

Do dietary spices impair the patient-reported outcomes for stapled hemorrhoidopexy? A randomized controlled study

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Received: 22 May 2010 / Accepted: 27 September 2010 / Published online: 26 October 2010
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Abstract

Background Postoperative pain is a concern for patients seeking hemorrhoid surgery. Stapled hemorrhoidopexy is popular due to better patient-reported outcomes (PROs). Pain is the index of PROs. Posthemorrhoidectomy patients usually opt for a spice-free diet due to fear of pain or anal pruritus induced by spices. Curcumin and piperin (spice constituents) have powerful antiinflammatory and antioxidant properties. Ability to resume a normal taste-habituated meal may improve PRO quality of life. Thus, spice-related paradoxical conservatism in stapled hemorrhoidopexy, which involves no open wound, needed to be studied.

Methods A prospective open-ended study (July 2008 to August 2009) investigated consecutive candidates for day-care stapled hemorrhoidopexy randomized by the date of birth method into a controlled group (receiving a spice-free diet) and a study group (receiving a spicy diet) after an ethics and informed consent protocol. A standard perioperative protocol was followed. At discharge, the patients were advised to resume a normal diet (spicy or bland) and instructed to maintain a pain diary (100-point visual analog scale [VAS]) and an analgesic diary. Paracetamol 650 mg was used for pain exceeding a VAS score of 25. Patients were followed on day 3 and weeks 1 and 3. Failure to be discharged from day care, failure to maintain patient diary,

and squamous epithelium in the rectal donut were the withdrawal criteria.

Results A total of 67 patients were randomized. The groups were well matched for demographics, comorbidities, types of anesthesia, hemorrhoidal grades, and withdrawal. Statistically significant improvement in PROs ($P < 0.05$) and a lower consumption of analgesic tablets were seen in the study group (spicy diet). No adverse event was reported in either group.

Conclusion Resumption of a spicy diet has no adverse impact on PROs after stapled hemorrhoidopexy. Reduced analgesic usage in the spicy diet study group needs to be evaluated further for any potential benefits of spices.

Keywords Hemorrhoidectomy · Hemorrhoidopexy · Patient-reported outcomes · Piles · Postoperative pain · Spices

Stapled hemorrhoidopexy has proved to be as safe as conventional hemorrhoidectomy [1]. Stapled hemorrhoidopexy performed using a circular stapler is premised on Thomson's theory of physiologic "anal cushions" and rectal mucosal prolapse [2]. Resection of internally prolapsing rectal mucosa repositions the anal cushions proximally [2]. The stapled line of anastomosis of rectal mucosa is proximal to the sensitive anal canal mucosa and dentate line. A simultaneous resection of the prolapsed mucosa and stapled anastomosis ensures absence of any open wound in the anorectum. Absence of a raw area in the anorectum makes this procedure less painful than conventional hemorrhoidectomy [1, 2].

Postoperative pain and comfort are important patient-reported outcomes (PRO) of hemorrhoidal surgery. Fear of adverse PROs leads to some dietary spice restrictions,

Presented at the 12th WCES, April 14–17, 2010, National Harbor, MD.

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especially in societies that use spices as an integral part of the normal diet. Consumption of spices by posthemorrhoidectomy patients is known to increase the intensity of adverse PROs and consumption of analgesics [3]. This has been attributed to the raw area in the anorectum after hemorrhoid surgery [3, 4].

Dietary spice restrictions may not be needed after stapled hemorrhoidopexy because no raw wound exists in the anorectum. No guidance was available in the literature regarding the need for restricting dietary spices after stapled hemorrhoidopexy. This study was undertaken to assess whether dietary spices impair PROs after stapled hemorrhoidopexy.

Patients and methods

This study was conducted from July 2008 to August 2009 by a single surgeon at his surgical center. The ethics committee of the center approved the study. Consecutive patients with symptomatic second-, third-, and fourth-degree hemorrhoids consenting to stapled hemorrhoidopexy were enrolled in the study. Patients with concomitant inflammatory perianal disease (abscess, fistula, inflammatory bowel disease) and those with uncorrected coagulation profile were excluded from the study. Patients were informed of the need to maintain symptoms diaries, and only those who understood the procedure for maintenance of the symptoms diary were included finally in the study.

The diagnosis of hemorrhoids was based on clinical presentation, clinical examination, and proctoscopy. Hemorrhoidopexy was explained to the patients, and their informed consent was obtained. Routine hematology, biochemistry, and a preanesthesia check were done. An ultrasound for significant postvoid residual urine (PVR) was performed for patients older than 45 years. Bedtime administration of tamsulosin 0.4 mg was started if the PVR was significant. All the preoperative clinical data were recorded on a standard sheet. The patients were randomized into a study group (to receive a normal spicy diet postoperatively) and a control group (to receive a spice-restricted diet postoperatively) according to the date-of-birth method (i.e., even or odd dates, respectively).

Perioperative antibiotic chemoprophylaxis (cefuroxime + metronidazole) was followed. The patients had surgery under general anesthesia (GA) or under regional anesthesia (RA) if GA was contraindicated. Standard technique for stapled hemorrhoidopexy as described in literature [5] was followed without any variation.

A standard 33-mm circular hemorrhoid stapler (Ethicon PPH03, Ethicon-Endosurgery, Cincinnati, OH) was used as reported by others [2, 5]. Hemostasis was always ensured at completion of the procedure. The resected “doughnut” was

sent for histopathologic examination (HPE) to rule out any squamous anal mucosa. Patients needing an operative reexamination for bleeding or squamous anal mucosa on HPE were excluded from the data analysis.

Once assessed by the anesthetist for recovery from GA/RA, patients were allowed diet, and no intravenous fluids were given beyond 2 h after surgery. In case of acute retention of urine, a catheter evacuation was performed. All the patients underwent surgery on a day care basis and were discharged within 6 to 8 h after surgery in case of GA and within 24 h in case of RA.

Patients were asked to maintain a diary for any significant pain (i.e., >25 on a 100-point visual analog scale [VAS]). They also were asked to record any adverse symptoms (i.e., perianal pruritus, burning sensation, pain or adverse events such as bleeding or fever). They were discharged with 3 days of oral antibiotics metronidazole and paracetamol. An additional 650-mg dose of paracetamol could be used as the analgesic on demand for pain at 25 on the explained scale.

The patients were followed by telephone until their first visit to us on postoperative day 3. They were advised to resume their normal activity, bath, commitments, diet, exercise, and family life thereafter. After day 3, the use and quantity of analgesia were regulated according to demand and requirement.

Adverse events precluding discharge from day care, failure to maintain the symptom diary, and any postoperative adverse event were the criteria for withdrawal of the patient from the study analysis. Patients were evaluated at the end of weeks 1 and 3. The data were prospectively tabulated using the standard spreadsheet program. Student's *t* test and a “test for proportions” were used for statistical analysis by an independent statistician.

Results

This study investigated hemorrhoid patients presenting with bleeding as the main symptom. All the patients had exhausted alternative treatments such as diet modification, stool softeners, sitz bath, nonspecific local ointments before surgery.

A total of 67 consecutive patients were prospectively randomized and included in the study from July 2008 to August 2009. The control group had a spice-free diet postoperatively, and the study group had a normal spice-rich diet. There were no adverse events precluding discharge from day care, no postoperative adverse events, and no squamous epithelium in the resected donut necessitating withdrawal of any patient from the study analysis. A total of 19 patients were withdrawn from the analysis due to noncompliance with diary maintenance. The number of

Table 1 Withdrawals from the study analysis

Group	Total	Withdrawals	Studied
Study	32	7	25
Control	35	12	23
<i>P</i> value	>0.05	>0.05	>0.05

withdrawals from the two groups did not differ significantly as shown in Table 1.

The two groups finally studied were well matched for age, gender, grades of hemorrhoids, symptoms, and type of anesthesia used for stapled hemorrhoidopexy. These data are shown in Table 2.

No evidence of squamous anal mucosa was found at any HPE of the doughnuts. No secondary hemorrhage was noted in either arm of the study during a 3-week follow-up period.

The adverse PRO scores were statistically identical in the two groups on follow-up day 3. At the third week of follow-up assessment, no patient in either group had recorded any adverse PRO. Significantly better PRO scores were seen in the study group (spicy diet), as shown in Table 3. The study group also reported a decreased requirement of analgesic intake during the 3-week study period. This benefit was statistically significant, as shown in Table 4.

Table 2 Demographics and clinical data

Characteristics	Control (nonspices)	Study (spices)	<i>P</i> value
Age (years)	(<i>n</i>)	(<i>n</i>)	
Mean	48.4	48.2	
Range	22–84	23–86	NS
Gender			
Males	18	19	NS
Females	5	6	NS
Clinical			
Grade 2	2	2	NS
Grade 3	17	16	NS
Grade 4	4	7	NS
Other symptoms			
Prolapse	14	17	NS
Mucus discharge	11	13	NS
Itching	13	14	NS
Pain	12	12	NS
Difficult hygiene	9	8	NS
Perianal soiling	6	5	NS
Anesthesia			
General	15	16	NS
Regional	8	9	NS

NS not significant

Table 3 Pain, perianal burning/irritation

Group	Studied (<i>n</i>)	Pain, perianal burning/irritation		
		Day 3 (<i>n</i>)	Week 1 (<i>n</i>)	Week 3 (<i>n</i>)
Study	25	20	2	0
Control	23	16	5	0
<i>P</i> value	NS	NS	Significant	NA

NS not significant, NA not available

Table 4 Analgesic tablets used in 3 weeks

Group	Studied (<i>n</i>)	Analgesic Tablets used	
		Mean (<i>n</i>)	Range (<i>n</i>)
Study	25	7	5–31
Control	23	11	10–27
<i>P</i> value	NS	Significant	

NS not significant

Discussion

Hemorrhoids, present in more than 50% of the population older than 40 years, require treatment only if symptomatic [2]. Thomson demonstrated that in symptomatic patients, the hemorrhoidal cushions slide downward together with mucosa due to fragmentation of Park's ligament [6]. All the patients had adequately tried the available nonsurgical methods such as sitz bath, stool softeners, fiber supplements, and a variety of local applications before opting for surgical consultation [7]. These methods had been tried by all the patients in both the arms of this study. This indicates that surgery is not the first option exercised by symptomatic hemorrhoid patients. Nonsurgical options such as band ligation and the like are popular but not practiced in our surgery.

Fear of postoperative pain is an important limiting factor for patients seeking treatment. Neither the patient nor the surgeon wants unnecessary pain [8]. Surgeons have contemplated the addition of sphincterotomy, anal dilation, the use of anal relaxant, and the like to reduce pain but without total satisfaction [9].

Development of the stapled mucosectomy technique was a step in addressing this concern about pain. Pescatori et al. [10] described stapled mucosectomy for the first time in 1997. Stapled hemorrhoidopexy has become popular over the short period since its introduction about a decade ago [11] because it is less painful [2]. This pain-related advantage attributable to stapled hemorrhoidopexy has been cited by a systematic review on stapled hemorrhoidopexy as a "trade-off" for long-term disadvantages such as prolapse and recurrence [12]. The short-term benefits of stapled hemorrhoidopexy have ensured its popularity, and the long-term adverse outcomes have been ignored [12].

Despite the perceived popularity, some concerns persist. Some workers have even entitled their work on this subject “Stapled Hemorrhoidectomy: Pain or Gain” [8]. Symptoms relating to anorectal pain are due to sphincter spasm as a reflex to passage of stool [6].

Spasm of the sphincter also can be induced by the spices or their products acting as irritants on the raw anorectal wounds [3, 13]. Spices are known to cause rectal hyperalgesic [14]. They also increase the postoperative symptoms after hemorrhoidectomy [3]. Findings have shown that spice consumption is directly related to symptoms such as pain and pruritus [3, 13, 14].

Stapled hemorrhoidopexy has no anorectal raw wound. It has become popular due to less pain, rapid recovery, and greater patient satisfaction [15]. Absence of a raw wound protects the patient from adverse effects of spices on PROs. This was established from the observations in our study. Not only was the absence of any adverse PRO in the study group significant but also the decreased requirement of analgesics in the study group. This potentially beneficial effect in the study group could be attributed to the benefit of spices in the absence of a raw wound.

The spices used in the Indian diet are a mixture of many ingredients. Turmeric, pepper, clove, chilies, and fenugreek seeds are the major universal components of spices routinely used in the Indian diet. Curcumin, the active ingredient of turmeric, exhibits strong antiinflammatory and antioxidant activities [16]. It also modulates the expressions of transcription factors, cell cycle proteins, and signal-transducing kinases that are potentially antiinflammatory [16–18]. It also has antiviral, antibacterial, and antifungal activities [17]. Fenugreek seeds are a rich source of soluble fiber [19].

The components of many spices potentiate the beneficial effects of curcumin [20, 21]. This has been established for many spice-derived nutraceuticals, especially for piperin found in pepper and the like [20, 21]. Clove oil has been shown to promote healing of anorectal wounds [22]. It has been shown to effect a significant reduction in resting anal pressure and all other anorectal manometric profiles [22]. All these known beneficial effects of the spices may contribute to better PROs in the patients continuing to have a spicy diet postoperatively after stapled hemorrhoidopexy, as seen in this study.

Postoperative pain is even reported as a deterrent in making the decision to undergo surgery [6]. A recent systematic review of stapled hemorrhoidopexy reports a significant benefit in 95% of the trials included after their compliance to defined criteria for inclusion was checked [12]. Yet post-evacuation pain remains a valid concern. This new-onset pain after evacuation may compromise the lifestyle, including ability to return to work [23]. A consensus statement on stapled hemorrhoidopexy has recommended inclusion of such symptomatic outcomes in the informed consent [24].

Stapled hemorrhoidopexy has rightly earned its place of acceptance and popularity. Its outcome has become better with experience and repeated adherence to the standard technique [7]. Stapled hemorrhoidopexy has been perceived widely as an appropriate procedure for grades 3 and 4 hemorrhoids. The initial treatment for lower-grade hemorrhoids is nonsurgical. Surgical intervention may become necessary if nonsurgical measures fail [12].

Patients with grade 2 hemorrhoids were included in the current study only after they had exhausted the nonsurgical options available. This is supported by inclusion of 11 trials with grade 2 hemorrhoids in a recent systematic analysis of 27 randomized trials of stapled hemorrhoidopexy [12]. The symptomatology, grading, and clinical appearance are known to be deceptive in predicting symptoms after surgery [7, 25].

The absence of any adverse PROs with the continuation of spices in the diet is encouraging. However, larger multicenter studies are needed to evaluate the reduced analgesic requirement seen with the use of spices. The sample in the current study was larger than in many of the studies included in a recent metaanalysis of stapled hemorrhoidopexy [12].

Ideally, the designing of randomized controlled trials (RCTs) for studying surgical interventions is a challenge [26]. Like surgery itself, the methodologic toolkit for these continues to evolve [26]. Improving the PROs in surgical practice is a genuine desire [27], with the aim to do things that matter [28]. Improved PROs is a function of inflammatory response determined by surgical stress [27]. Because spices are a rich source of antiinflammatory ingredients such as curcumin, piperin, and the like [16–22], they can potentially downregulate this PRO determining surgical inflammatory stress.

Historically, validation of surgical interventions by RCTs has been a concern [29]. This has been attributed to structural, cultural, and psychological resistance to the ideal applicability of RCTs [29]. Both the surgeon's and the patient's equipoise contribute to this handicap in designing ideal RCTs in surgery [29]. In surgical practice, RCTs are an important support system but not a substitute for decision making [30]. Given these observations, surgical RCTs need to be guided by flexible protocols without a pre-fixed sample size [31]. This helps in tracking the progress over time and provides a platform for the evolution of further and better-designed studies [31]. These observations support the outcome of the current study, which had a sample size larger than studies included in a recent metaanalysis of stapled hemorrhoidopexy [12].

No randomization method is absolutely free of designing defect [28]. The “date of birth” method continues to be used in some very recent high-impact studies reported [32] with ample advocacy [33].

No adverse PROs or potentially antiinflammatory effects of the spices leading to reduced analgesic usage were seen in our study. This can further improve patient satisfaction with stapled hemorrhoidectomy because a promise of an uncompromised diet in the postoperative period will add to its appeal.

Conclusion

Resumption of spices in the diet does not affect the PROs adversely after stapled hemorrhoidectomy. Larger multicenter studies are needed to determine whether spices have any additional benefits for PROs.

Acknowledgments The data maintenance and data analysis was done by Nayan Agarwal and Konark Malhotra, both of whom are aspiring doctors. Pooja Pant did all the documentation. I am thankful to them for their help.

Disclosure Brij B. Agarwal has no conflicts of interest or financial ties to disclose.

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