Evidence based treatment of hemorrhoids

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A number of different hemorrhoids’ treatment modalities were introduced and discussed during last two decades. Different level of evidence supports one or another approach and new data emerge constantly. Decision to apply particular method of treatment force clinicians to make thorough judgment. The article presents the newest data about different aspects of hemorrhoids management focusing on proof of efficacy.

Key words: hemorrhoids, conservative management, ligation, sclerotherapy, photocoagulation, surgical management, stapled hemorrhoidopexy.

Hemorrhoids are widespread condition affecting considerable part of population and with variety of clinical presentations. A big number of treatment tactics and modalities were discussed even from ancient times, but modern era of hemorrhoids management started since 1869. when John Morgan from London reported the first attempt to obliterate hemorrhoids by means of injection. Comprehensive revues from United States and UK highlights tree types of treatment: conservative (medical), outpatient (non-operative) and surgical. Different evidence supports one or another approach. The purpose of the paper – to give concentrated view on the most recent data available discussing different modalities of the hemorrhoids management.

CONSERVATIVE TREATMENT

Starting with the conservative treatment of hemorrhoids ones should realize that by this means it is not possible to correct pathophysiological changes and it is not necessary even to have such hope. The main goal of the medical treatment is to ameliorate clinical symptoms and to maintain remission.

A use of dietary fiber, topical agents and phlebotonics are among the agents that are most widely discussed as the means of conservative treatment.

Role of fiber in the treatment of hemorrhoids still is controversial. K.Y. Tan and F. Seow-Choen believe that the frequent straining and passage of large bulky stools as a result of fiber consumption will result in compromise of suspensor ligaments of Park at the anal cushions, leading to protrusion of hemorrhoid tissue. Some randomized double blind trials from 70-ies did not find any advantage of bulk-forming agent take in. Other conclusions were withdrawn from trials conducted in 80-ies and 90-ies: high-fiber diet reduced bleeding and pain in patients with hemorrhoids and addition of dietary fiber may improve internal bleeding hemorrhoids although with no immediate effect.

Cumulative data about effect of high consumption of fiber in hemorrhoids’ management where presented recently in meta-analysis performed by Pablo Alonso-Coello et al. Seven trials randomized 378 patients with symptomatic hemorrhoids (grades I – III) to fiber or a no fiber were included. Meta-analyses using random effects models suggested that fiber had an apparent positive effect. The risk of not improving/persisting symptoms decreased by 47% in the fiber group (RR = 0.53, 95% CI 0.38–0.73) and the risk of bleeding by 50% (RR = 0.50, 95% CI 0.28–0.89). Studies with multiple follow-ups showed consistent results over time.

Based on that data it could be stated that fiber treatment is safe, not expensive and could be an initial part in the management of hemorrhoids of various grades.

Local treatment with ointments and suppositories still is very popular among patients and general practitioners. It is believed that these agents give analgesic, anti-inflammatory and lubricant effect. Unfortunately, very little data exists to support rationale and efficacy of that. Majority of papers report safety, tolerance and very little - about efficacy, especially tested in randomized studies. Some exception could be made for an Escherichia coli culture
suspension, which was tested in a series of double blind randomized studies. These data were summarized in meta-analysis too. They demonstrated therapeutic efficacy of the ointment for the therapy of hemorrhoid complaints associated with an anal eczema. Limitations of these studies were: patients' pool, because patients with hemorrhoids and/or perianal eczema were included together, and efficacy parameters (changes for burning, itching, redness and soiling), which actually were not main symptoms of hemorrhoidal disease. Besides, producer company sponsored all these trials.

Since 90-ties a new group of drugs were proposed for the conservative treatment of hemorrhoids: phebotonics. A few formulas were tested: calcium dobesilate, trihydroxyethylrutosides, Ginkor Fort preparation, micronized purified flavonoidic fraction and others. Although all of these drugs may be venoactive, improving venous return, their mechanism remains unclear. Possible actions include increasing lymphatic drainage, improving venous tone, reducing capillary hyperpermeability and anti-inflammatory effects. Several randomized studies reported about safety and efficacy of flavonoids and practical guidelines incorporated them into hemorrhoids' management strategy. Recently meta-analysis of flavonoids for the treatment of hemorrhoids was performed and published. Authors stated, that flavonoids seemed to have a beneficial effect in the treatment of symptomatic hemorrhoids. The risk of not improving or having persisting symptoms decreased by 60 percent with flavonoids.

Injection sclerotherapy of hemorrhoids is the oldest type of the procedure for office treatment of hemorrhoids, but only some of them passed time test: sclerotherapy, rubber band ligation and infrared photoagulation. Infrared photoagulation achieves coagulation, ulceration and sclerosis of the hemorrhoid tissue by means of heat. It is more controlled and reproducible comparing with other office modalities. Efficacy of the photoagulation was tested comparing with other treatment methods. It was found that photoagulation is superior to sclerotherapy, equal to the bipolar diathermy and inferior to rubber band ligation. Rubber band ligation advocated by Barron in 1963. still remains a gold standard for the non-surgical procedure for the hemorrhoids. It combines some removal of hemorrhoid tissue with subsequent sclerosis and fixation. Published data showed that between 60 and 80 percent of the patients had banding were satisfied with the results. Efficacy of rubber band ligation was tested in a big number of trials and was summarized in two meta-analyses and one systematic review. It was concluded that ligation was superior comparing with other office treatment modalities, but with price of being more painful and was slightly inferior comparing with excision hemorrhoidectomy, which was the most effective method of hemorrhoids treatment.

**SURGICAL TREATMENT**

During the last decade interest in surgical options of hemorrhoids treatment increased again because K. Morinaga and A. Longo proposed new concepts and a few new surgical devises such as Harmonic Scalpel™, Ligasure™ and others were introduced into the market. Doppler guided hemorrhoidal artery ligation first time was reported in 1995. as a promising technique virtually non-painful. Method was tested by numerous retrospective and prospective trials which concluded that postoperative pain was minimal (6.4 - 18.1 of patients required an analgesic for 1 - 2 days), number of postoperative complications (0 - 6.9) was low and efficacy - high (69.2 - 92%). The big doubt about the true value and the place of the procedure raised almost complete absence of comparative studies. During the thirteen years period since introduction of the method only one prospective randomized trial was published. It demonstrated superiority of hemorrhoid artery ligation over conventional scissors hemorrhoidectomy because of minimal postoperative pain and equal efficacy after 1 year. Limitations of this study were: small number of patients (only 60 in both arms) and not very reliable method of randomization (date of the first visit). More trials to answer different questions about nature of the procedure, necessity of ultrasound detection of arteries and finally - about real efficacy are urgently needed.

Procedure for prolapse and hemorrhoids, introduced in 1998, was another surgical option proposing different approach to the hemorrhoids surgery. Differently from hemorrhoidal artery ligation this operation was widely accepted and tested throughout multiple trials analyzing safety, short and long term results.

Initially it was postulated that effect of the PPH was based on the repositioning of hemorrhoidal tissue and reduction of arterial inflow. Later it was demonstrated that...
the postoperative outcome did not depend on the complete interruption of the arterial flow because 1 month after PPH procedure all main branches of vessels were detected again in 80% of the patients. A few systematic reviews and meta-analyses were published indicating that PPH procedure was safe, quick, with less postoperative pain, shorter convalescence and out of work time. Recent analysis of late term results disclosed limitations of the procedure: late term results (rate of recurrence and necessity for further treatment) were inferior comparing with conventional hemorrhoidectomy. For a moment "if hemorrhoid recurrence and prolapse are considered the most important clinical outcomes, then conventional excisional hemorrhoidectomy remains the "gold standard" treatment for hemorrhoids.

In order to diminish postoperative pain of excisional hemorrhoidectomy new technologies were evaluated: mostly Harmonic Scalpel™ and Ligasure™. Up to the moment only four randomized prospective tails comparing Harmonic Scalpel™ and conventional procedure were published recruiting 381 patients in all arms altogether. Results of these trials were conflicting. Two of them reported superiority of new technique because of less postoperative pain, better patient satisfaction, but benefits were small. Other two have not found any advantages of Harmonic Scalpel™ over conventional procedure. Comparison of this operation with PPH has showed short-term benefits of reduced pain, shorter length of stay and earlier resumptions to work in favor of stapled procedure.

Data about application of Ligasure™ device during excisional hemorrhoidectomy were more uniform. Meta-analysis of short term outcomes, covering nine randomized tails from 2002 – 2006 period showed significantly reduced operative time (WMD - 8.67 minutes; 95% CI), blood loss (WMD - 23.08 mL; 95% CI), and pain the day after the operation (WMD - 2.31; 95% CI) following Ligasure™ hemorrhoidectomy. There was a decrease in time taken to return to work or normal activity, but it was of marginal significance (P =0.08). Subsequent randomized tails confirmed these data.

Both instruments were tested in one comparative randomized trail resulting in favor of Ligasure™ because of reduction of postoperative pain and operating time. Another trail compared Ligasure™ with new Station™ device, which used thermal energy and pressure to coagulate and divide tissue and disclosed benefits of the second procedure: less pain and reduced analgesic use. Three randomized trails compared Ligasure™ with other "pain-free" operation – PPH. Two trails have found significantly less pain after stapled procedure, but increased operation time and number of complications.

Proponents of classical approach to the excisional hemorrhoidectomy compared open and closed techniques in met-analysis way. Six prospective randomized studies, including 686 patients were analyzed. It was not found significant advantage between both techniques of hemorrhoidectomy. The pain scores, timing of the first bowel movement, length of hospital stay were similar in both arms. Only difference in wound healing was observed. It was concluded that "both the open and closed techniques were found to be equally effective and safe and withstood the test of time".

Finally, it is possible to say that hemorrhoids are benign disease and different methods to cure exist. Up to the moment not all of them have sufficient evidence of efficacy and plenty of questions have to be answered. Definitely, only one - the best method still doesn’t exist.

**SUMMARY**

**TRETiranje hEmoroida Bazirano na DOKAZ-IMa**

U toku poslednje dve dekade više modaliteta tretmana hemoroida je predloženo i razmatrano. Različiti dokazi podržavaju ove pristupe, a novi podaci se konstantno dobijaju. Odluka o korišćenju neke metode traži od lekara da temelji na dokaze o efikasnosti.

Ključne reči: hemoroidi, konzervativni tretman, ligature, skleroterapija, fotokoagulacija, hirurški tretman, stapler

**REFERENCES**


Abbreviations: Procedure for prolapse and hemorrhoids (PPH), weighted mean difference (WMD), confidence interval (CI)