Comparison of hemorrhoidal treatments: a meta-analysis

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Objective: To determine whether any method of hemorrhoid therapy has been shown to be superior in randomized trials.

Method: A meta-analysis of all randomized controlled trials assessing two or more treatment modalities for symptomatic hemorrhoids.

Main Outcome Measures: Response to therapy, the need for further therapy, complications and pain.

Results: Eighteen trials were available for analysis. Hemorrhoidectomy was found to be significantly more effective than manual dilatation of the anus ($p = 0.0017$) and associated with less need for further therapy ($p = 0.034$), no significant difference in complications ($p = 0.60$) but more pain ($p < 0.001$). Patients who underwent hemorrhoidectomy had a better response to treatment than did patients who were treated with rubber-band ligation ($p = 0.001$), although complications were greater ($p = 0.02$), as was pain ($p < 0.0001$). Rubber-band ligation was better than sclerotherapy in response to treatment for all hemorrhoids ($p = 0.005$) and for hemorrhoids stratified by grade (grades 1 and 2, $p = 0.007$, grade 3, $p = 0.042$), with no difference in the complication rate ($p = 0.35$). Patients treated with sclerotherapy ($p = 0.031$) or infrared coagulation ($p = 0.0014$) were more likely to require further therapy than those treated with rubber-band ligation, although pain was greater after rubber-band ligation ($p = 0.03$ for sclerotherapy, $p < 0.0001$ for infrared coagulation).

Conclusions: Rubber-band ligation is recommended as the initial mode of therapy for grades 1 to 3 hemorrhoids. Although hemorrhoidectomy showed better response, it is associated with more complications and pain than rubber-band ligation. Thus, it should be reserved for patients whose hemorrhoids fail to respond to rubber-band ligation.

Objectif : Déterminer, au moyen d'études randomisées, si une méthode de traitement des hémorroïdes est supérieure.

Méthode : Méta-analyse de toutes les études contrôlées et randomisées au cours desquelles on a évalué deux méthodes ou plus de traitement des hémorroïdes symptomatiques.

Principales mesures des résultats : Réaction au traitement, besoin d'autres traitements, complications et douleur.

Résultats : Dix-huit études étaient disponibles pour analyse. On a constaté que l'hémorroïdectomie était beaucoup plus efficace que la dilatation manuelle de l'anus ($p = 0{,}0017$) et que les sujets avaient moins besoin d'autres traitements ($p = 0{,}034$), qu'il n'y avait pas de différence importante au niveau des complications ($p = 0{,}60$) mais que la douleur était plus grande ($p < 0{,}001$). Les patients qui ont subi une hémorroïdectomie ont mieux réagi au traitement que ceux qui ont été traités par ligature élastique ($p = 0{,}001$) même si les complications ont été plus importantes ($p = 0{,}02$), tout comme la douleur ($p < 0{,}0001$). Les

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sujets ont mieux réagi à la ligature élastique qu'à la sclérothérapie dans le cas de toutes les hémorroïdes (p = 0,005) et des hémorroïdes stratifiées par catégorie (catégories 1 et 2, p = 0,007, catégorie 3, p = 0,042). Il n'y a eu aucun écart dans le taux de complication (p = 0,35). Les patients traités par sclérothérapie (p = 0,031) ou coagulation aux infrarouges (p = 0,0014) étaient plus susceptibles d'avoir besoin d'autres traitements que ceux qui ont été traités par ligature élastique, même si la douleur était plus grande après une ligature élastique (p = 0,03 pour la sclérothérapie, p < 0,0001 pour la coagulation aux infrarouges).

CONCLUSIONS : On recommande la ligature élastique comme première méthode de traitement des hémorroïdes de catégories 1 à 3. Même si l'hémorroïdectomie donne de meilleurs résultats, elle entraîne plus de complications et de douleur que la ligature élastique. C'est pourquoi il faudrait la réserver pour les patients dont les hémorroïdes ne réagissent pas à la ligature élastique.

Many modes of therapy have been advocated for the treatment of symptomatic hemorrhoids unresponsive to diet or application of local preparations. These include:

• Injection sclerotherapy (IS). Injection of a sclerosing solution submucosally, above the level of the dentate line. In contrast to injection of varicose veins, intraluminal injection should be avoided.

• Rubber-band ligation (RBL). A banding instrument such as a Barron ligator or a suction ligator is used. A pair of forceps is passed through the drum of the ligator, the hemorrhoid is grasped well above the dentate line and drawn into the drum of the ligator, and the trigger is released, placing a rubber band around the hemorrhoid.

• Infrared photocoagulation (IRC). An apparatus that produces infrared radiation focussed by a photoconductor is required. The probe is placed on the normal mucosa directly above the hemorrhoid, and 3 to 5 1-second pulses are used. Each pulse causes protein coagulation in an area 3 mm wide by 3 mm deep.

• Bipolar diathermy (BD). The diathermy system is similar to that used to treat bleeding peptic ulcers. Bipolar current is used to coagulate tissue. The advantage of bipolar therapy (like IRC) is the controlled depth of penetration (3 mm).

• Maximal dilatation of the anus (MDA) or the Lord procedure. The patient is anesthetized. The anus is slowly dilated to admit 8 fingers, "ironing out" any constrictions at the outlet.

• Surgical hemorrhoidectomy (SH). Either a closed (Ferguson) or an open technique may be used.

Although each type of therapy has its proponents, no single one has been proven superior. This is either because there is actually no difference between the various treatments or because the published randomized trials did not have sufficient power to show a significant difference when one did exist (type II error).

Meta-analysis is a tool that can cirumvent these problems. It is a "quantitative, systematic summary of a collection of separate studies for the purpose of obtaining information that cannot be derived from any of the studies alone."[1] Meta-analysis allows the combination of data from several studies to increase the statistical power of the analysis. We undertook a meta-analysis of all published randomized trials that compared two or more treatment methods for symptomatic hemorrhoids to assess the effectiveness of the various modes of therapy available.[2]

METHOD

Criteria for inclusion in this meta-analysis were published trials in which patients were randomly allocated to 2 or more treatment methods (other than diet or topical preparations) for hemorrhoidal disease, with documentation of clinically relevant outcome measures and a minimum follow-up of 6 months.

Overall results of response to therapy, need for further therapy, complications and pain were compared for all grades of hemorrhoids. Hemorrhoid grade was defined as follows: grade 1 — hemorrhoids that do not prolapse, grade 2 — hemorrhoids that prolapse on defecation but reduce spontaneously, grade 3 — hemorrhoids that prolapse and require manual reduction, grade 4 — hemorrhoids that prolapse and cannot be reduced.

When outcome data were stratified by grade of hemorrhoid, the results for response to therapy of grades 1 and 2 and grade 3 hemorrhoids were assessed. Grade 4 hemorrhoids were assessed in only 7 patients in all trials combined and, thus, were not included in our analysis.

RESULTS

Eighteen studies met the inclusion criteria. The following comparisons were amenable to meta-analysis because patients were randomized to the treatment groups in a minimum of 2 trials: MDA versus SH (6 trials),[3–8] RBL versus SH (3 trials),[5,6,9] IS versus IRC (2 trials),[10,11] IS versus RBL (4 trials)[6,12–14] and RBL versus IRC (3 trials).[10,15,16]

SH was found to be significantly more effective than MDA overall and for grade 3 hemorrhoids (p = 0.0017),

with less need for further therapy ($p = 0.034$), no significant difference in complications (although there was a trend toward an increased risk of incontinence after MDA, $p = 0.07$) but significantly ($p < 0.0001$) more pain after SH. Overall, patients who underwent SH also had a significantly better response to treatment than did patients who were treated with RBL ($p = 0.001$), although this was at a cost of a significantly greater risk of complications ($p = 0.02$) and pain ($p < 0.0001$). RBL was shown to be significantly ($p = 0.005$) better than IS in response to treatment. This difference was shown for both grades 1 and 2 ($p = 0.007$) and grade 3 hemorrhoids ($p = 0.042$), with no significant difference in the complication rate. Patients treated with RBL were less likely to require further therapy than those treated with either IS ($p = 0.031$) or IRC ($p = 0.0014$), although pain was significantly more likely to occur after RBL ($p = 0.03$ for IS and < 0.0001 for IRC). No difference was found between IS and IRC for any of the outcome measures.

Discussion

Grade 3 hemorrhoids

This meta-analysis suggests that the decline in the use of MDA for grade 3 hemorrhoids appears to have been justified. Patients have lower rates of response, are more likely to require further therapy and tend to have a higher rate of incontinence after MDA than after SH. There was no difference in response rates between SH and RBL for grade 3 hemorrhoids, but since the numbers of patients in the 2 trials compared were relatively small and a difference favouring hemorrhoidectomy was shown for all hemorrhoids, this likely represents a type II or beta error. However, RBL is an outpatient procedure that does not require the patient to take time off work, is associated with good response rates and significantly fewer complications with less pain than SH. Thus, it seems justifiable to use RBL as a first-line treatment for grade 3 prolapsing hemorrhoids, recognizing that SH will be necessary for some patients whose symptoms are not relieved.

RBL was shown to be superior to IS for grade 3 hemorrhoids with respect to response to therapy. IRC was not evaluated for grade 3 hemorrhoids in any of the trials; however, in view of the finding that patients who undergo IRC are more likely to require further therapy than those who have RBL for early hemorrhoids, it seems reasonable to assume that RBL would be more effective in treating more advanced disease.

Grades 1 and 2 hemorrhoids

For grades 1 and 2 hemorrhoids, RBL appears to be the treatment of choice. Patients who undergo RBL showed a significantly better response to therapy than did those treated with IS and a significantly decreased need for further therapy than patients having either IS or IRC. Although RBL was more painful than other outpatient modalities, complication rates were similar. Due to insufficient numbers of studies, BD could not be directly assessed in this meta-analysis. However, the mode of action of BD is similar to that of IRC, with each applying a depth of coagulation of 3 mm.[17] It seems likely that results of bipolar therapy would be similar to those of IRC in the long term.

Conclusions

RBL is recommended as first-line treatment for grades 1 and 2 hemorrhoids or grade 3 hemorrhoids that do not respond to diet or local preparations. SH should be reserved for patients who fail RBL. Although treatment of grade 4 hemorrhoids was not evaluated in this meta-analysis, SH is probably the treatment of choice in these patients.

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SESAP Critique
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Items 393 to 396

The rate at which local anesthetics are absorbed, distributed, and eliminated varies greatly and is the major determinant of the safety of a particular agent. There are two classes of local anesthetics. Amino esters (procaine, cocaine, and others) undergo degradation in the plasma via pseudocholinesterase, are relatively unstable in solution, and are much more likely to cause an allergic reaction. Amino amides (lidocaine, bupivacaine, and others) are degraded in the liver, are extremely stable in solution, and reports of allergic reactions to this group of agents are extremely rare. Within each class, the chemical structure of the agent influences the rate at which it is metabolized. Among the amides, lidocaine has a rapid onset and a duration of one to two hours, whereas bupivacaine has a slow onset and prolonged effect and potent intrinsic anesthetic action, and potent toxic potential. Among the esters, procaine is not a potent anesthetic and is the least toxic of the local anesthetics. Cocaine is an ester and is the only nonsynthetic, naturally occurring local anesthetic in clinical use to date. It has unique properties including a strong anesthetic capacity, powerful vasoconstrictive action, significant CNS toxicity, and addictive potential. It is readily absorbed through the mucous membranes and is the only local anesthetic that is not a vasodilator.

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