THE RELATIVE EFFICACY OF A HOMOEOPATHIC PAIN COMPLEX *(ARNICA MONTANA 30CH, BELLIS PERENNIS 30CH, CALENDULA OFFICINALIS 30CH, HYPERICUM PERFORATUM 30CH, PHOSPHORUS 30CH, STAPHYSAGRIA 30CH)* AND ALLOPATHIC ANALGESIC (STOPAYNE®) IN THE POST-OPERATIVE MANAGEMENT OF HAEMORRHOIDECTOMY

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology : Homoeopathy in the Department of Homoeopathy at Technikon Natal.

I, Lilly Sao Lai Leong, do hereby declare that this dissertation represents my own work, both in concept and execution.

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Dedication

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ABSTRACT

The purpose of this double-blinded study was to evaluate the relative efficacy of a homoeopathic pain complex (*Arnica montana* 30CH, *Bellis perennis* 30CH, *Calendula officinalis* 30CH, *Hypericum perforatum* 30CH, *Phosphorus* 30CH, *Staphysagria* 30CH) and on allopathic analgesic (Stopayne®) in the management of post-operative pain after haemorrhoidectomy; in terms of the patients' perception of the treatment. The hypothesis was to show that the homoeopathic pain complex would result in a similar response when compared to the allopathic analgesic without the dismay of adverse effects.

Thirty patients with haemorrhoids were carefully screened by an appointed nurse and selected according to a selection criteria (3.3.1 and 3.3.2). Haemorrhoidectomies were performed by two surgeons on all participating patients. The selected patients were then divided into two groups (allopathic or homoeopathic) using a simple random sampling method. Data were collected at the King Edward VIII Hospital.

Patients in group one received the allopathic analgesic i.e. Stopayne® and patients in group two received the homoeopathic pain complex consisting of*Arnica montana* 30CH, *Bellis perennis* 30CH, *Calendula officinalis* 30CH, *Hypericum perforatum* 30CH, *Phosphorus* 30CH and *Staphysagria* 30CH. These medications were administrated three times daily over a period of three days. Questionnaires (both in English and Zulu) were filled out by each patient over three consecutive days.

Results were statistically analyzed using the Mann-Whitney U-test for the inter-group relationships and the Wilcoxon Signed Rank test for the intra-group relationships. It was found that both groups improved significantly by the thrid consultation compared to the first

consultation. However, in the allopathic group, more patients required extra pain medications i.e. opioids (Omnopon®).

Thus it was concluded that the homoeopathic pain complex was effective in the management of pain after haemorrhoidectomy.

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DEFINITION OF TERMS

Abscess: a localized collection of pus buried in tissues, organs, or confined spaces (Dorland's, 1994:5).

Adenoma: a benign epithelial tumor in which the cells form recognizable glandular structures or in which the cells are clearly derived from glandular epithelium (Dorland's, 1994:26).

Allopathy: a term applied to that system of therapeutics in which diseases are treated by producing a condition incompatible with or antagonistic to the condition to be cured or alleviated (Dorland's, 1994:48).

Anaesthesia: loss of the ability to feel pain, caused by administration of a drug or by other medical intervention (Dorland's, 1994:74).

Anal stenosis: narrowing or stricture of anal canal (Dorland's, 1994:1576).

Analgesia: absence of sensibility of pain; absence of pain on noxious stimulation (Dorland's, 1994:67).

Antiemetics: an agent that prevent or alleviate nausea and vomiting (Dorland's, 1994:95).

Carcinoma: a malignant new growth made up of epithelial cells tending to infiltrate the surrounding tissues and give rise to metastases (Dorland's, 1994:265).

Defecation: the evacuation of faecal material from the rectum (Dorland's 1994:433).

Dementia: an organic mental syndrome characterized by a general loss of intellectual abilities involving impairment of memory, judgement, and abstract thinking as well as changes in personality (Dorland's, 1994:439).

Diabetes mellitus: a chronic syndrome of impaired carbohydrate, protein, and fat metabolism owing to insufficient secretion of insulin or to target tissue insulin resistance (Dorland's, 1994:457)

Fibrosis: the formation of fibrous tissue, as in repair or replacement of parenchymatous elements (Dorland's, 1994:628).

Fistula: an abnormal passage or communication, usually between two internal organs, or leading from an internal organ to the surface of the body; frequently designated according to the organs or parts with which it communicates (Dorland's, 1994:635).

Gangrene: death of tissue, usually in considerable mass and generally associated with loss of vascular supply and followed by bacterial invasion and putrefaction (Dorland's, 1994:678).

Haemorrhoidectomy: excision of haemorrhoids (Dorland's, 1994:751).

Hypertension: high arterial blood pressure (Dorland's, 1994:801).

Hypertrophy: the enlargement or overgrowth of an organ or part due to an increase in size of its constituent cells (Dorland's, 1994:802).

Papilla: a small nipple-shaped projection, elevation, or structure (Dorland's, 1994:1222).

Phlebitis: inflammation of a vein. The condition is marked by infiltration of the coats of the vein and the formation of a thrombus. The disease is attended by edema, stiffness, and pain in the affected part, and in the septic variety by pyemic symptoms. (Dorland's, 1994:1297.)

Periphlebitis: inflammation of the tissues around a vein, or of the external coast of vein (Dorland's 1994:1263).

Polyp: a morbid excrescence, or protruding growth, from mucous membrane (Dorland's, 1994:1331).

Proctoscope: a speculum or tubular instrument with appropriate illumination for inspecting the rectum (Dorland's, 1994:1358).

Proctoscopy: inspection of the rectum with a proctoscope (Dorland's, 1994:1358).

Prolapse of anus: protrusion of modified anal skin through the anal orifice (Dorland's, 1994:1361).

Pruritis ani: intense chronic itching in the anal region (Dorland's, 1994:1375).

Sigmoidoscope: a rigid or flexible endoscope with appropriate illumination for examining the sigmoid colon (Dorland's, 1994:1520).

Sigmoidoscopy: inspection of the sigmoid colon through a sigmoidoscope (Dorland's, 1994:1520).

Sitz bath: a bath in which the patient sits in the tub, the hips and buttocks being immersed (Dorland's, 1994:187).

Suppository: a medicated mass adapted for introduction into the rectal, vaginal, or urethral orifice of the body (Dorland's, 1994:1610).

Thrombosis: the formation, development, or presence of a thrombus (Dorland's, 1994:1707).

Thrombus: an aggregation of blood factors, primarily platelets and fibrin with entrapment of cellular elements, frequently causing vascular obstruction at the point of its formation (Dorland's, 1994:1708).

Ulcer: a local defect, or excavation, of the surface of an organ or tissue, which is porduced by the sloughing of inflammatory necrotic tissue (Dorland's, 1994:1770).

Ulceration: the formation or development of an ulcer (Dorland's, 1994:1771).

Varicose: of the nature of or pertaining to a varix; unnaturally and permanently distended: said of a vein; variciform (Dorland's, 1994:1795).

Varicosity: a varicose condition; the quality or fact of being varicose; varication (Dorland's, 1994:1795).

CHAPTER ONE

1.1 INTRODUCTION

"Pain is a protective mechanism for the body; it occurs whenever any tissues are being damaged, and it causes the individual to react to remove the pain stimulus" (Guyton, 1992:357).

Haemorrhoids are undoubtedly one of the most prevalent anorectal diseases that beset humanity. The incidence of haemorrhoids seemingly increases with age with at least 50% of people over the age of 50 experiencing some degree of haemorrhoid formation (Goligher, 1984:98).

Although symptoms arising from haemorrhoids may be self-treated, there are some cases where surgical interventions may be necessary. Surgical haemorrhoidectomy is often the most effective treatment especially when the anorectal architecture has been severely and irreversibly compromised (e.g., in the presence of an external component, ulceration, gangrene, extensive thrombosis, hypertrophied papillae, or associated features) (Corman, 1993:82). A standardized protocol for the anesthesia, including the pre-operative analgesia and antiemetics is to be followed for patients undergoing haemorrhoidectomy (Hunt et al., 1999).

Post-operative pain is one of the most commonly encountered complaints for those who have undergone surgery. Analgesia is therefore a matter of prime importance to the practicing physician and to his patients. However, in spite of the primal urgency of pain, its universality and its importance in medical practice, the physiology of pain is still not well understood (Power, 1993).

Some patients experience discomfort during the first 24 to 48 hours after haemorrhoidectomies and some with experienced severe pain mainly at the time of defecation. This however varies from patient to patient and is usually worse at the first motion. In some patients, the defecation act is easy and painless, other patients complain of a stinging sensation in the anal region during and after the motion (Goligher, 1984:137).

Even though pain cannot be categorized as a complication of surgery, it can nevertheless be the chief reason why patients avoid haemorrhoidectomies. Pain is such a subjective complaint that significant data evaluating it is inadequate (Corman, 1993:91).

Non-steroidal anti-inflammatory drugs (NSAIDs) have been traditionally used to relieve pain after minor surgery, with some patients experiencing adverse effects (Murphy, 1993). An ideal analgesic agent would be effective against either mild or severe pain and it should be free from adverse effects (Neal, 1997:92).

Samuel Hahnemann, the founder of homoeopathy, stated that "the highest ideal therapy is to restore health rapidly, gently, permanently; to remove and destroy the

whole disease in the shortest, surest, least harmful way, according to clearly comprehensible principles" (Hahnemann, 1996).

Homoeopathy is a system of medicine based on the vital principles that remedies which produce certain signs and symptoms in a healthy person can cure those same signs and symptoms in a diseased person and that the more a drug is diluted, the more powerful it becomes (Stanway, 1994:157).

According to a thorough literature investigation, no clinical trial has been carried out in the areas of homoeopathic management of post-operative pain. This dissertation aims not to explain the physiology of pain but only to evaluates the efficacy of the homoeopathic pain complex (*Arnica montana 30CH, Bellis perennis 30CH, Calendula officinalis 30CH, Hypericum perforatum 30CH, Phosphorus 30CH, Staphysagria 30CH)* in the control of post haemorrhoidectomy pain. The impact of this homoeopathic agent on the intensity, sensation and duration of pain will be evaluated.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

In 1997, a randomized controlled trial of trimebutine (anal sphincter relaxant) was conducted for the management of pain after haemorrhoidectomies. The trimebutine suppository was believed to reduce anal resting pressure thus relieving pain after haemorrhoidectomy. It resulted in a mean 35% reduction in resting anal pressure, but unfortunately no differences in the pain score was noted (Ho YH et al., 1997).

A double-blind randomized controlled trial was carried out in the UK, testing the effect of metronidazole in the management of pain after day-case haemorrhoidectomy. Metronidazole (400 mg) was assigned to patients three times a day for 7 days. Both the trial and placebo group received lactulose from 2 days before surgery and after surgery for 2 weeks. Patients took paracetamol or dihydrodoceine and paracetamol as required. Overall, both groups of patients experienced less pain, except on days 3 and 4. Patients in the metronidazole group had significantly decreased pain on day 5, 6 and 7. It was concluded that prophylactic metronidazole in day-care haemorrhoidectomy *suppressed* secondary pain and resulted in increased in patient satisfaction (Carapeti et al., 1998).

"The inadequacy of post-operative pain relief is shameful", said A M S Black (1991). Giving intermittent intramuscular injections of opioids is one of the main conventional approaches to treat extremely severe post-operative pain. Administration of opioids intrathecally or epidurally has also been noted on occasions. However, a rare probability of a depression in ventilation is possible. Thus patients receiving systemic opioids have to be closely observed.

Homoeopathy is completely different from conventional medicine, which is known as Allopathy, meaning 'different from suffering'. Drugs work against the disease and its symptoms, thus the prefix 'anti' are often found, e.g. anti-biotics, anti-depressant, anti-inflammatory, anti-pain drugs etc. However, homoeopathy means 'similar to the suffering'. Remedies, which are used to treat ill patients, are able to produce similar symptoms of the same disease belonging to that particular patient (Hammond, 1995:14).

"Homoeopathic medication does not replace missing substances; it does not aim to compensate a component system by the direct route; it does not counteract reactive process and suppress them". Suppression of any kind causes a prevention of the body to regulate itself. Therefore the essential aim of homoeopathic treatment is to stimulate the autoregulatory system to heal itself, *Natura sanat* (Koehler, 1989:15-16).

Homoeopathic treatment promotes a genuine and valuable alternative to the conventional treatment. The perspective on healing emphasizes the importance of establishing and maintaining a state of balance and harmony (MacEoin, 1997:6).

There is no doubt that the orthodox approach and treatment is effective; however we cannot deny that patients often have to deal with the consequences of adverse effects from the treatments. Reducing post haemorrhoidectomy pain gently, quickly, permanently is therefore vital. Homoeopathy can make a difference in the amelioration of pain after haemorrhoidectomy, thus enhancing the recovery from surgery, return to work and regain the quality of the patient's life.

2.2 DEFINITION OF HAEMORRHOID

Dilatation and tortuosity of veins is called varicosity. Varicosity of veins develops from chronic continuous or recurrent increase in pressure of blood within the veins caused by either 1) effects of gravity, or 2) obstruction of a major vein, leading to increased pressure in collateral veins (Anderson, 1985:14.38).

Thus haemorrhoid is defined as varicosities of the superior and inferior haemorrhoidal venus plexus, resulting from a persistent increase in venous pressure (Dorland's, 1994:751).

2.3 VENOUS DRAINAGE OF THE RECTUM

The rectum is drained via superior, middle and inferior rectal veins. These rectal veins anastomose freely with each other creating a rectal venous plexus consisting of 1) an internal rectal venous plexus that is found deep to the epithelium of the rectum and 2) an external rectal venous plexus that is external to the muscular walls of the rectum (Moore, 1992: 291).

2.4 AETIOLOGY AND PATHOGENSIS

The anal canal is surrounded by normal structures called vascular cushions. The submucosa form a discontinuous series of cushions mainly found in the left lateral, right anterior, and right posterior positions (Corman, 1993:55). The cushions are made up of muscularis submucosa (Corman, 1993:55) and also a rich arterial supply leading directly into the dispensable venous spaces (Hancock, 1992). It is postulated that the cushions, by filling with blood during defecation, protect the anal canal from injuries (Corman, 1993:55) and help to seal the upper anal canal and contribute to continence (Hancock, 1992).

2.4.1 MICROSCOPIC CHANGES

Primary Stage	No change in mucosa. Slight thickening in submucosa. Some infiltration with lymphocytes in submucosa.
Intermediate Stage	Mucosa is hypertrophied. Edematous submucosa with numerous infiltrated lymphocytes. Fibrous thickening of the walls of the veins.
Final Stage	Greater thickening in mucosa. Submucosa is markedly fibrosed. Partly obliterated veins are sheathed in dense fibrous tissue.

Table 1. Microscopic changes in haemorrhoid (Anderson 1967:287-288)

2.4.2 THE FOUR MAIN THEORIES

Corman (1993:56) has proposed four main theories which contribute to the cause of haemorrhoids. 1) Abnormal dilatation of the veins of the internal haemorrhoidal venous plexus, a network of the tributaries of the superior and middle haemorrhoidal veins, 2) abnormal distention of the arteriovenous anastomoses, which are in the same location as the canal cushions, 3) downward displacement or prolapse of the anal cushions and 4) destruction of the anchoring connective tissue system.

2.4.3 AETIOLOGY

2.4.3.1 Morbid anatomy

In the columns of Morgangi, dilated venules of haemorrhoids form an elongated mass and later becomes spherical. Due to chronic irritation, fibrosis occurs in the surrounding connective tissue which is then responsible for the final thickening. However, the most concerning factor is the occurrence of infection with the production of periphlebitis and often phlebitis and thrombosis. Periodic attacks of phlebitis and periphlebitis are designated as "attacks of haemorrhoids" (Anderson, 1967:287).

2.4.3.2 Anatomical features

The upright position of humans cause increased hydrostatic pressure within the haemorrhoidal blood vessels (Hodes, 1982:643). The portal system of veins is completely devoid of valves, hence in the erect position, the entire column of blood in the superior rectal, inferior mesenteric, splenic and portal veins from the

anal canal to the liver bears directly on the internal haemorrhoidal venous plexus (Goligher, 1984:100).

The haemorrhoidal veins are firmly supported by the walls of the canal under the contraction of the anal sphincters. However during defecation, the anal canal is exposed to atmospheric pressure and simultaneously, the pressure on the portal system increases by straining, causing distention of the haemorrhoidal veins (Goligher, 1984:100).

2.4.3.3 Hereditary

Certain races appear to be more predisposed to the development of haemorrhoids presumably due to some structural weakness of the wall of the haemorrhoidal veins. It is known that varicose veins of lower extremities and haemorrhoids often coexist, thus suggesting a more widespread defect of venous structure (Goligher, 1984:100) Hereditary factors are important to haemorrhoid formation, however it still remains controversial (Hodes, 1982:643).

2.4.3.4 Occupation

Occupations that involve severe muscular straining, prolonged sitting or prolonged standing contribute to the formation of haemorrhoids (Hodes, 1982:643).

2.4.3.5 Diet

Dietary patterns are an important cause for the development of haemorrhoids. Low-fiber diets and insufficient fluid intake contribute to hard and solid stools,

which in turn lead to constipation thus causing an excessive straining in defecation (Hodes, 1982:643).

2.4.3.6 Constipation, diarrhoea and straining at stool

The distention of the haemorrhoidal plexus during defecation will be greatly intensified if the patient suffers from constipation and has to strain repeatedly to pass large hard stools. Diarrhoea is usually associated with tenesmus and futile straining, thus producing a similar but slightly less injurious effect (Goligher, 1984:100).

2.4.3.7 Pregnancy

Pregnancy is by far is the most common cause of haemorrhoids. The gravid uterus causes increase pressure in the middle and inferior haemorrhoidal vessels and labour may intensify the condition thus producing intense symptoms after delivery (Hodes, 1982:643). However the haemorrhoidal condition always return to normal after the conclusion of the pregnancy. Unfortunately, some women are left with small haemorrhoids, which worsen with subsequent pregnancies or increase in age (Goligher, 1984:99).

2.4.3.8 Other factors

Haemorrhoids can be precipitated by constipation, diarrhoea, cathartic abuse, heart failure, portal hypertension, coughing, sneezing, vomiting, pregnancy, pelvic tumours, carcinoma of the rectum, physical exertion, and anal infection (Hodes, 1982:643).

2.5 CLASSIFICATION

Haemorrhoids are classified by location or by degree (Corman, 1993:57). They are classified as internal or external haemorrhoids, the former arising in the upper two-thirds of the anal canal which is lined by columnar-celled epithelium, and the latter in the skin-covered lower one-third of the canal or at the anal orifice itself (Goligher, 1984:98).

Haemorrhoidal vessels which are either in the anal canal or adjacent to the anus, that have ruptured thus forming a blood clot or haematoma are called thrombosed haemorrhoids (Hodes, 1982:643). External tags or skin tags are deformities if the external skin of the anal margin occur in folds (Corman, 1993:58). These tags consist of fibrous connective tissue (Hodes, 1982:643) and may result from a previously thrombosed haemorrhoid which has become organized into fibrous connective tissue (Corman, 1993:58).

By degree, haemorrhoids are classified as 1) first degree, where bleeding occurs only at the time of defecation, 2) second degree, where the haemorrhoids prolapse but reduces spontaneously back to the anal canal, 3) third degree, where the haemorrhoid prolapse and need manual reduction, and lastly 4) fourth degree, where the haemorrhoids are irreducible and remain in the prolapsed state permanently (Corman, 1993:57-58, Hancock , 1992).

2.6 CLINICAL FEATURES

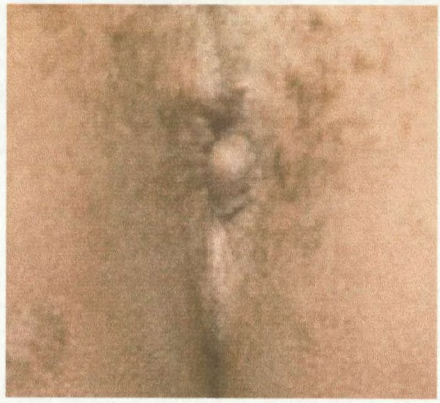
The cardinal symptoms of haemorrhoids are bleeding and prolapse. Although pain is not usually considered to be a symptom of uncomplicated haemorrhoids, severe pain may occur if the haemorrhoids become prolapsed and thrombosed. Discharge and anal irritation are other symptoms, which may develop (Goligher, 1984:101).

2.6.1 BLEEDING

Bleeding of bright red blood after defecation suggests haemorrhoids whereas darker blood mixed with stools, known as melena, or with much mucus strongly suggests a tumour (Hancock, 1992). Bleeding is usually associated with internal haemorrhoids and can occur before, during, or after defecation (Hodes, 1982:644). However when bleeding occurs from an external haemorrhoid, it is caused by an acute thrombosis followed by rupture. In younger patients, bleeding is more of a problem because the sphincter tone is higher where in older patients haemorrhoids prolapse more with bleeding occurring only when abraded by cleaning after defecation (Hancock, 1992). Secondary anaemia may develop due to chronic blood loss (Goligher, 1984:101).

2.6.2 PROLAPSE

This is an early symptom of uncomplicated haemorrhoids and is known as projection of haemorrhoidal or rectal tissue outside the anal canal. Protrusion of the rectal tissue may vary in size and usually appear after defecation, prolonged standing, or unusual physical exertion (Hodes, 1982:644).



Picture 1: Projection of haemorrhoidal tissue

Initially, prolapse of the haemorrhoids occur at defecation, appearing at the anal orifice during an expulsive effort, and immediately slipping back afterwards. At a later stage, the haemorrhoids may remain in a prolapsed condition after defecation and manual reduction of the haemorrhoids into the anal canal is necessary. These haemorrhoids may prolapse on any exertion such as sneezing, coughing, lifting, walking or on passing flatus. Finally, the haemorrhoids reach the final stage where they are permanently prolapsed with anal mucosa exposed and in contact with underclothing (Goligher, 1984:102). Permanently prolapsing haemorrhoids cause a mucoid discharge, which then leads to perianal irritation (Hodes, 1982:644).

2.6.3 ANAL IRRITATION, PAIN, SWELLING AND ITCHING

Due to a production of mucoid discharge, the perianal skin is moist and sodden causing irritation (Goligher, 1984:102). Irritation is characterized by burning sensations (may range from feeling of warmth to a feeling of intense heat), itching, pain or swelling (Hodes, 1982:644).

Pain is usually a sign of acute inflammation of the anal tissue and is characterized by a steady and aching pain, not relieved by defecation. Strangulation, thrombosis or ulceration of the haemorrhoids may cause severe pain (Hodes, 1982:644).

Pruritus (Itching) ani is a complex condition due to a combination of causes like skin sensitivity, skin maceration and local bacterial or fungal infection (Thomson et al, 1981:335). It may also be secondary to inflammation, swelling, irritation due to dietary factors, or moisture in the anal area. Poor anal hygiene and medications may also cause itching (Hodes, 1982:644).

2.7 COMPLICATIONS

Thrombosis is caused by the constriction of the anal sphincter resulting in an interference with the blood flow from a prolapsed haemorrhoid. This common complication may present as a painful lump. Gangrene and ulcers may develop on the haemorrhoids, leading to oozing of blood and sometimes haemorrhage, especially during defecation or standing. If ulcers and clots remain untreated and exposed, secondary infection may occur resulting in the formation of abscesses or fistulas (Hodes, 1982:645).

2.8 EXAMINATION AND DIAGNOSIS

Without prolapse of the anal tissue or bleeding as a dominant symptom, together with distended or displaced anal cushions on proctoscopy, haemorrhoids should not be diagnosed (Hancock, 1992).

2.8.1 INSPECTION

In first-degree haemorrhoids, no abnormalities are found in the anal region on simple inspection. In second-degree haemorrhoids, there are swellings in three main positions (right anterior, left lateral and right posterior) of the skin-covered parts of the haemorrhoids at the anal orifice. In third-degree haemorrhoids, great protrusions of the haemorrhoids are immediately recognizable. The outer part is covered with skin, the inner mucosa is red or purplish in colour, and a linear furrow marks the junction between these two regions. In chronic prolapse of the haemorrhoids, metaplasia of the lining of the epithelium to a squamous type is caused by frequent contact with clothing, seen as a pale white pannus. This can advance to the development of pruritis ani (Goligher, 1984:102).

2.8.2 PALPATION

Digital examination of the anal canal and rectum may be very uncomfortable especially if thrombosis has developed. In the early stages of haemorrhoids, they are soft, easily collapsible with venous swelling. However, due to chronic exposure of the prolapsed haemorrhoid to clothes, the submucous connective tissue undergoes fibrosis and the haemorrhoids are palpable (Goligher, 1984:103).

2.8.3 PROCTOSCOPY

This is a vital and essential step to diagnose internal haemorrhoids (Goligher, 1984:103). The patient is asked to bear down, the haemorrhoids tend to bulge into the end of the proctoscope resembling grapes (Goligher, 1984:103). To access the degree of prolapse and find abnormal perineal descent (Hancock, 1992), the patient is asked to maintain this expulsive effort while the withdrawal of the

proctoscope is continued until it emerges from the anal orifice (Goligher, 1984:103).

2.8.4 SIGMOIDOSCOPY

When proctoscopy fails to show any symptoms of haemorrhoids which account for the patient's bleeding, then sigmoidoscopy is very important to rule out the possibility of rectal or sigmoidal carcinoma (Goligher, 1984:103).

2.9 DIFFERENTIAL DIAGNOSIS

Polyp, adenoma, carcinoma, hypertrophied anal papilla and rectal prolapse have similar presentations of haemorrhoids, thus it is very important to confirm diagnosis via appropriate examinations and investigations (Corman, 1993:58).

2.10 MEDICAL TREATMENT OF HAEMORRHOIDS

2.10.1 NON-OPERATIVE TREATMENT

2.10.1.1 Bleeding

Since bleeding is related to straining, treatment should be directed to the cause of bleeding. A high fiber diet, bulking agents, stool softeners, suppositories or laxatives may control constipation. Diarrhoea may be treated by antidiarrheal medications and diet. A wide variety of commercial topical cream, lotions and ointments are all used to aid wounds healing and keeping the anal region free of secondary infections providing that good anal hygiene is maintained at all times (Corman, 1993:60).

2.10.1.2 Pain

Topical anesthetics may be used to relieve pain, burning, itching, discomfort and irritation temporarily (Hodes, 1982:645). Sitz baths are highly advisable in the management of anal problems. However, if pain is caused by gangrene, ulceration or thrombosis of the haemorrhoids, surgery is the best option (Corman, 1993:61).

2.10.1.3 Prolapse

In early stages of haemorrhoids, prolapse of the anal tissues which can be reduced spontaneously or manually is mainly caused by straining, thus the management will be similar for controlling bleeding. However, in the late stages, where there is a permanent prolapse, the most effective approach is via haemorrhoidectomy (Corman, 1993:61).

2.10.2 AMBULATORY TREATMENT

2.10.2.1 Rubber band ligation

A rubber band is placed at the base of the haemorrhoid, just above the dentate line to avoid severe discomfort. Banding the haemorrhoid will cut off all circulation, allowing the haemorrhoid to wither away after a few days (Hancock, 1992).

2.10.2.2 Sclerotherapy

0.5ml of a chemical solution which consists of sodium morrhuate, quinine and urea hydrochloride or Sotradecal is slowly injected submucosally into each haemorrhoid, resulting in shrinkage of the haemorrhoids. Alternatively, 3ml of a

5% phenol solution in almond, vegetable, or arachis oil may be used for the injection (Corman, 1993:63).

2.10.2.3 Infrared Coagulation

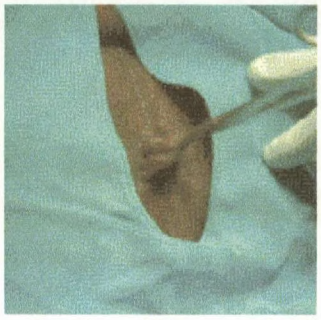
This is a favorable alternative for sclerotherapy. An applicator of an infrared coagulator will be applied at the same site where the physician would normally inject. This infrared coagulator transmits radiation in 1-second or 1,5-second pulses to the site causing protein coagulation 3mm wide and 3mm deep. A dark eschar forms within the next week, finally leaving a slightly puckered pink to red scar (Corman, 1993:73).

2.10.3 SURGICAL HAEMORRHOIDECTOMY

Patients undergoing haemorrhoidectomy, a small volume of enema will be administered in the morning of the operation. Laxatives are also given as a vigorous mechanical cleansing of the bowel thus ensuring that no stools will encumber the surgeon during the procedure. Local anesthetic may be given as pain control (Corman, 1993:82).

In cases where the anorectal architecture has been severely and irreversibly compromised, surgical haemorrhoidectomy is strongly suggested (Corman, 1993:82).

Milligan-Morgan's Open Haemorrhoidecto*my** is the most commonly used procedure in Britain today. The incision is carried to the upper anal canal with ligation of the haemorrhoidal pedicles. ***Parks' or Submucosal Haemorrhoidectomy is a method of submucosal dissection whereby it is possible to dissect out the haemorrhoid without destroying much of the epithelium of the anal canal. ***Ferguson's or Close Haemorrhoidectomy*** is also a submucosal dissection, with or without primary suture of the epithelium (Thomson et al.,1981:341-342).



Picture 2: Closed Haemorrhoidectomy

Not withstanding the technique employed, pain is a disconcerting sequel of haemorrhoidectomy regardless of the administered analgesia.

2.11 HOMOEOPATHIC TREATMENT OF POST-OPERATIVE PAIN

"Homoeopathy is a complete system of medicine which aims to promote general health, by reinforcing the body's own natural healing capacity"(Hammond, 1995:14).

2.11.1 POLYPHARMACY

When two or more remedies are prescribed simultaneously, either in alternation with each other or as a combined formula (complex) is called polypharmacy. The two methods of prescribing are according to individualization or diseased-based. Individualization prescribing is when several remedies are given concurrently or alternately according to indications in each patient's individual case. Diseased-based prescriptions constitute multiple remedies prescribed solely on the fact that they all have a degree of similarity to a particular disease process, without regards for patient's individual peculiar symptoms (Watson, 1993:71). A combination of as many as ten remedies may be used, but a number between five or seven is commonly used. It is common knowledge that certain remedies antidote other remedies thus a considerable amount of skill is needed in order to select a number of remedies for a complex in achieving a synergistic effect (Cook, 1989:73).

Thus the remedies selected have similar characteristic symptoms pertaining to the characteristics of pain experienced after an operation.

2.11.2 Arnica montana

Arnica montana is often prescribed in trauma and any type of injury without rationale (Morrison, 1993:36). *Arnica montana* is extremely suitable for sore, bruised condition of the body, making it a very important remedy in injuries, bruises and shocks (Kent, 1999:145). *Arnica montana* is indicated in injury with extravasation of blood, contusion, sprain; long-term consequences of trauma; and a general aggravation from exertion, motion, jar and touch (Morrison, 1993:37). Hahnemann says of Arnica montana, "It is beneficial (not only in "injuries caused

by severe contusions and lacerations of fibers") but also in the most severe wounds by bullets and blunt weapons, in the pains and other ailments consequent on extraction the teeth and other surgical operations, whereby sensitive parts have been violently stretched" (Tyler, 1995:85). The pains after trauma which respond best to *Arnica montana* are of a sore or bruised quality and is extremely useful in post-operative patients both for pain and to promote more rapid healing (Morrison, 1993:37). For internal use, Hahnemann recommended the 30th centesimal potency (Tyler, 1995:85).

2.11.3 Bellis perennis

Bellis perennis is recommended for trauma in general (Jouanny, 1984:68). Results of injuries to nerves and intense soreness with pains which are hard, aching, squeezing or throbbing worse for touch are all indicative for the prescription of *Bellis perennis* (Vermeulen, 1997:282). *Bellis perennis* is also very useful in sprains, bruises, lacerations, incisions, surgery and complaints of sore bruised sensations with extravasation (Morrison, 1993:63).

2.11.4 Calendula offinicalis

Calendula officinalis works as an antiseptic or to prevent serious infection when used topically but it also works dramatically to promote healing when taken in high potency internally (Morrison, 1993:92). *Calendula officinalis* is extremely useful in cuts with laceration, surface or open injuries (Kent, 1999:354). Kent also stated that diluted *Calendula officinalis can* be used locally in open wounds keeping it odorless and reducing the amount of pus, thus it assists the surgeon in healing surface wounds (Kent, 1999:354). *Calendula officinalis* is indicated when

the incision continues to ooze with no sign of healing; infected or suppurating incision (Morrison, 1998:393) and when the wounds are raw and inflamed with stinging pain and sensation as if beaten (Vermeulen, 1997:388).

2.11.5 Hypericum perforatum

Hypericum perforatum is unrivaled for its healing effects on injured nerves, and for injuries - especially to parts rich in nerves (Tyler, 1995:416). It is strongly indicated in lacerations involving very sensitive areas. It is also capable of preventing infections that can appear post-operatively (Borland, 1982:4). Tyler (1995:417) mentioned, "For aspirin and morphia only blunt the sensation; they never *cure* the pain - which *Hypericum officinalis* does." Jouanny also stated that this is a remedy for traumatism of nerves endings (Jouanny, 1984:181). The pain is characterized as stitching, shooting from a surgical site (Morrison, 1998:394) and sensations like tingling, burning, lacerating, shooting are all indicative of *Hypericum perforatum* (Vermeulen, 1997:863).

2.11.6 Phosphorus

Phosphorus is extremely useful in haemorrhage, excessive bleeding during or after surgery; disorientation, fearfulness, nausea, vomiting or weakness as a result of anesthesia (Morrison, 1998: 392). The blood from the haemorrhage tends to be very fluid and difficult to coagulate (Tyler, 1995:643) causing persistent bleeding from wounds (Vermeulen, 1997:1282).

2.11.7 Staphysagria

Mechanical injuries from sharp cutting instruments causing squeezing, stinging, smarting, cutting pain are great indications for a dose of *Staphysagria* (Vermeulen, 1997:1514). In the *Materia Medica Pura,* Hahnemann wrote," It is just to the most powerful medicines in the smallest doses that we may look for the greatest curative virtue in the most serious diseases of peculiar character for which this and no other medicine is suitable." Morrison agrees that this particular remedy is excellent for wounds which are red, sensitive and 'angry' with incisional pain that lasts long after healing after surgery (Morrison, 1998:392).

CHAPTER THREE

MATERIALS AND METHODS

3.1 OBJECTIVES

To study the efficacy of a homoeopathic pain complex (*Arnica montana 30CH, Bellis perennis 30CH, Calendula officinalis 30CH, Hypericum perforatum 30CH, Phosphorus 30CH, Staphysagria 30CH)* in the post-operative management of haemorrhoidectomy.

3.2 STUDY DESIGN

A double blind study, where thirty patients were evaluated following a standard haemorrhoidectomy. Fifteen patients were allocated to the allopathic (control) group, and the other fifteen to the homoeopathic (experimental) group.

Patients were randomly divided into two groups (the first group received allopathic medication i.e. Stopayne® Tablets and the second group received the homoeopathic post-operative pain complex). Thus each patient had an equal chance of being selected for either group. However additional medications i.e. opioids (Omnopon® i.e. papvavetum) were available upon request.

A list of numbers ranging from 1-30 were made, 30 pieces of paper were placed in a box, 15 were marked 'allopathic' and 15 'homoeopathic'. An independent person

drew one piece of paper at a time and allocated either 'allopathic or 'homoeopathic' to the list of numbers from 1-30. Each patient was allocated a number in sequence.

3.3 SUBJECTS

A minimum of thirty patients was accepted in this study. Patients were selected according to the inclusion and exclusion criteria (refer to 3.3.1 and 3.3.2) at King Edward VIII Hospital. Patients obtained from this hospital ensured that a mixed population of race was included. Patients were given information sheets (Appendix A) to ensure that patients understood what the trial entailed. A consent form (Appendix B) had to be filled out and signed by each participating patient thus making sure that patients participated on a voluntary basis.

All patients, with haemorrhoids were diagnosed by surgeons on call. A Closed Haemorrhoidectomy technique were carried out by two surgeons thus ensuring consistent techniques of the operations. All patients received a preoperative bowel preparation and Flagyl® (metronidazole 200mg) after the operation and stayed at the hospital for 3 days during the treatment.

3.3.1 Inclusion Criteria

- All patients must have undergone closed haemorrhoidectomy.
- Patients' ages ranged from 18 to 80 years.

3.3.2 Exclusion Criteria

- Patients younger than 18 years or above 80.

- Complications after haemorrhoidectomy, e.g. severe bleeding, anal stenosis, faecal impaction leading to the necessitation of additional intervention.
- Alcohol or drug abuse or any condition, e.g. mental illness or dementia associated with poor compliance.
- Patients suffering from any chronic illness, e.g. diabetes mellitus, hypertension, any heart diseases or asthma etc.
- Patients who were on any allopathic treatment for any other diseases.
- Pregnancy.

3.4 ETHICS

Ethics approval of the University of Natal, Faculty of Medicine, was obtained before beginning the clinical trial (Appendix G and H). The procedures of this trial were carefully explained to the patients (Appendix A), and they had to sign a consent form (Appendix B) if they decided to participate.

3.5 INTERVENTIONS

The homoeopathic pain complex containing *Arnica montana* 30CH, *Bellis perennis* 30CH, *Calendula officinalis* 30CH, *Hypericum perforatum* 30CH, *Phosphorus* 30CH, *Staphysagria* 30CH was prepared by a qualified Homoeopathic pharmacist from Pharma Natura (Pty) Ltd according to the British Homoeopathic Pharmacopoeia (Association's Scientific Committee 1993). The lactose tablets were impregnated at 1% volume/volume with the homoeopathic pain complex. The complex itself was made up in 96% alcohol.

In the allopathic group, Stopayne® Tablets contained 320mg of paracetamol, 8mg of codeine phosphate, 32mg of caffeine anhydrous, 150mg of meprobamate and tartrazine. This analegsic combinations had a schedule status of S5 and were distributed by Adocok Ingram Ltd.

3.6 MEASUREMENTS

The efficacy of the homoeopathic pain complex and the allopathic analgesic were measured using questionnaires. Each in-patient was given a McGill Pain Questionnaire and a Numerical Pain Rating Scale sheet during the first day of treatment after haemorrhoidectomy. These questionnaires were filled by the in-patients again on the second and third day of the treatment. The questionnaires were available in both English and Zulu.

3.7 STATISTICAL ANALYSIS

Since the sample size per group was small i.e. $n<30$ (15 per group), non-parametric tests were to be used. The subjective data obtained from the questionnaires were used to look for intra-group change by using the Wilcoxon signed-rank test. The Mann-Whitney U-test was used to perform inter-group comparisons (Daniel 1978: 31, 82). In each of the above tests the level of significance (α) was set at 5% or 0.05 (Daniel 1978: 31, 82). This is an integration of objectives one and two. The median, mean and standard deviation values of the homoeopathic group and allopathic group were used as descriptive statistics and bar charts (using SPSS 0.9) were constructed to illustrate significant results of the tests.

GROUPS ANALYSED

Group 1 constitutes the allopathic group.

Group 2 constitutes the homoeopathic group.

3.7.1.1 THE MANN-WHITNEY U - TEST

Comparison between Group 1 and Group 2:

The Mann-Whitney test was used to compare group 1 and 2. The two groups were regarded as being independent of each other (unpaired). The purpose of this test was to find out whether there was any significant difference between the two groups at the $\alpha = 0.05$ level of significance.

Hypothesis testing:

The null hypothesis H_o stated that there was no difference between the two groups with regard to the variable of interest. The alternative hypothesis H_1, stated that there was a difference between the two groups.

$H_o: \mu 1 = \mu 2$

$H_1: \mu 1 \neq \mu 2$

$\alpha = 0.05$ = level of significance of the test.

Decision rule:

For a two-tailed test:

Reject H_o if $P < \alpha = 0.05$

Accept H_o if $P \geq \alpha = 0.05$

P was the observed significance level of the test.

(McClave et al., 1997:722)

3.7.1.2 WILCOXON'S SIGNED RANK TEST FOR GROUP ONE

Comparison within Group 1:

The Wilcoxon's sign ranked test was used within group 1 to determine whether there was any significant improvement between the first consultation and the third consultation (beginning and end) within the allopathic group. All tests were done at the $\alpha = 0.05$ level.

Hypothesis testing:

The null hypothesis H_o stated that there was no improvement, with regard to the questionnaires, between the first and third consultation within group 2. The alternative hypothesis H_1 stated that there was an improvement between the first and third consultation.

H_o : There was no improvement

H_1 : There was an improvement

$\alpha = 0.05$ = level of significance of test.

Decision rule:

For a one-tailed test:

P = (Reported P-value / 2) if $\{H_0$ is of form > and Z is positive
$\{H_1$ is of form < and Z is negative

$P = 1$ - (Reported P-value / 2) if $\{H_0$ is of form > and Z is negative
$\{H_1$ is of form < and Z is positive

$\alpha = 0.05$

P was the observed significance level of the test.

(McClave et al., 1997:730)

3.7.1.3 WILCOXON'S SIGNED RANK TEST FOR GROUP TWO

Comparison within Group 2:

The Wilcoxon's sign ranked test was used within group 2 to determine whether these was any significant improvement between the first consultation and the third consultation (beginning and end) within the homoeopathic group. All tests were done at the $\alpha = 0.05$ level.

Hypothesis testing:

The null hypothesis H_0 stated that there was no improvement, with regard to the questionnaires, between the first and third consultation within group 1. The alternative hypothesis H_1 stated that there was an improvement between the first and third consultation.

H_0 : There was no improvement

H_1 : There was an improvement

$\alpha = 0.05$ = level of significance of test.

Decision rule:

For a one-tailed test:

P = (Reported P-value / 2) if $\{H_0$ is of form > and Z is positive
$\{H_1$ is of form < and Z is negative

$P = 1$- (Reported P-value / 2) if $\{H_0$ is of form > and Z is negative
$\{H_1$ is of form < and Z is positive

$\alpha = 0.05$

P was the observed significance level of the test.

(McClave et al., 1997:722)

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter contains the results obtained after statistically analysing the data gathered from the measurement criteria:

- Shortform McGill Pain questionnaire (Appendix E).
- Numerical Pain Rating Scale questionnaire (Appendix F).

4.2 CRITERIA FOR THE ADMISSIBILITY OF THE DATA

- Only data collected from the clinical trial was accepted.
- Haemorrhoidectomies were conducted by one of the two surgeons (Mr B. Singh and Mr J. N. Moodley).
- All diagnostic case history (Appendix C) and physical examinations were performed by Mr B. Singh or Mr J. N. Moodely.
- All questionnaires (two per patient for three days consecutively) were completed in the presence of Mr B. Singh or Mr J. N. Moodley and appointed nurse.

4.3 TABLE 4.1 : Comparison between Group 1 (Allopathic) and Group 2 (Homoeopathic) using the Mann-Whitney U – test for Shortform McGill Pain Questionnaire (Appendix E)

$\alpha = 0.05$ = level of significance

$P < \alpha$: allopathic and homoeopathic groups are different

$P \geq \alpha$: allopathic and homoeopathic groups are not different

Question No.	Allopathic Vs Homeopathic	Probability Value (P-Value)	Conclusion
1) Throbbing	Consultation 1	0.432	No difference
	Consultation 3	0.389	No difference
2) Shooting	Consultation 1	0.424	No difference
	Consultation 3	0.004	Different
3) Stabbing	Consultation 1	0.096	No difference
	Consultation 3	0.000	Different

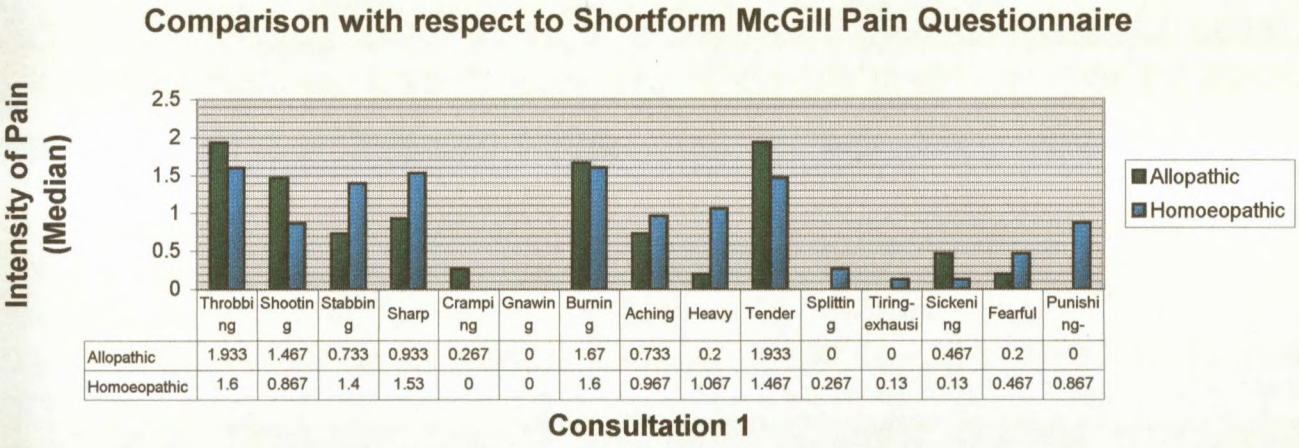
Table 4.3 continues

Question No.	Allopathic Vs Homeopathic	Probability Value (P-Value)	Conclusion
4) Sharp	Consultation 1	0.309	No difference
	Consultation 3	0.001	Different
5) Cramping	Consultation 1	0.550	No difference
	Consultation 3	1.000	Different
6) Gnawing	Consultation 1	0.317	No difference
	Consultation 3	0.317	No difference
7) Burning	Consultation 1	0.897	No difference
	Consultation 3	0.007	Different
8) Aching	Consultation 1	0.892	No difference
	Consultation 3	0.141	No difference
9) Heavy	Consultation 1	0.001	Different
	Consultation 3	0.007	Different
10) Tender	Consultation 1	0.061	No difference
	Consultation 3	0.068	No difference
11) Splitting	Consultation 1	0.073	No difference
	Consultation 3	1.000	No difference

Table 4.3 continues

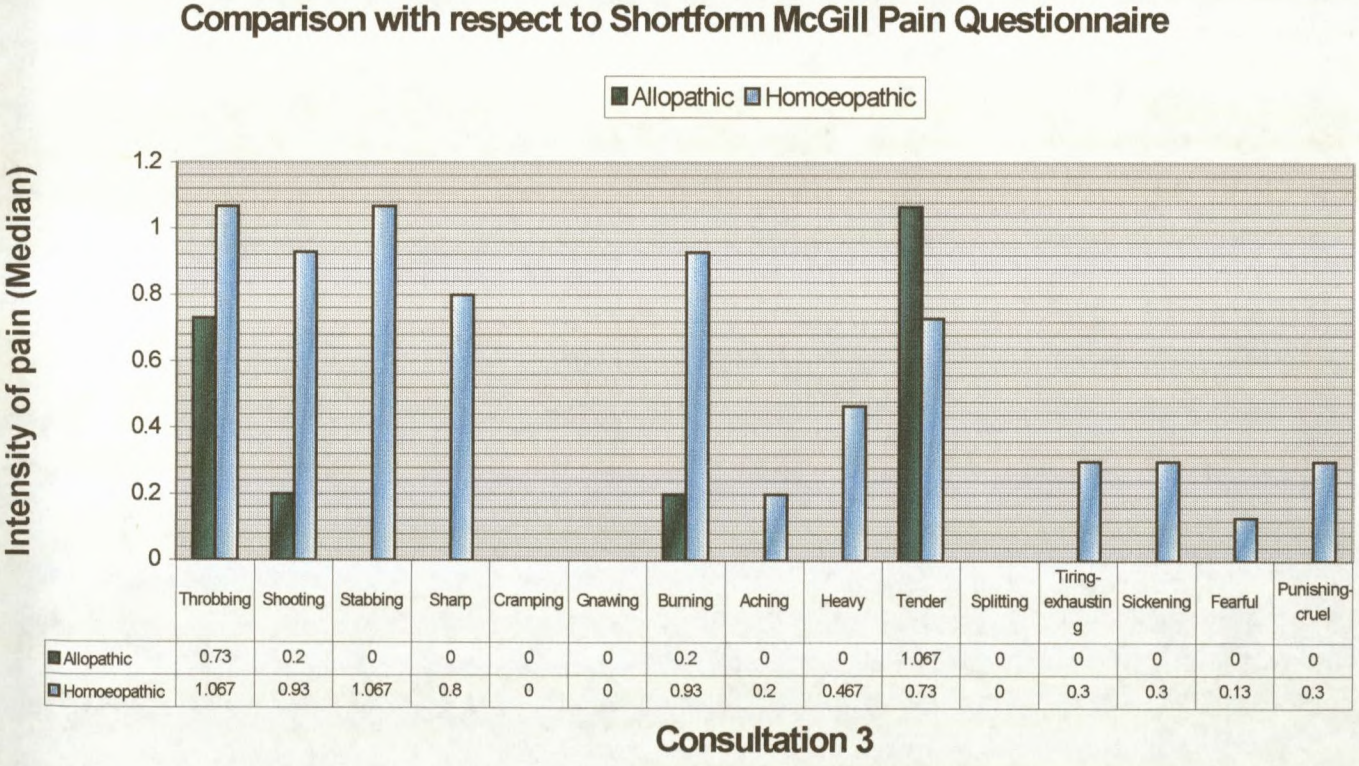
Question No.	Allopathic Vs Homeopathic	Probability Value (P-Value)	Conclusion
12) Tiring-exhausting	Consultation 1	0.326	No difference
	Consultation 3	0.317	No difference
13) Sickening	Consultation 1	0.453	No difference
	Consultation 3	0.317	No difference
14) Fearful	Consultation 1	0.190	No difference
	Consultation 3	0.073	No difference
15) Punishing-cruel	Consultation 1	0.012	Different
	Consultation 3	0.073	No difference

4.4 FIGURE 4.1: Comparison between Group 1 (Allopathic) and Group 2 (Homoeopathic) showing the median readings for the Shortform McGill Pain Questionnaire (Appendix E) for Consultation 1



	Throbbing	Shooting	Stabbing	Sharp	Cramping	Gnawing	Burning	Aching	Heavy	Tender	Splitting	Tiring-exhausi	Sickening	Fearful	Punishing-
Allopathic	1.933	1.467	0.733	0.933	0.267	0	1.67	0.733	0.2	1.933	0	0	0.467	0.2	0
Homoeopathic	1.6	0.867	1.4	1.53	0	0	1.6	0.967	1.067	1.467	0.267	0.13	0.13	0.467	0.867

4.5 FIGURE 4.2 : Comparison between Group1 (Allopathic) and Group 2 (Homoeopathic) showing the median readings for the Shortform McGill Pain Questionnaire (Appendix E) for Consultation 3



4.6 TABLE 4.2 Comparison between Group 1 (Allopathic) and Group 2 (Homoeopathic) using the Mann-Whitney U - test for the Numerical Rating Scale (Appendix F)

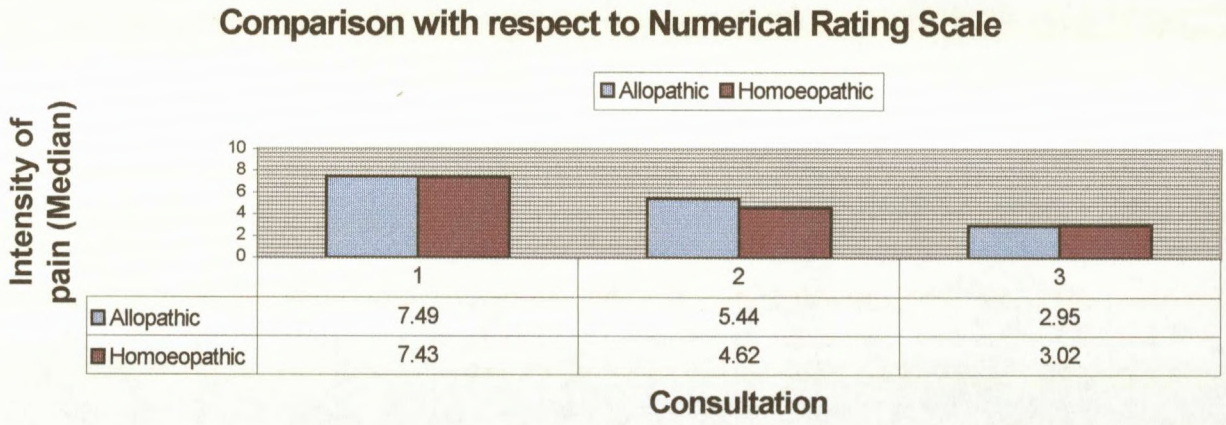
$\alpha = 0.05$ = level of significance

$P < \alpha$: allopathic and homoeopathic groups are different

$P \geq \alpha$: allopathic and homoeopathic groups are not different

Allopathic Vs Homeopathic	Probability Value (P-Value)	Conclusion
Consultation 1	0.618	No difference
Consultation 2	0.534	No difference
Consultation3	0.771	No difference

4.7 FIGURE 4.3 : Comparison between Group 1 (Allopathic) and Group 2 (Homoeopathic) showing the median readings for the Numerical Rating Scale (Appendix F) Questionnaire for Consultation 1, 2 and 3



4.8 TABLE 4.3 : Comparison within Group 1 (Allopathic) using Wilcoxon signed rank test for the Shortform McGill Pain Questionnaire (Appendix E)

$\alpha = 0.05$ = level of significance

P = (Reported P-value / 2) if {H_o is of form > and Z is positive
{H_1 is of form < and Z is negative

P = 1- (Reported P-value / 2) if {H_o is of form > and Z is negative
{H_1 is of form < and Z is positive

If $P < \alpha$, Reject H_o = Improvement

If $P < \alpha$, Accept H_o = No improvement

Question No.	Probability Value (P-Value) P = Reported P-value / 2	Conclusion
1) Throbbing	0.0005	Improvement
2) Shooting	0.0015	Improvement
3) Stabbing	0.007	Improvement
4) Sharp	0.0046	Improvement

4.8 Table 4.3 continue

Question No.	Probability Value (P-Value) P = Reported P-value / 2	Conclusion
5) Cramping	0.09	No improvement
6) Gnawing	0.50	No improvement
7) Burning	0.0015	Improvement
8) Aching	0.004	Improvement
9) Heavy	0.1585	No improvement
10) Tender	0.001	Improvement
11) Splitting	0.50	No improvement
12) Tiring-exhausting	0.1585	No improvement
13) Sickening	0.017	Improvement
14) Fearful	0.1585	No improvement
15) Punishing-cruel	0.1585	No improvement

4.9 TABLE 4.4 : Comparison within Group 2 (Homoeopathic) using Wilcoxon signed rank test for the Shortform McGill Pain Questionnaire (Appendix E)

$\alpha = 0.05$ = level of significance

P = (Reported P-value / 2) if {H_o is of form > and Z is positive
{H_1 is of form < and Z is negative

P = 1- (Reported P-value / 2) if {H_o is of form > and Z is negative
{H_1 is of form < and Z is positive

If $P < \alpha$, Reject H_o = Improvement

If $P < \alpha$, Accept H_o = No improvement

Question No.	Probability Value (P-Value) $P = \frac{\text{Reported P-value}}{2}$	Conclusion
1) Throbbing	0.0105	Improvement
2) Shooting	0.022	Improvement
3) Stabbing	0.0165	Improvement
4) Sharp	0.100	No improvement

4.9 Table 4.4 continue

Question No.	Probability Value (P-Value) P = Reported P-value / 2	Conclusion
5) Cramping	0.1585	No improvement
6) Gnawing	0.3275	No improvement
7) Burning	0.0145	Improvement
8) Aching	0.048	Improvement
9) Heavy	0.004	Improvement
10) Tender	0.006	Improvement
11) Splitting	0.051	No improvement
12) Tiring-exhausting	0.0415	Improvement
13) Sickening	0.0415	Improvement
14) Fearful	0.051	No improvement
15) Punishing-cruel	0.0155	Improvement

4.10 TABLE 4.5 : Comparison within Group 1 (Allopathic) using Wilcoxon signed rank test for the Numerical Rating Scale (Appendix F)

$\alpha = 0.05$ = level of significance

P = (Reported P-value / 2) if {H_o is of form > and Z is positive
{H_1 is of form < and Z is negative

P = 1- (Reported P-value / 2) if {H_o is of form > and Z is negative
{H_1 is of form < and Z is positive

If $P < \alpha$, Reject H_o = Improvement

If $P < \alpha$, Accept H_o = No improvement

Consultation	Probability Value (P-Value) P = Reported P-value / 2	Conclusion
1 and 3	0.0005	Improvement

4.11 TABLE 4.6 : Comparison within Group 2 (Homoeopathic) using Wilcoxon sign ranked test for the Numerical Rating Scale (Appendix F)

$\alpha = 0.05$ = level of significance

P = (Reported P-value / 2) if {H_o is of form > and Z is positive
{H_1 is of form < and Z is negative

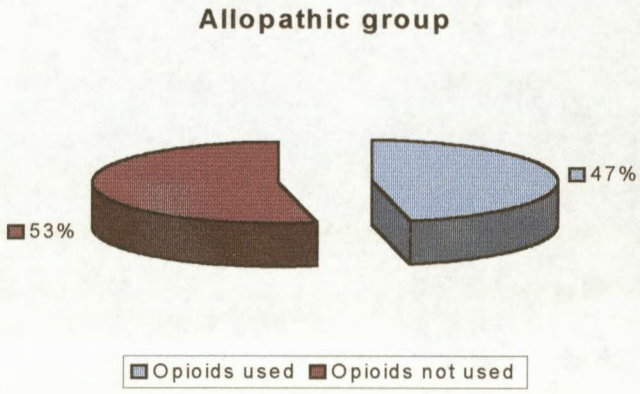
P = 1- (Reported P-value / 2) if {H_o is of form > and Z is negative
{H_1 is of form < and Z is positive

If $P < \alpha$, Reject H_o = Improvement

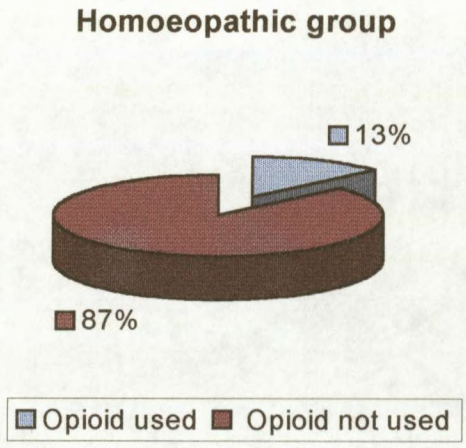
If $P < \alpha$, Accept H_o = No improvement

Consultation	Probability Value (P-Value) P = Reported P-value / 2	Conclusion
1 and 3	0.0005	Improvement

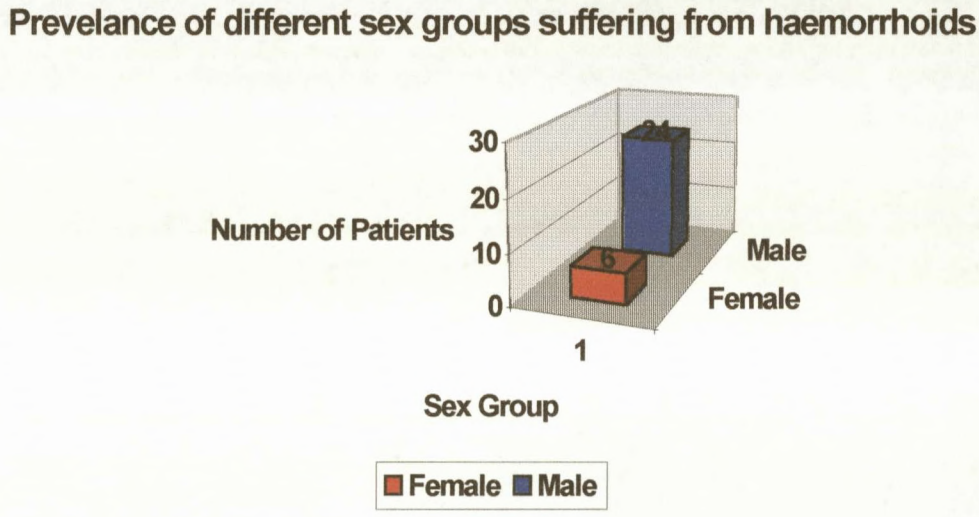
4.12 FIGURE 4.4 : Percentage of patients who required opioids in Group 1 (Allopathic)



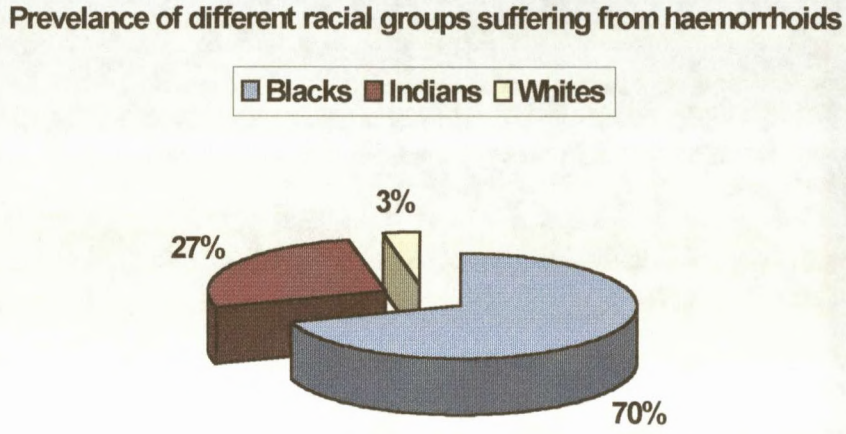
4.13 FIGURE 4.5 : Percentage of patients who required opioids in Group 2 (Homoeopathic)



4.14 FIGURE 4.6 : Comparison between different sex groups suffering from haemorrhoids



4.15 FIGURE 4.7 : Comparison between different race groups suffering from haemorrhoids



CHAPTER 5

DISCUSSION

The outcome of this clinical trial showed that there was an improvement in both allopathic and homoeopathic treatment for the post-operative pain management of haemorrhoidectomy in all patients.

The inter-group relationships (Table 4.1) between Group 1 (Allopathic) and Group 2 (Homoeopathic) for the Shortform McGill Pain Questionnaire (Appendix E) disclose the following: There was no significant difference in the results between the two groups during consultation 1 except for question 9 and 15. Consultation 3 showed a statistically significant difference between the two groups for question 2, 3, 4, 5, 7, 9, 10 and 15. The median readings of the Shortform McGill Pain Questionnaire during consultation 1 and 3 were used to present a visual illustration for the findings with bar charts (Figure 4.1 and 4.2). In Figure 4.1 the inter-group relationship showed that the pain intensity was higher in the allopathic group in the following categories: throbbing, shooting, cramping, burning, tender, sickening. But in consultation 3 (Figure 4.2), the homoeopathic group reflected a higher pain intensity than the allopathic group in most categories. However both allopathic and homoeopathic group showed that the intensity of pain decreased during consultation 3 compared to consultation 1.

The inter-group relationships (Table 4.2) between the allopathic and homoeopathic group for the Numerical Pain Rating Scale Questionnaire revealed that there were no significant difference during consultation 1, 2 and 3. In Figure 4.3 the inter-group relationship showed that the pain intensity was higher in the allopathic group except for consultation 3. But both groups

demonstrated a marked decrease in the intensity of pain during consultation 3 compared to consultation 1.

The intra-group relationships (Table 4.3) within the allopathic group for the Shortform McGill Pain Questionnaire (Appendix E), showed a statistically significant improvement in half of the categories namely: throbbing, shooting, stabbing, sharp, burning, aching, tender and sickening. In the Numerical Rating Scale (Appendix F), there was also an improvement in the intra-group relationships between consultation 1 and 3. However, it was important to announce that 7 (47%) out of 15 patients required rescue medication i.e. opioids (Figure 4.6) during the course of the trial.

The intra-group relationships (Table 4.4) within the homoeopathic group for the Shortform McGill Pain Questionnaire (Appendix E), reflected a statistically significant improvement in most of the categories namely: throbbing, shooting, stabbing, burning, aching, heavy, tender, sickening, fearful, and punishing-cruel. In the Numerical Rating Scale (Appendix F), there was also a significant improvement in the intra-group relationships between consultation 1 and 3. Unlike the allopathic group, only 2 patients (13%) out of the 15 in the homoeopathic group needed administration of opioids (Figure 4.5).

It was also necessary to note that the prevalent sex group suffering from haemorrhoids were male with a reading of 24 out of 30 patients, whereas only 6 out of the 30 were female patients (Figure 4.6). It was also valuable to mention that most patients were Blacks (70 %) and the rest were Indians (27%) and Whites (3%) (Figure 4.7).

All the results showed that the homoeopathic pain complex (*Arnica montana* 30CH, *Bellis perennis* 30CH, *Calendula officinalis* 30CH, *Hypericum perforatum* 30CH, *Phosphorus* 30CH, *Staphysagria* 30CH) was just as effective as allopathic analgesic (Stopayne®) in the management of post-haemorrhoidectomy pain.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

This double blinded study distinctly showed that the homoeopathic pain complex (*Arnica montana* 30CH, *Bellis perennis* 30CH, *Calendula officinalis* 30CH, *Hypericum perforatum* 30CH, *Phosphorus* 30CH, *Staphysagria* 30CH) was effective in the management of pain after haemorrhoidectomy without the apprehension of adverse effects. It is also worth mentioning that homoeopathic remedies are more cost effective than allopathic medications. Even though the results showed that the allopathic analgesic (Stopayne®) was effective too, a great number of patients in the allopathic group still required extra pain medication i.e. opioids.

Pre-operative administration of the homoeopathic pain complex as a prophylactic management and frequent administration of the homoeopathic pain complex for a longer period of time may result in a quicker improvement hence it is worth to explore further.

Homoeopathic simillimum treatment of the individual patients may be more effective than administrating a homoeopathic complex. Different potencies of the individual remedy in the homoeopathic pain complex may also modify different results.

Other signs and symptoms (e.g. bleeding, defecation etc.) and the duration of the healing process after haemorrhoidectomy are also worth to research further.

The majority of the patients participated were Blacks and Indians thus it is recommended that prospective investigations involving other and larger population group will show a better reflection of the prevalence in different races suffering from haemorrhoids.

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APPENDIX A

PATIENT INFORMATION SHEET

(ENGLISH AND ZULU)

Appendix A (English Version)

TITLE OF RESEARCH PROJECT: **The relative efficacy of a homoeopathic pain complex (*Arnica montana 30CH, Bellis perennis 30CH, Calendula officinalis 30CH, Hypericum perforatum 30CH, Phosphorus 30CH, Staphysagria 30CH)* and allopathic analgesic (Stopayne®) in the post-operative management of haemorrhoidectomy.**

NAME OF RESEARCHER: **Sao Lai Leong**
NAME OF SUPERVISOR: **Mr B. Singh [B. Sc ; MBChB FCS (S.A)]**
NAME OF CO-SUPERVISOR: **Dr C.M. Hall [B. Sc (P.U for CHE); M Tech. Hom (TN)]**

Dear patient,
Thank you for participating in this clinical trial. The purpose of this study is to find out if homoeopathic medicines can allievate pain after haemorrhoidectomy. Here are important information which you will need to know about the procedures during the study.

- At your first visit, you will be assessed by a nurse.
- If you comply with the selection criteria, which will be explained by the researcher, you will be accepted into the study group.
- You will be randomly divided into two groups (the first group will be receiving allopathic i.e. conventional medication and the second group will be receiving the homoeopathic post-operative pain complex). An independent person will draw one piece of paper at a time and allocate which group you will be in.
- The individual homoeopathic remedy in the homoeopathic post-operative pain complex is not known to produce any side effects.
- Before you receive any treatment, you will have to undergo a haemorrhoidectomy (a surgical procedure to remove haemorrhoids/piles).
- Your treatment will last up to 3 days and the researcher will need to see you 3 times during the period of the treatment.
- Treatment will not provide risk, discomfort and danger in anyway.
- You are to take either medication exclusively whilst in the research programme and should not take any other medication for the treatment of post-operative pain. However you are allowed to take medication for chronic conditions.
- If you still experience no improvement during the clinical trial (whether you are in the allopathic i.e conventional group or homoeopathic group), you are entitled to receive other medication for the post-haemorrhoidectomy pain.
- Upon receiving the medication, you will also receive an explanation of, and instructions of how to take the medications.
- Your participation in this research program is on a voluntary basis and will not cost you anything.
- You are free to decline your participation or to withdraw at any time, without obligation.

Appendix A (Zulu Version)

ISIHLOKO SOCWANINGO LWEPROJEKTHI: **Imiphumela ebalulekile ye-homeopathic(ukwelapha ngamakhambi esintu) management ye-haemorroidectomy (okungukuhlinzwa kususwa imithambo).**
UMFUNDI WOCWANINGO **Sao Lai Leong (Lilly)**
IGAMA LOMQAPHI : **Mr B. Singh [B. Sc (UDW); MBChB FCS (S.A)]**
IGAMA LOMSIZI WOMQAPHI: **Dr C.M. Hall [B. Sc (P.U for CHE); M Tech. Hom (TN)]**

Siguli,
Ngiyabonga ngokuzibandakanya kwakho kulo-lu-cwaningo. Ingqikithi yalolu cwaingo lwephrojekthi ukutholo imiphumela engenza, noma engasiza ekuqedeni ubu(izi)nhlungu obudalwa ukuhlinzwa kushlinzwa kususwa imithambo (phecelezi in haemorrhoidectomy). Nakhu okumele ukwazi mayelana nalolu cwaningo:

- Ngokuvakasha kwakho okokuqala , uzohlolwa unesi
- Uma ulandela noma uthobela ukwahlulelwa/ isahlilelo esizochazwa umcwaningi , uzokwamukeleka kuleliqoqo locwaninga .
- Nizohlukaniswa nibe amaqoqo amabili(iqoqo lokuqala lizothola umuthi okuthiwa i-allopathic bese kuthi iqoqo lesibili lizonikezwa i-homeophathic post - operative pain complex).Umuntu emunye uzotomula iphepha elilodwa ngesikhathi bese eyakhetha ukuthi iliphi iqoqo azoba kulona.
- Umuthi ngamunye okule ngxube ye homoeopathic post-operative pain ayinakho ukwenza ukuthi agule.
- Ngaphambi kokuba uthole noma yimuphi umuthi wokwelapha , uzokwenziwa i-haemorroidectomy(inqubo yokuhlinzwa kususwe imithambo engaphansi).
- Imithi yakho yokwelapha izohlala izinsuku ezintathu nomcwaningi uzodinga ukuku-bona kathathu ngesikhathi uqhubeka nokuthatha imithi.
- Imithi ayizukuba nabo ubudedengu , ukungaphatheki kahle nobungozi ngaleyondlela.
- Kuzofanele uthathe imithi ngokuhlukile eceleni ngesikhathi usohlelweni locwaningo futhi kufanele ungayithathi imithi ye-treatment of post-operative pain.
- Uma ungawuzwa umehluko ngesikthathi ulashwa kulolucwaingo (ngabe uthatha umuthi we homoeopathy, nomz ngabe uthatha enye inhlobo yomuthi), uvmelekile ukuthatha eminye umuthi noma ezinye izinhlobo zemithi ezelapha izihlungu ezibangelwa ukuhlinzwa kususwa imithambo (post-haemorrhoidectomy pain)
- Uma seninikezwa imithi , nizothola futhi incazelo yomuthi nendlela yokuthatha imithi.
- Iqhaza olithathayo kuloluhlelo locwaningo lingokuthanda kwakho futhi akukho ozokukhokha ngalokho.
- Unelungelo lokunqaba ukubamba iqhaza noma ungayeka kumbe uhoxe noma inini, ngaphandle kokuphoqwa.

APPENDIX B

PATIENT CONSENT FORM

(ENGLISH AND ZULU)

Appendix B (English Version)

INFORMED CONSENT FORM

TITLE OF RESEARCH PROJECT: **The relative efficacy of a homoeopathic pain complex (*Arnica montana 30CH, Bellis perennis 30CH, Calendula officinalis 30CH, Hypericum perforatum 30CH, Phosphorus 30CH, Staphysagria 30CH)* and allopathic analgesic (Stopayne®) in the post-operative management of haemorrhoidectomy.**

NAME OF SUPERVISOR: **Mr B. Singh [B. Sc ; MBChB FCS (S.A)]**

NAME OF CO-SUPERVISOR: **Dr C.M. Hall [B. Sc (P.U for CHE); M Tech. Hom (TN)]**

DATE OF FIRST APPOINTMENT: _____

Patient's Full Name:_____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO
2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to?_____
7. Do you understand the implications of your involvement in this study? YES/NO
8. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time, and
   b) without having to give reason for withdrawing
9. Do you agree to voluntarily participate in this study? YES/NO
10. Do you understand the difference between an allopathic and homoeopathic treatment? YES/NO

If you have answered "No" to any of the above, please obtain the information before signing.

I _____ hereby give consent for the proposed procedure to be performed on me as part of the above mentioned research project.

PATIENT/SUBJECT* Name _____ (in block letters) SIGNATURE _____

WITNESS Name _____ (in block letters) SIGNATURE _____

RESEARCH STUDENT Name **Sao Lai Leong (Lilly)** SIGNATURE _____

Appendix B (Zulu Version)

INFORMED CONSENT FORM

ISIHLOKO SOCWANINGO LWEPROJEKTHI:

Imiphumela ebalulekile ye- homeopathic(ukwelapha ngamakhambi esintu) management ye-haemorroidectomy (okungukuhlinzwa kususwa imithambo)

IGAMA LOMQAPHI : **Mr B. Singh [B. Sc (UDW); MBChB FCS (S.A)]**
IGAMA LOMSIZI WOMQAPHI: **Dr C.M. Hall [B. Sc (P.U for CHE); M Tech. Hom (TN)]**
USUKU LOKUVAKASHA OKOKUQALA :_____
Igama eliphelele lesiguli : _____
DWEBA INDILINGA EMPENDULWENI OKUYIYONA-YONA
1.Usuke walifunda iphepha elinolwazi ngocwaningo? YEBO/CHA
2.Usuke waba nalo ithuba lokubuza imibuzo emayelana nalolucwaningo? YEBO/CHA
3.Usuke wazithola izimpendulo ezigculisayo ngalembuzo yakho? YEBO/CHA
4.Usuke waba nalo ithuba lokuxoxisana ngalolucwaningo? YEBO/CHA
5.Usuke waluthola yini ulwazi ulwazi olwanele ngalolucwaningo? YEBO/CHA
6.Ubani oke wakhuluma naye?----------
7.Uyawazi umphumelo ngokuzimbandakanya kwakho kulolucwaningo? YEBO/CHA
8.Uyazi ukuthi ukhululekileukuhoxisa kulolucwaningo? YEBO/CHA
a)noma yinini ,futhi
b)ngaphandle kokunika isizathu sokuhoxisa.
9.Uyavuma ukubamba iqhaza ngokuzinikela(voluntarily)kulolucwaningo? YEBO/CHA
10.Uyawazi umehluko phakathi kwe -allopathic ne homeopathic treatment. YEBO/CHA

Uma ungavumelani nalemibuzo engenhla (noma u ngo "Cha"), zama ukuthola ulwazi mayelana nalolu cwaningo ngaphambi koku sayina.
Mina_____**ngiyavuma ukuzimbandakanya kulolu cwaningo phojekthi, nokuba kwenziwo ucwaningokumina.**

ISIGULI /INJONGO* Igama_____UKUSAYINA_____
(ngamagama amakhulu)

UFAKAZI Igama _____UKUSAYINA_____
(ngamagama amakhulu)

UMFUNDI WOCWANINGO **Sao Lai Leong (Lilly)**UKUSAYINA_____
(ngamagama amakhulu)

APPENDIX C

DIAGNOSTIC CASE HISTORY

(ENGLISH AND ZULU)

Appendix C (English version)

DIAGNOSTIC CASE HISTORY

Date:_____
Name:_____ Surname:_____
Age:_____ Sex:_____ Marital Status:_____
Date of Birth:_____ Place of Birth:_____
Home Address:_____ Telephone no:_____
_____
_____
Work Address:_____ Telephone no:_____
_____
_____
Occupation:_____

MAIN COMPLAINT:_____

PAST MEDICAL HISTORY:_____

PAST SURGICAL HISTORY:_____

FAMILY HISTORY:_____

SYSTEMS REVIEW:_____

PHYSICAL EXAMINATION (VITALS, JACCOL HH):_____

Appendix C (Zulu Version)

DIAGNOSTIC CASE HISTORY

USUKU:_____
IGAMA:_____ISIBONGO:_____
IMINYAKA:_____UBULILI:_____NGOKOMSHADO:_____
USUKU LOKUZALWA:_____INDAWO OWAZALELWA KUYO:_____
IKHELI LASEKHAYA:_____INOMBOLO YOCINGO:_____
_____
_____
IKHELI LASEMSEBENZINI:_____INOMBOLO YOCINGO:_____
_____
_____
NGOKOMSEBENZI:_____
_____
ISIKHALAZO ESISEMQOKA:_____
_____
_____
_____
_____
UMLANDO ODLULE NGEMITHI:_____
_____
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UMLANDO ODLULE NGOKUHLIZWA:_____
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UMLANDO WOMNDENI:_____
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UKUBHEKA INQUBO:_____
_____
_____
_____
UKUHLOLWA KOMZIMBA(VITALS,JACCOL HH):_____
_____
_____
_____

APPENDIX D

INSTRUCTIONS ON HOW TO TAKE MEDICATIONS

(ENGLISH AND ZULU)

Appendix D (English Version)

How to take your medicine:

1) The tablets will be crushed for you and will be dissolved in water.

2) Take your remedies **away from meals** at least half an hour before a meal or one hour after. Avoid eating **MINT** before or after taking medication.

3) The remedies must be stored away from **camphor** (e.g Vicks products) light, heat, and electromagnetic radiation (T.V's, computers,. etc).

4) Try to avoid the intake of coffee during your treatment.

Appendix D (Zulu version)

Indlela/Ithathwa kanjani imithi :

1.Amaphilisi uzocutshelwa wona bese efakwa emanzini ancibilike.

2.Thatha imithi ngaphambi kokudla noma-ke nje uhhafu wehora ngaphambi kokudla noma uyithathe emva kwehora usuqede ukudla. Gwema ukudla i-minti (peppermint) ngaphambi kokuthatha imithi noma emva kokuthatha imithi.

3.Umuthi kufanele ubekwe kude ne-camphor(isib. imikhiqizo yakwa-Vicks)ukukhanya,
ukushisa,nezinto ezinomazibuthe(omabonakude ,amakhompuyutha , njll.)

4.Zama ukugwema ukuphuza ikhofi ngesikhathi udla imithi yokulapha.

APPENDIX E

SHORTFORM McGILL PAIN QUESTIONNAIRE

(ENGLISH AND ZULU)

Appendix E (English version)

SHORT FORM McGILL PAIN QUESTIONNARIE - Ronald Melzack

Patient's name:_____
Date:_____

THROBBING	0)_____	1)_____	2)_____	3)_____
SHOOTING	0)_____	1)_____	2)_____	3)_____
STABBING	0)_____	1)_____	2)_____	3)_____
SHARP	0)_____	1)_____	2)_____	3)_____
CRAMPING	0)_____	1)_____	2)_____	3)_____
GNAWING	0)_____	1)_____	2)_____	3)_____
HOT-BURNING	0)_____	1)_____	2)_____	3)_____
ACHING	0)_____	1)_____	2)_____	3)_____
HEAVY	0)_____	1)_____	2)_____	3)_____
TENDER	0)_____	1)_____	2)_____	3)_____
SPILLTING	0)_____	1)_____	2)_____	3)_____
TIRING-EXHAUSTING	0)_____	1)_____	2)_____	3)_____
SICKENING	0)_____	1)_____	2)_____	3)_____
FEARFUL	0)_____	1)_____	2)_____	3)_____
PUNISHING-CRUEL	0)_____	1)_____	2)_____	3)_____

Appendix E (Zulu version)

SHORT FORM McGILL PAIN QUESTIONNARIE - Ronald Melzack

Igama lesiguli : _____
Usuku : _____

KUYANTSONTSOTHA	0)____	1)____	2)____	3)____
KUNEZIDUBULO	0)____	1)____	2)____	3)____
KUYAGWAZA	0)____	1)____	2)____	3)____
KUYAHLABA	0)____	1)____	2)____	3)____
KUNAMAJAQAMBA	0)____	1)____	2)____	3)____
KUYASHOSHOZELA	0)____	1)____	2)____	3)____
KUYASHISA	0)____	1)____	2)____	3)____
KUBUHLUNGU	0)____	1)____	2)____	3)____
KUYASINDELA	0)____	1)____	2)____	3)____
KUNGCONYWANA	0)____	1)____	2)____	3)____
KUYAQAQAMBA	0)____	1)____	2)____	3)____
KUYAKHATHALEKA	0)____	1)____	2)____	3)____
KUYAGULISA	0)____	1)____	2)____	3)____
KUYASABISA	0)____	1)____	2)____	3)____
KUBUHLUNGU-NGOKU-HLUKUMEZEKA	0)____	1)____	2)____	3)____

APPENDIX F

NUMERICAL PAIN RATING SCALE QUESTIONNAIRE

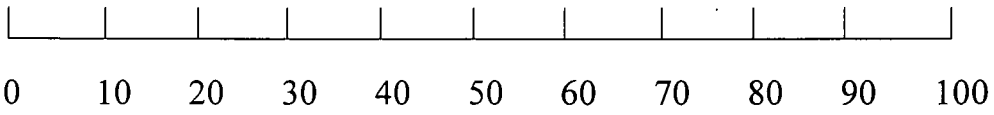
Appendix F (English version)

NUMERICAL RATING SCALE

Please indicate which number best describe your intensity of your pain

Patient's name : _____ Date:_____
Time:_____

No Pain **Pain as bad as it could be**



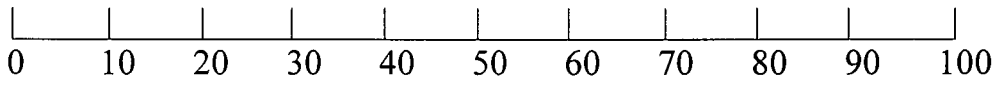
Appendix F (Zulu version)

NUMERICAL RATING SCALE

Cacisa ukuthi iyiphi inombolo echaza kahle-hle izinga lobuhlungu bakho

Igama lesiguli :_____ Usuku :_____
Isikhathi :_____

ABUKHO UBUHLUNGA **UBUHLUNGU OBUBI KAKHULU**



APPENDIX G

ETHICAL APPROVAL FROM UNIVERSITY OF NATAL, FACULTY OF MEDICINE

UNIVERSITY OF NATAL
DURBAN CAMPUS

Nelson R Mandela School of Medicine
Faculty of Health Sciences
Postgraduate Office

✉ Private Bag 7 Congella 4013 South Africa
Telephone +27 (0)31 260 4416
Facsimile +27 (0)31 260 4410/4416
e-mail: postgrad-med@nu.ac.za

Ms SL Leong
39 Acacia Road
Glenwood
4001

email: lillyl@mweb.co.za

24 July 2001

Dear Ms Leong

PROTOCOL: The efficacy of a homeopathic pain complex in the post-operative management of haemorrhoidectomy. SL Leong. Technikon (with B Singh, Surgery). Ref E157/00

Further to my letter of 1 March 2001 I confirm that all queries raised by the members of the Research Ethics Committee have been dealt with and full ethical approval was granted on 1 March 2001. All necessary documents have been submitted including the permission to conduct a research study/trial signed by the Chief Medical Superintendent of King Edward VIII Hospital.

Yours sincerely

Anita Walker
Postgraduate Administration
Aw/ethics/leong/5

Authorised Signatory for:

Research Ethics Committee
Nelson R Mandela School of Medicine

APPENDIX H

APPROVAL FROM KING EDWARD VIII HOSPITAL

KwaZulu-Natal Provincial - Health Services
King Edward VIII Hospital

Office of the Chief Medical Superintendent

Postal Address: Private Bag , Dalbridge , 4014. • Telephone: 031 3603015 • Fax: 031 2061457 • Email Address: mhlambi@dohke8.kznhl.gov.z

Reference: KE 2/7/1
Research Programming.

Ms Lilly Leong
39 Acacia Road
Glenwood
Durban
4001

REQUEST TO CONDUCT RESEARCH AT KING EDWARD VIII HOSPITAL.

1. I am pleased to inform you that your application dated 2 March is approved.

2. Please furnish the following to King Edward VIII Hospital Management:

   (i) a copy of the progress report to the Ethical Committee or quarterly reports from other institutions.
   (ii) full acknowledgement of King Edward VIII Hospital's role in the study, in all publications and reports.
   (iii) A copy of the publication or report on completion of study.

3. King Edward VIII Hospital Management reserves the right to terminate the permission for the study should circumstances so dictate.

4. Thanking you in anticipation.

Yours\Sincerely

Dr S.A. Mhlambi
Chief Medical Superintendent.