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PRACTICE PARAMETER

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The treatment of hemorrhoids: guidelines of the Italian Society of Colo-Rectal Surgery

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Introduction

The choice of the best surgical technique must always be based not only on the surgeon's personal experience but above all on the scientific evidence supporting the superiority of one surgical technique over another. Results of the surgical treatment of hemorrhoids can be assessed on the basis of its effect on various parameters, namely postoperative pain, time taken to return to normal working and relational activities, hospital stay, the incidence of early and late complications, aesthetic and functional results, the incidence of recurrence and finally, cost. Thus, any comparison of different techniques must take into account all these factors.

These guidelines aim to offer some therapeutic decision-making support based on the best scientific evidence available at the time; in other words they are to be taken as advisory rather than prescriptive rules. Therefore, they are not static but dynamic, susceptible to continual variations in concomitance with the introduction of new techniques and the accumulation of scientific evidence of their validity. The proposed guidelines are based essentially on close analysis of the international literature carried out by MedLine searches using the keyword hemorrhoids in association with hemorrhoidectomy, long-term results, randomized controlled trials, and stapler.

The levels of scientific evidence of any therapeutic choice, and hence the degree of recommendation of the given technique, have been indicated in 1992 [1] and have already been accepted by several scientific societies. These levels of evidence and degrees of recommendation are summarized as follows:

Levels of scientific evidence

I. Evidence from meta-analyses of multiple prospective, randomized controlled trials, or else from randomized controlled trials or trials with a low incidence of false-positive and false-negative results

II. Evidence from at least one randomized trial, even with high false-positive and false-negative results (low power of the trial)
III. Evidence from non-randomized cohort studies or well conducted case-control studies
IV. Evidence from comparative studies with historical controls or non-comparative case series
V. Evidence from case reports

Degrees of recommendation
A. Level I evidence or results in accordance with multiple level II or III trials
B. Evidence from level II, III or IV trials with generally concordant results
C. Evidence from level II, III or IV studies with non-concordant results
D. Scarce or empirical evidence

Definition of hemorrhoids

The vascular hemorrhoidal cushions, which play a role in maintaining fecal continence, are a normal component of the anal canal and are composed of vascular tissue (with a high number of arterovenous anastomoses with no interposed capillary network) and connective tissue with a rich content of elastic fibers and collagen, lined by simple cylindrical epithelium that is sometimes multilayer but never keratinized. Hemorrhoid disease is a pathological condition characterized by bleeding and prolapse of the hemorrhoidal cushions, sometimes complicated by thrombosis.

Indications for surgical treatment

Although surgeons of the different schools have notably different attitudes towards the issue of the advisability of surgery or not, the indication for surgical treatment must certainly include repeated bleeding episodes which are difficult to control pharmacologically (after having excluded other possible causes of rectal bleeding), external prolapse of the hemorrhoidal tissue, and a tendency to repeated hemorrhoidal thrombosis. Severe anemia secondary to hemorrhoidal bleeding should never be an indication for surgery even in high-risk patients.

Classification

The choice of treatment depends mainly on the grade of hemorrhoids. Traditionally, four grades are distinguished [2]: *grade I*, bleeding but no prolapse; *grade II*, prolapse during straining to defecate but spontaneous re-entry; *grade III*, the prolapse must be pushed back into the anus by hand; *grade IV*, the prolapse is permanently external and cannot be pushed back inside. Besides this traditional classification, other categories have been proposed, taking into account the distribution of the prolapse by circumference or by quadrants, as well as acute events such as abscess development, thrombosis and presence of excessive anal tone. Although the use of this new classification system (PATE 2000) [3] is desirable to obtain a better clinical picture of the patient, it has been slow to enter common practice due to its greater complexity. Nevertheless, if it were to enter routine practice it would ensure greater uniformity and comparability of patients eligible for treatment, especially in the context of prospective randomized trials.

Some general considerations can be made:
1. Patients tend to attribute any anal symptom to hemorrhoids and often associate these with eating habits, working activities (e.g. sedentary, standing, physical effort), climatic conditions or bowel characteristics. There is no scientific evidence correlating the onset of hemorrhoids or the exacerbation of their symptoms with any of the previous factors: not even with the consumption of hot chilli peppers. Nevertheless, the adoption of a balanced diet, limiting the consumption of alcohol and spices, and ensuring a sufficient intake of fiber and water can bring about regularization of bowel movements and so improve the symptoms.
2. Portal hypertension is not a cause of onset of hemorrhoids, although it may be associated with the underlying disease. So-called rectal varices must not be confused with hemorrhoids.
3. The finding of rectal bleeding, especially if associated with anemia, must be considered an indication for total colonoscopy to exclude other colonic disease in patients over 50 years of age. In the case of patients with familial or other risk factors for colorectal neoplastic disease, colonoscopy is advisable after the age of 40 years.
4. Hemorrhoids are not hereditary, although a family history of hemorrhoidal disease is often reported, probably related to common dietary habits [4].
5. The possible causal role of constipation in hemorrhoids is controversial and one epidemiological study excluded a cause-effect relationship [5].
6. Although some surgical techniques are still considered valid, they have been gradually abandoned in light of new therapeutic options and in consideration of the results of comparative studies reported in the literature. Included among these are: hemorrhoidectomy according to Whitehead; Parks' and Lord's procedures (anal divulsion); laser hemorrhoidectomy; and cryotherapy.

7. The need for microscopic evaluation of hemorrhoidal specimens is still controversial because less than 1 in 20 000 hemorrhoids contains occult malignancy. However, pathological analysis of the resected specimens is wise.

Guidelines on the use different treatments for hemorrhoids

There is a sufficiently wide consensus in the literature that *grade I hemorrhoids* should be treated conservatively, even if no meta-analysis has been conducted (degree of recommendation, B). Besides dietary treatment, namely a high-fiber diet and a lot of water [6] to facilitate defecation, the use of flavonoids [7, 8] seems to provide important help in controlling the symptoms, thanks to its effects on the microcirculation (degree of recommendation, B). Only in cases refractory to medical treatment is infrared coagulation, or elastic ligature if possible, advised.

Regarding *grade II hemorrhoids*, a meta-analysis conducted in 1995 [9] demonstrated that the technique yielding the best long-term results was elastic ligature according to Barron [10] (degree of recommendation, A). Other mini-invasive techniques (e.g. sclerotherapy and photocoagulation), alone or in association, yield satisfactory results in expert hands [11], but have been abandoned by most proctologists in favor of elastic ligature.

The new ultrasound-guided techniques for transanal arterial ligature (e.g. hemorrhoidal artery ligation and transanal hemorrhoidal dearterialization) [12, 13], although originally proposed for grade II hemorrhoids, have often been successfully applied to grade III hemorrhoids as well, they seem to be an important therapeutic resource for coloproctologists as they have few complications, the procedure is mini-invasive and the short-term results are good. In a first randomized trial of transanal hemorrhoidal dearterialization (THD) versus Milligan-Morgan hemorrhoidectomy, significantly better short-term results were obtained in the group treated with THD, in terms of less postoperative pain, hospital stay and time to return to work, while the results at the 1-year follow-up were comparable (degree of recommendation, B) [14]. Unfortunately, no other comparative studies are at present available (e.g. THD versus stapler) nor are long-term results permitting a correct assessment from the evidence-based medicine standpoint.

Grade III hemorrhoidal prolapse is the most common indication for surgical treatment, and four meta-analyses [15–18] established the superiority of stapled hemorrhoidopexy over the Milligan-Morgan technique, as regards postoperative pain and time to return to work. Some variations of the technique, such as the use of a double purse-string rather than a single one, yielded better results in a recent randomised controlled trial [19]. The incidence of the most common complications after hemorrhoidectomy (mainly bleeding and incontinence) does not appear to be significantly different from that after stapled hemorrhoidopexy, although some rare and difficult to treat complications (e.g. rectovaginal fistulas, occlusion of the lumen, obstructed defecation, hour-glass rectum, intramural hematomas, persistent anal pain, sepsis) have been reported [20]. Urgency to defecate is also a frequent early symptom, although fortunately it is nearly always transitory. Biofeedback training has been tried with little success in these cases.

In case of a weak sphincter or damage caused by previous procedures, as well as post-surgical anal substenosis, great care must be taken when using the stapler as there is a high risk of causing a latent situation of fecal incontinence to become clinically manifest. Some authors have proposed the use of antibiotic prophylaxis when performing stapled hemorrhoidopexy [21, 22], since the concern aroused by the reports of a few serious cases of retroperitoneal sepsis, but no clinical trials have been run to demonstrate the utility of this precaution (degree of recommendation, C). One important aspect of hemorrhoidopexy is its higher cost than the traditional procedure. Even though the potential reduction in hospital stay and the earlier return to work have economic advantages in terms of lower health care and social costs, respectively, a randomized study [23] demonstrated that in any case the stapler procedure is more costly. Besides, in Italy, reimbursement of surgical treatment of hemorrhoids does not take into account the extra expense for the disposable device, so that stapled hemorrhoidopexy continues to have negative repercussions on the hospital budget.

After the Milligan-Morgan technique on the other hand [24], there is a greater frequency of anal stenosis and in some cases it causes some loss of the anal mucosa sensitive epithelium. Analysis of the long-term results after the Milligan-Morgan and Ferguson techniques has also pointed out a worrying incidence of fecal incontinence (up to 30%) [25, 26]. Only a few papers have presented long-term results for the stapler technique, which has been introduced on a large scale only in 1998. Although an Italian study [27] of 100 cases with a 3-year follow-up claimed a similar recurrence rate, a more recent study with a follow-up of 46 months showed a significantly higher percentage of recurrences after stapled hemorrhoidectomy [28]. Further studies are ongoing to the clarify this important issue.

The negative aspects of stapled hemorrhoidopexy are at present the greater cost of the disposable stapler and, probably, a higher incidence of residual hemorrhoids or recurrence, especially in studies that included patients with grade IV hemorrhoids [17, 28, 29]; however, this has not been confirmed by other studies [30, 31].

Postoperative pain has always been the greatest problem after the Milligan-Morgan hemorrhoidectomy, and various tips have been proposed to reduce this problem:

1. Avoid using of the "ballerina" (an endoanal gauze tampon inserted for hemostatic purposes).
2. Use antibiotics (metronidazole), on the assumption that the pain may be sustained by a bacterial infection.
3. Perform internal lateral sphincterotomy.
4. Perform chemical sphincterotomy with nitroderivatives or calcium antagonists.
5. Limit thermal damage due to the electric scalpel by using laser, radiofrequency or ultrasound scalpels.
6. Close the mucosa according to Ferguson.

Each of these methods (except abolishing the endoanal ballerina) is supported by some studies but contested by others, so the degree of recommendation of these techniques for reducing the pain is low (degree, C). The use of radiofrequency seems to speed recovery and reduce the rate of postoperative bleeding, but an analgesic effect has not been confirmed by all studies [32–35]. The use of ultrasound (Ultracision) in hemorrhoidectomy also appears to improve these parameters [36], although in a comparative study of Ligasure versus Ultracision the results were in favor of radiofrequency [37] (grade of recommendation, B).

Other techniques that have not yet been validated for the treatment of grade III hemorrhoidal prolapse include internal Delorme procedure (manual or radiofrequency mucosectomy and manual transanal suture) or, as mentioned previously, US-guided transanal dearterialization. Lastly, it should be remembered that repeated elastic ligature has been successfully used in grade III hemorrhoids and is recommended by the American Society of Colon and Rectal Surgeons [38], although the long-term success rates are sometimes lower than those for grade II hemorrhoids. In a recent Cochrane library review comparing elastic ligature and hemorrhoidectomy, excision was preferable to ligature [39].

In true *grade IV hemorrhoids* (irreducible hemorrhoidal prolapse, a clinical condition that occurs in less than 10% of surgical hemorrhoid cases), Milligan-Morgan hemorrhoidectomy, preferably using a radiofrequency (Ligasure, Tyco Healthcare) or ultrasound (Ultracision, Ethicon) scalpel, is still the most rational choice. Good results have been reported using stapled hemorrhoidopexy for grade IV hemorrhoids, too [40], but some perplexity is aroused as to the correct classification of these cases, since the physiopathological premises underlying the use of the stapler do not apply in these cases. In other words, mucohemorrhoidal prolapse does not have the mobility required to perform haemorrhoidopexy. A comparative study of long-term results [27], in fact, demonstrated that in grade IV hemorrhoids the rates of recurrence and patient dissatisfaction with the stapler treatment are significantly higher than after the Milligan-Morgan procedure (degree of recommendation, B).

There is still another issue to be discussed, namely the treatment of *single hemorrhoidal prolapse* or true rectal mucosal prolapse confined to a single quadrant. In these conditions different classification criteria need to be applied, such as those proposed by Gaj et al. [3], which delineate a better patient profile on the basis of which to choose the therapy. In these cases, the clinician may choose more conservative surgery, such as excision of the prolapse only under local anesthesia in outpatient or day surgery regimen, perhaps using an ultrasound or radiofrequency scalpel. Although long-term results on the validity of this approach are not available, sufficiently good short-term results have been documented [41] (degree of recommendation, C).

Hemorrhoidectomy in day surgery regimen

A number of studies has demonstrated the feasibility of hemorrhoidectomy [42] or stapled hemorrhoidopexy [43] in day surgery, with a considerable savings in health care costs. Day surgery treatment should in any case be confined to well selected patients in good physical and mental health, with grades I or II hemorrhoids and living within 50 km of the hospital facility. Clearly, prior written informed consent must be obtained; adequate pain-killers must be prescribed and an emergency telephone number should be given to the patient for use in case of need.

Exceptional situations

Internal and external hemorrhoidal thrombosis during pregnancy

Due to its frequent association with constipation and increased endopelvic pressure, pregnancy often brings on hemorrhoids that can even thrombose, requiring specialist treatment. Although the general attitude tends toward conservative treatment, hemorrhoidectomy (closed hemorrhoidectomy) has been successfully performed without risk to the fetus [44] (degree of recommendation, C). No relevant reports of the use of other hemorrhoidectomy techniques in pregnancy have been made. As to conservative treatment with phlebotrophic drugs (rutosides), 2 randomized placebo-controlled trials have shown greater efficacy of pharmacological treatment, but the observation in one study of one fetal malformation in the pharmacological group (and of a dead fetus in the control group) raised some doubts as to the safety of this treatment [45].

Treatment of hemorrhoids in patients with coagulation defects

In patients with coagulation deficiencies (both congenital and drug-induced), traditional hemorrhoidectomy poses a

higher risk of hemorrhage. Positive experiences have been reported using Ligasure [46] but also using the circular stapler (degree of recommendation, C). In patients under warfarin sodium treatment, the therapy should be replaced with low molecular weight heparin before surgery and for the first postoperative week.

Treatment of patients with immune deficiencies

In patients with HIV infection, leukemia and lymphoma, treatment of hemorrhoids must be reserved to cases of real need, in view of the possible HIV contamination of the operators due to profuse bleeding, and because there is a high risk of sepsis. The choice of surgical technique should aim at the least intraoperative bleeding, such as hemorrhoidectomy with Ligasure under adequate antibiotic coverage to prevent infections (degree of recommendation, C). In such cases, it is useful to histologically analyze the resected tissue as there is a risk that anal lymphoma is mistaken for inveterate external hemorrhoids.

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