OUTCOME AFTER
HAEMORRHIDOPEXY

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Outcome after Haemorrhoidopexy

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Art direction: Dennis Netzell

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New ideas pass through three periods:

1. It can’t be done
2. It probably can be done, but it’s not worth doing
3. I knew it was a good idea all along!

Arthur C Clarke (1917-2008)

To my beloved wife, children
and my parents
ABSTRACT

Background: This dissertation is composed of five individual studies of the stapled haemorrhoidopexy operation. The operation was launched to an international audience in 1998 by the Italian surgeon Antonio Longo. In conventional surgery the prolapsed piles are excised from the anodermal part of the prolapse up through the anal canal into the lower rectal mucosa where the pile is divided with diathermy or suture ligated and excised. It leaves open wounds throughout the anal canal. These wounds can be very painful, especially at defecation, and will take from three to six weeks to heal. In the stapled haemorrhoidopexy operation symptomatic haemorrhoids are seen as a disease of anodermal, haemorrhoidal and rectal mucosal prolapse of varying degree. The main component of the prolapse is the redundancy of rectal mucosa. By pushing back the prolapse into the anal canal followed by excision of the mucosal redundancy above the anal canal with a circular stapler devise a mucosal anastomosis is fashioned. This anastomosis is situated immediately above the haemorrhoids and will attach them to the rectal muscular wall to prevent further prolapse. The operation is associated with substantially less pain and a quicker recovery.

Methods: For the five studies, a total of 334 patients were operated for haemorrhoidal prolapse. The first operations were performed in February 1998. All patients were assessed preoperatively and postoperatively with the same set of protocols as follows. The symptoms of haemorrhoids were scored with a questionnaire to patients to obtain their independent statements of the frequency of each of five cardinal symptoms: pain, bleeding, pruritus, soiling and prolapse in need of manual reduction. A diary was used by patients to report daily pain scores, use of pain medication and speed of recovery within the first 14 postoperative days. The surgeon rated the deranged anal anatomy before and after surgery. We also developed an algorithm based on the patients’ statement of digital reduction of prolapse (grade 3) and
the surgeon’s assessment of lesser prolapse at proctoscopy (grade 2). Absence of prolapse was grade 1. The surgeon also provided statements about the conduct of the operation and rated the technical complexity. The information, for all patients, was entered into an electronic data base.

**Results:** One registry based study and one prospective randomised controlled trial assessed the advantage of performing the operation under perianal local anaesthetic block. The postoperative pain and surgical outcome was independent of the type of anaesthesia. No operation under local block had to be converted to general anaesthesia. Anodermal prolapse is seen in 70 percent of the patients. In a registry-based study we found that excision of the anodermal folds did not increase the postoperative pain provided the excision stopped at the anal verge. In 270 patients with precise preoperative and postoperative classification we found that the symptomatic load was identical for grades 2 and 3. The symptoms were independent of the anodermal prolapse. The symptoms were greatly reduced when the operation turned out grade 1 prolapse. The long-term result was assessed in 153 patients operated 1 year to 6 years previously. The need for early re-intervention was 6.2 percent representing technical error to reduce the prolapse. At the final evaluation 12 patients (8.2 percent) complained of a mucoanal prolapse in need of digital reduction. The mean symptom burden had been reduced from 8.1 to 2.5 points but 17 percent had at least one cardinal symptom with a weekly frequency.

**Conclusions:** Stapled haemorrhoidopexy should be performed as day surgery under local anaesthesia. Any remaining anodermal prolapse should be excised. The optimal long-term outcome is grade 1A or 1B with low symptom score. There was an 87 percent chance of cure of the prolapse with the first haemorrhoidopexy. About half the failures were insufficient primary surgery and half a relapse of the prolapse.
LIST OF PAPERS

This thesis is based on following papers, which are referred to in text by their Roman numerals:


**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>HAL</td>
<td>Haemorroidal Arterial Ligation</td>
</tr>
<tr>
<td>THD</td>
<td>Transanal Haemorrhoidal De-arterialisation</td>
</tr>
<tr>
<td>IBS</td>
<td>Intestinal Bowel Syndrome</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analog Scale</td>
</tr>
<tr>
<td>RBL</td>
<td>Rubber Band Ligation</td>
</tr>
<tr>
<td>PPH</td>
<td>Procedure for Prolapsing Haemorrhoids</td>
</tr>
<tr>
<td>HCS</td>
<td>Haemorrhoidal Circular Stapler</td>
</tr>
<tr>
<td>CAD</td>
<td>Circular Anal Dilator</td>
</tr>
<tr>
<td>PSA</td>
<td>Purse String Anoscope</td>
</tr>
<tr>
<td>ST</td>
<td>Purse string Thresher</td>
</tr>
<tr>
<td>GA</td>
<td>General Anaesthesia</td>
</tr>
<tr>
<td>LA</td>
<td>Local Anaesthesia</td>
</tr>
</tbody>
</table>
INTRODUCTION

Haemorrhoids have been described since the beginning of medical history. The first known documentation is from around 2250 BC in the Code of King Hammurabi in Babylon where symptoms of haemorrhoids are described. The first topical treatment is described in an Egyptian papyrus 1700 BC and the first surgical excision is described by Hippocrates in the Hyppocratic treatises 460 BC. The word haemorrhoid is derived from ancient Greek (haema = blood and rhoos = flowing). It is said that the French emperor, Napoleon Bonaparte suffered from haemorrhoids. At the battle of Waterloo Napoleon had difficulties riding his horse and spent most of the time in bed. When he walked around it was noted that he walked with difficulties with the legs spread apart. Historians mean that this “crise hemorrhoidale” impaired his battlefield conduct and made him loose the battle\(^1\).

Haemorrhoids can be a major part of the colorectal surgeon’s workload not only in the outpatient clinic but also in the operating theatre. My personal experience is an increasing interest in proctology, and haemorrhoid disease in particular, with colorectal surgeon seniority. This may be explained by the complexity of the proctological disorders and the challenge in solving complex issues. Both Goligher’s\(^2\) and Corman’s\(^3\) seminal books on colorectal surgery treat haemorrhoids extensively. Only the chapters on cancer of the colon and rectum are longer. With this long history of haemorrhoids and its documentation one would think that the nature of haemorrhoids and their treatment would be well elaborated. This is far from the reality.

The past decade has provided new treatment for haemorrhoids such as the stapled haemorrhoidopexy (stapled anopexy), which is now resulting in large numbers of scientific publications. Other new treatment options such as haemorrhoid arterial ligation (HAL) and the transanal haemorrhoidal de-arterialisation (THD) are gaining in popularity, but the scientific evidence is not yet produced. A search in the PubMed (www.pubmed.org) with the word “haemorrhoids” resulted in a total of 4366 articles. Randomised controlled trials total 300 with the earliest trial in 1967. Despite this, the nature of hae-
morrhoid disease is not fully understood nor its treatment. There are several hypotheses on the aetiology and there are several theories about the pathogenesis of haemorrhoids. The treatment result is often worse than usually stated in the literature with many patients complaining of persistent symptoms and disturbed continence after surgery.4-7

This thesis is about haemorrhoidal disease that potentially needs surgical treatment. Indeed, all patients of these studies had a stapled haemorrhoidopexy (stapled anopexy) operation. Many other patients who are treated non-surgically may have the symptoms that are ascribed to the haemorrhoids, with one exception; they do not have mucocanal prolapse that needs manual reduction when passing a motion. The prolapse is the main indication for surgical treatment.
BACKGROUND

Anatomy

The anal canal is 3-4 cm in length in males and slightly shorter in females, from the anal verge (lower margin of the internal sphincter) up to the puborectalis muscle. The muscular layer of the rectal wall becomes thicker on the anal canal forming the internal sphincter muscle. This muscle layer is surrounded by the conjoined longitudinal muscle, and the external sphincter muscle. The internal lining of the anal canal consists of keratinizing squamous epithelium up to the dentate line. Cranial to the dentate line the anal canal wall is lined with columnar epithelium. The junctional zone where the anal skin and bowel mucosa meet is referred to as the transitional zone. This mucocutaneous junction, or the dentate line, is a drainage site for anal glands into the crypts of Morgagni. Furthermore plenty of sensory nerve fibres end at this level.

The mucosa and submucosa above the dentate line form an asymmetric mucosal wall including the haemorrhoid cushions or piles. These have a relatively constant position; the left lateral position, right anterior and right posterior pile.

Figure 1. The invariable positioning of the anal cushions (haemorrhoids) in human.
Microscopically, the epithelial layer is thicker on the cushions with a concentration of smooth muscle fibres and connective tissue in the submucosa contributing to the bulkiness. Furthermore, there is a concentration of vascular plexa (internal haemorrhoidal plexus) in the cushions allowing them to vary in size. The smooth muscle fibres in the cushions can be seen histologically in a foetus as a continuation of the conjoined longitudinal muscle and internal sphincter muscle\textsuperscript{9,10}. These muscle bundles together with an organized connective tissue stroma (Trietz fibres) are believed to be the anchoring system that attaches the blood vessels of the cushions and the overlying mucosa to the muscle wall\textsuperscript{10}. The suspended cushions, in the upper part of the anal canal, are considered to form a valve that contributes to the continence for gas and liquid stool. This means that when the pressure in the distal part of the rectum increases, the return of blood flow from the haemorrhoidal venous plexus decreases with enlargement.

Due to copyright restrictions figure 1 is removed. The figure is published in:

Haas PA, Fox TA, Jr., Haas GP. The pathogenesis of hemorrhoids. Diseases of the colon and rectum 1984;27(7):442-50. Figure 1.
of the cushions as a result. The three enlarged cushions seal the inlet of the anal canal like a valve to prevent leakage of liquids and gas. Lestar et al\textsuperscript{11} suggested that the haemorrhoids contribute approximately 15-20\% of the mechanism of anal closure.

**Vascular nature of haemorrhoids**

There exist internal and external haemorrhoidal plexa formed by three arteries. The internal haemorrhoidal plexus is located above the dentate line and the external haemorrhoidal plexus located peripheral to the anal verge. The superior haemorrhoidal arteries originate from the inferior mesenteric artery and are the terminal branches of the superior rectal artery. Additional blood supply is received from the middle haemorrhoidal artery, originating from the internal iliac artery, and the inferior haemorrhoidal artery originating from the internal pudendal artery. There is a variation in the contribution of blood supply to the haemorrhoidal plexus. For instance, in specimen studies an average of 5 branches (0-8) from the superior rectal artery were found to form the superior haemorrhoidal arteries\textsuperscript{8}. Furthermore, 70 percent of the specimens had substantial contributing blood supply to the anal mucosa from the middle haemorrhoidal artery and 42 percent from the inferior haemorrhoidal artery\textsuperscript{8}.

The superior haemorrhoidal veins arise from the internal haemorrhoidal plexus and drain into the portal venous system, while the middle and inferior haemorrhoidal veins arise from the external haemorrhoidal plexus and drain into the caval venous system. However, there is free communication between the internal and external haemorrhoidal plexus. An important point is that this communication between the internal and external venous plexus makes it unlikely that a portal vein obstruction can lead to haemorrhoidal disease. The lymphatic drainage also has a demarcation at the dentate line. Above the dentate line the lymphatic drainage follows the superior haemorrhoidal artery and vein and drain into the para-aortic lymph nodes while the lymph vessels below the dentate line drain into the inguinal nodes. It is suggested that the arrangement with drainage to different venous systems has importance with reference to spread of infection or malignant disease\textsuperscript{12}. 

— **BACKGROUND** —
The theories and mechanisms of symptomatic haemorrhoids

_**Sliding and lining theory:**_ Treitz (1853) was the first to describe the anchoring connective tissue and smooth muscle deriving partly from the longitudinal conjoined muscle and partly from the internal sphincter into the submucosa of the anal canal. He described how these layers of meshwork acted as supporting scaffold to the haemorrhoidal venous plexus, thereby supporting the mucosa itself and preventing it from prolapsing into the anal canal when passing a motion. This submucosal muscle and connective tissue layer has been named “sustentator tunica ani” by Kohlrausch (1854), “corregator tunica ani” by Ellis (1854), “muscularis submucae ani” by Fine (1940), “Parks’ fibres” (1954) after Sir Alan Parks at St Mark’s, and finally “muscularis canalis ani” by Hansen (1976). The anatomical study by Thomson names this mucosal layer after its discoverer as the “Treitz’s muscle”. He could show that the Treitz’s muscle was easily found in all specimens; emerging from the internal sphincter muscle and distributed in three ways to form a network around the haemorrhoidal venous plexus, to fan out into the perianal skin and to rejoin to the conjoined longitudinal muscle surrounding the distal portion of the internal sphincter. He described the thickening of the anal submucosa as cushions with a constant triradiate configuration without correlation to the arterial anatomy. Microscopically Haas could show a parallel thin and compact layer of connective tissue in the submucosal layer. With advancing age the same layer becomes thicker, looser, disintegrated and broken. The age related changes and scar formation have been proposed to cause descensus and prolapse of the anal cushions. This theory corresponds to our clinical experience where “haemorrhoids” are indeed a mucoanal prolapse rather than vascular pathology. It is notable that the prolapse may involve only a single cushion or it may be circumferential. Despite the anatomical, histological and clinical evidence of mucoanal prolapse it is still debated whether mucoanal prolapse or vascular enlargement is the core event of haemorrhoidal disease.

_**Varicous vein theory:**_ Thomson illustrated that the presumed enlargement of the haemorrhoidal veins were normal structures. He emphasised that the haemorrhoidal venous plexus is present from birth.
and found in every adult as normal parts of the human body\textsuperscript{8,15}. With the assumption that the varicous vein theories are a result of secondary pathological changes found in the haemorrhoidal venous plexus, Thomson could demonstrate its invalidity as primary importance.

It was thought that elevation of the venous pressure results in the development of haemorrhoids. Morgagni believed that the human upright posture could cause haemorrhoids. Several other circumstances such as lack of valves in the portal vein or even a rise in abdominal pressure were thought to contribute the development of haemorrhoids. Studies have found the same incidence of haemorrhoids in patients with portal hypertension as in the general population\textsuperscript{16-18}. Graham-Stewart and Burkitt\textsuperscript{19,20} suggested that distended haemorrhoidal veins were secondary to straining at defecation. Recently, an increased calibre and greater arterial flow of the terminal branches of the superior rectal artery was demonstrated and correlated with the presence of haemorrhoids. The increased calibre was also demonstrated to be associated with advancing age\textsuperscript{21}.

*Vascular hyperplasia theory:* assumes that piles are a result of a vascular erectile metaplasia. Virchow (1863) and Allingham (1973) considered the piles to be haemangiomatous in nature. This bloating ability was thought to form a part of the continence mechanism. There is little evidence in support of this theory.

### Symptoms of mucoanal prolapse

The five cardinal symptoms of haemorrhoids are:

- Anal pain
- Defecatory bleeding
- Anal soiling
- Anal irritation and pruritus
- Mucoanal prolapse

Bleeding is the most common symptom described in the literature besides the prolapse. In those elected for surgery it has been attempted to correlate the severity of the symptoms with the grade of prolapse. The symptoms, however, seem weakly correlated to the extent of the prolapse. The symptoms in each patient can vary over time especially with regard to the intensity of bleeding. Deteriorated bowel habits like Intestinal Bowel Syndrome (IBS) is often associated with increased
frequency of bowel movements that may cause inflammation of the prolapse within the anal canal. External prolapse, once established, will be present every time the patient moves the bowel.

**Anal pain**

Pain is present as a symptom in 43 percent of the patients\(^{22}\). Pain is therefore a common symptom in haemorrhoids with a specific character. It is related to the prolapse and is relieved when the prolapse is digitally reduced. Acutely thrombosed and prolapsed haemorrhoids are associated with rather severe pain. Consumption of capsin in red chili after haemorrhoid surgery did significantly increase postoperative pain and anal burn sensation\(^ {23}\).

**Bleeding**

Bleeding is the most common symptom of haemorrhoids\(^ {22,24,25}\). Bleeding occurs in connection with defecation. The blood is never incorporated in the stool but seen as stains on the stool or on the toilet paper and occasionally colouring the cabinet. A prolapse of the cushions will give an impaired venous return and venous stasis if not reduced. This can cause inflammation of the cushions with erosion of the epithelium resulting in bleeding\(^ {26}\). The bleeding from haemorrhoids rarely causes anaemia. If present, a GI-tract investigation is required to exclude other causes of anaemia\(^ {27,28}\). In adults, it is relevant to exclude primarily malignancy as a cause to this symptom.

**Soiling**

The mucoanal prolapse disrupts the closing mechanism of the normal piles. There is a difference between faecal soiling due to anal incontinence of weak sphincters and the mucus soiling due to the mucosal prolapse. The mucous discharge (soiling) may occur during daily activity and in between defecations.

**Pruritus**

Anal pruritus is related to irritation of the perianal skin. Without a functional cushion valve sealing of the anal canal, a chronic exposure to moisture from the mucus discharge will cause anal irritation\(^ {2}\). Skin tags can cause a moist environment in its folds and also cause irritation. Anal pruritus is common in anorectal disorders and may also be idiopathic.
Prolapse
The fragmentation of the connective tissue that supports the anal cushions results in descensus of the same cushions. A single cushion can prolapse or there may be a total circumferential prolapse (all cushions). The prolapse may be minor with spontaneous reduction or manifest, requiring digital replacement.

Anal incontinence
Faecal incontinence occurs in 2.2 percent of a normal population according to telephone interviews and 4.1 percent in women over 65 years of age. In case of loose stools, 10.9 percent of women and 9.7 percent of men suffered from faecal incontinence in 1600 randomly selected subjects from a Swedish community. With solid faeces the prevalence dropped to 1.4 percent in women and 0.4 percent in men. Symptoms of incontinence are potentially more common in patients with haemorrhoidal prolapse because the prolapsed cushions normally contribute to the mechanism of anal closure. There are reports describing the presence of impaired continence before surgical treatment of haemorrhoids. There are also reports of high incidence of disturbed anal continence after surgery of the haemorrhoids.

Resolution of symptoms
The rationale of the surgical treatment is to either excise the prolapsing piles or to restore the anatomy with fixation of the piles at the upper end of the anal canal. Because the symptoms are a consequence of the prolapse, the restoration of the anal anatomy will resolve the symptoms, in part or entirely. If each symptom is measured before and after a treatment, the difference is an estimate of the capacity of the treatment to resolve the symptoms.

Fuegler et al. studied preoperative and postoperative frequencies of each symptom after stapled haemorrhoidopexy. After surgery, 24 percent of the patients complained of prolapse, 20 percent of bleeding, 25 percent of anal pain, 31 percent of faecal soiling and 44 percent of the patients complained of local discomfort. Despite the residual symptoms, 65 percent of the patients with positive symptoms were satisfied. Other studies have also shown persistent symptoms of haemorrhoids after surgery.

There are two common ways to describe and analyze subjective data as provided by the patient: Firstly by assigning each symptom an inten-
sity value using Lickert scales or a visual analog scale (VAS)\textsuperscript{34,35}. In such methods the patient is asked to rate the symptom from little to much. Alternatively, by assessing the symptom according to its frequency\textsuperscript{36,37}. In such methods the patient is asked to rate the occurrence of the symptom from rarely to always. Patient may have different thresholds for a symptom. For instance, the intensity of bleeding for one patient can be described quite differently by another patient. Measures based on frequency may be easier to understand because the underlying time frame is common to patients and researcher. It assumes, however, that patients can reliably make the distinction between symptoms that occur every day versus every week but not every day.

Classification

The current classification as described by Goligher grades haemorrhoids from grade I to grade IV. First degree haemorrhoids project slightly into the lumen of the anal canal when the veins are congested during defecation. Second degree haemorrhoids form larger swellings that protrude into the anal canal and descend towards the anal orifice; they may appear externally during straining but return spontaneously after defecation. When the piles protrude during defecation and require digital replacement, they are graded as third degree. Fourth degree haemorrhoids are manually irreducible\textsuperscript{2}. There are several classifications for haemorrhoids (table 1). It is not unusual to read the description of haemorrhoidal grade in the randomized trials as “prolapsing internal haemorrhoids”, “symptomatic prolapsing haemorrhoids” or “all 3\textsuperscript{rd} and 4\textsuperscript{th} degree haemorrhoids”.

The correlation between the symptoms of haemorrhoids and grade of prolapse is poorly documented. It has been attempted to combine the symptom of bleeding with degree of prolapse\textsuperscript{38}, but all symptomatic haemorrhoids do not bleed. Other symptoms such as soiling, pruritus, and pain are also considered.

A disadvantage with the current classification is that the presence of skin-tags is disregarded although skin-tags may become symptomatic. Skin-tags can be inflamed and painful. A chronic inflammation of the skin-tags may result in fibrosis and patients have been known to attempt to digitally reduce the external component in the absence of mucosal prolapse. In Goligher’s textbook the definition of grade IV is “skin covered components which cannot properly be returned to
the anal canal”. I have not yet seen a patient with mucosal prolapse that cannot be reduced. If a prolapse is irreducible, a skin-covered component is always present. It is the anodermal part of the prolapse that is irreducible.

Table 1. Major classification schemes proposed in the literature.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Goligher²</th>
<th>Lunnis³⁸</th>
<th>Morgado³⁹</th>
<th>Thomson²⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>-</td>
<td>Non prolapsing anal cushions</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Grade I</td>
<td>Merely project into the lumen of the anal canal</td>
<td>Non prolapsing small haemorrhoids</td>
<td>Bleeding haemorrhoid disease</td>
<td>Bleeding</td>
</tr>
<tr>
<td>Grade II</td>
<td>Piles may appear externally whilst the patient is straining but return spontaneously</td>
<td>Prolapsing intermediate haemorrhoids</td>
<td>Prolapsing haemorrhoid disease</td>
<td>Prolapse at defecation (with or without bleeding) with spontaneous return to anal canal</td>
</tr>
<tr>
<td>Grade III</td>
<td>Protrude during defecation, remain prolapsed until they are digitally replaced within the anus</td>
<td>Large haemorrhoids that prolapse and need aid to reduce. Bleed frequently and often profusely</td>
<td>Thrombotic haemorrhoid disease</td>
<td>Prolapse (with or without bleeding) requiring replacement.</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Skin-covered components cannot be properly returned to the anal canal.</td>
<td>Very large haemorrhoids. Prolapse, which is permanent and irreducible. Bleed profusely.</td>
<td>Mixed haemorrhoid disease</td>
<td>-</td>
</tr>
</tbody>
</table>

Many grade II haemorrhoids are misclassified as grade III haemorrhoids when doctors are misled by the size of the haemorrhoid during examination with the anoscope³⁸. In a published randomized trial of 60 patients the authors found 19 patients with grade III haemorrhoids and 27 patients with grade IV haemorrhoids in the whole study population. In the following sentence they describe the presence of symptoms and emphasize a total of 3 patients complaining of prolapse⁴⁰. In another trial conducted in Taiwan, 596 patients with grade
III prolapse were included. Of these, only 22.7% had prolapse as the leading complaint\textsuperscript{25}. This indicates the need of a standardized classification for wider application.

A classification of haemorrhoid prolapse is of interest because the treatment may be selected based on the stage of prolapse. It is also important to ascertain grade specific treatment modalities and scientifically describe outcome by stratifying to the prolapse grade. With stage specific results the understanding of the effectiveness of each treatment is enhanced.

In my mind the classification used today could be improved by including the external component as a separate entity. A reliable and easy to use classification of the anodermal, haemorrhoidal as well as the mucosal prolapse is important for several reasons. The mucosal prolapse is evident in patients who digitally reduce a prolapse and easily diagnosed by asking the patient about this need. The anodermal prolapse reveals itself as anal tags and polyps on the surgeon’s inspection of the anus. If the treatment aims to remove both features, a before and after record should reliably assess the potential of each treatment method in these respects.

**Anaesthesia**

Coca leaves have been used as a topical anaesthetic by South American Indians for thousands of years. Neimann from Germany isolated cocaine from the coca leaf. In 1880 Anrep described that a subcutaneous injection with cocaine causes reversible anaesthesia of the surrounding skin. The first synthetic cocaine like substance was produced in 1905. Since then several chemical compounds have been developed such as lidocaine, mipvacaine, bupivacaine and ropivacain.

For the local anaesthetic block we used an anaesthetic agent with relatively fast onset, long duration and low toxicity with minimal risk of side effect (ropivacaine, Astra-Zeneca, Södertälje, Sweden). Compared with bupivacaine, ropivacaine has lower toxicity and a more benign toxicity profile\textsuperscript{41-45}. There have been reports on cardiac arrests after bupivacaine administration\textsuperscript{46}. On the other hand, ropivacaine provides approximately 10% shorter duration of analgesia compared with bupivacaine.

<table>
<thead>
<tr>
<th></th>
<th>Ropivocaine Narop®</th>
<th>Mepivacaine Carbocain®</th>
<th>Bupivacaine Marcain®</th>
<th>Lidocaine Xylocain®</th>
<th>Prilocaine Citanest®</th>
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<tr>
<td>Concentration</td>
<td>2mg/ml 5mg/ml 7.5mg/ml</td>
<td>5mg/ml 10mg/ml 20mg/ml</td>
<td>2.5mg/ml 5mg/ml</td>
<td>5mg/ml 10mg/ml 20mg/ml</td>
<td>5mg/ml</td>
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<td>Onset (min)</td>
<td>1-5</td>
<td>2-4</td>
<td>5-8</td>
<td>2-4</td>
<td>2-4</td>
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<tr>
<td>Duration</td>
<td>2-6 h</td>
<td>20-30 min</td>
<td>2-7 h</td>
<td>1-3 h</td>
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<tr>
<td>Maximal dose</td>
<td>300 mg</td>
<td>350 mg</td>
<td>150 mg</td>
<td>3mg/kg</td>
<td>600 mg</td>
</tr>
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</table>

Several regional anaesthetic methods are suitable for anorectal procedures. In caudal block the anaesthetic solution is injected through the sacrococcygeal space into the sacral canal. The sacral hiatus can be difficult to identify with a failure rate of 5-10 percent \(^{47}\) and higher occurrence of urinary retention\(^{48}\). Local block of the anus can be described as three separate methods; submucosal infiltration, intersphincteric infiltration and perisphincteric block with infiltration into the ischiorectal fossae. The anus is richly supplied with sensory nerve fibres of the anoderm up to the dentate line while the mucosa is relatively insensitive. The nerve supply to the anus is illustrated in figure 3.

*Figure 3. Nerve supply of the anus.*
One method injects the analgesic solution into the submucosa in four quadrants, the bulge is then digitally squeezed into the sub-dermal plane distal to the dentate line. There are also suggestions to use a hook-like needle to puncture the mucosa above the dentate line and inject the solution while advancing distally. Infiltration of the submucosa of the anal canal can be done without sedation. Esser performed stapled haemorrhoidopexy with local infiltration of the perianal skin and into the submucosal plane in four quadrants. The infiltration was performed under conscious sedation with success in all cases. Marti described a technique with infiltration of the posterior ischiorectal fossae followed by subdermal infiltration of the anal verge without infiltration of the anus itself. Analysis of 3725 patients demonstrated a complication rate of 0.6% by Marti’s technique. A series of 400 haemorrhoidectomies were treated with a modification of Marti’s posterior block with an additional 360° infiltration of the perianal skin and a small infiltration of each pile. Only 5 percent of the cases needed intravenous injection of fentanyl as a supplement to the block. A posterior ischiorectal block applied with the surgeon’s index finger in the anus as a guide was described by Delikoukos. Stapled haemorrhoidopexy has been performed with intersphincteric block with no instance of conversion to general anaesthesia. Imbelloni et al used a nerve-stimulator to administer bilateral pudendal nerve block. Others have used local infiltration as a complement to general anaesthesia or spinal block for postoperative pain relief. We have described a perianal local block given perisphincteric to target the anus rather than specific nerves and implemented it in stapled haemorrhoidopexy. The variations to achieve anal analgesia are illustrated in table 3.
Table 3. Variation in applying local anal block described in scientific papers. *When requested. †With adrenaline.

<table>
<thead>
<tr>
<th>Author</th>
<th>Method of local anaesthesia</th>
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<td></td>
<td>Ischiorectal block</td>
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<td>Esser&lt;sup&gt;52&lt;/sup&gt;</td>
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</tr>
<tr>
<td>Ong&lt;sup&gt;59&lt;/sup&gt;</td>
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<td>Mariani&lt;sup&gt;58&lt;/sup&gt;</td>
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<tr>
<td>Gabrielli&lt;sup&gt;55,66&lt;/sup&gt;</td>
<td>✓</td>
</tr>
<tr>
<td>Luck&lt;sup&gt;62&lt;/sup&gt;</td>
<td>✓</td>
</tr>
<tr>
<td>Ho&lt;sup&gt;57&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Vinson-Bonnet&lt;sup&gt;63&lt;/sup&gt;</td>
<td>✓</td>
</tr>
<tr>
<td>Nyström&lt;sup&gt;65&lt;/sup&gt;</td>
<td>✓</td>
</tr>
</tbody>
</table>

The haemorrhoidectomy procedure

The Milligan-Morgan<sup>67</sup> procedure is the gold standard for haemorrhoid surgery. The original description by Milligan and Morgan is not the method used today. The authors describe how the incisions by scissors were extended through the “corregator cutis ani” until the subcutaneous portion of the external sphincter is laid bare. After dissecting the entire haemorrhoid pedicle (both external and internal haemorrhoid plexus) including their covering skin and mucosa, a ligature was tied to the base while an assistant exerted traction of the pedicle. In this manner, the ligature, which included the longitudinal muscle, will be fixed at the site of the distal portion of the internal sphincter unable to slide upwards. It was intended to prevent open wounds in the anal canal. Finally, any redundant skin was trimmed and the wounds external to the anal canal were left open<sup>67</sup>. Today, most surgeons excise the pedicles with monopolar diathermy because
it bleeds less. With traction of the skin-tag and pedicle, the tension produced allows dissection in a plane that preserves the subdermal fascia that is continuous with the fascia that covers the internal sphincter. This procedure minimizes loss of tissue within the anal canal. The external haemorrhoidal plexus remains deep of the subdermal fascia. This technique was first described by Sharif in 1991.

The postoperative course after haemorrhoidectomy is often extremely painful. Studies that compare dissection with scissors or diathermy did not show any difference in postoperative pain. In 1959 Ferguson and Heaton described a method of closed haemorrhoidectomy meaning that the wounds are fashioned to allow suture closure. It was proposed to reduce postoperative pain and provide faster wound healing. However, there is no consistent finding of lesser postoperative pain.

The haemorrhoidopexy procedure

In 1998, Longo described a conceptually new technique for haemorrhoid surgery. The new concept was based on the lining and sliding theory for the pathogenesis of the disease. The procedure, unlike the conventional methods, aims to restore the anal anatomy by anchoring the cushions in their normal position rather than of excising the piles. Using a circular stapler devise, a circumferential excision of redundant rectal mucosa above the cushions is made (prolapsectomy). The mucosal anastomosis is targeted at 2 cm above the dentate line. A higher or lower staple line affects the outcome in various ways. The mucosal anastomosis is proposed to re-anchor the cushions to the rectal wall.

Mucoanal prolapse of grade 2 and 3 is the indication for performing a stapled haemorrhoidopexy. It means either a prolapse that needs manual repositioning or a prolapse seen by the surgeon at proctoscopy while asking the patient to strain. The external components are not resolved with stapled haemorrhoidopexy alone. For that reason a hybrid operation with complementary diathermy excision of skin-tags may be required.

When introduced, it was described as an operation with less pain and short convalescence compared with conventional haemorrhoidectomy. This has been confirmed in all the randomized trials.
The most common complications are postoperative staple line bleeding, urinary retention, excessive pain and defecatory urgency. Other moderate but rare complications reported include staple line stenosis and rectal mucosal pocket. Severe complications have also been reported, such as Fournier’s gangrene, even with lethal outcome, retroperitoneal sepsis or pelvic sepsis, rectal perforation, recto-vaginal fistula and rectal obstruction. In a study of 205 healthy patients randomized to stapled haemorrhoidopexy or conventional haemorrhoidectomy, perioperative positive blood cultures were equally common among the groups. A systematic review to assess the scale of problems concerning haemorrhoid treatment was conducted by a group in the UK. Twenty-nine papers identified 38 patients with severe infectious complications after haemorrhoid treatment. Of these, 17 patients had undergone Rubber band ligation (RBL), 10 conventional haemorrhoidectomy, 7 stapled haemorrhoidopexy and one cryotherapy. They emphasized that as seven patients had undergone stapled haemorrhoidopexy in its short existence it may represent an increased risk of the procedure or just reflect the increased interest and reporting associated with a new procedure. These authors noted that the last report on perineal sepsis secondary to RBL was published in 1989 and emphasized the risk of hidden statistics. Immunodeficiency can lead to disastrous consequences after haemorrhoid treatment and such patients should be treated conservatively when possible. Technical errors have been suggested as a probable cause of severe complications such as Fournier’s gangrene, rectal obstruction and pelvic sepsis.

Until February 2008 a total of 30 randomized trial of stapled haemorrhoidopexy versus conventional haemorrhoidectomy have been published in the English literature. The technique for conventional haemorrhoidectomy in these trials was the open technique of Milligan-Morgan or the closed method of Ferguson. Five meta-analyses have been published. To sum up, there are significant advantages of the stapled haemorrhoidopexy in the following respects: operation time, postoperative pain, length of hospital stay and duration of convalescence. In the short and long-term perspective the recurrent prolapse rate was significantly higher for patients undergoing stapled haemorrhoidopexy. In published case series a remarkable variation of the long term results is seen, ranging from 0.3 percent
to 27.1 percent\textsuperscript{138}. One report treating grade IV prolapse reported recurrence rate of 58 percent\textsuperscript{139}. Grade IV prolapse according to the traditional classification is skin-covered components which cannot be reduced. The stapled haemorrhoidopexy procedure removes redundant mucosa but cannot remove the skin covered external components of grade IV prolapse. Surgeons must be prepared to do a hybrid operation that combines the stapled procedure with a diathermy excision of the external component. In patients with excessive mucosal prolapse, the capacity of the stapler device to excise the mucosa may be exceeded. It has been proposed to use two staplers in this situation which gives significantly better result\textsuperscript{140}. Others have proposed lowering the staple line and even including anoderm in the excision with improved result\textsuperscript{137}, or applying additional traction sutures to segments with more prominent mucosal prolapse\textsuperscript{141}.

The trial results are difficult to interpret because of the considerable variation in patient selection, variation in operative technique and the inconsistency of the definitions of recurrence. It must also be considered that the majority of the trials were conducted in the early stage, conceivably before the technique had matured and the learning curve had been overcome.
AIMS OF THE THESIS

- To assess the advantage of performing stapled haemorrhoidopexy under local perianal block. First in a prospective case series and repeated in a randomized controlled trial (Paper I and II).

- To advance the problem of management of the external component that is often left untreated in stapled haemorrhoidopexy procedure. In particular to find out if excision of any residual skin-tags is possible without detracting from the advantage of less pain and faster recovery with stapled haemorrhoidopexy (Paper III).

- To develop and validate a classification algorithm of mucosal prolapse and anodermal prolapse (external component) for use preoperatively and postoperatively for precise description of success or failure of any treatment of haemorrhoids. In addition, to study the relationship between anatomical prolapse and the associated symptoms of bleeding, pain, soiling and pruritus (Paper IV).

- To assess the long-term results of stapled haemorrhoidopexy in a set of patients using uniform methods of data acquisition and pre-determined definitions for failure, recurrence, symptom burden and impaired continence (Paper V).
PATIENTS AND METHODS

Patients

Altogether these studies comprise 334 patients with the distribution of patients throughout all papers described in figure 4. 180 patients in paper IV were operated in an international multicenter randomized study. 18 Hospitals provided the data. All other patients with the stapled haemorrhoidopexy procedure were operated in the Department of Surgery at Linköping University Hospital. All patients were assessed in the same manner in the outpatient clinic. Prior to the visit, a bowel function questionnaire was sent to the patient. The surgeon spent 30 minutes with each patient and the anatomy was described in an anatomical protocol in addition to the patient journal note. The patients were operated with the use of prospective protocols for symptoms and technical aspects of the operation. All information was entered into an electronic database.

*Figure 4. Venn diagram on patients included in the studies of the thesis.*
Methods

As part of the research programme specific instruments were developed to evaluate this new operation. In particular, a questionnaire was used to capture patient self-reported symptoms before and after surgery. The intention was to ask patients about the symptoms and ask the surgeons to define the deranged anal anatomy according to standardized answers to questions in an anatomical protocol. At the time of the operation patients were provided a diary that covered the first 14 days after surgery. In the diary patients entered their pain experience each day (visual analogue scale), the recovery to normal ability and any unexpected events. The symptom questionnaire was mailed to patients before their appointment and most, but not all, patients returned a completed form before and again after surgery. Some patients failed to return the diary after surgery.

Bowel function questionnaire

A questionnaire of self-reported symptoms associated with the haemorrhoids was completed by the patient before the operation and repeated at a clinical visit 3-6 months postoperatively. The patient rated the frequency of five cardinal symptoms of haemorrhoids: anal pain, anal irritation or pruritus, bleeding, soiling, and prolapse of haemorrhoids that needed manual reposition at defecation. Each of the five symptoms was scored according to its frequency: less than once per month (0 point), every month but not every week (1 point), 1-6 days per week (2 points) and every day (3 points). The points for each of the five symptoms were summed for a maximum of 15 points (figure 5). The numerical difference between the preoperative score and that obtained at follow-up was assumed to represent the treatment effect of the operation for each patient.
Figure 5. Patient self-reported symptom questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Less than once a week</th>
<th>1-6 times weekly</th>
<th>Every day (always)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often do you have pain from the anus?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. How often do you have itching or discomfort of the anus?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. How often do you have bleeding when passing a motion?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. How often do you soil your underclothes (soiling from the anus)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. How often do you reduce a prolapsing haemorrhoid with your hand when passing a motion?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Anatomical protocol at examination

Whenever patients visited the outpatient clinic, at preoperative examination and at follow-up 3-6 month after surgery or at the final examination, the surgeon assessed the pathology: the appearance of the anus with presence of mucoanal prolapse and the number of prolapsed haemorrhoids. This was done during proctoscopy while the patient was asked to strain. In addition, the surgeon rated the external component at three levels: no external component or skin tags, one or few tags, and circumferential external component. The surgeon also assessed the resting pressure of the anal canal and squeeze pressure of the sphincters by digital examination (figure 6). At the preoperative examination, the surgeon rated the appearance of the disease in relation to other patients with haemorrhoidal disease using a 7-point scale ranging from minor to severe disease. At the postoperative examination, special attention was directed towards ascertaining any adverse event in the post-treatment course and sign of staple line stenosis. Again, using a 7-point scale, the surgeon rated the success in relieving all signs of haemorrhoidal disease. This information was entered into a standardized anatomical protocol and registered in the database.
Figure 6. Anatomical protocol for the assessment of anal anatomy.

1. Anal appearance on inspection:
   - Normal
   - Mild prolapse
   - Major prolapse
   - Circumferential prolapse

2. Prolapse of haemorrhoids:
   - None
   - On traction
   - Spontaneous
   - Total

3. Number of haemorrhoids that are prolapsed:
   - None
   - One
   - Two
   - All

4. Presence of skin tags:
   - Not at all
   - A few
   - Quite a few circumferential
   - Many or

5. Resting pressure of the anal canal:
   (digital examination)
   - Normal
   - Mildly subnormal
   - Clearly subnormal
   - Very low or absent

6. Squeeze pressure of the external sphincter:
   (digital examination)
   - Normal
   - Mildly subnormal
   - Clearly subnormal
   - Very low or absent

Development of the Classification

No patient had any conventional classification of mucoanal prolapse documented in the protocols. This was by intention. Instead, the surgeons were asked to rate the anatomy according to standardized responses to questions about the anatomy. We first divided the patients into two groups based on the patients’ self-reports about the need to manually reduce a haemorrhoidal prolapse. Patients who denied the need for such reduction were subdivided according to the surgeon’s statement in the anatomical protocol whether or not a prolapse was present. In this manner three grades of prolapse were obtained: grade 1, no prolapse; grade 2, prolapse in the opinion of the surgeon; and grade 3, prolapse that was reduced manually by the patient. Each grade of prolapse was further subdivided according to the presence of
an external component: A, none; B, one or few; and C, circumferential. A grade III prolapse in the traditional classification corresponds to grade 3A, 3B or 3C according to this classification and a grade II haemorrhoid corresponds to grade 2A, 2B or 2C, while a traditional grade IV prolapse may be translated as a Grade 3C if there is mucosal prolapse that the patient reduces manually. Grade 4 prolapse in our classification, is reserved for the emergency situation with thrombosed and prolapsed haemorrhoids. For details of the algorithm, see figure 7.

*Figure 7. Algorithm for grading haemorrhoids*

Does patient reduce a prolapsing haemorrhoid with the hand when passing a motion?

No

Surgeon assessment of prolapse on proctoscopy

No

Grade 1

Yes

Grade 2

Acute thrombosed and prolapsed haemorrhoids

Yes

External component of anodermal tags and polyps:

A - None

B – One or few tags

C - Circumferential

Grade 3

Grade 4
The stapled haemorrhoidopexy (anopexy) operation

A uniform method has been employed throughout the course of these studies. The PPH 01 kit comprising the haemorrhoidal circular stapler device (HCS33), the Circular anal dilator (CAD33), the purse string anoscope (PSA33) and the purse string threader (ST100) was marketed in January 1999. In 2004 the new stapler PPH03 was marketed. The utensils of the entire kit were used for all the operations. The large majority of the patients were operated in the prone position. As we developed the local perianal block and adopted it as the standard analgesic method, only patients who were part of the randomised trial and patients who specifically requested a general anaesthetic were not operated under local block. About 90 percent of the operations were done in a day case setting, admitting for an overnight stay only those who for medical or social reasons could not be discharged the same day.

The anal anatomy will appear quite different with the patient in the prone position compared with the lithotomy position. In particular, the haemorrhoid vasculature is empty while the mucosal redundancy of the lower rectum becomes more apparent. The overall impression is one of less protrusion of the anus and relative absence of haemorrhoids. Using local perianal block will provide less relaxation of the sphincters compared with a general anaesthetic in the lithotomy position. In consequence, the anal prolapse will again appear less prominent.

With the patient prone, the anal anatomy was further studied with respect to any external component of anodermal prolapse and folds or polyps of the anoderm. Especially women are prone to have an anterior anal prolapse, often, but not always, in combination with prolapse of the right anterior pile and its associated mucosa. The mucosal component of the prolapse can be delivered by means of a swab inserted into the rectum and subsequently pulled out through the anus. In case of redundancy, the mucosa will appear outside of the anal verge, typically at the site of the piles that form the prolapse (see figure 1).

The procedure then continues with testing that the anus is sufficiently wide to accept the CAD. In rare instances the anus was found to be too narrow in which case the anopexy was aborted and converted to a conventional haemorrhoidectomy. The CAD tube,
which is 3 cm long, was inserted with the aim of reducing as much of the anodermal prolapse as possible and expecting the tube to pass the dentate line with about one centimetre. When this can be achieved the anatomy of the anal canal has been restored. It also provides better exposure of the lower rectum, which makes the insertion of the purse string suture easier. The CAD was always sutured to the perianal skin.

The purse string suture was begun at the point of the most prominent mucosal prolapse. The reason is that the site of the knot joining beginning and end of the purse string suture will be the site of the widest excision because of the traction on the ends of the suture. The suture was applied between 3 cm and 4 cm above the dentate line. We have rarely used two purse string sutures, one for each half of the circumference, although this has been proposed to provide a more even excision. An alternative that accomplishes the same effect is to make a loop opposite to the starting point and use the loop to even the pull on the mucosa by bringing the loop out through one of the channels of the stapler head while the ends are brought out through the other channel.

Once the purse string suture was applied the ends were pulled with a finger inside the suture to assess that it was submucosal throughout the entire circumference without skips where the mucosa was not captured. Retracting the finger while still pulling on the suture ends the finger could now assess the presence of deep pockets outside the purse string signifying a too high placement of the suture. If this was found a second suture was placed about one centimetre closer to the dentate line covering the segment with a too high suture placement.

The stapler was inserted so the anvil passed the purse string suture and aligned with the direction of the anal canal and the patient’s midline. The stapler was closed at a distance of 4 cm above the anal verge as marked on the stapler head. In women the posterior vaginal wall was ascertained to be free. Then it was fired. After removal of the stapler, the mucosal anastomosis was inspected for bleeding spots that were secured with a stitch or diathermy. The distance of the staple line above the dentate line was measured to the nearest half centimetre.

The specimen, shaped like a doughnut, was always inspected for completeness and its width was estimated as well as the presence of
any trace of the rectal muscular wall. This was found in the large majority of the specimens. Finally any remaining skin tags were gently tested with forceps and excised if longer than 1 cm. Circumcising the skin and dissecting free the tag, with preservation of the underlying subdermal fascia, completed this excision. Deep of this fascia is the external haemorrhoidal plexus which was left untouched with diathermy coagulation of any bleeder. The excision stopped at the lower border of the internal sphincter and did not extend into the anal canal proper. The subdermal fascia is continuous with the submucosal fascia that covers the internal sphincter.

**Operation protocol**

After each operation, the surgeon filled out an operation protocol. Information concerning the type of anaesthesia, surgical positioning of the patient, operation time, theatre time and blood loss was registered. The height of the final staple line above the dentate line was measured to the nearest half centimetre. The appearance of the excised doughnut was recorded. No measurement of the doughnut size was performed besides the visual inspection of the width and trace of smooth muscle fibres. The surgeon described if the doughnut was complete circumferential or in 2 or more pieces. The presence and number of skin tags and their excision were recorded. Finally the surgeon rated the complexity of the procedure in relation to own experience of treatment for haemorrhoids. For this, we used a 7-point scale ranging from simple to difficult. In addition to the operation protocol, a detailed surgical note was dictated in all operations.

**Local anal block**

Premedication was not prescribed preoperatively. In the operating theatre the patient was placed prone with a pillow under the hips and the legs held together. When the patient had found a comfortable position that could be endured for about 45 minutes, the buttocks were taped apart for better exposure and the perianal area was cleansed with antiseptic solution before the area was draped. Patients were offered a headset to listen to music during the operation. The perianal block was applied before any anal examination. Narop® (ropivacaine, AstraZeneca, Södertälje, Sweden) was the anaesthetic agent in all instances. By mixing 20 ml of a 7.5 mg/ml solution with 20 ml of 2 mg/ml solution, we obtained forty millilitres of 4.75-mg/
ml solution for the perianal block. A 20-ml syringe was fitted with a
60-mm intramuscular needle and the solution was injected approxi-
mately 3 cm from the anal verge through the anococcygeal ligament
into the ischiorectal fossae to the level of the levator muscle. Five
ml of the anaesthetic solution was injected while withdrawing the
needle. The needle was then directed 45° anteriolaterally and 5 ml
was injected on both sides in the perisphincteric space while the nee-
dle was withdrawn. This was repeated in the same fashion anteriorly
in the perineum. The discomfort experienced by the patients within
these two injections was a sting in the perianal skin. The deposition of
anaesthetic solution into the perisphincteric space did not cause fur-
ther discomfort. However, anteriorly in the mid-line the needle passes
through a node of transverse muscle fibres which is felt as a slight re-
sistance when deploying the anaesthetic solution. Incautious injection
of the anaesthetic solution at this level will cause the patient pain. The
anaesthetic block was completed with 5 ml columns of anaesthetic
solution on each side of the anus. As illustrated in figure 8, a total of
eight columns of 5 ml solution are deployed circumferentially in the
perisphincteric space. The onset of anaesthesia is approximately 5
minutes, with blockage of the branches to the anus from the anococ-
cygeal and pudendal nerves: the inferior haemorrhoidal nerve portion
and the anterior sphincteric nerve portion. Complete anaesthesia of
the perianal skin and the anal canal ensues with relaxation of the
sphincters that are rendered painless to dilatation.

Before introduction of the stapler, the submucosa beneath the
purse-string suture was infiltrated with 10 ml of Narop, 2 mg/ml.
This ensured complete painlessness during closure and firing of the
stapler.

A total amount of 210 mg of ropivacaine was used for each pe-
rianal local block. Today a solution of Narop 5 mg/ml is available;
this solution will be used in the future instead of the 4.75 mg/ml
solution.
Patient’s diary and recovery

The postoperative pain experience was the main outcome variable in papers I-III. Before leaving the hospital, patients were given a diary covering the first 14 postoperative days. The patients were instructed verbally and in writing to enter a figure that best described the pain experienced during most of the day (daily average pain) and another figure for the maximum pain experienced at any time of the day using a 10-point visual analogue scale (0 = no pain, 10 = worst imaginable pain). The use of pain medication was recorded in the diary as a dichotomous variable. Patients were given 1 gram paracetamol four times daily together with 50 mg diclofenac for a maximum of 3 tablets per day. No morphine analgesics were provided. The time to recovery was defined as the postoperative day the patient had rated him/her as “normal” or had returned to work as recorded in the diary.
**Statistical methods**

Categorical data were compared by Fisher’s exact test and with chi-square test. For continuous data the student t-test were used. The non-parametric Mann-Whitney U-test was used to test the difference in pain scores between groups and compare the 7-point scale ratings of anatomy, complexity and operation success. In paper IV, analysis of variance (ANOVA) was used to compare symptom score across the different grades, external component included. A permutation test, with the software set at ten-thousand loops, was used to test the difference in the sum of daily average pain, peak pain and staple height between the two groups in paper II. Paired data of before and after treatment results were examined with paired samples Wilcoxon sign rank test (paper V).

Data were presented as mean with ranges or standard deviation (SD) unless otherwise indicated (paper I-III, V). In paper IV, data is presented with mean score for each symptom combined with number of patients at each stage and with each symptom.

Two–tailed probability of less than 5% ($p$-value<0.05) was considered statistically significant.

Data were analysed using STAT-VIEW (SAS Institute Inc., Cary, North Carolina, USA) version 4.4 for Windows, MINITAB version 14 (Minitab Inc., State Collage, Pennsylvania, USA) and SPSS version 13.0 (SPSS, Chicago, Illinois, USA).

**Ethics**

The studies were performed according to the Helsinki declaration of good clinical practice. The Ethics committee at the Faculty of Health and Science approved the protocol for paper II. The protocol for paper V was submitted for ethical review but was returned as follow-up studies involving no new intervention are not subject to the committee’s approval in Sweden. Descriptive studies that were based on data from the prospective registry were not considered for ethical approval (paper I, III, IV).
RESULTS

Paper I, II

The two studies (paper I and II) used identical protocols but paper I was a data base study while paper II was a prospective randomized trial. Therefore I will mainly report the results from paper II and only comment paper I.

Eighty-eight patients were considered for this trial but 30 declined participation because of preference for either method of anaesthesia. Of the 58 patients that were randomized, seven were excluded leaving 25 patients in the general anaesthesia (GA) group and 26 patients in the local anaesthesia (LA) group. Forty patients (78 percent) stated a need to manually reduce a prolapse (grade 3 prolapse). The local anaesthesia was complete in all patients with no conversion to general anaesthesia. Skin-tags were present in 71 percent of the patients and excision of skin-tags was performed in 61 percent. The mean height of the staple line differed between the groups where the LA group had a staple line 3 mm closer to the dentate line compared with those operated under general anaesthesia ($p=0.019$). The time to apply the local block was included in the operation time resulting in significantly longer time needed for the operation under perianal block (30.1 vs. 24.7 minutes, $p=0.004$).

84 percent of the patients in the GA and 88 percent in the LA-group returned the postoperative diaries. The mean sum of VAS points for the daily average pain was 23.1 (GA) and 29.4 (LA); $p=0.38$. The peak pain was 42.1 (GA) and 47.9 (LA); $p=0.54$. The resolution of the peak pain and daily average pain is shown in figure 9.
Figure 9. Resolution of postoperative pain (VAS) for the two groups: GA (general anaesthesia) and LA (local perianal block). There was no statistical difference between the groups.

Figure 10. The proportion of patients remaining on postoperative pain medication each postoperative day: GA (general anaesthesia), LA (local perianal block). No Statistical difference between the groups.

The consumption of paracetamol and diclofenac declined throughout the immediate postoperative period without significant difference between the groups as shown in figure 10. Remarkably, 38 percent of the patients in the GA-group considered themselves normal or had returned to work on the first postoperative day. The corresponding value in the LA group at the same time was 4 percent with a significant statistical difference ($p=0.004$). The subsequent postoperative days up till day 14 revealed no statistical difference in this respect (figure 11).
No major complication was reported in either group. One patient in the LA group was re-operated on the same day because of postoperative bleeding. Two patients in the LA group and one in the GA group had excessive pain postoperatively. The pain resolved in all patients. At follow-up 3-6 month after the operation no patient had a recurrence of prolapse in either group with a decrease in symptom load at an average of 7.0 points in the GA-group and 6.1 points in the LA group. One patient in each group declined follow-up examination.

The result confirms the feasibility of performing stapled haemorrhoidopexy under local perianal block. The same feasibility is described in paper I. In that paper, 33 patients were operated under local anaesthesia. As controls 18 patients underwent the same procedure under general anaesthesia. The postoperative pain scores for each day and total sum of VAS for the postoperative period was statistically similar but numerically in favour of the local anaesthetic block. The staple line height was mean 20 mm for both groups.

Paper III

In this paper the aim was to discover any correlation between excision of skin-tags and increased postoperative pain. There were 24 patients who had no excision of skin-tags while 17 patients had such excision performed. The two study groups were comparable regarding age, sex, grade of prolapse, symptom scores, operative complexity scores and postoperative outcome scores. The postoperative pain experience over 14 days was almost identical, being 23 VAS points in
both groups for the daily average pain and 42 and 43 points for the peak pain as illustrated in figure 12. The resolution of pain over 14 days postoperatively is shown in figure 13.

Figure 12. The sum of daily pain scores from postoperative day 1 through day 14 with and without excision of skin tags. No statistical difference between groups.

Figure 13. The resolution of postoperative pain with and without excision of skin tags.

--- RESULTS ---

Paper IV

In this paper the aim was to develop a classification algorithm that included the anodermal external component and to study the symptomatic load in relation to the grade of prolapse. All 180 patients in a concluded multicenter randomized clinical trial who were operated for haemorrhoid prolapse were designated as the test set. Precisely half the patients had had a diathermy haemorrhoidectomy and the other half a stapled anopexy. Sixteen percent of the patients in the test group and validation group did not complete the questionnaire or attend the follow-up examination at 3-6 month after surgery. The preoperative anatomical grades did not differ between the test group and validation group, including the presence of skin-tags. However, more patients had circumferential skin-tags in the test group (22.2 percent
vs 8.9 percent) and correspondingly more patients with “quite a few” skin tags were observed in the validation group (65 percent vs 50 percent) (Figure 14).

Analysing each symptom with respect to the grade of prolapse we found significant differences for two symptoms. The score for preoperative pain was higher in patients with grade 3 prolapse ($p=0.027$). The score for preoperative soiling was higher for grade 2 prolapse ($p=0.031$), Table 4. Points for soiling were independent of the presence of skin tags. Postoperatively 86 percent in the test set and 95 percent in the validation set had an anatomical grade of 1A or 1B (figure 15). Even when the anatomy was restored after the operation (grade 1A or B), pain were reported in 18 percent of the cases, pruritus in 40 percent, defecatory bleeding in 23 percent and soiling in 40 percent (Table 4).
Table 4. Patient self-assessed preoperative and postoperative symptom scores for the four cardinal symptoms (pain, pruritus, bleeding and soiling). Each symptom was graded from zero to 3 points. Results are the mean score for each symptom, the number of patients within anatomical stage (N) and the number of patients with positive symptoms (n).

<table>
<thead>
<tr>
<th>Preoperative grade</th>
<th>2A N=19</th>
<th>2B N=45</th>
<th>2C N=19</th>
<th>3A N=54</th>
<th>3B N=103</th>
<th>3C N=29</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.05 (12)</td>
<td>1.51 (34)</td>
<td>1.68 (16)</td>
<td>1.63 (42)</td>
<td>1.78 (89)</td>
<td>1.76 (26)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1.21 (13)</td>
<td>1.36 (31)</td>
<td>1.37 (15)</td>
<td>1.59 (43)</td>
<td>1.40 (77)</td>
<td>1.83 (25)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1.63 (17)</td>
<td>1.56 (40)</td>
<td>1.58 (16)</td>
<td>1.65 (46)</td>
<td>1.67 (92)</td>
<td>1.76 (26)</td>
</tr>
<tr>
<td>Soiling</td>
<td>1.89 (17)</td>
<td>2.02 (41)</td>
<td>1.63 (15)</td>
<td>1.57 (47)</td>
<td>1.61 (85)</td>
<td>1.72 (23)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Postoperative grade</th>
<th>1A N=108</th>
<th>1B N=94</th>
<th>1C N=1</th>
<th>2A N=5</th>
<th>2B N=3</th>
<th>2C N=2</th>
<th>3A N=6</th>
<th>3B N=9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>0.23 (18)</td>
<td>0.33 (18)</td>
<td>1.00 (1)</td>
<td>0.00 (0)</td>
<td>0.33 (1)</td>
<td>1.00 (1)</td>
<td>1.50 (4)</td>
<td>1.56 (7)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>0.63 (44)</td>
<td>0.57 (37)</td>
<td>1.00(1)</td>
<td>0.20 (1)</td>
<td>0.67 (2)</td>
<td>1.00 (1)</td>
<td>1.67 (5)</td>
<td>1.00 (5)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>0.30 (23)</td>
<td>0.33 (25)</td>
<td>0.00 (0)</td>
<td>0.20 (1)</td>
<td>0.67 (2)</td>
<td>1.00 (1)</td>
<td>1.17 (5)</td>
<td>1.11 (5)</td>
</tr>
<tr>
<td>Soiling</td>
<td>0.44 (35)</td>
<td>0.65 (45)</td>
<td>3.00 (1)</td>
<td>0.80 (3)</td>
<td>0.33 (1)</td>
<td>0.50 (1)</td>
<td>0.67 (3)</td>
<td>1.22 (7)</td>
</tr>
</tbody>
</table>

— RESULTS —

Paper V

The intention of this study was to assess the long-term outcome after stapled haemorrhoidopexy. 153 patients had complete preoperative information. Sixty-seven percent of the patients had a grade 3 prolapse preoperatively; the remaining patients were grade 2 prolapse. We found a tendency towards more grade 3 prolapse in men (p=0.09). The symptom burden did not significantly differ by gender or grade. The predominant symptoms in grade 2 were bleeding and soiling whilst pain and prolapse were more important in grade 3. A gender difference was the tendency for men to have more of bleeding and soiling in grade 3. The predominant continence problems presented preoperatively were soiling and involuntarily breaking
wind. For grade 3 there was also a more frequent use of a protection pads. There were significant gender related differences in grade 3 with women having more of involuntary gas incontinence ($p<0.01$) and more frequent use of protection pads ($p<0.05$). Grade 3 prolapse was more likely to have disturbed continence.

At closure a total of 145 patients returned the bowel function questionnaire and were therefore subject to further analysis as paired data. The overall symptom relief was significant ($p<0.001$) for all grades and both genders. The preoperative and postoperative symptom scores are presented in table 5. The external component was not statistically related to the symptom score. At closure, a total of 25 patients reported a symptom burden of 5 points or more. Seven of these patients reported remaining prolapse and 11 had also impaired continence function. Among the 25 patients we identified 5 patients that had worse symptom scores at closure. Of these, 2 patients had recurrence of prolapse, one patient had urgency symptoms and 2 patients complained of bowel dysmotility disorder (figure 16).

Table 5. Preoperative and postoperative self-reported symptom score shown as mean score by symptom. Each of the symptoms improved significantly (paired Wilcoxon signed ranks test, $p<0.001$)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Peroperative (mean)</th>
<th>Postoperative (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.65</td>
<td>0.38</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1.31</td>
<td>0.68</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1.67</td>
<td>0.40</td>
</tr>
<tr>
<td>Soiling</td>
<td>1.86</td>
<td>0.68</td>
</tr>
<tr>
<td>Prolapse</td>
<td>1.67</td>
<td>0.30</td>
</tr>
<tr>
<td>Median of total score (range)</td>
<td>8 (2-15)</td>
<td>1 (0-13)</td>
</tr>
<tr>
<td>Mean total score (SD)</td>
<td>8.12 ($\pm$2.89)</td>
<td>2.51 ($\pm$2.89)</td>
</tr>
</tbody>
</table>

Overall, there was a significant postoperative reduction of incontinence points ($p=0.001$). This reduction was most prominent for the use of pads and soiling whilst involuntary breaking wind improved less ($p<0.035$). The incontinence scores are presented in table 6.
Table 6. Patient incontinence score pre and postoperatively shown as mean score values. Each of the symptoms improved significantly (paired Wilcoxon signed ranks test)

<table>
<thead>
<tr>
<th>Continence</th>
<th>Preoperative (mean)</th>
<th>Postoperative (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involuntarily breaking wind</td>
<td>1.21</td>
<td>1.03</td>
</tr>
<tr>
<td>Soiling</td>
<td>1.47</td>
<td>0.83</td>
</tr>
<tr>
<td>Leakage loose stool</td>
<td>0.71</td>
<td>0.45</td>
</tr>
<tr>
<td>Leakage when not loose</td>
<td>0.33</td>
<td>0.12</td>
</tr>
<tr>
<td>Use of protective pad</td>
<td>0.95</td>
<td>0.46</td>
</tr>
<tr>
<td>Median of total score (range)</td>
<td>4 (0-14)</td>
<td>2 (0-12)</td>
</tr>
<tr>
<td>Mean total score (SD)</td>
<td>4.68 (±3.55)</td>
<td>2.88 (±2.87)</td>
</tr>
</tbody>
</table>

The external component was not significantly related to the incontinence scores. However, there was a tendency for more skin tags with higher incontinence scores. It was also more common with a higher degree of skin tags among females and this was partly related to increasing age. We defined impaired continence as a score of 6 points or more at closure. Sixty-three patients met the criteria preoperatively and 25 patients at closure. Eleven of these patients had also failed control of haemorrhoid symptoms (Figure 16). The presence of incontinence at closure was associated with treatment failure of the prolapse and correlated with a worse preoperative incontinence score (Pearson 0.49, \( p < 0.001 \)).

Figure 16. Venn diagram linking outcome at closure for prolapse that required manual repositioning, symptoms of haemorrhoids, and anal incontinence.
Failure and recurrence
Within the first year we identified 5 patients with failed or inadequate control of prolapse. Four of these patients were re-operated; in two a new stapled anopexy and in two a Milligan-Morgan haemorrhoidectomy. In the entire cohort 12 patients were re-operated because of insufficient result. Nine patients were re-operated because of prolapse with 7 being cured, and 3 patients had symptomatic skin-tags removed (Table 7). At closure a total of 12 patients reported a prolapse that needed manual reduction on a weekly or daily frequency. Their preoperative symptom and continence scores did not significantly differ from the other patients. Overall they had an amelioration of symptom scores but less than average.

Table 7. Re-interventions during the follow-up period until closure (1 to 6 years).

<table>
<thead>
<tr>
<th>Re-operation</th>
<th>(n=12)</th>
<th>Months since primary operation; mean (range)</th>
<th>Persistent prolapse at closure n=2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemorrhoidectomy</td>
<td>6</td>
<td>13 (3-19)</td>
<td>1</td>
</tr>
<tr>
<td>New Stapled Anopexy</td>
<td>2</td>
<td>6 (5-7)</td>
<td>-</td>
</tr>
<tr>
<td>Skin-tag excision</td>
<td>3</td>
<td>10 (3-16)</td>
<td>-</td>
</tr>
<tr>
<td>Rubber band ligation</td>
<td>1</td>
<td>27</td>
<td>1</td>
</tr>
</tbody>
</table>

Complications
We diagnosed postoperative complications in 30 patients. The early postoperative adverse events consisted of voiding problems (n=11), excessive pain (n=6) and bleeding (n=2). One patient with bleeding needed re-intervention. The voiding problems were resolved by catheter drainage. Excessive pain was medically controlled but one patient needed hospital admission. Late adverse events were staple line stenosis (n=2, one dilated), faecal urgency (n=8) and a diverticulum of the staple line (n=1). The urgency resolved spontaneously in 4 patients whilst 4 patients had urgency at closure. The patient that developed a diverticulum of the staple line underwent a diverticulectomy.
GENERAL DISCUSSION

We have adopted Thomson’s lining and sliding theory as the pathogenesis for the development of a mucoanal prolapse or prolapsing haemorrhoids. Histological and anatomical studies support this theory and dismiss other theories. The fact is that haemorrhoids are a normal anatomical structure in the anal canal with an important physiological function to maintain adequate continence for gas and liquid. Although this theory is the most convincing, it may not be the sole explanation for the development of a mucoanal prolapse.

Surgery according to conventional methods, such as the Milligan Morgan procedure or Ferguson procedure, aims to excise the haemorrhoid and prolapsed anal cushions. Both the internal and external haemorrhoidal plexa are traditionally included in the excision. Anatomical studies primarily describe the anatomy in patients suffering from haemorrhoidal disease and compare it with healthy individuals. There are no published anatomical studies comparing preoperative and postoperative anatomical changes in the anal canal. Can anal cushions regenerate? How is the circulation affected? Are new vascular plexa established in the same positions or do the accessory haemorrhoidal cushions grow and take over the continence function of the excised piles? Such studies could be of value for further understanding of the disease.

According to Thomson, haemorrhoidal disease is a prolapse of the anal cushions. This is secondary to rupture and disintegration of the connective tissue that anchors the cushions to the bowel wall. It is still unclear why the rupture arises. Studies have confirmed that the connective tissue becomes disintegrated and broken with age\textsuperscript{13}. It has been shown that the incidence of haemorrhoidal disease decreases after 65 years of age\textsuperscript{142}.

It has also been speculated that constipation may cause the development of haemorrhoids through a correlation to dietary aspects\textsuperscript{19,143}. Haemorrhoidal disease is more frequent among black American population and rather rare among African population\textsuperscript{143,144}. Johanson\textsuperscript{142} could illustrate a different epidemiological pattern of constipation with regard to haemorrhoids, where the prevalense of haemorrhoids
increases, while the prevalence of constipation decreases with higher socio-economic status. Even if there is no evidence for the correlation with constipation and haemorrhoids\textsuperscript{145}, the dietary fiber intake may still play an important role in the aetiology\textsuperscript{146}. There is an association between haemorrhoidal disease and bowel dysmotility disorders\textsuperscript{147,148}. Diarrhoea or bowel disorders result in more frequent bowel movements compared to the normal population. These frequent bowel movements can cause strain to the anal lining which may become more likely to disrupt the connective tissue that anchors the cushions\textsuperscript{149}. Consequently one must emphasize the importance of bowel habits in the medical history of patients with haemorrhoidal disease. In patients who present with bowel dysmotility disorder or frequent bowel movements for other reasons, the treatment should primarily be directed towards normalising bowel habits.

Classification

The traditional classification is imprecise with a potential risk of misclassification. The external component is not clearly incorporated in the classification\textsuperscript{38}. There are also controversies if traditional grade II haemorrhoids are true prolapse or not. Indeed, traditional grade II haemorrhoids are defined as a prolapse that may appear externally while straining but return spontaneously and should therefore be defined as prolapse of piles. There is also a tendency towards misclassification between the traditional grade II haemorrhoids and grade III haemorrhoids when surgeons may be impressed by the size of the haemorrhoids rather than the need to digitally reposition the haemorrhoids after defecation\textsuperscript{38}. On the whole, there is an inclination to inflate the grades of prolapse. An Italian group suggested a new classification; the PATE 2000\textsuperscript{150} and revised it in 2007\textsuperscript{151}. The foundation for this classification is the description of Prolapse, Acute events, anal Tone and External component. All these headings have several options making this classification complex and troublesome to apply for surgeons.

A classification is necessary to describe the anatomy of the disease in a uniform manner that allows comparison across various studies. Treatments vary from conservative to a range of invasive treatments. During all studies, we deliberately avoided grading the patients according to the traditional classification. Instead, we used standardized
questions from the patient’s bowel function questionnaire and the anatomical protocol by the surgeon. In this way, we produced a strict algorithm with one patient reported and two surgeon directed questions. This classification algorithm is easy to use and may also be used postoperatively for assessment of the treatment effect.

The surgery should be tailored to the particular anatomical circumstances in each patient. For example, the stapled haemorrhoidopexy operation effectively removes the mucosal prolapse but may inadequately treat the external component. The best results can be expected for grade 2A and 3A where the external component is absent. When a significant external component is present, a hybrid operation where the haemorrhoidopexy is combined with diathermy excision of the external components may be necessary. Otherwise, a conventional operation may be required. Diathermy excision of any residual external component has been avoided in haemorrhoidopexy due to fear of increased postoperative pain. In paper 3 we illustrated that complementary excision of the external components outside the anal verge does not increase postoperative pain provided the excision is carried out externally to the anal canal and with preservation of the subdermal fascia. Others have shown that additional excision of perianal skin tags resulted in increased postoperative pain; however no information on the technique for the excision was available.

Symptoms

It is commonly thought that the only symptoms that are correlated to haemorrhoidal disease are bleeding and prolapse. When pain has been present, surgeons have tried to find other causes like anal fissure, internal sphincter spasm and even incarcerated thrombotic haemorrhoids as the explanation. The assumption throughout our studies has been that the prolapse is the source of all haemorrhoidal symptoms (bleeding, pain, soiling and pruritus). We have illustrated that all symptoms are almost equally present when patients have a prolapse. This has also been confirmed in other publications. We could see a statistical association between preoperative pain and grade 3 prolapse and soiling was more pronounced for grade 2 in Paper IV. However, we could not establish a correlation between the grade of the preoperative prolapse and the total symptom burden. Restoring the anatomy by reversing the prolapse will resolve the symptoms. However, our measurements
of the postoperative grade showed that some patients still had symp-
toms. Even when the anatomy was restored postoperatively to grade 
1A or 1B, patients reported some haemorrhoidal symptoms although 
the frequency of the symptoms had significantly decreased (Table 4). 
The same pattern could be seen in paper V (Table 5). Fueglistaler et 
al.\textsuperscript{22} reported postoperative symptoms ranging from 20 percent anal 
bleeding to 38 percent local discomfort. Postoperative symptoms that 
were recorded as moderate or severe ranged from 2 percent for bleed-
ing to 12 percent for local discomfort. Our results illustrate the same 
pattern with occurrence of postoperative symptoms ranging from 21 
percent for pain to 42 percent for pruritus in paper IV and 25 percent 
to 44 percent in paper V. These results could be discouraging but the 
fact is that there were significant reductions in all symptoms when pre 
and postoperative symptom scores were compared. A symptom score 
reduction of approximately 6 points was seen (paper I, II, IV, V). It is 
the much lower frequency with which the symptoms appear that ex-
plains the low total symptom points after surgery. Indeed, the surgical 
treatment rationale is to restore the anal anatomy, which according to 
our results diminishes the symptoms. Because the operation does not 
provide complete symptom resolution in all patients, it is tempting to 
reason that this is because the prolapse was insufficiently treated.

Continence

The preoperative information in paper V showed that 131 patients 
(86 percent) scored one or more points for incontinence. The cor-
responding number of patients at closure was 107 (73 percent). The 
improvement was statistically and clinically significant for all inconti-
nence symptoms. We identified 3 patients with worsened incontinence 
at closure. Two of these had mainly urgency incontinence and one is 
a paraplegic patient. The mean incontinence score preoperatively was 
4.7 points and postoperatively 2.9 points on a scale with maximum 
15 points. The decline reflects, as with the haemorrhoid symptoms, 
a change of the frequency with which the symptoms occur. The most 
common incontinence symptom was involuntary breaking wind, 
which also was the symptom with the least improvement. At closu-
re, 17 percent (25/145) had incontinence according to the definition 
used in this study. It is obvious that there exists a profound symmetry 
between symptoms of haemorrhoid prolapse and symptoms of anal
incontinence preoperatively. After surgery the symmetry remains but both sets of symptoms are much improved.

Two meta-analyses observed no difference in continence status after either a haemorrhoidopexy or the conventional haemorrhoidectomy \(^86,88\). However, because incontinence is a feared complication of haemorrhoid surgery there is information about this postoperative outcome but little information about the pre-operative continence status. Six of 14 studies reported zero incontinence after surgery while 7 studies reported from 3 percent to 31 percent \(^22,111,115,118,121,123,127-132,152,153\). Our studies showed that signs of impaired anal continence are as common as the symptoms directly associated with haemorrhoidal prolapse. Involuntary breaking wind and soiling are particularly common in patients suffering from haemorrhoidal prolapse. There is clearly an overlap between symptoms recorded in the Cleveland clinic incontinence score \(^37\) and those recorded by us for haemorrhoidal prolapse. The correlation of the two groups of symptoms becomes even more obvious in the similar frequency patients wear a protective pad, especially during day-time. The change in lifestyle, recorded as personal or social inconvenience, is equally common in patients with haemorrhoidal prolapse and those with anal incontinence. Short of leakage of solid faeces, signs of anal incontinence and those of mucoanal prolapse overlap and were almost equally common. The postoperative symptom resolution is also similar. This congruency suggests that a future comprehensive symptom score for mucoanal prolapse should combine the two sets of symptoms.

Local anaesthesia

Marti performed over 5132 anal procedures over a 12 year period. Of these 3725 cases (72.6 percent) were performed under local anaesthesia as outpatient procedures. The complication rate was 0.6 percent for all patients \(^54\). As illustrated earlier, local anaesthetic agents can be injected in the anal region in the submucosal plane, intersphincteric space or the perisphincteric space. Isolated infiltration of the submucosal plane when performing stapled haemorrhoidopexy is insufficient because the anus must dilate to accommodate the CAD. The anaesthetic must produce sufficient relaxation of the sphincters. Our method a submucosal infiltration is an advisable complement since the perianal injection blocks the infralevator space but the staple line
is above this level. The submucosal injection was always added after the insertion of the purse-string suture to avoid submucosal oedema due to the anaesthetic solution or accidental bleeding secondary to the injection. Secondary bleeding or oedema could diminish the surgical view and potentially influence the outcome of the operation. Injection in the intersphincteric space and into the sphincter is painful to the patient and should therefore be avoided or performed under adequate conscious sedation.

In the non-randomised study (paper I) the postoperative pain scores were statistically similar but numerically lower following perianal block. In the study with randomised design (paper II) there was again statistically similar pain but the numerical difference was in favour of general anaesthesia. In paper one, the mean height of the staple line was 20 mm for both groups. In paper 2, we unpremeditatedly had lowered the staple line to a mean of 16 mm in the local anaesthesia group and 19 mm in the general anaesthesia group. The statistical analysis revealed a significant inverse correlation between the height of the staple line and the total pain experience (p=0.038) a circumstance that may explain the numerically greater pain experience in the LA group. One retrospective study reported that the height of the staple line predicted postoperative pain and return to work. According to this study, patients with a staple line 22 mm above the dentate line required less pain management and the staple line height was inversely related to the time to return to work. The authors suggested that a staple line at 22 mm is an important factor to reduce pain and speed recovery. While we agree that the staple line should be targeted at 20 mm the reason is not primarily pain control but concerns that a higher staple line inadequately controls the mucosal prolapse and invites recurrence of redundant mucosa below the staple line. A too high staple line is a possible explanation for the worse recurrence rate after anopexy compared with conventional haemorrhoid excision. A too low staple line may increase the risk of developing incontinence and also potentially cause recurrent prolapse of redundant mucosa above the staple line.

There are many advantages with performing stapled haemorrhoidopexy under local anaesthesia. In the randomised trial we invited 88 patients to participate in the trial. Thirty patients declined participation due to preferences. Nine of these patients preferred local
anaesthesia. If patients are allowed an active choice of the treatment options it will inspire a sense of participation. Local anaesthesia also facilitates ambulatory surgery. Even if the operation time increases with approximately 5 minutes because of the anal block, time is gained with shorter turnover between cases. The method is easy to learn and safe for the patient with low complication rate. Postoperative nausea secondary to general anaesthesia is avoided and the early postoperative pain is significantly reduced, usually for a period of 6 hours up to 24 hours. Our studies (paper I and II) could not demonstrate any difference in total postoperative pain, complications or time to normal activities during the first 14 days after surgery. Also the short-term result (3-6 month) after the operation was comparable between the two groups. No patient has been converted to general anaesthesia because of a non-functional anal block.

**Stapled haemorrhoidopexy**

The majority of the published randomised trials show that stapled haemorrhoidopexy is quicker to perform with shorter hospital stay, less painful than the conventional technique, leads to faster return to normal activities and is as safe as conventional surgery. These meta-analyses indicated worse long-term outcome with higher recurrence rate for the stapled procedure. There is however a significant heterogeneity between the trials of the meta-analysis.

The definition of recurrence is vague in all the randomised trials. According to the definition used by us, published trials with one-year follow-up or shorter provide an estimate of the technical failure rate of the operation. The most recent Meta-analysis shows 11.8 percent (25/212) failures in 7 studies with less than 1 year of follow-up. This is an overestimation since one study only included grade IV haemorrhoids where 8/15 patients were deemed failures. In 14 studies with longer than 1 year follow-up the recurrent prolapse rate was 8.8 percent (52/591). It suggests that at least half of the recurrences after stapled haemorrhoidopexy are in fact technical failures, and that grade IV haemorrhoids exceed the capacity of the stapled technique. The anodermal prolapse and its secondary fibrosis that is typical of grade IV haemorrhoids are really not amenable to the stapled technique alone. However, grade IV haemorrhoids can also be interpreted to mean an excessive mucosal prolapse in some
studies. Boccasanta et al.\textsuperscript{140} found in a randomised trial that using two staplers increased the rate of prolapse control in grade IV haemorrhoids.

In long-term follow-up we re-operated 9 patients for inadequate surgery or recurrent prolapse of whom 7 were cured at closure of the study. Our re-operation rate of 6.2 percent is similar to the 6.7 percent reported in 11 trials\textsuperscript{88}. For comparison, the re-operation rate was 4.8 percent after conventional surgery in the same trials, which was not statistically different. The need for non-surgical re-intervention was estimated in another meta-analysis that found 6.3 percent after haemorrhoidopexy and 5.9 percent after conventional operation\textsuperscript{90}.

When the re-operations and the status at closure are combined the total prolapse rate was 19 patients (13.1 percent). The published recurrence rate ranges from 0.3 percent in 3711 patients\textsuperscript{137} to 27.1 percent in 258 patients\textsuperscript{138}. The latter author included all repeat haemorrhoidopexy and excision surgery performed after the index haemorrhoidopexy. In the absence of precise definitions with respect to prolapse, external component and symptoms before surgery the outcome of the haemorrhoidopexy becomes very difficult to assess. The exact preoperative definitions must then be used postoperatively to obtain a credible estimate of the treatment effect that can be compared across studies. While the definitions are less important in randomised trials, as long as they are applied equally across the study groups, explicit definitions are necessary to compare outcome from case series.

The scientific effort to determine benefits, risks and long-term outcome after a stapled haemorrhoidopexy is far from complete. The procedure has been widely accepted in the last decade and more than a million operations have been performed worldwide although proportionally less in Sweden. The technique should now have been standardized with many of the initial technical errors eliminated. Therefore, a new randomised trial is of interest, with strict criteria for patient selection, definition of prolapse and report of all haemorrhoid symptoms as well as incontinence symptoms before and after surgery.

The stapled haemorrhoidopexy has challenged traditional concepts which has been extremely fruitful in terms of published research. To patients it provides a less painful option of treatment for a seemingly banal but very distressful mucoanal prolapse.
CONCLUSIONS

The perianal local anaesthetic block for stapled haemorrhoidopexy was developed and evaluated in this thesis. It gives similar postoperative course and result as the same operation under general anaesthesia. Patients accepted the perianal block and its use simplified the management of patients within the day surgery unit as well as facilitated the patients return to home.

Remaining parts of the anodermal prolapse, commonly termed the external component, should be excised. It did not increase the pain provided the excision does not extend into the anal canal proper.

An algorithm for preoperative classification of both the mucosal and the anodermal prolapse as well as for postoperative assessment of the result of the operation was developed and validated. There was no unique symptom profile associated with any degree of prolapse. Restoring the anal anatomy diminished the symptoms associated with the prolapse. The classification can reliably define failure to revert the prolapse as well as later recurrence of the prolapse.

Stapled haemorrhoidopexy effectively cured the mucoanal prolapse in 87 per cent of the patients long-term. Restoration of the anatomy was followed by significant improvement of all symptoms of the prolapse and anal incontinence. In some 17 percent, however, at least one cardinal symptom remained with a weekly frequency.
Tack

Denna avhandling hade inte varit genomförbar utan stöd från handledare, medförfattare, kollegor och familj. Nedan vill jag rikta ett speciellt tack till följande:

Per-Olof Nyström, inte bara min huvudhandledare utan även god vän och klinisk mentor. Jag kan inte tillräckligt uttrycka min uppskattning och ödmjukhet över ditt engagemang och dina kunskaper. Utan dig hade denna avhandling varit mer av en börda än den inspirationskälla till forskningen som den bidragit till. Jag kommer aldrig få nog av våra diskussioner och hoppas att denna avhandling är startskottet på något mer.

Rune Sjödahl, min biträdande handledare. För att din dörr alltid är öppen för mig och mina ibland inte så intelligent frågor. Dock så har dina svar alltid varit både förklarande och visa.


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Johan Söderholm, trots att jag inte tillhör ditt forskningsteam så har du behandlat mig som en av dina doktorander. Jag kanske inte visar det ofta men uppskattar det hjärtligt.

Olof Hallböök och Claes Lenander, för den värdefulla kritiken vid halvtidskontrollen.
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Nicholas Wyon för hjälp med textredigeringen.

Dennis Netzell för hjälp med lay-out.

Viveca Axén för all hjälp med det administrativa inför disputationen.

Mor och Far, ni har alltid haft högre tankar om mig än vad jag själv någonsin ansett vara möjligt. Kanske har ni rätt?

Sammanfattning


I två arbeten har vi beskrivit en metod för att utföra staplad hemorrojdopexi under lokalbedövning jämfört med patienter opererade under sövning. Metoden var genomförbar på alla patienter men ger ingen skillnad i smärtan i smärtan i närmaste dagarna efter operationen. Operationsresultatet blir likvärdigt. Lokalbedövningen förenklar behandlingens genomförande.


I den sista studien undersöktes resultatet av staplad hemorrojdopexi för patienter som opererats 1 år till 6 år tidigare. Totalt hade 153 patienter fullständig information före och efter operationen. För 87 procent av patienterna hävdes prolapsen med staplade hemorrojdopexi medan 6 procent hade behövt en ny operation och 7 procent fortfarande hade en prolaps av hemorrojderna vid den slutliga utvärderingen.

Sammanfattningsvis beskriver denna avhandling en metod för att operera hemorrojder under lokalbedövning med fördelar i den kliniska vardagen. Vi har föreslagit en alternativ klassifikation som tar med hudflikarna och har visat att hudflikarna kan avlägsnas utan ökad smärta efter operationen. Slutligen har operationsmetoden utvärderats i ett långt perspektiv vilket visat att 87 procent av patienterna blir av med prolapsen. Målet med operationen är att återställa anatomin i analkanalen och analöppningen för att därigenom bota symtomen av hemorrojderna.
SAMMANFATTNING PÅ ARABISKA

خلاصة:

تمّ توصيف ومعالجة البواسير لألاف السنين. منذ الثلاثينيات (1930)، كان القطع (البتر) الجراحي يمثل طريقة العلاج المقياس للبواسير المشعة التي تخرج من القناة الشرجية. ويتبع عن هذه الطريقة جراح مفتوحة في القناة الشرجية تترك للشفاء طبيعيًا، مما قد يسبب آلامًا للمرضى. وقد زاد الألم سوءًا حيث يدخل المريض الحمام. عام 1998، قام الجراح الإيطالي أنطونيو لونغو بطرح فكرة جديدة لوضع (إجراءات عملية جراحية) البواسير، وبمعنى أن ترفع البواسير وتثبت في موقعها الطبيعي على القناة الشرجية.

تسمى هذه العملية عملية استئصال البواسير بواسطة التقسيم (التقييس). وقد كان القسم الجراحي التابع للمستشفى الجامعي في لينكوبينغ الأول، خارج نطاق إيطاليا، لمعالجة المرضى عبر استخدام هذه الطريقة. ومع اعتماد هذه الطريقة للمرة الأولى تمّ تسليط الضوء على ميزتين أساسيتين، الأولى تمكن في عدم وجود جرح مفتوح بعد العملية، مما جعلها خالية من الألم، أما الميزة الثانية فهي قدرة المريض على عودة نشاطه الطبيعي بشكل سريع بعد العملية. وساهمت عدة دراسات سريريّة برهنة هذا الأمر لاحقًا. تخلل دراستين من هذه الدراسات وصف لطرقية استئصال البواسير مع بنج موصى، مقارنة بمرضى خضعوا للتخدير. وكانت هذه الطريقة سهلة التطبيق على جميع المرضى غير أنها لم تنتج فرقًا بالنسبة للألم بعد العملية. جاءت نتائج العملية متساوية وساهم البنج الموضعي في تبسيط العلاج. إنّ المرضى الذين يعانون من عوارض تؤدي إلى إنسداد (تدلي) البواسير يكون لديهم أيضًا "رفع جلدي". على فتحة الشرق في 70% من الحالات، تتضمن العملية التقليدية قطع الرفع الجلدي وإزالتهما غير أنّ الوضع يختلف في حالة استئصال البواسير إذ غالباً ما يمتنع الجراحون عن قطع الرفع الجلدي وإزالتهما اعتقادًا بمنح هذه الطريقة تزيد الألم بعد العملية.

وفي دراسة ما تمتّ مقارنة بعض المرضى الذين خضعوا لعملية استئصال
البواسير بواسطة التثبيت وعانوا أيضاً من رفع جلديّة، بمجموعة أخرى من المرضى الذين خضعوا فقط لعملية استئصال البواسير بواسطة التثبيت. وقد وصف المرضى الألم الذي عانوا منه خلال 14 يوماً بعد إجراء العملية وأظهرت النتائج أثاراً متساوية لكلا المجموعتين. لهذا السبب نقوم دائماً بإزالة الرفع الجلديّ عند الاقطاء. تصنف البواسير حسب حجم الجزء المنسد وحسب فرق المسافة بين البواسير. والغشاء المخاطي. ويضمن التصنيف التقليدي للحالة لبعض الحدود مما يؤدي إلى صعوبة فهم الجراحة ودرجة ها ما خضع المرضى الذين يعانون من وضع مماثل إلى عمليّات بناء على دراسات مختلفة. وقد طُورّنا تصنيفًا "بديلًا" بناء على حاجة المريض إلى إعادة تثبيت الجزء المنسد في مكانه الطبيعي بواسطة البد وبناء على سؤالين تتوجيههما إلى الجراح حول ما إذا كان الانسدال مرنًا، خلال الفحص، فيما يتعلق أيضاً بعدد الرفع الجلديّة. وتمّ تجريب التصنيف الجديد على 180 مريضاً أخرين. وتبين بالنتيجة أنه بالإمكان وصف نتائج العلاج التشريحي عبر استخدام وتوجيه الأسئلة ذاتها للجراح والمرضى بعد إجراء عملية. في الدراسة النهائية تمّ فحص نتائج عملية استئصال البواسير بالثبيت، التي خضع لها المرضى منذ فترة تتراوح بين السنة والنصف سنوات. في المجموع حصلنا على 153 مريضاً شكلت لديهم معلومات كاملة في فترة ما قبل وما بعد العملية. تمّت إزالة الانسدال لـ87% من المرضى في حين احتاج 6% من المرضى إلى عملية جديدة ولا يزال 7% من المرضى يعانون من استئصال متعدد بالبواسير، خلال التقييم الأخير. كخلاصة، يقوم هذا البحث بوصف طريقة إجراء عملية البواسير بالبنج الموضعي مع المنافق التي قد تتظاهر، أثناء الاستخدام السريري اليومي. وقد اقترحنا تصنيفًا "بديلًا" يضمن رقعة "جدلية" كما أظهرنا أنه بالإمكان إزالة الرفع الجلديّة دون تكبد آلام بعد إجراء عملية. بالإضافة إلى ذلك، تمّ تقييم طريقة عملية على مدى طويل مما أظهر أن 87% من المرضى شفوا من الانسدال. هدف العملية هو ترميم التشريح الطبيعي للقناة الشرجية والفتحة الشرجية من أجل معالجة العوارض الناتجة عن البواسير. 

--- SAMMANFATTNING ---
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