TREATMENT OF THE HEMORRHOIDS AND ANAL MUCOSAL PROLAPSE USING ELASTIC BAND LIGATURE – EARLY AND LONG TERM RESULTS

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The aim of the study was to evaluate the results of the treatment of internal hemorrhoids and anal mucosal prolapse using elastic band ligation and to compare this method to chosen surgical procedures.

Material and methods. The study included 648 patients (363 males and 285 females). 474 patients were treated using an elastic band ligature and 174 patients underwent surgical hemorrhoidectomy. The average age of the patients in both groups was similar – 49 years. The treatment tolerance was evaluated in the prospective study group. The intensity and duration of pain was assessed on the first and second postoperative day using a Verbal Rating Scale.

Results. 86.5% of the patients were cured using Barron’s procedure, success rate for second-degree hemorrhoids was 89% and for third degree – 85.2%. Surgical hemorrhoidectomy was effective in 92% of patients. Early failure of elastic ligature was noted in 2.5% of patients. The recurrences of hemorrhoidal symptoms were observed in 11% of Barron’s group and in 8% after hemorrhoidectomy. The intensity of pain was much higher among patients after surgical hemorrhoidectomy. The average of the pain score in the 4th hour was 0.3 for the elastic band ligation and 1.4 for the surgical treatment. In the 24th hour – 0.2 and 1.7 respectively. Mean postoperative stay was 3.8 days.

Conclusions. Rubber band ligation is highly effective and well tolerated. Relatively minor pain following this procedure is found in only 9.5% of patients. The disadvantages of surgical hemorrhoidectomy are: important postoperative pain and long time of wound healing that impair the recovery to professional activity.

Key words: hemorrhoids, mucosal, prolapse, rubber band ligation, hemorrhoidectomy

Around 50 percent of the population over the age of 50 years experience symptoms of hemorrhoidal disease at least once in their life (1, 2). Only few people look for specialist’s help for different reasons. Most cure themselves using commonly known ointments and suppositories.

Anatomical structures such as hemorrhoidal cushions contribute to a part of resting anal tone (in 15%) (1, 3). The most common symptom of hemorrhoidal disease is painless, often recurrent anal bleeding related with defecation. Intensive bleedings may even be a cause of iron deficiency anemia (1, 3). Pain also appears to be an important complaint, when inflammation of the tissue, oedema and thrombosis occur. The onset is mostly sudden, after passage of large stool or straining.

Proper regulation of fluid intake and high-fiber diet (20-30 g/day), avoiding straining and constipation or diarrhea are the first step in conservative treatment.

Rubber band ligation of internal hemorrhoids was first described in 1958 by Bleisedell and a few years later modified by Barron (4, 5). This method is recognized to be one of the most effective among other instrumental treatments such as: sclerotherapy, infrared coagu-
Treatment of the hemorrhoids and anal mucosal prolapse using elastic band ligature

Furthermore, rubber band ligatures may be used for the removal of the mucosal anal prolapse often accompanying hemorrhoidal disease (6).

The aim of instrumental, non-excisional methods is to cause a local ischemia within hemorrhoidal tissue and a scar. Surgical resection is recommended for fourth-degree hemorrhoidal disease or failure of other methods of treatment.

The aim of the study was to evaluate the results of treatment of internal hemorrhoids and mucosal anal prolapse using an elastic band ligature and to compare this method to surgical procedures.

MATERIAL AND METHODS

The study included 648 patients: 363 males (56%) and 285 females (44%) treated for symptomatic hemorrhoidal disease.

The structure of the age is shown in tab. 1. The disease affected mostly patients between 40 and 60 years of age. The cases below 30 years were rare.

The study was divided into 2 groups: retrospective and prospective. The retrospective group consists of 500 patients treated between 1996-2004. In 388 of them Barron’s method was used, in 112 – surgical excision.

148 patients were qualified to the pr group of the study between 2005-2007. 62 of them underwent a surgical treatment, 86 – elastic band procedure. The prospective group of the study allowed to evaluate the tolerance of the treatment.

Rubber band ligation

Elastic band procedure was performed in outpatients. The hemorrhoidal tissue was ligated using a rubber band. The principle of ligation was to put the elastic bands on the hemorrhoidal cushions within insensitive mucosa above the dentate line. This ligation was applied in patients suffering from second and third-degree of hemorrhoidal disease. All of the patients were treated in lithotomy position.

The excess of rectal and anal mucosa was also removed using this method. After a few days strangulated tissue sloughs leaving an area of inflammation which turns into a small scar that fixes mucosa to underlying tissue (1, 3, 5, 7-13).

All 474 patients were treated using hemorrhoidal ligation. Rubber band ligation procedure was always performed by the same experienced surgeon. There was a rule accepted for the Barron’s method to ligate only one cushion per session. The time interval between consecutive ligations was minimum 4 weeks. There was no need to use any local or systemic anasthesia. The average number of ligation procedures performed in one patient was two. They ranged from 1 to 14.

Surgical hemorrhoidectomy

Hemorrhoidectomy was performed in symptomatic fourth and third-degree hemorrhoids. A failure of instrumental treatment of second-degree hemorrhoids was also an indication for surgical removal. Patients with 3 or more anal cushions were included in the study. Antico-
agulant treatment had to be discontinued. General anesthesia was used in 45 patients (26%), spinal in 129 (74%). Routine antibiotic prophylaxis was used.

The patients were operated on in lithotomy position. The hemorrhoids were removed using classical excision in 174 patients, such as Milligan-Morgan (61 pts) or Fergusson (56 pts). A Liga Sure device was applied in 43 patients. Easily digestible diet and light laxatives (lactulose or paraffin oil) of 15 ml three times a day were prescribed.

Postoperative pain control

Analgesic drugs were given intravenously or taken orally directly after the surgery. Non-steroid anti-inflammatory drugs were routinely recommended, the dose and frequency of the analgesic therapy depended on the pain intensity. If NSAID were not effective, we did not hesitate to use strong opioids.

Warm, soapy sitz baths were necessary to get additional analgesic and relaxing effect. They were recommended several times a day starting the first postoperative day.

Mean postoperative stay was 3.8 days. After the first bowel movement patients were discharged.

The results of the treatment were assessed in outpatients in the second, fourth and twelfth week after surgery.

In both methods the following factors were considered:
1. Results of the treatment
   Cure or success was defined as permanent or significant relief of symptoms
   Failure was defined as modest or no improvement
   Recurrence – return of the symptoms within more than 3 months after the end of the treatment
   The tolerance was evaluated in the prospective part of the study between 2005-2007. The intensity of pain was assessed using Verbal Descriptor Scale VDS (14-17). It’s a serial scale, using Arabic numerals from 0 to 4 with corresponding terms describing the pain intensity:
   0 – no pain,
   1 – mild,
   2 – discomforting,
   3 – intense,
   4 – excruciating.
   Pain intensity was assessed using the verbal scale on the first and second postoperative day (4 and 24 hours after the surgery).
3. Hospitalization time.

Statistical evaluation

– We reported means, standard deviation (SD) and standard error.
– Differences between the groups were compared using the chi-square test, depending on the size of the population Yate’s or
Fisher’s corrected; statistical significance was set at P value of 0.05.
- T-Student test was used for normally distributed data.
- Data were analyzed using STATISTICA software.

RESULTS

The outcomes of 474 patients treated with Barron’s procedure were compared with the outcomes of 110 patients who underwent surgical haemorrhoidectomy.

The results of treatment in both methods are illustrated in tab. 2.

Barron’s procedure success rate was 86.5% vs. 92% following surgical haemorrhoidectomy.

52 patients (11%) treated using elastic band had recurrence of haemorrhoidal disease observed from 3 months to several years after the end of the treatment (average: 3 years). Despite disease relapse 34 patients from this group decided to continue their treatment using Barron’s method. Only in 12 patients (2.5%) Barron’s procedure failed. Surgical treatment was necessary in 18 patients (3.8%) after rubber band ligation. There were no failures in the surgical method. Postoperative hospitalization ranged from 1 to 10 days (mean: 3.8 days).

The side-effects after elastic banding occurred rarely. Bleeding, feeling of discomfort and pain were the most common. Only single episodes of small anal bleedings were observed during defecation. It occurred as blood traces on the toilet paper or rarely as clots on the stool. Drip-drop of blood to lavatory pan was sometimes observed, too. This kind of bleeding was observed in 84 (17.8%) patients, usually a few days after the procedure and stopped spontaneously. 13 (2.6%) patients had intensive bleeding from anus. It stopped on its own in majority of cases. Hospitalization was necessary only in two of them. Surgical treatment and blood transfusion was necessary in one patient.

There was no serious bleeding after surgical haemorrhoidectomy. In 22 patients small bleeding during or after defecation was observed for a couple of days. It stopped after the wounds healed. Intensive bleeding occurred in 2 patients and required a proctologic consultation.

Acute inability of miction was observed in 16 patients after haemorrhoidectomy. These problems were temporary and needed urinary bladder catheterisation from 1 to 5 days.

One patient (S.R., 60 years old) complained of faecal soiling after Milligan-Morgan procedure (Liga-Sure modification). On manometry impaired internal anal sphincter tone and poor function of external anal sphincter were found.

A 57-years old woman after Milligan – Morgan operation suffered from incontinence. Stricture of the anus was observed in one patient (W.M., 46 years old) 3 months after surgery using Liga-Sure method for recurrent haemorrhoids. She was treated by repeated anal dilatations.

Pain in this study was experienced only in 9.5% of patients managed by Barron’s proce-

<table>
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<th>Complications</th>
<th>Barron %</th>
<th>Surgical hemorrhoidectomy %</th>
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<tbody>
<tr>
<td>Success</td>
<td>86,5</td>
<td>92</td>
</tr>
<tr>
<td>Failure</td>
<td>2,5</td>
<td>0</td>
</tr>
<tr>
<td>Recurrence</td>
<td>11</td>
<td>8</td>
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<tr>
<td>Bleeding</td>
<td>20,4</td>
<td>21,8</td>
</tr>
<tr>
<td>Perianal discomfort, straining</td>
<td>3,8</td>
<td>-</td>
</tr>
<tr>
<td>Micturition disorders</td>
<td>-</td>
<td>14,5</td>
</tr>
<tr>
<td>Gases and fecal incontinence</td>
<td>-</td>
<td>1,8</td>
</tr>
<tr>
<td>Anal stenosis</td>
<td>-</td>
<td>0,9</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>-</td>
<td>0,9</td>
</tr>
<tr>
<td>Pain</td>
<td>9,5</td>
<td>100</td>
</tr>
<tr>
<td>Use of analgesics</td>
<td>3,8</td>
<td>100</td>
</tr>
<tr>
<td>Pain &gt; 48 h</td>
<td>3,6</td>
<td>73,6</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>no need</td>
<td>~ 3,8 days</td>
</tr>
</tbody>
</table>
The pain was mild or discomforting in intensity. The majority of patients (96.2%) did not require any analgesics, 3% of patients used non-steroid anti-inflammatory drugs, and only 4 patients (0.8%) needed mild opioids. All patients after surgical procedures suffered from pain and in all of them analgesics were used.

The average grade of pain using VRS score in 4th postoperative hour was 0.3 for the elastic band ligation and 1.4 for the surgical treatment. At the 24th hour it was 0.2 and 1.7 respectively.

Table 3 illustrates the intensity of experienced pain.

Comparison of the results. Statistical analysis
1. The difference between the types of treatment and success rate was not statistically significant (p=0.13).
2. No statistically significant difference between the types of treatment and failure rate (p=0.092) or recurrence (p=0.4) was found.
3. There was a strong statistically significant difference between the method of treatment and pain (p<0.000).

DISCUSSION

Haemorrhoids are a very common disease, and despite being well known for centuries there is no one efficient method of treatment. The disease has multifactor background but is usually connected with constipation and pathology of the act of defecation. Ligation of haemorrhoids, since it was invented by Blaisdell and modified by Barron, has been one of the most often employed methods of treatment (1-5, 18).

It is obvious that the use of elastic bands is not indicated in permanent protruded fourth degree haemorrhoids, because of their sensitive innervations. The ligation of the vascular pedicle together with soft haemorrhoidal tissue is possible only inside the anal canal. Necrosis of the ligated haemorrhoid is not the only effect of the procedure, but also partial retraction of protruding tissue into the anal canal may be achieved. However, the external part of haemorrhoidal complex with the overgrowth of skin fold still remains intact and it may be a cause of persistent complaints. Ligation of haemorrhoids using elastic bands is an inexpensive, easy in use, well tolerable method of treatment with low rate of complications (1, 3, 5, 10-13, 18, 19).

In this study 86.5% of the patients were cured, that means they were symptom-free or the symptoms were very mild. Success rate in other authors’ studies ranges from 79% to 89% (19-24).

Other authors indicate the efficiency of rubber-band ligation completed by cryotherapy or sclerosing therapy (25, 26, 27).

In Iyer and co-authors retrospective study for symptomatic haemorrhoids treatment with rubber band ligation complete cure was defined as total withdrawal of symptoms or significant improvement of haemorrhoidal bleeding to be experienced not more than once a month. A group of 494 patients out of 701 was considered as cured (70.5%). The cure rate was similar in patients treated for different stages of haemorrhoidal disease. A higher failure incidence and necessity for haemorrhoidectomy were noted in patients in whom 4 and more rubber band ligations were done (19).

In spite of Barron, who suggested ligation of only a single haemorrhoid during a visit with one-month interval between interventions, some authors indicate that ligation of 3 haemorrhoids at the same time may be more ef-

<table>
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<th>Degree of pain</th>
<th>Barron</th>
<th>Hemoroidektomia / Hemorrhoidectomy</th>
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<tbody>
<tr>
<td></td>
<td>4-hour</td>
<td>24-hour</td>
</tr>
<tr>
<td>0 – no pain</td>
<td>69</td>
<td>75</td>
</tr>
<tr>
<td>1 – mild</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>2 – discomforting</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>3 – intense</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4 – excruciating</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Average pain intensity grade</td>
<td>0.3</td>
<td>0.2</td>
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Treatment of the hemorrhoids and anal mucosal prolapse using elastic band ligature

The degree of experienced pain and the patient's emotional state affect the tolerance of the treatment method. Various so-called scales of pain, are used for a self-assessment of pain intensity (14-17). A five-degree Verbal Rating Scale (VRS) was employed in this study. It was quite a simple and helpful device used for the assessment of pain intensity after Barron’s procedure and surgical haemorrhoidectomy. The average grade of pain in the 4th hour after the rubber band ligation was higher than after 24 hours. The situation was opposite in surgical haemorrhoidectomy cases – the majority of patients assessed their pain as more severe in the 24th hour than in 4th hour after procedure, which could be due to a longer effect of anaesthesia.

Barron observed that the pain intensity was the most severe just after ligation of haemorrhoid and it lasted usually for 24 to 48 hours. He supposed that recession of pain may be due to the formation of necrosis in ligated haemorrhoid, whilst the endings of the nervous fibres are destroyed (5, 30). High intensity of pain just after rubber band ligation might be explained by its low location in the anal canal. Formation of an excessive oedema of the hemorrhoidal tissue may be an indication for band removal (1).

According to data published by American Gastroenterological Association the pain appears in 5% to 60% of all patients treated with Barron’s method. The pain is usually mild and easy to manage using warm sitz baths and local anaesthetics (12, 13).

Looking at the intensity of pain experienced by patients after rubber band ligation and surgical procedures, Barron’s procedure appears to be more advantageous. After haemorrhoidectomy the pain lasted longer. Also VRS scale indicated higher grades corresponding with higher intensity of pain. MacRae and co-authors support those results (11).

It is necessary to remember that intense postoperative pain may lead to impaired micturition (31-33). In the literature this complication occurred in 2% to 36% of patients treated with surgical haemorrhoidectomy and in less than 5% of patients after rubber band ligation (13, 24). Other causes of difficult micturition were: epidural anaesthesia, tamponage of the anus after haemorrhoidectomy leading to compression of the urethra, adenomatous prostate. Opioids influence also function of the bladder muscles.

In our study this complication occurred in 14.5% of the patients after haemorrhoidectomy versus 0% in the Barron’s group.

The anal bleeding with mild intensity is one of the most common features occurring after both methods. In the Barron’s method the bleeding is usually a consequence of falling off of the necrotic tissue or slipping off of the rubber band. To avoid this complication some practitioners recommend using double rubber bands (1, 5, 18, 34). Mild bleeding persists usually from a few days to two weeks after the procedure (1, 13, 31). Bleeding from another, not yet ligated haemorrhoid is possible too.

The literature reports cases of massive bleeding requiring hospitalization, a surgical intervention and even blood transfusion (19).

The onset of sepsis after ligation of haemorrhoids may suggest: high fever, pain and oedema of the perineal region with obstructed miction. The higher risk of such complications occurs in Barron’s patients suffering from impaired immunity, intestine inflammatory diseases or disturbed haemostasis and a faulty sterilisation of the instruments (7-10).

In 2006 McCloud and co-authors reported 38 cases of life-threatening sepsis after surgical or instrumental treatment of haemorrhoids. There were 17 cases after Barron’s procedure in this group. Six patients died (35).

The data analysis in 16 consecutive publications, carried out by MacRae and co-authors, confirms that rubber band ligation, as an outpatient procedure, is less effective, but with lower risk of complications and pain compared to surgical haemorrhoidectomy. They prove that Barron’s ligation should be the first step treatment in patients with first to third-degree of symptomatic haemorrhoids. The indication for surgical haemorrhoidectomy in these cases should be reserved for failed rubber-band ligations (11).

Complications after surgical haemorrhoidectomy resulted from wide excision of the anal canal tissue, proximity of the anal sphincters and a tendency to scar formation within anal margin. Surgeon’s gesture may inadvertently result in internal and external sphincters
damage leading to incontinence. According to Herman and co-authors’ opinion, proctologic operations are the fourth cause of this complication with its incidence at about 12% (36).

Faults in respecting the golden rule of sparing adequate bridges of the anal mucosa may result in anal canal stricture (37). This complication may require further surgical treatment.

CONCLUSIONS

1. Barron’s method of treatment for haemorrhoidal disease as well as for prolapse of the anal mucosa is characterised by: high efficiency, excellent tolerance, low rate of complications and recurrences.

2. Important postoperative pain and long wound healing are the disadvantages of surgical hemorrhoidectomies.

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