021*
1 degree enlarged	76 (40.0)	71 (37.6)	78 (41.3)	
2 degree	90 (47.4)	99 (52.4)	73 (38.6)	
3 degree prolapsed	24 (12.6)	19 (10.0)	38 (20.1)	
Missing	1	-	1	
Severity of bleeding				0.842
Severe	2 (1.1)	4 (2.1)	4 (2.1)	
Moderate	23 (12.0)	29 (15.3)	24 (12.6)	
Mild	55 (28.8)	58 (30.7)	60 (31.6)	
None	111 (58.1)	98 (51.9)	102 (53.7)	
Degree of edema				0.789
Severe	10 (5.2)	10 (5.3)	13 (6.8)	
Moderate	64 (33.5)	62 (32.8)	69 (36.3)	
Mild	87 (45.6)	84 (44.4)	71 (37.4)	
None	30 (15.7)	33 (17.5)	37 (19.5)	
Degree of erythema				0.742
Severe	16 (8.4)	12 (6.4)	19 (10.1)	
Moderate	47 (24.6)	39 (20.6)	41 (21.7)	
Mild	72 (37.7)	75 (40.0)	66 (34.9)	
None	56 (29.3)	63 (33.3)	63 (33.3)	
Missing	-	-	1	

[a] Micronised purified flavanoid fraction
* Significant at $p < 0.05$

stages, had to be followed. The measurement in clinical parameters of hemorrhoidal disease cannot be distinctly investigated, so medical examination, history of diseases, and self-assessed symptom scoring tend to be subjective and biased. Hemorrhoidal disease is associated with dietary behavior and lifestyle such as low fiber food and less liquids intake, less exercise and movement, the use of laxatives and rest. These factors could not be directly controlled so there are a variety of behaviors in each individual that have unavoidable effects on treatment and statistical results. The present study shows good distribution and no significant difference in patient characteristics and there was no significant difference between groups in baseline and self-assessed symptom scores. Based on physical examination and self-assessed symptom scores after treatments, the present study revealed effectiveness of treatments in all three groups except puritis and protoscopic findings. Comparison between the three groups showed non-significant difference in favor of all groups especially in cessation of bleeding, which was the major parameter in the present study.

This result did agree with the study of Vajrabukka et al[8], which indicated no statistical difference between used Daflon 500 mg® and placebo for the treatment of acute hemorrhoids and by evaluating symptoms such as bleeding, pain and anal discomfort improvement. However, there was an effect on subjective thinking and bias from educational level in these study groups, who were mostly laborers. Three patients withdrew from the present study. The two in the placebo group experienced drowsiness and severe headache side effects. The significant factor that affected treatments is that the self-assessed symptom is subjective and most Thais patients tended to please their doctors so there was some bias in their response.

There should be a development in proctoscopy in further studies. Some devices should be connected to computerized systems so that the details and size of hemorrhoids could be recorded. The assessment could be effectively evaluated, bias and error could be minimized. Other parameters such as size, pressure, temperature, and so on could be adapted to get objective and significant substantial data. Besides, the criteria of selecting subjects should not be specified

Table 4. Patient's self assessment on efficacy of the treatment

Symptom	n	Improve n (%)	p-value	Odds ratio (95% CI)	p-value
Bleeding					
C. quadrangularis L.	176	118 (67.1)	<0.001*	0.70 (0.44-1.12)	0.132
MPFF	174	118 (67.8)	<0.001*	0.85 (0.53-1.39)	0.522
Placebo	178	132 (74.2)	<0.001*	Ref (1)	-
Pain					
C. quadrangularis L.	176	49 (27.8)	<0.001*	1.20 (0.76-1.89)	0.434
MPFF	174	57 (32.8)	<0.001*	0.95 (0.61-1.48)	0.821
Placebo	178	58 (32.6)	<0.001*	Ref (1)	-
Discharge					
C.quadrangularis L.	176	11 (6.3)	0.022*	1.26 (0.82-2.74)	0.432
MPFF	174	9 (5.2)	0.004*	1.35 (0.79-3.17)	0.473
Placebo	178	11 (6.2)	0.006*	Ref (1)	-
Puritis					
C.quadrangularis L.	176	14 (7.9)	<0.001*	1.35 (0.68-2.63)	0.402
MPFF	174	12 (6.9)	0.077	1.24 (0.62-2.49)	0.539
Placebo	178	17 (9.6)	0.003*	Ref (1)	-
Prolapse					
C.quadrangularis L.	176	8 (4.5)	0.109	1.64 (0.72-3.72)	0.233
MPFF	174	6 (3.5)	0.508	1.79 (0.77-4.17)	0.173
Placebo	178	11 (6.2)	0.210	Ref (1)	-

* Significant improvement after 7 days of treatment

Table 5. Investigators' assessment on efficacy of the treatment

Symptom	n	Improve n (%)	p-value	Odds ratio (95% CI)	p-value
Protoscopic degree					
C. quadrangularis L.	176	19 (10.8)	0.087	1.09 (0.55-2.15)	0.805
MPFF	174	15 (8.6)	0.056	0.89 (0.41-1.73)	0.644
Placebo	178	18 (10.1)	0.010*	Ref (1)	-
Bleeding					
C. quadrangularis L.	176	19 (10.8)	<0.001*	1.19 (0.64-2.22)	0.582
MPFF	174	28 (16.1)	<0.001*	0.75 (0.42-1.33)	0.322
Placebo	178	25 (14.0)	<0.001*	Ref (1)	-
Edema					
C. quadrangularis L.	176	69 (39.2)	<0.001*	1.15 (0.75-1.76)	0.522
MPFF	174	54 (31.0)	<0.001*	1.19 (0.77-1.83)	0.43
Placebo	178	68 (38.2)	<0.001*	Ref (1)	
Erythrema or Proctitis					
C.quadrangularis L.	176	15 (8.52)	<0.001*	1.01 (0.63-1.62)	0.98
MPFF	174	33 (19.0)	<0.001*	1.38 (0.84-2.26)	0.207
Placebo	178	45 (25.3)	<0.001*	Ref (1)	-

* Significant improvement after 7 days of treatment

only in acute stage cases in order to recruit more patients from different groups. Assessment of earlier symptoms groups would get indistinct results and non-significant differences.

In conclusion the experimental comparative study of efficacy and side effects of *C. quadrangularis* L.;Vitaceae, micronised purified flavanoid fraction (MPFF) [Daflon 500 mg] and placebo in the treatment

of acute hemorrhoids did show the same results. They play no role in the improvement and do not appear to be a valuable option for the treatment of acute hemorrhoidal symptoms in early stages. Long-term studies should be conducted for effects in preventive and curative action.

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การศึกษาประสิทธิผลและผลข้างเคียงของการใช้สมุนไพรเพชรสังฆาตและยาที่มีส่วนผสม flavaniod ในการรักษาโรคริดสีดวงทวารที่มีอาการเฉียบพลัน

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วัตถุประสงค์: *เพื่อศึกษาประสิทธิผลและผลข้างเคียงของการใช้สมุนไพรเพชรสังฆาตและยาที่มีส่วนผสม flavaniod ในการรักษาโรคริดสีดวงทวารที่มีอาการเฉียบพลัน*

วัสดุและวิธีการ: *การศึกษาแบบไปข้างหน้าโดยการสุ่มและ ปกปิดทั้งสองด้าน กลุ่มตัวอย่างคือผู้ป่วยโรคริดสีดวงทวารระยะเฉียบพลันจาก 3 โรงพยาบาลจำนวน 240 คน ในแต่ละโรงพยาบาลแบ่งเป็น 3 กลุ่ม ๆ ละ 80 คน จะได้รับยาที่มีส่วนผสม flavaniod, สมุนไพรเพชรสังฆาต และ placebo (ใน 4 วันแรก ครั้งละ 3 เม็ด เช้าและเย็น หลังอาหาร และ 3 วันหลัง ได้รับครั้งละ 2 เม็ด เช้าและเย็น หลังอาหาร) ผู้ป่วยจะได้รับการประเมินอาการต่าง ๆ คือ เลือดออกทางทวารหนัก เมือก อาการคัน รอยแดง หรือ อักเสบรอบทวารหนัก และการสัมภาษณ์เพื่อสอบถามอาการ การประเมินโดยการให้ระดับคะแนนจากความรุนแรงของอาการโรค จากระดับ 0 ถึง 3 ในวันแรกและวันที่เจ็ดของการรับยา ทั้งนี้มีการตรวจเลือดและติดตามผลข้างเคียงของการได้รับยาหรือสมุนไพรควบคู่ไปพร้อมกันด้วย*

ผลการศึกษา: *ผู้ป่วย 570 คน (หญิง 299 คนและชาย 271 คน) เข้าร่วมในการศึกษากลุ่มตัวอย่าง ไม่มีความแตกต่างกันในด้านอายุ เพศ อาชีพ และประวัติของโรคริดสีดวงทวาร ส่วนใหญ่ผู้ป่วยทุกกลุ่ม อาการเลือดออกเฉียบพลันจะหยุดในวันที่ 2 ของการให้ยา ผู้ป่วยทุกกลุ่มมีอาการดีขึ้นหลังการให้ยาครบ 7 วัน ผลการวิเคราะห์ทางสถิติพบว่าประสิทธิผลของการรักษาไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติในผู้ป่วยทุกกลุ่ม ทั้งนี้ไม่มีผลข้างเคียงเกิดขึ้นในการรักษา*

สรุป: *ประสิทธิผลของการรักษาริดสีดวงทวารในระยะเริ่มต้น ด้วยยาที่มีส่วนผสม flavaniod, สมุนไพรเพชรสังฆาต และ placeboไม่แตกต่างกัน ควรจะมีการศึกษาในระยะยาว เพื่อศึกษาว่าสมุนไพรเพชรสังฆาตมีผลในการป้องกันและการหายขาดจากโรคริดสีดวงทวารได้หรือไม่*