

Red Hot Chili Pepper and Hemorrhoids: The Explosion of a Myth: Results of a Prospective, Randomized, Placebo- Controlled, Crossover Trial

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PURPOSE: Spicy foods are appreciated by a large part of the world population but have been blamed for causing hemorrhoids or exacerbating their symptoms, although no epidemiologic studies have been performed supporting this hypothesis. In this double-blind, randomized, placebo-controlled, crossover trial, we have studied the effects of a single dose of red hot chili pepper on the hemorrhoidal symptoms. **METHODS:** Fifty patients with second-degree and third-degree symptomatic hemorrhoids were randomly assigned to take a capsule containing red hot chili powder or placebo during lunch, scoring five hemorrhoidal symptoms (bleeding, swelling, pain, itching, and burning) on a visual analog scale. After one week, crossover treatment was administered according to the same methodology. Other treatments and foods potentially related with anorectal symptoms were discontinued during the study periods. **RESULTS:** Patients assigned low scores to their

hemorrhoidal symptoms before the study and the scores remained unchanged during the 48 hours after both placebo and chili pepper treatment, the latter showing no statistically significant effects. **CONCLUSIONS:** There is no scientific evidence that a spicy meal based on red hot chili pepper may worsen hemorrhoidal symptoms and, therefore, there is no reason to prevent these patients from occasionally enjoying a spicy dish if they so wish. [Key words: Red hot chili pepper; Hemorrhoids]

Spicy foods are highly appreciated by a large part of the world population, particularly in the Orient, Mexico, and South Italy but also in the United States, where hot chili pepper is a basic ingredient in Creole, Cajun, and Mexican-American cuisines. The pungent effect of red hot pepper (*capsicum annuum*, *Solanaceae*) is mainly caused by its content of capsaicin (N-vanillyl-8-methylalphanonamide), a well-known drug that has been extensively studied for its pro-apoptotic and anticancer properties,¹⁻³ anti-inflammatory effects (anti-tumor necrosis factor α),⁴ and for its application in several diseases involv-

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ing the vanilloid receptors, such as bladder overactivity,⁵ uremic pruritus,⁶ and neuropathic pain⁷ (diabetic, postherpetic).

To our knowledge, no epidemiologic studies of the effects of regular ingestion of spicy foods, as in Indian, Mexican, and other cuisines, have been published yet to ascertain whether they might have a role in the pathogenesis or exacerbation of hemorrhoid symptoms. However, chili foods have been given the blame for deleterious effects on the onset and deterioration of hemorrhoid symptoms, and for that reason they are usually forbidden by general practitioners and coloproctologists to their patients affected by hemorrhoids. Surprisingly, the medical literature is completely lacking in any information about such effects and, therefore, this medical prescription seems to be based essentially on empirical cultural and traditional bases rather than scientific evidence.

For this reason, we performed a prospective, randomized, placebo-controlled, double-blind, cross-over trial to evaluate any cause-effect relationship between the ingestion of chili pepper and hemorrhoidal symptoms.

PATIENTS AND METHODS

After obtaining written, informed consent and approval from the ethics committee, 50 patients (28 males) older than aged 18 (median age, 50 (interquartile ranges, 37 and 57) years and affected by second-degree or third-degree hemorrhoids entered the study. Hemorrhoidal degrees were classified according to Goligher.⁸ From January to March 2005, ten patients each were recruited in five colorectal units of the Italian Society of Colorectal Surgery operating in different parts of Italy to include different dietetic regimens. Eighteen patients were affected by second-degree hemorrhoids and 32 patients by third-degree hemorrhoids. Only six patients (12 percent) were affected by chronic constipation and only two of them used oral laxatives routinely. Their symptoms at the time of the first outpatient visit included some degree of rectal bleeding at defecation in all, anal swelling in 45 patients, moderate itching in 10, anal burning in 5; the patients scored the severity of these symptoms in the range 1 to 5 on a total score of 10.

Patients affected by peptic ulcer, gastroesophageal reflux, dyspepsia, associated colorectal diseases (Crohn's, fistulas, fissure, dermatitis, proctitis), or

acute hemorrhoidal thrombosis were excluded from the study. Further exclusion criteria were pregnancy and an inability to understand the end points of the study and to complete the forms for data recording.

Each patient was enrolled after a full proctologic examination, including proctoscopy or flexible sigmoidoscopy. A more extensive endoscopic evaluation for diagnostic screening purposes was performed in patients older than aged 50 years, or older than aged 4 years if they had a positive family history for colorectal cancer.

Dosage

The quantity of red hot chili pepper powder to be added to a normal dish to make it spicy enough, recommended by a member of the Association of Teachers of Italian Cuisine (AICI), is indicated as the "tip of a knife." Twelve expert cooks were asked to take a knife-tip of red hot chili pepper powder, which was then weighed. The mean weight was 9.7 (range, 8–12) mg, therefore, the quantity of chili powder to be used in the active capsules was conventionally set at 10 mg.

The capsules were confectioned by a pharmacy and prepared according to the Italian "Farmacopea Ufficiale." They were numbered consecutively, but the sequence of placebo and red hot chili pepper powder was randomized. Red hot chili pepper powder was obtained by milling the fruit and seeds of *capsicum frutescens* free from foreign bodies and bacterial contamination and produced for alimentary use by Herboristeria Erbofarmosan, Bari, Italy. The active capsules contained 10 mg of red hot chili pepper powder and 70 mg of gluten and lactose-free microcrystalline cellulose.

Placebo capsules contained 80 mg of microcrystalline cellulose. The capsules were colored blue to prevent identification of the chili pepper powder, which is red.

Study Design

After the baseline selection each patient was treated for one week with flavonoids capsules and stool softeners before commencing the study. During the study period, patients were instructed to avoid any other foods potentially related to gastrointestinal and hemorrhoidal symptoms, such as pepper, alcoholic drinks, coffee, and chocolate. They also were encouraged to adopt a fiber-enriched and water-enriched diet.

Each center participating in the study received ten sets containing two capsules each. Each patient was given a package with the two capsules numbered consecutively and was instructed to score, on a 10-cm visual analog scale (VAS) without intersections, the severity of the primary hemorrhoidal symptoms, such as bleeding and swelling, and secondary hemorrhoidal symptoms, such as itching, pain, and anal burning, before and 6, 24, and 48 hours after the ingestion of one of the capsules (containing placebo or red hot chili pepper powder) during lunch. The patients were asked to note down the code number of the capsule taken each time. One week later, they repeated the treatment taking the other capsule (crossover treatment). Both the patients and the doctors were unaware of the content of each capsule because the randomization

code was known by the chemist only. Other drugs were discontinued during the treatment period.

Statistics

A sample size calculation showed that a minimum of 20 patients in each arm would be required to demonstrate an increase of hemorrhoidal symptoms at the 5 percent level of significance with a power of 90 percent.

The statistician opened the randomization code when she analyzed the data. Results were tabulated on an Excel[®] spreadsheet and then analyzed by using the SPSS[®] statistical package for Windows[®] (SPSS[®], Chicago, IL)

The difference between groups for each of the symptoms scored was assessed using the Mann-

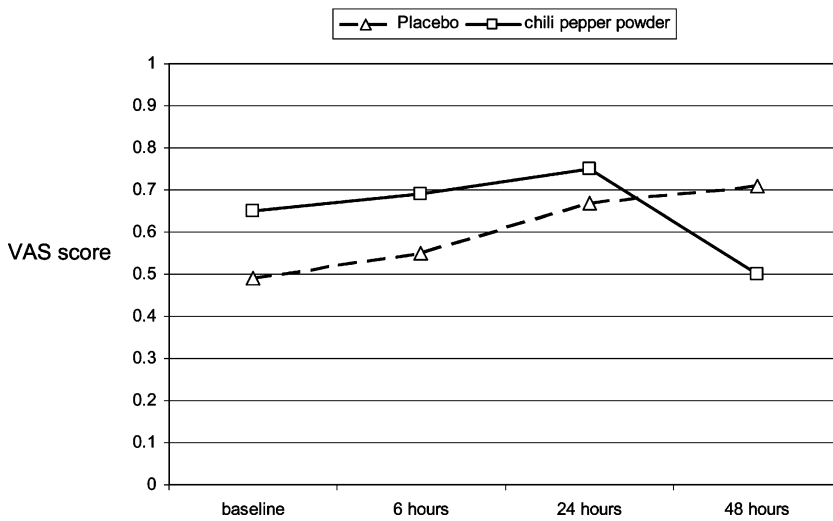


Figure 1. Effect of placebo and red hot chili pepper treatment on anal pain in patients with hemorrhoids (Visual Analog Scale between 0 and 10).

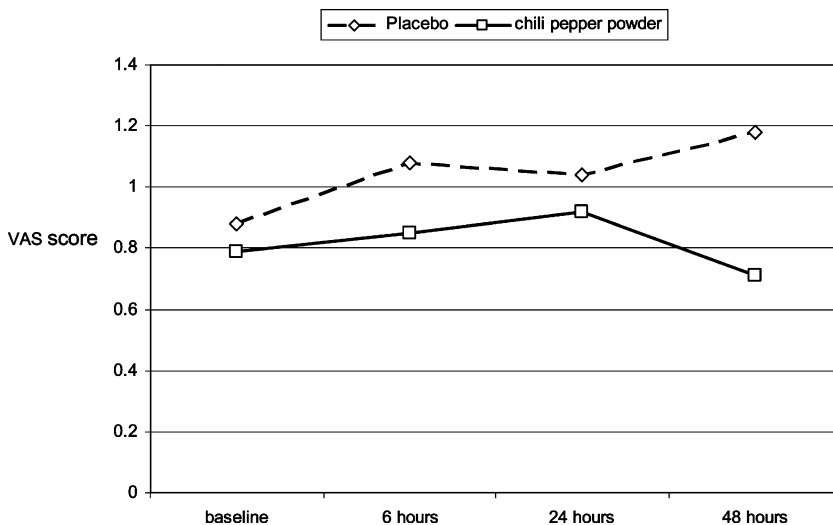


Figure 2. Effect of placebo and red hot chili pepper treatment on anal burning in patients with hemorrhoids (Visual Analog Scale between 0 and 10).

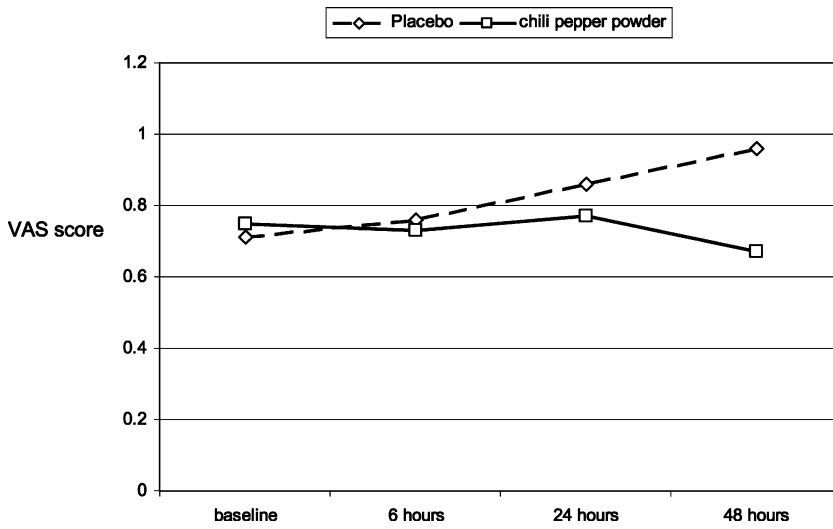


Figure 3. Effect of placebo and red hot chili pepper treatment on anal swelling in patients with hemorrhoids (Visual Analog Scale between 0 and 10).

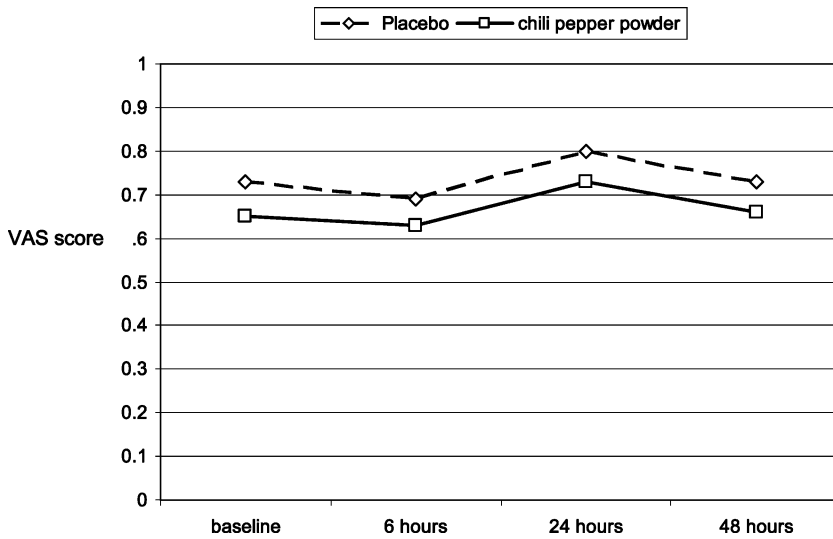


Figure 4. Effect of placebo and red hot chili pepper treatment on anal bleeding in patients with hemorrhoids (Visual Analog Scale between 0 and 10).

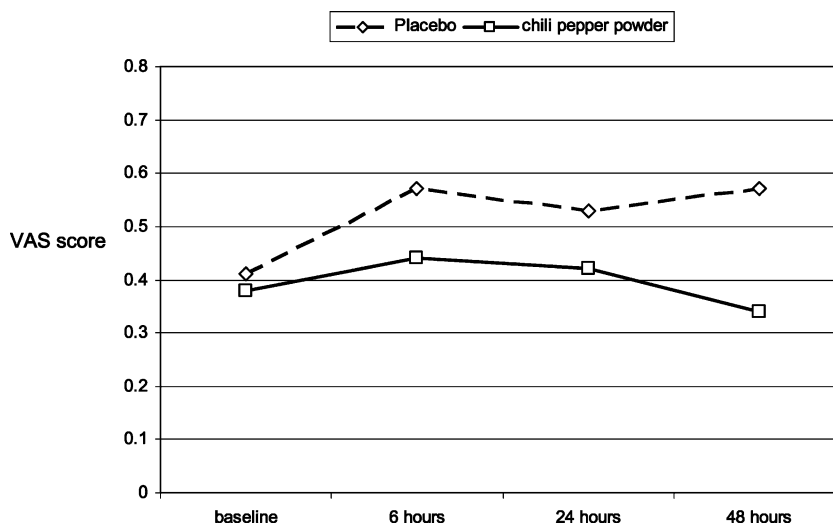


Figure 5. Effect of placebo and red hot chili pepper treatment on anal itching in patients with hemorrhoids (Visual Analog Scale between 0 and 10).

Whitney *U* test for independent samples. Data were presented as median and interquartile ranges. The Friedman nonparametric test was applied to evaluate the difference in the symptoms' score after red hot chili pepper powder or placebo treatment during the study period. Bonferroni's correction $\alpha = 0.05/5 = 0.01$ was used to compensate for an inflated Type I error rate with five variables.

RESULTS

Forty-eight patients completed the protocol, one did not return the spread sheets, and the other did not complete the trial because of accidental opening of one of the capsules. All the 48 patients who completed the study followed the dietary instructions and scored their anal symptoms as indicated in the protocol.

The baseline median symptom scores expressed on a 0 to 10 VAS were comparable in the two groups. In fact, during placebo treatment the median score was 0.5 for anal pain, 0.9 for burning, 0.7 for swelling, 0.72 for bleeding, and 0.4 for itching. The corresponding value during chili pepper treatment was 0.65 for anal pain, 0.8 for burning, 0.75 for swelling, 0.65 for bleeding, and 0.4 for itching. These values remained low in all patients during both placebo and red hot chili pepper treatment (Figs. 1–5). Statistical analysis did not show any difference in the symptoms' score after red hot chili pepper or placebo treatment with regard to bleeding, swelling, anal pain, itching, or burning during the study period.

DISCUSSION

Review of MEDLINE on capsaicin (the active substance in chili pepper) revealed 7,547 citations documenting the high interest of researchers in the medical properties of this vegetable drug, but no items were cited for the association of capsaicin (or red chili pepper) and hemorrhoids. The only paper⁹ dealing with hemorrhoids and red pepper, published in 1956 claimed beneficial effects for this therapeutic agent on vascular disorders, including hemorrhoids. This may be caused by its anti-inflammatory and antioxidative activities.¹⁰ Another epidemiologic study¹¹ on 50 patients with hemorrhoids compared with 50 controls found a statistically different dietary habit in the hemorrhoidal patients with regard to the

use of several ingredients in their diet, including fat, alcohol, pimento, and pepper, but no mention was made of red chili pepper. Therefore, the medical literature is completely silent on this topic, contrasting strongly with common popular feeling and medical prescriptions. The effects of red chili pepper on anorectal function were recently investigated by Golanchanvit *et al.*¹² on a small sample of healthy volunteers, showing a slight decrease in the rectal urgency sensation at the barostat study but no effects on other manometric parameters.

Usually, patients tend to attribute their various anorectal symptoms to the content of the meal eaten the day before, trying to establish a cause-effect relationship. Our study reproduces the ingestion of a spicy food at lunch except for the pungent sensation in the mouth, which is bypassed because the capsule containing chili pepper powder is swallowed. The capsule opens in the stomach and its content is absorbed in the jejunum so that a systemic effect, if present, should manifest in the hours after ingestion. The results of this study clearly demonstrate that a moderate use of chili pepper during a meal has no effects at all on hemorrhoidal symptoms, which can, instead, probably be exacerbated by several other conditions, including constipation and hard and poorly hydrated stools. It should be noted that only six of our patients had a history of constipation.

CONCLUSIONS

Our results have allowed us to explode the myth, showing that there are no reasons to prevent patients with hemorrhoids from tasting a chili dish if they so wish, and gaining other possible benefits from the use of this fashionable spice. In view of the above results, we are planning to extend the study by administering hot chili pepper for a prolonged period in such patients to assess whether there could be any cumulative effect.

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