A ONE-YEAR FOLLOW-UP OF THE QUALITY OF LIFE AFTER STAPLED HEMORRHOIDOPEXY*

WOJCIECH CZARZASTY, WIESŁAW JANUSZ KRUSZEWSKI, JACEK ZIELIŃSKI, MARCIN NIZNIK

Surgical Department, Ministry of the Interior and Administration Hospital in Gdańsk
Kierownik: dr med. J. Chybicki

Oncological Surgery Department, Gdynia Centre of Oncology, Maritime Hospital in Gdynia;
Division of Propedeutics of Oncology, Medical University of Gdańsk

Oncological Surgery Department, Medical University of Gdańsk
Kierownik: prof. dr hab. J. Jaśkiewicz

Articles presenting treatment outcomes of stapled hemorrhoidopexy are rarely based on detailed analyses of the quality of life.

The aim of the study was the assessment of changes within one year of treatment in the quality of life of patients who underwent stapled hemorrhoidopexy using QLQ-C30 form (version 3).

Material and methods. 120 patients with grade III and IV internal hemorrhoidal disease treated with stapled hemorrhoidopexy were enrolled in the study. They answered questions from QLQ-C30 form and were subjected to examination a day before surgery and 1 day, 7 days, 4 weeks, 6 and 12 months after surgery. Assessment included operation site inspection, pain intensity measurement in VAS scale and parameters incorporated in QLQ-C30 form evaluation.

Results. The overall quality of life decreased immediately after surgery (a day after 50% vs. 60% before surgery), but rapidly improved in one week and in one month periods (60% and 80% consecutively) reaching a plateau one month after surgery. Recurrence of the disease was not observed. Bleeding from anastomosis site and severe pain in anal area immediately post surgery as a result of improper purse-string suture placement were the main complications.

Conclusions. In patients with grade III or IV hemorrhoidal disease, stapled hemorrhoidopexy ensures a rapid improvement in the quality of life after surgery to the level experienced prior to the operation. 7-day convalescence period is sufficient. After one month, the overall quality of life improves significantly and reaches a plateau.

Key words: quality of life, stapled hemorrhoidopexy

Patients with hemorrhoidal disease grade III and IV and those with failure of non-invasive treatment of hemorrhoidal disease usually require surgical treatment (1, 2). Surgical procedures involve excision of hemorrhoids or are performed without excision of the hemorrhoidal tissue. Excisional hemorrhoidectomy is associated with a high risk of significant postoperative pain and prolonged, up to 6 weeks, wound healing (1, 3, 4, 5). In 1998 Longo proposed a new non-excisional surgical procedure PPH (i.e. procedure for prolapse and hemorrhoids), which repositions and fixates the hemorrhoids to its proper location in the anal canal [stapled hemorrhoidopexy (SH)]. Blood supply to hemorrhoids is restricted through circumferential excision of the rectal mucosa and submucosa using circumferential

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The excision is performed in an area deprived of somatic sensation i.e. above the dentate line. SH’s benefits include decreased postoperative pain, absence of a wound requiring care and a short period of convalescence (1, 3, 5, 7).

Limitations include: increased risk of complications such as hemorrhoidal thrombosis, rectal anastomotic leakages with pelvic sepsis, rectal obstruction, retrorectal hematomas (5, 8, 9, 10). SH is considered as a safe, fast and effective treatment for hemorrhoidal disease. Treatment and follow-up outcomes vary subtly among different authors. Patients’ quality of life was rarely considered an assessment criterion (11, 12, 13).

This article focuses on the analysis of outcomes and complications after SH based on own material. Patients’ quality of life evaluated using QLQ-C30 form (version 3) was considered a crucial assessment factor (14).

MATERIAL AND METHODS

Patients

The study involved 120 patients with hemorrhoidal disease grade III and IV out of 183 patients treated using SH in Surgical Dpt. of Ministry of the Interior and Administration Hospital in Gdańsk from 2002 to 2006. Haemorrhoids in all patients originated from the internal haemorrhoidal venous plexus of the anal canal above the dentate line. The exclusion criteria for the remaining 63 patients were concomitant disorders (n=11) which included anal fissure (n=4), anal fistula (n=2), condylomata acuminata (n=1), Crohn’s disease (n=2), ulcerative colitis (n=1), colon cancer (n=1). 52 patients refused to participate in the study. The study analyzed the treatment outcomes of 53 female patients (44%) and 67 male patients (56%). 93 patients (77.5%) had hemorrhoidal disease grade III and 27 patients (22.5%) – grade IV. Patients’ age ranged from 21 to 78 years (average 50.6, median 51). The largest group comprised of patients between 41 and 50 years of age (32%) and between 51 and 60 (28%). The main symptom was rectal bleeding.

Course of treatment and follow-up

The surgical procedure was performed under spinal subarachnoid anesthesia. The procedures were carried out utilizing SapiMed Transanal Mucostomy Kit from TYCO (TYCO Healthcare Group LP. Norwalk, Connecticut, 06856 USA) and size 31 mm reusable circumferential stapler from the same manufacturer. Anal divulsion was not performed. Transparent anoscope which is a part of the kit has a scale and an opening in its distal part, which enables placement of the purse-string suture 3-0 with 5/8 of circle needle, 4 to 5 cm above the dentate line. After the mucosal ring was excised and remaining layers anastomosed using stapling device, bleeding sites were oversewn using horizontal sutures. Concomitant skin tags were not excised although their existence was noted. Patients were usually discharged one day after surgery with instructions to use liquid paraffin, lactulose, phlebotropic agents and if necessary pain killers. Assessment performed a day before surgery, a day after surgery and during follow-up visits included the patient completing the QLQ-C30 form (version 3) and measuring pain intensity in VAS 10-point grading scale. Patients were asked about the quality and bowel habits, continence and other disturbing symptoms e.g. bleeding. Assessment included digital rectal examination and anoscopy to check for recurrence and anal stricture. Follow-up assessments were carried out 7 days, 4 weeks, 6 and 12 months after surgery.

Factors evaluation

Evaluated factors included duration and course of surgical procedure, duration of hospital stay, treatment outcomes and complications in the whole study group as well as in group A and B considering pain intensity in VAS scale before surgery, with cutting point $\text{VAS} = 5.52$ in k-means method [$A$ – lower pain intensity ($n = 72$, mean VAS = 2.26, standard variation 0.872, variance = 0.760) and $B$ – higher pain intensity ($n = 48$, mean VAS = 4.68, standard variation 0.803, variance = 0.645)]. QLQ-C30 form (version 3) was employed for quality of life evaluation. Acquired data was grouped into functional and symptomatic scales. The functional scales assessed the global quality of life, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning. Symptomatic scales evaluated pain, fatigue, nausea and vomiting, dyspnea, insomnia, loss of ap-
petite, constipation, diarrhea and financial difficulties.

Statistical analysis

Parametric data were analyzed using ANOVA tests with post-hoc Scheffe’s comparisons. For non-parametric data description, median values, modal values and ranges were applied. Cluster analysis was performed employing k-means method with the aim of variance maximization between received clusters. Correlation analysis was performed employing Pearson r method for parametric variables and Spearman r method for discrete variables. Correlation with coefficient $r > 0.6$ was considered strong. Difference between evaluated factors was considered significant for $p$ value $< 0.05$. Computation was performed using STATISTICA 7.1 PL software.

RESULTS

Mean duration of the procedure was 42.5 minutes (20 to 90 min.), median 40 min. The patient was admitted the day before surgery. Medium duration of hospital stay was 3.2 day, median 3 days. There were 6 cases (5%) of early postoperative complications. On the day of surgery, bleeding from anastomosis site occurred in 3 patients (2.5%). Placement of gauze tampon in anal canal and in rectum was sufficient to manage the bleeding in two cases. Third patient required placement of additional sutures in anastomosis area and a transfusion of two units of erythrocyte concentrate. The next patient reported severe pain in anal area (8 points in VAS scale) the first day after surgery and had increased body temperature to 38º Celsius. Digital rectal examination (DRE) revealed painful mass in the wound area with bloody discharge. Symptoms subsided after 3 days of antibiotics treatment, which was continued until the sixth day after surgery. Severe pain was reported as the only symptom by two (1.8%) other patients (8 and 10 points in VAS scale). DRE revealed that wound is located at the dentate line in both the patients. Narcotic analgesics and nitroglycerin ointment were administered. As a result pain was reduced and patients discharged on the second day after surgery. In 12-month follow up there were no late complications e.g. clinically significant anal stricture, persistent pain or recurrence.

Figure 1 shows mean pain intensity in VAS scale in study group during follow-up period. Results of comparison test are presented in Table 1. Significantly reduced pain was recorded from first day after surgery. 7 days after surgery pain was even weaker, reaching its minimum 1 month after procedure and remained stable throughout the follow-up period. Figure 2 presents global quality of life values based on QLQ-C30 form defined as results of comparison in Table 1. Surgery lowered the quality of life significantly. 7 days
after surgery the quality of life returned to values recorded prior to the procedure. One month after surgery global quality of life improved significantly. Table 1 presents results of functional scales analyses excluding cognitive functioning. As early as one week after surgery, physical functioning returned to preoperative values. The same time frame enabled role functioning to significantly improve, while a month after surgery it went beyond preoperative values. Emotional functioning a week after surgery reached higher values than before procedure and kept improving further. Social functioning was affected by disease. It significantly improved 7 days after procedure, while one month after surgery social functioning reached highly satisfactory level and remained at this level throughout the follow up. Cognitive functioning was neither affected by illness nor the treatment.

There was a very strong correlation (r = 0.88, p<0.05) between pain score in VAS scale and symptomatic scale in QLQ-C30. Pain decreased as a result of surgery, dropping below 20% of the maximum value 7 days after procedure. One month after surgery pain was below 10% of the maximum value. This level was retained throughout the follow-up period (fig. 3, tab. 2). Constipation intensity increased immediately after surgery, which can be attributed to increased pain. It decreased 7 days after surgery, correspondingly to pain, and significantly reduced a month after procedure. Insomnia was increased perioperatively, but improved and was stable after 7 days. Financial difficulties appeared in perioperative period, yet it continuously improved starting from a week after surgery (tab. 2). Symptomatic scales analyses revealed that fatigue slightly increased on the first day after surgery, but it was not a sig-
Table 2. Results of multiple comparison test (post-hoc Scheffe’s test) for selected parameters from symptomatic scales of QLQ-C30 form, version 3. One-way analysis of variance, p < 0.001 as significant

<table>
<thead>
<tr>
<th>Estimated parameter</th>
<th>Estimation time *</th>
<th>Test results, p value</th>
</tr>
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<tr>
<td>Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>0.181</td>
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<tr>
<td></td>
<td>2</td>
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</tr>
<tr>
<td></td>
<td>3</td>
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<tr>
<td></td>
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<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Insomnia</td>
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<tr>
<td></td>
<td>2</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0.237</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0.121</td>
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<tr>
<td></td>
<td>5</td>
<td>&lt;0.001</td>
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<tr>
<td>Constipation</td>
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<td>0.226</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>&lt;0.001</td>
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<tr>
<td>Financial difficulties</td>
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<td></td>
<td>2</td>
<td>0.997</td>
</tr>
<tr>
<td></td>
<td>3</td>
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<tr>
<td></td>
<td>4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>&lt;0.001</td>
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</table>

* Estimation time postoperatively: 1 – 1 day, 2 – 7 days, 3 – 1 month, 4 – 6 months, 5 – 1 year

Significant factor for study population. Nausea and vomiting, dyspnea, appetite loss, diarrhea were not treatment related symptoms (below 20% of maximum value).

Quality of life depended on pain intensity before the procedure. It was always lower in group B, but significantly only 7 days and one year after surgery (fig. 4, tab. 3). No significant differences were observed in group A and B in physical functioning which was very good from the second day after surgery. Pain presumably affected emotional functioning which was higher before and one day after surgery in group A. Emotional functioning reached > 80% of the maximum value after one month in both groups. There was no difference between groups in cognitive functioning. Role functioning showed no differences as well. Presumably higher pain intensity in group B affected role functioning before surgery, yet during follow-up visits it was not observed. Role functioning improved in both groups along with pain reduction, reached higher level after 7 days and remained stable after a month.

Patients in group B experienced significantly higher pain intensity immediately and a week after surgery, although it was considerably lower than before the treatment (fig. 4, tab. 3). A month after surgery pain was reduced to < 20% of the maximum value. The study showed no significant differences concerning fatigue in symptomatic scale analysis. Only immediately after the procedure there was a strong trend indicating increased fatigue in group B (p = 0.06), which can be attributed to aggravated pain experienced before surgery. Nausea and vomiting, dyspnea,
Table 3. Comparison of selected parameters in low pain intensity group (A) and high pain intensity group (B) during follow-up, p < 0.05 as significant

<table>
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<th></th>
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<th>2*</th>
<th>3*</th>
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<td>p = 0,253</td>
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<td>p = 408</td>
<td>p = 0,799</td>
<td>p = 0,826</td>
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<td>Emotional functioning</td>
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<td>p &lt; 0,001</td>
<td>p = 0,079</td>
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<td>Constipation</td>
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<td>p = 0,814</td>
<td>p = 0,737</td>
<td>p = 1</td>
<td>p = 1</td>
<td>p = 1</td>
</tr>
</tbody>
</table>

0* – before operation, 1* – 1 day postoperatively, 2* – 7 days postoperatively, 3* – 1 month postoperatively, 4* – 6 months postoperatively, 5* – 1 year postoperatively

DISCUSSION

SH proves to be a method of treatment that allows faster pain reduction and shorter period of convalescence comparing to excisional methods. Complication rates for both techniques are comparable. Absence of surgical wound requiring additional care is the underlining advantage of SH (1, 3, 4, 5). Despite a few exceptions (15, 16), the authors indicate more frequent recurrences after SH (1, 4, 5, 17). According to authors from China recurrence rates after SH are lower. They believe that skin tags excision is considered as recurrence treatment erroneously (3). In our study we did not observe any recurrence during the period of 12 months after surgery. As with other authors, our study showed that the crucial point of the procedure was proper purse-string suture placement (5, 7, 8, 15, 18). It was placed 4-5 cm above the dentate line. Many authors present satisfying results with 3-4 cm margin, which allows scar to be localized at least 2 cm from dentate line (16, 20-22). Placing the purse-string suture too close to dentate line could result in persistent pain and lower overall quality of life (5, 8, 20). In two patients with severe pain after surgery we discovered that purse-string suture was placed too low.

Thickness of the excised tissue ring is a crucial element of surgical technique, with the assumption to excise ring of rectal mucosa and submucosa. Although presence of muscular fibers in the specimen does not necessarily affect complication rate (13, 19, 23), excision of deeper intestinal layers may lead to perforation or fistula and intense pain (8, 10). In our study these complications did not occur. In female patients purse-string suture placement was controlled per vagina. All patients were operated by the same surgeon with extensive experience in surgical treatment of hemor-
rhoidal disease. Some authors underline that surgeon’s experience is a key factor concerning outcomes in SH (5, 16).

Pain is one of the important symptoms of hemorrhoidal disease. Average range of pain intensity in VAS scale before surgery was 3-3.5 point. After the procedure, pain was quickly reduced (2.4-3 points one day and 1.5-1.8 one week after surgery) and continued to decrease (1-1.2 point four weeks, 1 point six months and a year after surgery). This corresponds to other authors findings (18). In many other reports pain intensity after SH was assessed in different time periods and using various methods (e.g. amount of taken analgesics, pain intensity during defecation). Generally there was a fast and considerable improvement after SH (7, 11, 13, 15, 16, 21, 22, 24). In our study pain intensity before surgical treatment reached 60% of the maximum value in group B only, i.e. in group of patients with higher pain intensity before surgery. In group A pain intensity was minor (on average 20% of the maximum value). While pain intensity in group A remained unchanged (20%) on first day after surgery, in group B it was reduced by 20 percentage points to 40% of the maximum value. Although one month after surgery there was no significant difference in pain intensity between the groups, it was higher in group B throughout the follow-up period. The study revealed differences in dynamics of changes concerning quality of life in parameters for patients in group A and B (tab. 3, fig. 4 and 5). Changes in pain intensity in both groups suggest existence of circle of pain induced by chronic pain in group B. Inferior quality of life for extended period of six months after surgery as a result of pain may call for quicker decisions on surgical treatment.

QLQ-C30 form (version 3) analyzes quality of life more extensively than Medical Outcomes Study Short Form (SF-36) (14). We found no references to articles employing QLQ-C30 form in hemorrhoidal disease treatment using SH. Average quality of life before surgery was at 60% of the maximum value. It decreased on the first day after surgery to 50%. One week after the procedure it was on average 60%, while after 4 weeks, 6 and 12 months it reached a stable 80% of the maximum value, i.e. significantly higher level (fig. 2, tab. 1). Thus it is justified to measure changes in quality of life in patients treated with SH in period extending beyond one month after surgery. Other authors corroborate that claim suggesting period of at least 6 weeks (5, 11, 18, 21). Low pain intensity and absence of wound care resulted in quality of life returning to preoperative values 7 days after surgery. In accordance with many authors, the high quality of life within a short period after surgery is the distinct advantage of SH (5, 15, 16). Certain authors share the opinion that higher recurrence rate after SH eliminates the advantage in longer period (1). Vital criterion for SH assessment is the convalescence period. General quality of life after 7 days was equal to that before the procedure (60%). Thus we can assume a convalescence period of 7 days. Mean sick leave time in study population was 7 days. Other authors estimate sick leave time after SH at 3 to 16 days (5, 7, 22, 24).

CONCLUSIONS

The surgical treatment of hemorrhoidal disease grade III and IV utilizing SH method leads to rapid reduction of pain intensity in comparison with the preoperative period and to an improvement in all quality-of-life parameters which were affected by hemorrhoidal disease, as assessed by QLQ-C30 questionnaire. These benefits allow for short convalescence period of 7 days, minimizing the sick leave time.
REFERENCES


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Adress correspondence: 80-104 Gdańsk, ul. Kartuska 4/6