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ORIGINAL RESEARCH

Impact of *Capsella bursa-pastoris* (Shepherd's Purse) Herbal Tea Preparations on Symptoms and Severity of Hemorrhoidal Disease: A Prospective Randomized Study

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Abstract

Objectives: Medicinal herbs have been used to treat hemorrhoidal disease for centuries. Given its anti-oxidant and anti-inflammatory mechanisms, *Capsella bursa-pastoris* (Shepherd's purse) may potentially lead to regression of the hemorrhoidal plexuses. In this context, the objective of this study is to investigate the effect of *Capsella bursa-pastoris*, an affordable and easy-to-use herbal medicine, on the severity and physical examination findings of hemorrhoidal disease in patients, who receive conventional treatment for hemorrhoids.

Material-Method: This study was designed as a prospective, randomized study. The population of the study comprised symptomatic patients who presented with second and third-degree hemorrhoids to the Internal Medicine and General Surgery departments of Istanbul Medipol University Hospital, İstanbul, Turkey, between October 2021 and February 2022. The patients were randomized into two groups: the control group, that is, the group of patients, who were to receive conservative treatment only for three months, and the study group, that is, the group of patients who were to receive conservative treatment and use herbal tea preparations of *Capsella bursa-pastoris* for three months. Demographic (age and gender) and baseline and 3-month clinical characteristics were recorded. The study's primary outcome was the changes observed in the symptoms and physical examination findings of hemorrhoidal disease in the study group relative to those in the control group.

Results: The study sample consisted of a total of 218 patients, who were randomized into the study and control groups, with 109 patients in each group. Significantly older patients were seen in Group CT (39.5 ± 14.6 and 35.5 ± 11.7 years, p=0.030). There was no significant difference between the groups in terms of other characteristics (p>0.05). At the 3rd-month follow-up examination, it was determined that there were significantly fewer patients with bleeding and difficulty during defecation in the study group compared to the control group (p=0.001 for both cases). Patients in the study group had significantly lower VAS scores for pain and the number of affected quadrants compared to those in the control group (p<0.001 for both cases). The proportion of patients with Grade II and III hemorrhoidal disease was significantly lower in the study group.

Conclusion: The findings of this study, which revealed significant improvements in the symptoms and physical examination findings of hemorrhoidal disease, suggest that the use of *Capsella bursa-pastoris* herbal tea may benefit patients with symptomatic hemorrhoids.

Keywords: Hemorrhoids, Phytotherapy, Medicinal Herbs, *Capsella bursa-pastoris*

INTRODUCTION

Herbal products have enjoyed widespread medicinal use globally throughout history[6,13]. Turkey's noted use of plants for medicinal purposes owes much to the relatively rich diversity of its flora, and its extensive history and culture of such usage[4]. Although there are different indications for each medicinal plant in different regions of the World, documentation of the medicinal utility of the less known plants has gained importance for several decades[4,6]. Different herbal plants have been investigated for their potentially beneficial effects in patients with hemorrhoidal diseases[2,10,11,19,24]. It has been suggested that plants with anti-inflammatory, analgesic and venotonic properties may prevent and cure hemorrhoidal diseases[19].

Capsella bursa-pastoris (Shepherd's purse), a member of the Cruciferae family, is an edible plant. Its leaves and roots can be eaten both raw and cooked.[3] The tea formulations made from the whole plant or the dried herb have been used for different purposes.[2] In addition to its hemostatic and oxytocic properties, *Capsella bursa-pastoris* is also known

for its anti-oxidant, anti-inflammatory, anti-ulcer, and in-vivo anti-cancer activities.[2,3,6,21,24,27] As a result, its use has been investigated in several experimental and clinical treatments, including for hemorrhoids,[3] hepatic steatosis and hypercholesterolemia,[4] urinary tract infections,[13] cataracts,[26] nose bleeding,[4] and heavy menstrual bleeding.[6,20]

Capsella bursa-pastoris has been used as a traditional medicine to treat hemorrhoidal disease in Anatolia and the Middle East.[2,3,25] Furthermore; it is also used as a foodstuff in many regions of Turkey.[15] Apaydin Yildirim et al.[3] reported the anti-oxidant activity of *Capsella bursa-pastoris* in an experimental rat model of hemorrhoids. However, there is no clinical study to date, in which the use of *Capsella bursa-pastoris* was evaluated in patients with hemorrhoids.

In view of the foregoing, the objective of this study is to evaluate the effect of *Capsella bursa-pastoris*, an affordable and easy-to-use herbal medicine, on the severity and physical examination findings of hemorrhoidal disease in patients, who receive conventional treatment for hemorrhoids.

MATERIALS AND METHODS

Research design

This study was designed as a prospective, randomized study. The study protocol was approved by the local ethics committee at Istanbul Medipol University (15.11.2021, E-10840098-772.02-5855). The study was carried out in accordance with the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from each patient included in the study.

Study population

Patient older than 18 years of age, who presented with symptomatic second and third degree hemorrhoids to the Internal Medicine and General Surgery departments of Istanbul Medipol University Hospital, Istanbul in Turkey between October 2021 and February 2022 comprised the study population. The diagnosis of hemorrhoids was made based on a detailed history of symptoms and rectal and anoscopic examinations. The disease severity was determined according to the Goligher scale.[7] Patients with 1st and 4th-degree hemorrhoids, perianal pathologies, a previous interventional or surgical hemorrhoid treatment history, coagulation disorders, and those who were pregnant,, or lactating, or using anticoagulants, were excluded from the study. The patients were informed that they were free to withdraw from the study at any time.

Study sample

A pilot study was carried out to determine the sample size. Accordingly, 20 hemorrhoid patients were divided into two groups: patients treated with conservative medical treatment only and those treated with conservative medical treatment plus the herbal tea, *Capsella bursa-pastoris*. The type I error (α value) was 0.05, and the power of the study (1-β) was 80%. The comparative analysis of the VAS scores for pain revealed a 1.4±1.5 point decrease in the VAS scores in the group treated with conservative medical treatment plus *Capsella bursa-pastoris* compared to the score in the group treated with conservative medical treatment alone. Accordingly, it was determined that at least 19 patients must be included in each group. The sample size was increased by 10% to allow for possible dropouts. As a result, it was determined that the sample should include a minimum of 42 patients, with 21 patients in each group. The sample size calculation was conducted using the MedCalc® Statistical Software version 19.7.2 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2021).

Interventions

All patients included in the study underwent a complete physical examination and symptom assessment. Patients were divided into study and control groups via sequential randomization. Patients in the control group were administered the conservative treatment only, whereas the patients in the study group were administered the conservative treatment and herbal tea preparations of *Capsella bursa-pastoris* (Temmuz Organic Company, Konya, Turkey). Both the conservative treatment and the treatment using herbal tea preparations were continued for three months. The conservative treatment included diosmin plus hesperidin (Daflon®, diosmin 450 mg, hesperidin 50mg, tablet, twice a day, Servier Turkey, Istanbul, Turkey) and trimebutine plus ruscogenin (Recbutin®, trimebutine base 5.8%, ruscogenin 0.5%, rectal cream, twice a day, Abdi Ibrahim, Istanbul, Turkey). The patients in the study group were instructed to drink one cup (200 ml) of *Capsella bursa-pastoris* tea one hour before sleep. A total of 90 tea bags were provided to each patient in the study group, and their consumption was checked at one-month intervals.

Data collection

Patients' demographic (age and gender) and clinical characteristics (difficulty and bleeding during defecation, visual analogue scale (VAS) score for pain, severity of the hemorrhoidal disease, and the number of affected quadrants of hemorrhoids) were collected during the face-to-face interviews conducted at the beginning of the study. The patients rated the degree of pain they were feeling in relation to the hemorrhoidal disease using a visual analogue scale (VAS) between zero (no pain) and ten (most severe pain). The investigator who assessed the VAS scores of the patients was blinded to the groups. The severity of the hemorrhoidal disease was graded via a rectal examination with anoscopy as grade 2 or 3.[7] Based on the quadratic distribution, the number of the quadrants of the hemorrhoidal plexuses was also recorded. Hemorrhoids present in all four quadrants were defined as circumferential hemorrhoids.[22]

At the 3rd-month follow-up examination, the patients were asked about the difficulty and bleeding they had during defecation and to re-rate the degree of pain they were feeling in relation to the hemorrhoidal disease using VAS. The severity of patients' hemorrhoidal disease was re-graded, and the number of the affected quadrants was recorded once more. Any adverse clinical events that might be caused by the consumption of *Capsella bursa-pastoris* tea preparations were queried in detail.

Statistical analysis

The study's primary outcome was the changes observed in the symptoms and physical examination findings of hemorrhoidal disease in the study group relative to those in the control group. For this reason, statistical analyses of the clinical variables associated with the hemorrhoidal disease and its outcomes in line with the different treatment modalities administered were conducted both within and between the groups.

Descriptive statistics were expressed as mean ± standard deviation values in the case of continuous variables that were determined to conform to the normal distribution and as median values along with minimum-maximum values in the case of continuous variables that were determined not to conform to the normal distribution. Categorical variables were expressed as numbers and percentages. The Shapiro-Wilk, Kolmogorov-Smirnov, and Anderson-Darling tests were used to determine whether the numerical variables conformed to the normal distribution.

The independent samples t-test was used to compare the two independent groups, i.e., the study and the control groups, where numerical variables, including age, conformed to the normal distribution. On the other hand, the Mann-Whitney U test was used to compare two independent groups, i.e., the study and the control groups, where numerical variables including VAS scores and the number of the affected quadrants, did not conform to the normal distribution.

The Pearson's chi-squared test and the Fisher-Freeman Halton test were used to compare the differences between categorical variables (gender, severity of the hemorrhoidal disease, bleeding, and difficulty during defecation).

The changes in bleeding and difficulty the patients had during defecation over time were analyzed separately for each group using McNemar's test.

"Jamovi project (*Jamovi*, version 2.3, 2022, retrieved from https://www.jamovi.org) and JASP software package (Jeffreys's Amazing Statistics Program, version 0.16.1, retrieved from https://jasp-stats.org) were used in the statistical analysis. Probability (*p*) values of ≤ 0.5 were deemed to indicate statistical significance.

RESULTS

The study sample consisted of 218 patients, who were randomized into the study and control groups, with 109 patients in each group. The patients in Group CT were significantly older than those in Group Caps (39.5 ± 14.6 and 35.5 ± 11.7 years, p=0.030). Female patients comprised the majority in both groups (91.7% in the study group and 89.95% in the control group). There was no significant difference between the groups in terms of gender, bleeding and difficulty during defecation, VAS score for pain, the disease severity, and the number of affected quadrants (p>0.05) (Table 1). The changes observed in the symptoms and physical examination findings of hemorrhoidal disease in the study group relative to those in the control group are given in Table 2.

Accordingly, there were significantly fewer patients with bleeding and difficulty during defecation in the study group compared to the control group at the end of the study period (p=0.001 for both cases). Patients in the study group had significantly lower VAS scores for pain compared to those in the control group and the number of affected quadrants was also comparatively lower (p<0.001 for both cases) (Figure 1). The proportion of patients with Grade I hemorrhoidal disease was significantly higher in the study group compared to that in the control group (71.6% vs.

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20.2%). In parallel, the proportion of patients with Grade II and III hemorrhoidal disease was significantly lower in the study group than in the control group (Table 2).

Table 1.Baseline demographic and clinical characteristics of the groups.

	Group CT[a] (n=109)	Group Caps[b] (n=109)	p-values
Age (year) †	39.5 ± 14.6	35.5 ± 11.7	**0.030***
Sex ‡			
Male	11 (10.1)	9 (8.3)	0.814
Female	98 (89.9)	100 (91.7)	
Bleeding during defecation ‡	75 (68.8)	75 (68.8)	0.999
Difficulty during defecation ‡	80 (73.4)	80 (73.4)	0.999
VAS score for pain §	6.0 [1.0- 9.0]	6.0 [1.0- 9.0]	0.999
Number of affected quadrants §	2.0 [1.0- 4.0]	2.0 [1.0- 4.0]	0.873
Grades for hemorrhoids ‡			
Grade II	52 (47.7)	52 (47.7)	0.999
Grade III	57 (52.3)	57 (52.3)	

a: conservative treatment group, b: herbal tea group, †: mean ± standard deviation, ‡: n (%), §: median [min-max], VAS: Visual analog scale

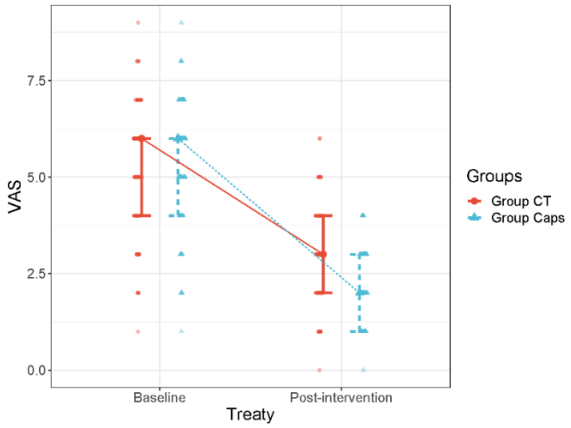

Figure 1. Box violin plot graphs for post-interventional VAS scores for pain

Table 2. Inter- and intra-group analyses of the changes in the clinical symptoms and physical examination findings between the study groups.

	Group CT (n=109)	Group Caps (n=109)	p-values
Bleeding during defecation ‡			
Baseline	75 (68.8)	75 (68.8)	0.999
Post-intervention	59 (54.1)	34 (31.2)	**0.001**
p-value	**<0.001**	**<0.001**	
Difficulty during defecation ‡			
Baseline	80 (73.4)	80 (73.4)	0.999
Post-intervention	79 (72.5)	54 (49.5)	**0.001**
p-value	0.999	**0.005**	
VAS[c] score for pain §			
Baseline	6.0 [1.0- 9.0]	6.0 [1.0- 9.0]	0.999
Post-intervention	3.0 [0.0- 6.0]	2.0 [0.0- 4.0]	**<0.001**
p-value	**<0.001**	**<0.001**	
Number of affected quadrants §			
Baseline	2.0 [1.0- 4.0]	2.0 [1.0- 4.0]	0.873
Post-intervention	2.0 [0.0- 3.0]	1.0 [0.0- 3.0]	**<0.001**
p-value	**<0.001**	**<0.001**	
Grades for hemorrhoids ‡			
Grade I	22 (20.2)	78 (71.6)	**<0.001**
Grade II	66 (60.6)	29 (26.6)	
Grade III	21 (19.3)	2 (1.8)	

a: conservative treatment group, b: herbal tea group, c: Visual analog scale, ‡: n (%), §: median [min-max]

Additionally, the comparison of groups' baseline and post-intervention clinical features revealed that there were significant improvements in the hemorrhoidal disease-related clinical symptoms and physical examination findings of the patients in both groups and that these improvements were significantly more prominent in the study group (Table 2). Accordingly, in the control group, there was a significant post-interventional decrease in the number of patients with bleeding during defecation ($p<0.001$), but not in the number of patients with difficulty during defecation ($p=0.999$), whereas in the study group, there was a significant post-interventional decrease in both the number of patients with bleeding during defecation ($p<0.001$) and the number of patients with difficulty during defecation ($p=0.005$). In addition, there were significant post-interventional decreases in the median VAS score for pain and the number of the affected quadrants in both groups.

DISCUSSION

The findings of this prospective randomized study revealed that the combination of *Capsella bursa-pastoris* herbal tea preparations with the standard conservative treatment significantly affected the hemorrhoidal disease-related symptoms and the physical examination findings in a positive direction when compared with stand-alone standard conservative treatment.

The positive effects of *Capsella bursa-pastoris* on the hemorrhoidal disease-related symptoms and the physical examination findings have been noted in the literature and attributed to its anti-oxidant and anti-inflammatory properties.[12] Additionally, it was reported that *Capsella bursa-pastoris* plays a role in the biosynthesis of several active substances, including tannins, sulforaphanes, tyramines, sterols, flavonoids, choline, acetylcholine, and histamine.[3,20,25] Apaydin Yildirim et al.[3] demonstrated the anti-hemorrhoidal effects of ethanol and water extracts of *Capsella bursa-pastoris* on croton oil-induced hemorrhoids in rats. Accordingly, *Capsella bursa-pastoris* reduced the severity of hemorrhagic necrotic enteritis and the levels of cytokines and lipid peroxidation in serum, as well as myeloperoxidase and anti-oxidants in the recto-anal tissues. Naafe et al.[20] and Ghalandari et al.[6] reported the positive effects of hydroalcoholic extracts of *Capsella bursa-pastoris* on heavy menstrual bleeding and early post-partum hemorrhage creating contractions in the uterine smooth muscle cells and hormonal effects. Although the underlying physiological action mechanisms of *Capsella bursa-pastoris* in creating the positive effects noted, were not considered in previous studies or in this study for that matter, it would not be unreasonable to speculate that the anti-inflammatory properties of *Capsella bursa-pastoris* were primarily responsible.

Gulec et al.[8] investigated the anion and cation contents of the herbal products in Turkish folk remedies used for hemorrhoidal diseases. Sargin et al.[1] reviewed the ethnobotanical survey of medicinal plants in a region in Turkey. In two reviews from Iran, Hashempur et al. (6) and Memariani et al. (21) did not mention *Capsella bursa-pastoris* among 105 medicinal plants belonging to 51 families that were used to treat hemorrhoidal symptoms. However, *Capsella bursa-pastoris* has not been mentioned in any of these studies for its effects on hemorrhoidal diseases. This may be simply due to the lack of clinical studies on the usage of *Capsella bursa-pastoris* in patients with hemorrhoids.[1,8] Hence, one of the objectives of this study is to fill this gap in the literature.

There are several phytotherapeutic substances with various application routes used in the treatment of hemorrhoids. Malekuti et al.[16] reported the effect of Myrtus communis anti-hemorrhoidal ointments on the hemorrhoidal symptoms of post-partum women. In another study conducted in Iran, the authors investigated the use of Allium ampeloprasum subspecies Iranicum (Leek) extract cream in patients with symptomatic hemorrhoids.[19] Such herbs have active substances such as tannins, saponins, flavonoids, phenocolic acids, and alcohol.[7,9,10,16,19] It was reported in Hashempur's review that more than half of the herbs with anti-hemorrhoidal usage in Iran exhibited anti-inflammatory and analgesic effects.[11] Several mechanisms have been put forward to explain the anti-hemorrhoidal properties of these active substances including improvement of the venous tone, increases in lymphatic drainage, protection of capillary bed microcirculation, inhibition of inflammatory reactions and decreases in capillary permeability.[9] Additionally, it has been reported that flavonoid-containing herbs were more potent in controlling hemorrhoidal symptoms, given their edema protective mechanisms.[9] Taken together with the results reported in the literature, the findings of this study suggest that a herbal product's active anti-hemorrhoidal ingredients are more

important than the type and application route of the herbal products in inducing the clinical improvements in the symptoms of hemorrhoidal disease.

The medicinal herbs used in the treatment of hemorrhoids are administered in different forms, including oral capsules or creams/ointments.[9,10,14,17,19,23] Herbal tea represents one of the most common forms of use of medicinal herbs. *Capsella bursa-pastoris* was used in both capsule and drop form in previous human studies.[6,20] Another study investigated the effect of vagitories, which contained shepherd's purse, on vaginitis.[5]

Limitations

Apart from its strengths, such as being the first study to demonstrate the anti-hemorrhoidal activity of *Capsella bursa-pastoris* in humans and to analyze the herbal tea formulations of *Capsella bursa-pastoris* on hemorrhoidal symptoms, there were also some limitations to this study. First, it was designed as a single-center study. Secondly, patients' adherence to herbal tea consumption was not measured in detail. Lastly, the groups differed significantly in age, which might have produced a bias in the outcomes.

CONCLUSION

The findings of this study, which revealed significant improvements in the symptoms and physical examination findings of hemorrhoidal disease, suggest that Capsella-bursa pastoris herbal tea products may be recommended to patients with symptomatic hemorrhoids.

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Authors sontributions: The idea, design, data collection and statistical evaluation: [TM]; Drafting of the article, evaluation and interpretation of the findings, and review of the article for intellectual content: [EY].

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