

Post-operative experiences of patients undergoing laparoscopic gynaecological surgery at an academic training hospital

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfillment of the requirements for the degree of Master of Medicine in Anaesthesiology, Johannesburg, 2018

Declaration

I, Mishkah Mahomed, declare that this research report is my own work. It is submitted for the admission to the degree of Master of Medicine in Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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Abstract

Background:

There is a global trend towards performing gynaecological surgery laparoscopically. The anaesthetic technique should complement the minimally invasive nature of the surgical technique.

Developing an understanding of patients' experiences following laparoscopic gynaecological surgery is the first step toward improving the anaesthetic technique utilised for these surgeries, thereby aiming to improve the patient's peri-operative surgical experience.

Method:

We performed a retrospective descriptive study from 1 August 2014 to 31 December 2016 on all available PAIN OUT data for patients having undergone a laparoscopic gynaecological procedure at a university teaching hospital in South Africa. Data on pain experiences and side effects was captured.

PAIN – OUT is an international pain database. The main focus of PAIN – OUT is to improve the management of post-operative pain. In order to facilitate the aim of PAIN – OUT, data about post-operative pain from medical facilities internationally was collected and pooled into one database. The database may provide feedback and benchmarking for staff in each centre about how patients are being managed especially with concern to pain patients may experience. The hope is that the information will help healthcare workers improve the management of pain for their patients.

Results:

Data representing 55% of cases for the period under review was available. The median age of all patients recruited to the study was 37 years old. All participants were of African descent.

The median numerical rating scale (NRS) score for 'worst' and 'least' pain since surgery for all patients having undergone a laparoscopic gynaecological procedure was 5 and 3 respectively; the difference being statistically significant $p < 0.0001$.

Sixty percent of patients reported drowsiness, 48.2% of patients experienced nausea or vomiting and 22.7% of patients experienced pruritus. The median scores for drowsiness, nausea or vomiting and pruritus was 2, 0, 0 respectively.

Conclusion:

Although most patients experienced post – operative pain, and side effects experienced were higher than recommended standards of care, the severity of pain and side effects experienced may be said to be tolerable. Although side effects were noted, they were not statistically significant. The findings of this study do not clearly prove if the side effects were from opiates or not. Side effects experienced may be from opiates administered or from the surgical procedure itself.

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Section 1: Overview

Synopsis of Research

Tubal Ligation surgery is an accepted and preferred means of sterilisation by a significant number of women, especially women who have completed their families or in whom pregnancy may pose a significant risk to their health.

Evidence reveals a trend toward performing these surgeries laparoscopically. The numerous advantages of laparoscopic surgery often facilitates an earlier hospital discharge and allows the patient to return to a pre-surgical level of function as soon as possible. It is imperative that the anaesthetic technique and analgesic strategy employed facilitates this objective.

There are numerous factors that may prolong or complicate the recovery period. These may be anaesthetic or surgical in nature. Inadequately treated post-operative pain can have dire consequences for these patients. Other complications (either from the surgical or anaesthetic management employed) may include nausea and vomiting, drowsiness or pruritus, all of which may delay recovery.

The study made use of a retrospective, contextual and descriptive design.

Rahima Moosa Mother and Child Hospital (RMMCH) participated in the international pain registry called PAIN OUT. Improving post – operative pain management is the primary focus of PAIN OUT. Data on the anaesthetic and analgesic practices for adult patients having surgery at RMMCH and who fulfilled the inclusion criteria, and consented to being included in the registry, were included in the web-based PAIN OUT registry. The information was captured according to the Standard Operating Procedures (SOPs) of the PAIN OUT study.

Each patient who qualified for inclusion in the registry completed a Patient Outcome Questionnaire (POQ). A Process Questionnaire (PQ) was completed from data collected from the patient's medical and nursing records for each participant by a trained investigator.

This study is a retrospective analysis of the PAIN OUT data for patients who underwent

a laparoscopic tubal ligation at RMMCH from 1 August 2014 – 31 December 2016. Parameters described in the objectives were explored.

All gynaecological laparoscopic procedures may be associated with pain, nausea and vomiting, drowsiness and pruritus both as a result of the procedure itself (due, for example, to the creation of a pneumoperitoneum) or as a result of the anaesthetic technique employed (e.g. use of opioids as part of a multimodal analgesia approach). It was therefore of interest to describe the occurrence and severity of the mentioned variables in patients who had undergone gynaecological laparoscopic procedures for various other reasons and compare it to the laparoscopic sterilisation population.

The primary objective of this study was to describe the pain scores of patients after laparoscopic gynaecological surgery at RMMCH. In addition, we describe the occurrence and severity of the patients' side effects which include nausea and vomiting, drowsiness and pruritus. Demographics of the patients involved as well as a review of analgesia used peri-operatively (as this may contribute to the post-operative side effect profile) is described.

The secondary objective of this study was to compare these variables in patients who had laparoscopic gynaecological procedures for reasons excluding tubal ligations with patients who had laparoscopic tubal ligation surgery.

Best patient outcome is the ultimate goal of all health care practitioners. This research project aims to interrogate how we can achieve this goal for women undergoing laparoscopic tubal ligation surgery.

1.1. Introduction

Laparoscopic surgery is associated with numerous advantages over a more traditional open surgical approach. It is minimally invasive; the healing process is less painful and recovery from surgery is more rapid (1).

Tubal ligations are elective surgical procedures that are often performed on healthy women who play vital roles in their respective family structures and who are significant contributing members to the country's economy. A study published in 1991 in *Anaesthesia*, surveying post-operative pain in women undergoing diagnostic laparoscopic procedures as well as laparoscopic sterilisations revealed that the mean age of women undergoing laparoscopic tubal ligations recruited to the study were between 33.2 and 33.3 years old (2). With continued feminisation of the labour force in South Africa (3), women in this age group contribute significantly to our economy and are often mothers to younger children who require care and nurturing. It is imperative for them to expeditiously return to a pre-surgical level of function.

Observations in certain institutions suggest that there is a trend towards performing tubal ligation surgery laparoscopically in South Africa. In the United States of America (USA), laparoscopic procedures are noted to be the sterilisation procedure of choice in women who are not sterilised at the time of a caesarean section (4). A similar trend was noted in the United Kingdom of Great Britain and Northern Ireland (UK), with the most common method of permanent sterilisation being a laparoscopic tubal ligation carried out under a general anaesthetic as a day case (5).

Day case or out-patient surgery offers significant advantages to the patient, the health care facility and the community (6). The increasing burden of health care costs places an enormous strain on the global economy, and this effect is magnified in developing countries like South Africa. With the rapid advances in medicine, day case surgery is becoming a viable and attractive option for numerous surgical procedures (7). Laparoscopic tubal ligation surgeries are suitable to be performed as day case or out-patient procedures. However, it is important to note that out-patient procedures only benefit the patient if potential post-operative complications are adequately anticipated, prevented or managed (6). It is crucial that the anaesthetic technique

employed affords the patient with the best opportunity to recover expeditiously and with the minimal tolerable level of pain for the specific patient.

Importantly however, laparoscopic surgery is not without its unique risks. These can occur as a result of the laparoscopic technique employed or, more importantly to the anaesthetic technique, as a result of the physiological changes associated with the creation of a pneumoperitoneum (8). Consequently, the anaesthetic technique employed should be refined to anticipate and deal with these laparoscopic specific risks. Furthermore, complications associated with the anaesthetic technique and analgesic approach should be taken into consideration as these may delay recovery and hospital discharge (6). Laparoscopic associated risks and complications of the anaesthetic technique used may impede the patient from fulfilling discharge criteria for day-case surgery.

Side-effects such as pain, nausea and vomiting may complicate laparoscopic surgical techniques by creation of a pneumoperitoneum with carbon dioxide which often rapidly distends the pneumoperitoneum and results in trauma and inflammation (9). Opiates, often used for pain management during laparoscopic tubal ligations, are associated with their own risks of nausea and vomiting but may also cause significant pruritus and drowsiness (10). These potential complications of the procedure and the side effects of these drug treatments warrants exploration.

There are numerous reasons for the pain associated with laparoscopic tubal ligations. Pain after laparoscopic procedures has been described in the abdomen (upper and lower), the shoulders and back. Shoulder tip pain has been reported in as many as 63% of patients. The precise aetiology is still unclear (11).

This shoulder tip pain has been explained by excitation of the phrenic nerve by insufflation of the abdomen by carbon dioxide (11). Further mechanisms of pain after laparoscopic procedures, as reviewed by Fourgeaud, Schoeffler and Diemunsch (1993) (9) include rapid peritoneal distension (this can result in release of mediators of inflammation, traction on nerves and shearing of vessels), creation of a pneumoperitoneum, and peritoneal inflammation. Local pain associated with incisions for the operative ports should also not be overlooked.

Laparoscopic sterilisations have been noted to cause worse pain than laparoscopies for diagnostic procedures. Ischaemia or damage to the fallopian tubes

during sterilisation procedures have been postulated as the reason for this. Davis and Miller (1988) (12) noted the pain was worse for up to four hours after the procedure but on discharge from hospital the pain was similar. These surgeries were done as day cases. It was also noted that the severity of lower abdominal pain experienced also depends on the method of sterilisation employed (12).

The surgical technique used may also influence the pain experienced after surgery. There are numerous methods of ligating the fallopian tube including Pomeroy Tubal Ligation, use of tubal rings and clips, tubal coagulation (either monopolar or bipolar), fimbriectomy or hysteroscopic procedures to name a few (13). Each method may be associated with specific types of pain that may account for the pain of laparoscopic sterilisations being associated with worse pain than laparoscopies for diagnostic procedures (12).

Inadequate pain management may also foster the development of chronic disabling pain. Severe acute pain as well as chronic pain is distressing and may reduce quality of life for the patient. By the nature of minimally invasive surgery, laparoscopic surgery is associated with short-lived but intense pain and a majority of patients will require opioid analgesia at some point peri-operatively. High quality analgesia is essential to prevent a delay in hospital discharge (8). However, opioid analgesia is not without side effects such as pruritus, sedation and nausea and vomiting. These side effects can be disconcerting for a patient and will reduce patient satisfaction after surgery (10).

Among patients receiving opioids the incidence of pruritus varies widely. Between 2% and 100% of patients who receive opioids may report pruritus. Patient satisfaction is reduced by the discomforting side effect of pruritus. The incidence varies with the route of administration of the opioid analgesic (14). The reported incidence of pruritus after intravenous administration of an opioid is reported to be as high as 50% (10%-50%) which is greater than the reported incidence after oral administration (2%-20%). The reported incidence of pruritus after spinal or epidural administration can range between 30% and 100% (15).

Mechanisms of opioid induced pruritus is elusive. There is however increasing evidence that opioid receptors play a significant role in the pathogenesis. Spinal inhibitory pathways, prostaglandins, dopamine and serotonin receptors have also

been mentioned in the pathogenesis of opioid induced pruritus (16).

Opioids can also have a sedative effect which occurs especially in opioid naïve patients (17). Patients undergoing laparoscopic tubal ligations are often devoid of any pathology and are more likely to be opioid naïve, and therefore have an increased risk of experiencing sedation as a result of opioid use (18). Furthermore, although tolerance to this side effect usually develops, it is unlikely to develop over the short period of time for which an opioid is required in these patients (10).

Laparoscopic tubal ligations are associated with an appreciably high rate of post-operative nausea. A 1998 study published in the Eastern Mediterranean Health Journal reported that as many as 50% of patients undergoing laparoscopic procedures required an anti-emetic post-operatively for nausea or vomiting. The nausea is believed to be (in part) due to irritation of the abdominal cavity caused by Carbon Dioxide residue (19).

Opioids produce nausea and vomiting by a number of mechanisms. Central and peripheral sites have been implicated. The gastrointestinal tract has been implicated as a peripheral site while the vomiting center, vestibular apparatus, chemoreceptor trigger zone and cerebral cortex are central sites where opioids may act and result in nausea and vomiting (20). Therefore, these patients are at high risk of nausea and vomiting as a result of either the procedure or opioids and in many cases, both factors may contribute to the distressing side effect.

Developing an understanding of patients' experiences following laparoscopic tubal ligation surgery in the South African setting is the first step towards improving the analgesic approach utilised for these surgeries, and thereby aiming to improve the patient's peri-operative surgical experience.

By describing and comparing pain scores, drowsiness, nausea and vomiting and pruritus in patients undergoing laparoscopic gynaecological procedures for reasons other than laparoscopic tubal ligations, we aim to establish if laparoscopic tubal ligation surgery is indeed associated with worse pain and may provide the stepping stone for a movement away from a 'blanket' analgesic approach for all gynaecological laparoscopic procedures.

Data from the PAIN OUT database compiled at RMMCH on patients who had undergone a laparoscopic gynaecological procedure was retrospectively reviewed. PAIN OUT is a data registry. The framework of PAIN OUT is to create a web-based database, the 'Pain Registry'. Data is obtained from various hospitals around the world. The aim of the registry is to provide reliable information about the occurrence and severity of post-operative pain. It may also be used to identify gender and age-related differences in treatments and outcomes in post-operative pain. The main focus of the registry is to improve the management of post-operative pain. The same Standard Operating Procedure (SOP) and questionnaires are utilised internationally to standardise results.

1.2. Problem Statement

The appropriate analgesia strategy for laparoscopic tubal ligations has not been identified. The analgesic approach employed should address the unique risks and complications associated with a laparoscopic procedure. However, complications of the anaesthetic technique itself as well as potential side effects of strategies employed for post-operative pain cannot be ignored. These considerations are particularly important in the demographic of women undergoing laparoscopic tubal ligation surgery.

Pain (Numeric rating scale) scores as well as the occurrence and severity of post-operative nausea and vomiting, drowsiness and pruritus after laparoscopic tubal ligations is not known in our setting nor is the occurrence of these variables known in patients undergoing laparoscopic gynaecological procedures for reasons other than laparoscopic tubal ligations.

1.3. Aim

The aim of this study was to establish patient pain scores after laparoscopic gynaecological surgery as well as to describe the incidence and severity of side effects such as nausea and vomiting, drowsiness and pruritus.

1.4. Objectives

The primary objective of this study was to:

- a) Describe patient pain scores after laparoscopic gynaecological surgery
- b) Estimate the frequency and severity of side effects after laparoscopic gynaecological surgery
- c) Describe the demographics of women undergoing laparoscopic gynaecological surgery
- d) Describe perioperative analgesia used for laparoscopic gynaecological surgery at an academic training hospital

The secondary objective of this study was to:

- a) Compare the above variables in patients presenting for laparoscopic gynaecological procedures other than laparoscopic tubal ligations to the results of patients presenting for laparoscopic tubal ligation surgery.

1.5. Research Assumptions and Research Definitions

PAIN OUT – International research project designed to create a web based ‘Pain Registry’ with the aim to provide reliable information regarding effective pain management.

Standard Operating Procedures (SOP’s) – Manual intended as a guide for staff in clinical sites participating in the PAIN OUT study. The SOP provides background information on the study, describes the questionnaires used and provides guidance and advice on data collection

Patient outcome questionnaire – Questionnaire filled out by patients. The questionnaire is completed without assistance.

Process questionnaire – Collected from the patients’ medical records by a trained research assistant. Administrative information, including demographics, patient history and medication use

Numeric (pain) Rating Scale (NRS) – Patients are asked to make three pain ratings which correlates to current pain experienced, worst pain experienced, and

best pain experienced over the previous twenty four hours. The average of the three ratings is used to represent the patient's pain score. Patients are asked to rate their pain on a scale from 0 (no pain) to 10 (worst pain imaginable) (21).

1.6. Demarcation of Study Field

This study was conducted on data obtained from the PAIN OUT database. The database was compiled from questionnaires completed by each patient and a trained investigator on patients who underwent laparoscopic gynaecological procedures at RMMCH.

RMMCH is a tertiary academic hospital located in Coronationville, Gauteng. It is affiliated to the University of the Witwatersrand.

1.7. Ethical Considerations

Application to conduct the study was made to the Postgraduate Office of the Faculty of Health Science and the Human Research Ethics Committee (Medical) at the University of the Witwatersrand.

Approval to access stored records on data collected from patients having undergone laparoscopic gynaecological procedures was obtained from the gatekeeper of the PAIN OUT registry which was carried out at the hospital concerned.

This was a retrospective study. Only the researcher and supervisors of the study have access to the raw data. There is no identifying patient data on the database and the data therefore remained confidential.

This study was conducted according to the principles of the South African Guidelines for Good Clinical practice (22) and the Declaration of Helsinki (23).

1.8. Research Methodology

Research design

A research design ensures that the problem statement is effectively addressed. It is a strategy selected to incorporate the various aspects of a study into a coherent whole.

'It constitutes the blueprint for the collection, measurement, and analysis of data' (24) (25).

For the purposes of this study a retrospective, descriptive study was used. It is contextual in nature.

The researcher collected data from past records as is the case with a retrospective study. Data was collected from the PAIN OUT data registry compiled from Patient Outcome Questionnaires which patients who met the inclusion criteria completed as well as process questionnaires which investigators completed from data obtained in the patients file. Both these questionnaires were completed for each patient who was included in the PAIN OUT study.

In a descriptive study the researcher defines the sample but does not manipulate any variables in any way. The intention of the study is for variables to be described (26).

The objectives of this study were to describe post-operative experiences of patients undergoing laparoscopic gynaecological procedures at an academic training hospital with special emphasis on laparoscopic tubal ligations. No intervention was instituted.

The study was contextual as it focused on a particular group of people (27). It set out to describe the post-operative experiences of women undergoing laparoscopic gynaecological procedures at Rahima Moosa Mother and Child Hospital (RMMCH), a hospital affiliated to the University of the Witwatersrand

Study Population

The study population consisted of women undergoing laparoscopic gynaecological procedures at RMMCH. A special emphasis and the primary study population was women undergoing laparoscopic tubal ligation surgery.

Information was obtained from the PAIN OUT data base.

Information regarding post-operative pain scores and side effects of nausea and vomiting, drowsiness and pruritus was obtained from the data base. Demographic data of patients under review as well as perioperative analgesia used were also obtained from the data registry.

Study Sample

Sample Size

A minimum of 62 patients in total were required for the study based on a proportion of 50%±20% of patients experiencing pain and side effects of opiates described with a power of 90% and a significance level of 5%. A majority of patients presenting for laparoscopic gynaecological procedures are laparoscopic sterilisations. Therefore, a minimum of 37 patients undergoing laparoscopic tubal ligation surgery were to be included. However (as explained below), consecutive, convenience sampling was used and all patients for which data was collected were included in the study over a specified period of time.

Sample Method

Convenience sampling refers to the inclusion of the most readily available patients. This is done in a non-random manner. Consecutive sampling means that an attempt is made to include every patient meeting the inclusion criteria until the sample size is achieved (28).

For purposes of conducting the research all patients for whom data was captured (convenience sampling) who had undergone a laparoscopic gynaecological procedure at RMMCH and who met the inclusion criteria (consecutive sampling) were reviewed. Patients who presented for laparoscopic tubal ligation surgery were singled out as the primary focus of the study.

Inclusion and Exclusion Criteria

Inclusion Criteria

As per the PAIN OUT study inclusion criteria, all women who underwent laparoscopic gynaecological procedures at RMMCH who fulfilled the following criteria:

- Time of data collection was on the first post-operative day
- The patient was in the ward for a minimum period of 6 hours after the procedure.
- The patient was of consenting age or over (18 years for purposes of the study)
- The patient had consented to participate in the study

- The patient outcome questionnaire as well as the process questionnaire were completed and were available.

Exclusion Criteria

All patients who did not fulfil the inclusion criteria of the PAIN OUT study were already excluded from the database.

Data Collection

Data collection resumed once approval was granted by all necessary parties.

Each patient's record in the database who underwent a laparoscopic tubal ligation was identified by an International Classification of Diseases (ICD) code unique to that procedure. ICD codes for patients who presented for laparoscopic gynaecological procedures other than tubal ligation surgery were identified for the specific procedure so as to establish the nature of procedures included in the group. These patients were however grouped as one.

Relevant information obtained from the PAIN OUT data registry that allowed the researcher to achieve the objectives was consolidated on a data collection sheet (Appendix F).

Each record was assigned a study number. This was recorded together with the results on a Microsoft Excel™ spreadsheet. During data analysis only the study number was used.

The data collection sheet is included as Appendix F.

Data Analysis

Data was captured and recorded on a Microsoft Excel™ spreadsheet. In conjunction with a bio - statistician, data was analysed using the GraphPad InStat™ program.

Descriptive statistics was used to analyse the data.

Categorical data was summarised using frequencies and percentages. Normally distributed continuous variables were summarised using means and standard deviations. Continuous variables that are not normally distributed were summarised using medians and interquartile ranges.

Comparisons, where statistically powered were done using t – tests or Mann – Whitney tests as appropriate.

Pain and side-effect scales were expressed as medians (range and Interquartile range [IQR]). A p-value was established using the Wilcoxon matched pairs signed rank test for the difference between the pain scores for worst and least pain experienced. Data for intra-operative and post-operative analgesia was expressed as % (number) and a median with (IQR). When comparing data for laparoscopic tubal ligation (TL) surgery with laparoscopic gynaecological procedures for reasons other than laparoscopic TL surgery, all p-values are from the Mann – Whitney comparison for non – parametric data.

1.9. Significance of the study

Anecdotal evidence reveals a trend toward performing Tubal Ligation procedures laparoscopically in our setting with the primary aim of expediting a safe hospital discharge. Laparoscopic tubal ligation surgery is appropriate for day case or outpatient surgery (6) (7).

However, post-operative pain and side effects of the analgesic approach employed can render this aim un–achievable. It is therefore imperative to establish the occurrence and severity of these parameters to allow for beneficial alterations of the anaesthetic technique in future.

Developing an understanding of patients' experiences following laparoscopic tubal ligation surgery in our resource constrained setting is the first step towards improving the analgesic strategy utilised for these surgeries, and thereby aiming to improve the patient's peri- operative surgical experience.

Describing patient's experiences following all laparoscopic gynaecological procedures and comparing these to patients undergoing laparoscopic tubal ligation surgery aims to give the health care practitioner a better understanding so the strategy for analgesia employed may be tailored for these procedures to expedite the overall aim.

1.10. Validity and Reliability of the Study

The validity of a study is the extent to which the instrument accurately reflects the variables that are to be measured (29).

Reliability is how consistently a technique measures either a variable or a concept (29).

Reliability and validity of the study was ensured in the following ways:

- Only the researcher and/or supervisors and/or gatekeeper of the raw data filtered the ICD code related to the specific procedure under review from the Microsoft Excel™ programme it was captured on.
- Aspects of the patient outcome questionnaire and process questionnaire that were under review was largely obtained by the patient or health care worker having to tick a box. Demographic data, drugs used, and procedures which the patient presented for required an objective answer.
- Health Care workers who completed the Process Questionnaires did so as per the Standard Operating procedures (SOP) of the PAIN OUT study.
- All patients had the surgery between 8am and 1pm on a Wednesday morning. All data was collected (the patient outcome questionnaire as well as the Process questionnaire) the following day at approximately the same time.
- By virtue of a retrospective study, information may not be altered to achieve a certain outcome.
- The same data collection sheet was used for each record to ensure consistency and allowed for standardisation of data collection.
- A single researcher compiled the data collection sheet for each patient ensuring it was done in a standardised manner.
- Every tenth data sheet was checked to ensure the data is accurately captured
- Data was analysed under the guidance of a statistician.

1.11. Potential Limitations

Limitations are ‘...shortcomings, conditions or influences...that place restrictions on your methodology and conclusions’ (30). They are often influences that are not within the researcher’s control (30).

Retrospective nature of the study – various limitations exist in the form of incomplete

documentation and problems with verifying information.

Contextual nature of the study – generalisation of results was difficult as the study is limited to the population presenting to RMMCH specifically.

Most laparoscopic gynaecological procedures were performed on a Wednesday morning between 8 am and 12 am at RMMCH. However, data was collected at any point the following day as long as the patient was in the ward for at least six hours post-procedure and the data was collected on the first post-operative day. The discrepancy between patients in the time elapsed between surgery and data collection may have resulted in differences in pain scores and side effects reported.

Another limitation was relying on completed patient outcome questionnaires and process questionnaires. An assumption was made that all patients who answered the questionnaires understood what the question was asking of them and that all health care workers who completed the process questionnaires did so diligently as per the standard operating procedure (SOP) of the PAIN OUT study.

Even though consecutive, convenience sampling was used (the strongest form of convenience sampling), convenience sampling in itself may be a limitation.

1.12. Project Outline

Time Frame

Task	Nov-16	Dec-16	Feb-17	Mar-17	Apr-17	May-17	Jul-17	Aug-17	May-18	Jun-18
Proposal										
Literature Review										
Proposal submission										
Ethics committee										
Postgraduate Committee Submission										
Data Collection										
Data Analysis										
Article										

Task	Nov-16	Dec-16	Feb-17	Mar-17	Apr-17	May-17	Jul-17	Aug-17	May-18	Jun-18
Editing										
Submission										

Financial Plan

Costs for the study included paper and printing costs

The Department of Anaesthesiology at the University of the Witwatersrand bore the costs of paper and printing

	Cost per page	No. of pages	No. of Copies	Total Cost
Proposal	R1	20	10	R200
Ethics Form	R1	10	25	R250
Postgraduate form	R1	1	6	R6
Finalised Report	R1	90	4	R360
Binding	R1	R150	3	R450
Grand Total				R1266

Section 2: Literature Review

2.1 Introduction

Laparoscopic surgery is defined by the medical dictionary as an 'operative procedure performed using minimally invasive surgical technique for exposure that avoids traditional incision; visualization is achieved using a fiber optic instrument, attached to a video camera' (31).

The introduction of laparoscopic surgery was during the early 1900's. Christian Jacobeus, George Kelling and Dimitri Ott initially described the technique. In 1901, the abdominal cavity of a pregnant women was inspected by Von Ott (32). Kelling and Jacobeus described the technique in the same year (32). Jacobeus, from Stockholm, was the first to report in 1910 the inspection of the peritoneum, pleura and pericardium laparoscopically in humans (17). Initially, a majority of laparoscopic procedures were performed for diagnostic purposes (32), however, tubal sterilisations and treatment of endometriosis were both performed laparoscopically fairly early on (33). For the most part, gynaecologists developed the instrumentation, techniques and operating principles of operative laparoscopy (17). It was popular for gynaecological procedures earlier on and later gained popularity in the field of general surgery (32).

Although laparoscopic surgery was only formally introduced in 1991 in South Africa when a number of workshops were held in Groote Schuur, Johannesburg and Pretoria, the origins of laparoscopic surgery in South Africa go back to 1940 when a sympathectomy was performed thorascopically by Bob Goetz. There is record of Jack Heselson performing a diagnostic laparoscopic procedure in the 1960's in South Africa (17).

Statistics regarding laparoscopic procedures in South Africa are sparse but following international trends, anecdotal evidence suggests an increase in the number of procedures performed laparoscopically as well as a rise in the number of laparoscopic gynaecological procedures.

Patients may present for laparoscopic gynaecological procedures for various reasons which may include diagnostic procedures, therapeutic procedures or a combination of

the two where a diagnostic laparoscopic procedure is initially performed and depending on the finding, an appropriate intervention may be instituted.

Data published in 1998 by Chapron et al. (34) revealed results of a series of 29 966 cases of diagnostic and operative gynaecological laparoscopic procedures performed between the January 1987 and December 1995. Diagnostic gynaecological laparoscopic procedures comprised 19.9% of the cases, minor laparoscopic procedures comprised 19.8% of the total number of procedures, major laparoscopic procedures constituted the majority at 48.8% and advanced laparoscopic procedures were the least at 11.5%.

The appeal of day-case surgery is increasing world-wide with escalating health care costs and advances in anaesthetic and surgical techniques. The cost-effective benefit of day-case surgery is well recognised (7). Numerous surgical procedures are amenable to day-case surgery. Endoscopic approaches for procedures are especially well suited to day-case surgery because of the numerous advantages the surgical approach confers (7). Many gynaecological procedures may be performed laparoscopically and may meet requirements to be carried out as day-case procedures.

Tubal ligations are elective surgical procedures that are often performed on healthy women who play vital roles in their respective family structures and who are significant contributing members to the country's economy. A study by Edwards et al. (1991, United States of America [USA]) (2) surveying post-operative pain in women undergoing diagnostic laparoscopic procedures as well as laparoscopic sterilisations revealed the mean age of women undergoing laparoscopic tubal ligations recruited to the study was 33.2 years old. In another study by Higgins et al. (1994, Baltimore) (35) 50 patients undergoing laparoscopic tubal ligation surgery had a mean age of 32,5 years old.

With continued feminisation of the labour force in South Africa (3), women in this age group contribute significantly to our economy and are often mothers to younger children who require care and nurturing. It is imperative for them to expeditiously return to a pre-surgical level of function. A day-case laparoscopic technique may facilitate this aim.

In a study by Rognas et al. (2004, Denmark) (36) data on 681 women who were sterilised laparoscopically on a day-case basis was reviewed. Of these patients, eleven required overnight admission for complications or side effects related to the surgery or anaesthetic approach.

As many as 50% of patients may experience wound pain 24 hours after laparoscopic surgery (37). Post-operative pain is the most commonly reported complication of ambulatory or day-case surgery and anaesthesia (37).

There is substantial evidence in published data concerning side effects of opiate use such as nausea and vomiting, pruritus and sedation (38).

Hospitalised patients who experience opiate related adverse events have been found to have poorer clinical outcomes than patients who experienced no adverse events (39). Among post-surgical patients, opiate related adverse events may increase the risk of in-patient mortality by 3.4 times. In addition, opiate related adverse events have been found to increase 30-day readmission rates by 36%, hospital stays by 55% and health care costs by 47% (39).

Dolin et al. (2005) (38) identified over 800 original papers and reviews of published articles concerned with post-operative pain management. Of the 800 papers, data was extracted from 183 studies related to post-operative nausea and vomiting (PONV), 89 related to sedation and 166 related to pruritus. The overall mean incidence of nausea was 25.2% and of emesis or vomiting was 20.2%. Sedation was classified as either mild or excessive. The mean for mild sedation was 23.9% and for excessive sedation, 2.6%. The overall mean incidence of pruritus was 14.7%. From a review of published data in excess of 100 000 patients, the authors stated it is possible to set standards of care after major surgery for nausea (25%), vomiting (20%), minor sedation (24%), excessive sedation (2,6%) and pruritus (14,7%). Where the aim is to adequately manage acute pain, practitioners should strive to achieve incidences of side effects lower than these standard of care values.

Literature pertaining to laparoscopic surgery will be reviewed with particular emphasis on the advantages of the technique over a more traditional open approach. A more in-depth review of the literature pertaining to the laparoscopic sterilization patient population will be included. The anaesthetic technique and options for laparoscopic

procedures will be included as it is crucial to gain an understanding of the topic at hand.

Laparoscopic surgery should allow for an earlier hospital discharge. Most gynaecological laparoscopic procedures should be amenable to day-case surgery. Therefore, literature regarding day-case surgery will be reviewed as well as potential reasons for a delay in hospital discharge. The objective of an earlier, safer hospital discharge may only be achieved with the proviso that the anaesthetic technique is not inadequate (especially with regard to analgesia) but also that it does not result in or potentiate undue complications such as pain, nausea and vomiting, drowsiness and pruritus. These will be specifically reviewed in the literature as they may relate to both the analgesic approach utilized for patients undergoing laparoscopic gynaecological procedures as well as the laparoscopic surgery itself. They may be significant contributing factors to a delay in hospital discharge and may contribute to negative patient experiences and outcomes.

PAIN OUT, an international research project forms the basis of this MMED. A literature review that excludes information on what the PAIN OUT project is would be incomplete.

2.2 Laparoscopic Surgery

2.2.1 Advantages

Laparoscopic surgery is associated with numerous advantages over a more traditional open surgical approach. It is minimally invasive; the healing process is less painful and recovery from surgery is more rapid (1). There are numerous reasons for a more rapid recovery. This includes (but is not limited to) reduced manipulation of the bowel and peritoneum which results in lower rates of post-operative ileus (8). Results of a multicenter trial to assess the safety and benefit of a laparoscopic technique compared with an open technique for colon resection for curative treatment of patients with cancer of the right or left colon revealed that laparoscopic colectomy was associated with recovery of bowel function earlier on. The mean number of days to the patient's first bowel movement post-operatively was 3.6 days for laparoscopic procedures and 4.6 days for a laparotomy. The mean difference was one day ($p < 0.0001$) (40). As a result, patients may be fed via an enteral route earlier than with open surgical

techniques, limiting the requirements for intravenous fluids which may be associated with oedema, poor wound healing and a prolonged post-operative recovery time (8).

Two groups of investigators evaluated management of ectopic pregnancies in randomised controlled trials. Vermes et al. (17) randomised 30 patients to undergo salpingostomy for ectopic pregnancies laparoscopically and 30 patients by laparotomy. Although the complication rates were similar in both groups, the group who underwent the laparoscopic salpingostomy had shorter recuperation rates and hospital stays (17). Veldkamp et al. (2005, Netherlands) (40) supported these findings in patients who underwent laparoscopic colectomies. They had shorter hospital stays, a mean difference of 1.1 days, ($p < 0.0001$), when compared to patients who had open colectomies.

There is a lower incidence of post-operative wound infections associated with laparoscopic surgery (8). A retrospective analysis by Varela (41) of a database of patients who underwent laparoscopic or open surgeries between 2004 and 2008 included over 131 000 patients. Patients treated laparoscopically were 72% less likely to experience a surgical site infection. The incidence of surgical site infection was 0.5% after a laparoscopic procedure as compared to 1.8% after an open surgery. This was maintained after stratification by severity of illness, admission status and wound classification. A more aesthetically pleasing cosmetic result is an added benefit to laparoscopic procedures (42).

A variety of physiological and immunological alterations that should contribute to the patient's host defense is evoked by the trauma of surgery. Tissue trauma may be as a result of the incision site, dissection of tissues, manipulation of organs, ischaemia and hypoxia caused by vascular compromise and exposure to air, to mention a few. An exaggerated response to the trauma of surgery may result in immunosuppression as negative feedback loops are initiated to deal with the hyper-inflammatory state. The resulting immunosuppression may significantly contribute to post-operative morbidity and mortality (42).

Surgical stress may alter the function of both mononuclear and polymorphonuclear cells which are important for the prevention of post-operative infections. Laparoscopic surgery induces a smaller injury and therefore a proportionally reduced immunological change and response. Comparative analysis of cellular immunity after laparoscopic surgery and more traditional open techniques demonstrates immunologic advantage

conferred by laparoscopic techniques as evidenced by consistently lower levels of inflammatory cytokines postoperatively after laparoscopic procedures, indicating a smaller degree of surgical insult and acute inflammatory reaction. In addition, when laparotomy is avoided, functions of peritoneal macrophages are better preserved (42).

Furthermore, a reduction in the severity of post-operative pain and earlier mobilisation and functional recovery of patients who have undergone laparoscopic procedures may be attributed to a reduced inflammatory response and lower levels of immunosuppression (42).

Laparoscopic procedures have been demonstrated to result in less post-operative pulmonary dysfunction, a speedier recovery of pre-operative pulmonary function levels and lower levels of atelectasis than open surgery (43). Post-operative pain is reduced, and opiate requirements are often lower as a result. Mais et al. (1996, Italy) (44) conducted a study on 40 women who presented for a myomectomy and compared post-operative pain after laparoscopic myomectomies and myomectomies performed via a laparotomy. They assessed patients on day 0, 1, 2 and 3 after surgery. Post-operative pain intensity was higher after laparotomy than after laparoscopic procedures ($p < 0.05$). Patients undergoing the laparoscopic procedure required a mean of 1.9 analgesic injections post-operatively as compared to a mean of 4.1 injections after a laparotomy. A larger ($p < 0.05$) proportion of patients did not require analgesia on the second post-operative day (85% vs. 15%), were discharged from hospital on the third post-operative day (90% vs. 10%) ($P < 0.05$) and feeling fully recovered on day 15 (90% vs 5%) ($p < 0.05$) after laparoscopy compared with laparotomy.

All these added benefits may facilitate earlier mobilisation and ambulation and chest physiotherapy if required (45). This data may be extrapolated to women who present for laparoscopic gynaecological surgery, especially women who present for laparoscopic sterilisations as they are often healthy, younger women with little or no premorbid pathology (2) (3).

A reduction in adhesion formation is another important advantage of laparoscopic surgery. Surgical procedures result in trauma at the operative site. It has been proposed that the localised hypoxia that occurs at these sites suppress fibrinolysis. Fibrin deposition persists between adjacent tissue surfaces and with organisation of these deposits adhesions are formed. Formation of adhesions is a common problem after surgery and may present with complications that often require re-admission. The

complications especially in women who present for gynaecological procedures may include infertility, chronic pelvic pain and intestinal obstruction, to mention a few of the more common complications. With laparoscopic surgery, trauma is reduced, and adhesions may be prevented (46). In a study by Lundorff et al. (17), 73 patients underwent a second laparoscopy to evaluate adhesion formation. The initial surgery had been for ectopic pregnancy. Adhesions involving the ipsilateral tube were less common in patients who had prior laparoscopic treatment than in patients who had a laparotomy as operative management (17).

A major advantage to the individual patient but also to institutions at large is the economic benefit of having patients discharged safely and earlier on along the period of recovery. There are also economic benefits when one looks into the cost saved from fewer complication rates (8). Maruri and Azziz (1993) (47) looked at the economic benefits of treating ectopic pregnancies via a laparoscopic route. They looked at all laparoscopic pregnancies performed in 1987 in the United States and found that the economic benefit of laparoscopic treatment of ectopic pregnancies is well recognised when compared with treatment via a laparotomy. The benefits include fewer days in hospital, faster recovery times, and better cosmetic outcomes. The cost-benefit analysis indicated a savings of \$105,600,000.00 in direct hospitalization costs and \$65,000,000.00 in increased employer or patient income because of a more rapid return to work time. Furthermore, they elaborated that savings in decreased home care requirements could not be calculated.

Literature regarding the actual economic benefits of laparoscopic surgery in South Africa is not freely available. A study conducted in the South African setting by Snyman et al. (48) compared women who were thought to have a ruptured ectopic pregnancy and were treated either with a laparoscopic technique or a laparotomy. The time it took to perform the procedure, the total length of time spent in hospital, the amount of analgesia and blood products required, post-operative pain scores and how long it took for patients to fully recover and return to their places of employment were all measured. These factors all have economic implications.

Laparotomies were performed quicker than laparoscopic procedures (30.5 compared to 67.3 minutes, $p < 0.001$) (48). The longer operating time may result in an increased cost to the facility. However, pain scores, length of hospital stay and analgesic requirements were significantly lower in the laparoscopy group (48). Without actual

figures to compare, the exact saving may not be known. However, the benefits of a reduced hospital stay and less analgesic requirements would result in a cost saving. In addition, when comparing laparoscopy with laparotomy, women in the former group returned to work eight days earlier and the time to full recovery was significantly longer in the laparotomy group. The number of women requiring blood transfusions was significantly less in the laparoscopic group. In the laparotomy group, 26.5% of women required blood transfusion compared with only 14.5% in the laparoscopy group ($p=0.01$) (48). This will result in a significant cost benefit especially in a resource constrained environment such as the South African economic climate.

2.2.2 Physiological Changes

Laparoscopic surgery is associated with a number of physiological changes which are of special interest from an anaesthetic point of view. Knowledge of the physiological changes that may occur may allow for anticipation of potential complications and guide the anaesthetic technique employed.

Table 1 summarises the effects of Carbon Dioxide insufflation on various organ systems.

Table 1: Summary of the organ systems affected by insufflation of Carbon Dioxide (15)

Organ System	Effect
Cardiovascular	↑ Systemic Vascular Resistance (SVR) ↓ Preload → ↓ Cardiac Output and Arterial Blood Pressure ↑ Pulmonary Vascular Resistance (PVR)
Respiratory	↓ Pulmonary Compliance ↓ Functional Residual Capacity → Pulmonary atelectasis, Altered ventilation and perfusion relationships, Hypoxaemia ↑ Carbon Dioxide (Insufflated Carbon Dioxide is absorbed)
Splanchnic	↓ Blood flow to Kidney → Acute Kidney Injury ↓ Blood flow to Liver Tissue acidosis (reduced mesenteric and

Organ System	Effect
	gastrointestinal mucosal blood flow)
Neurological	↑ Intra-Cerebral Pressure → Cerebral Oedema Temporary neurological dysfunction

Key: ↑ Increased/ Elevated; ↓ Reduced

2.2.3 Risks and Complications

The risks associated with laparoscopic surgery may be categorised into five categories. These include patient specific risks, surgical risks, positional risks (surgeons often require extremes of position such as Trendelenburg or reverse Trendelenburg positions), risks associated with altered physiology as a result of creation of a pneumoperitoneum and risks associated with a combination of the above-mentioned risks (8).

Complications may be more insidious when compared with more traditional open approaches and it is imperative to maintain a high index of suspicion (8).

Results from a prospective multicenter observational study at 72 hospitals conducted in The Netherlands over a period of one year to evaluate complications after laparoscopic gynaecological procedures revealed the following (49):

Table 2: Complications after laparoscopic gynaecological procedures (49)

Complication	Rate: Number (%)
Death	2 (0.008)
Necessity to convert to laparotomy	84 (0.33)
Haemorrhage of epigastric vein and intestinal injury	Most frequently observed complications, 90% required conversion to a laparotomy
Complication rate for diagnostic laparoscopic procedures	(2.7)
Complication rate for sterilisations	(4.5)
Complication rate for operative laparoscopy	(17.9)

Complication	Rate: Number (%)
Complication total	145 (0.56)
Total number of laparoscopic procedures	25 764

Data published in 1998 by Chapron et al. (34) revealed results of a series of 29 966 cases of diagnostic and operative gynaecological laparoscopic procedures.

The results published of the complications were based on the type of laparoscopic surgery i.e. diagnostic, minor, major and advanced laparoscopic gynaecological procedures.

Table 3: Complication Rates of gynaecological laparoscopic surgery based on type of laparoscopic gynaecological surgery (34)

Laparoscopic procedure	Total Number Performed	Complications Per 1000
Diagnostic laparoscopy	5983	1.84 (N=16)
Minor laparoscopic procedures	5922	0.84 (N=5)
Major laparoscopic procedures	14622	4.3 (N=63)
Advanced laparoscopic procedures	3439	17.45 (N=60)
Total	29966	4.64 (N=139)

Table 4 summarises surgical risks as well as risks associated with positioning in patients undergoing laparoscopic procedures.

Table 4: Surgical risks and risks associated with positioning in patients undergoing laparoscopic procedures (8)

Surgical Risks	Risks associated with positioning
• Damage to solid viscera • Damage to bowel or bladder • Vascular injury → haemorrhage • Retroperitoneal haematomas →	• Injury at pressure points • Injury to eyes • Cerebral oedema • Upper airway oedema → post-

Surgical Risks	Risks associated with positioning
haemorrhage • Venous gas embolism → Circulatory arrest	operative stridor • Migration of tracheal tube • Lower limb compartment syndrome REVERSE TRENDELENBURG • Hypotension • Myocardial and cerebral ischaemia

Risks associated with altered physiology of the pneumoperitoneum arise as a result of insufflation of Carbon Dioxide to allow for sufficient visualisation. The Carbon Dioxide insufflation results in increased abdominal pressure which may compromise individual organ systems (8).

2.3 Anaesthesia for Laparoscopic Surgery

The anaesthetic technique employed for patients presenting for laparoscopic gynaecological procedures should accommodate surgical requirements but it should also allow for physiological changes that may occur during the procedure that may either be as a result of the position that is required or as a result of creation of a pneumoperitoneum (19).

In addition, recovery from anaesthesia should be rapid in order to facilitate the operative aim of an earlier hospital discharge and there should be very few (if any) residual effects of the anaesthetic in order to meet discharge criteria and facilitate a safe hospital discharge (19).

2.3.1 Anaesthetic Considerations for Laparoscopic Surgery

The choice of anaesthetic technique for most laparoscopic surgeries is a general anaesthetic. It consists of a cuffed endotracheal tube, muscle relaxation with a neuromuscular blocking agent and controlled, intermittent positive pressure ventilation (17, 8, 19).

A general anaesthetic is preferred as there may be a degree of patient discomfort associated with creation of a pneumoperitoneum (17). The cuffed endotracheal tube protects against gastric acid aspiration (8).

Ventilation may often be challenging during laparoscopic gynaecological procedures due to creation of a pneumoperitoneum but also due to positioning that the surgeons may require (8).

Hypercarbia may be induced by several factors including absorption of Carbon Dioxide from the peritoneal cavity, depression of ventilation by the administration of anaesthetic agents and mechanical impairment of ventilation by the creation of a pneumoperitoneum and positions such as steep Trendelenburg positions (17). Positive pressure ventilation allows for control of pulmonary ventilation to allow for optimal control of Carbon Dioxide. It has also been shown to improve alveolar recruitment and oxygenation. In addition, peak pressures are minimised and higher instantaneous flow peaks may be achieved (8, 19).

The anaesthetist should bear in mind that there is a possibility that the procedure may have to be converted from a laparoscopic procedure to a laparotomy for various reasons (19). This potential eventuality should be anticipated and appropriately prepared for.

The incidence of laryngospasms (especially on emergence), coughing and voice changes post-operatively is clinically and statistically significantly reduced when a Laryngeal Mask Airway (LMA) is used instead of an Endotracheal Tube (ETT) (50).

The numerous advantages of a regional anaesthetic approach over a general anaesthetic with a cuffed endotracheal tube are mentioned below. An additional consideration would be the cost saving of a regional technique over a general anaesthetic in terms of number of anaesthetic agents used as well as equipment required for each approach (51).

All things considered i.e. the potential risks of a cuffed ETT tube and general anaesthetic as well as the advantages of either a LMA or a regional in comparison makes use of an alternate option more appealing where possible.

The use of regional anaesthesia has emerged as an alternative choice for laparoscopy. Various reports suggest the safety of the use of spinal, epidural and combined spinal-epidural anaesthesia in laparoscopic procedures. This was revealed in a study published by Bajwa and Kulshrestha (2016) (52). They published a review article on anaesthesia for laparoscopic surgery, specifically comparing a regional and general technique. A prospective randomised study by Arati et al. (2009, India) (53) revealed

results of a comparative analysis of spinal and general anaesthetic techniques for laparoscopic cholecystectomy. In a total of 100 patients, complications of 50 spinal and 50 general anaesthetics were compared and noted:

Table 5: Post-operative adverse events in patients undergoing laparoscopic cholecystectomy under a spinal or general anaesthetic (53).

Post-operative events	Spinal Anaesthesia	General Anaesthesia
Nausea and Vomiting	10%	8%
Right Shoulder Pain	8%	6%
Urinary Retention	4%	0%
Post Spinal Headache	2%	0%
Respiratory Depression	0%	0%

The following table highlights adverse events that may be experienced by patients undergoing laparoscopic cholecystectomies under a spinal anaesthetic technique.

Table 6: Intra-operative adverse events in patients undergoing laparoscopic cholecystectomy under a spinal technique (53).

Intra-operative adverse events	Percentages (%)
Shoulder Pain	18
Hypotension	8
Hypertension	0
Bradycardia	16
Abdominal Pain	6
Conversion to GA	4
Operative Difficulty	4

The advantages of regional anaesthesia includes: effective pain control in the post – operative period, prevention of airway manipulation, lower levels of nausea and vomiting, an awake and spontaneously breathing patient intraoperatively and early ambulation and recovery. However, regional anaesthesia may be associated with side effects such as shoulder pain as a result of diaphragmatic irritation, the requirement of a higher sensory level with associated relatively severe hypotension, shoulder

discomfort due to diaphragmatic irritation, and organ compromise caused by pneumoperitoneum (52).

The following table outlines the sample size of various studies comparing general and spinal anaesthetic techniques for laparoscopic procedures as well as the year in which the study was published.

Table 7: Studies comparing general and spinal anaesthetic techniques for laparoscopic procedures

Study	Year	Sample size
Sinha et al. (54)	2008	4645
Turkstani et al. (51)	2009	50
Imbelloni et al. (55)	2010	68
Ellakany (56)	2013	40

Adequate analgesia, lower opiate consumption and better pain scores are desired end points of any anaesthetic technique. All the above studies found significantly lower pain scores with lower analgesic consumption in the post – operative period in patients who received a spinal anaesthetic (51, 54-56). In addition, the surgical conditions were comparable between the two groups (56). The total length of hospital stay was not significantly different but the total cost of anaesthesia was significantly less in the spinal anaesthesia group (51). Sinha et al. (2008) (54) concluded that spinal anaesthesia is a safe option with numerous advantages over a general anaesthetic technique in the correct patient population. In addition, significantly fewer patients experienced vomiting compared with those under a general anaesthetic.

Shoulder tip pain and hypotension are side effects that may be worse in the case where a regional anaesthetic is employed (52).

Table 8 compares the incidence of various side effects (based on various studies) in patients receiving a spinal anaesthetic technique for laparoscopic procedures.

Table 8: Comparison of side effects of Nausea and Vomiting, Shoulder Pain and Hypotension among different authors in patients receiving a Spinal anaesthetic for a laparoscopic procedure

Complication	Arati (53)	Ellakany (56)	Imbelloni (55)	Sinha (54)	Turkstani (51)
Nausea and Vomiting	10%	0%		2.09%	
Shoulder Pain	8%		47%	12.29%	48%
Hypotension	8%	40%	41%	18.21%	32%

The above studies mentioned suggest that regional anaesthesia may be considered comparable to a general anaesthetic technique in laparoscopic procedures. This is with special regard to complications (both intra- and post-operative), surgical conditions and the duration of time spent in hospital, but may be superior to general anaesthesia with respect to post-operative analgesia, nausea and vomiting and an expedited recovery.

An additional consideration is that in order to reduce the discomfort associated with creation of a pneumoperitoneum and surgical stimulation of gastrointestinal structures, a higher level of blockade is required (T2-T4). The higher block may produce myocardial depression which may be detrimental especially because creation of a pneumoperitoneum already compromises cardiac function (19). No studies reviewed in the literature for the purpose of this review mentioned respiratory discomfort or patient dis-satisfaction as a result of respiratory discomfort.

In an article by Cunningham (1998) (17) on the anaesthetic implications of laparoscopic surgery, it is stated that higher levels of sympathetic denervation induced by an epidural block where lignocaine was used, circulatory and ventilator responses to Carbon Dioxide in awake, healthy patients were not impaired. The author goes on to describe data of seven healthy females who had an epidural for a laparoscopic tubal ligation procedure with no significant changes in ventilator variables even while in a Trendelenburg position.

2.4 Day-Case Surgery

The cost-effective benefit of laparoscopic surgery is well recognised (7).

Costs were reduced to 45% – 70% of in-patient costs in patients who had hernia repairs performed as day-case procedures (57). Reductions in the length of hospital stay reduces hospital costs per case. However, there may be 'knock on' effects or costs transferred to others who are in caring positions, including nurses, the patient's GP (general practitioner) and carers who assist at home. In addition, there may be social costs or savings linked to the time patients and their family members or care givers are away from work (57).

Discharge of patients after day-case procedures includes consideration on recovery post anaesthesia. Certain criteria need to be met prior to allowing a patient to leave the health care facility. Excessive fatigue or sedation, nausea, vomiting or intolerable, unrelieved pain are some of the most common reasons for a delay in hospital discharge and account for many unexpected hospital admissions (7). Major advances in anaesthetic techniques such as use of short acting agents and more widespread use of local or regional techniques may allow for more cases to be performed as day-case procedures by minimising factors that usually result in admission (7).

2.4.1 Complications After Day-Case Surgery

With modern advances in anaesthesia, major morbidity and mortality with day-case surgery is extremely rare (37).

The incidence of cerebrovascular accidents, myocardial infarction, and pulmonary thrombo-embolic phenomena was lower than would be expected among a similar age group who had not undergone day-case procedures in a group of 38 958 patients who were studied after day-case surgery. The risk of dying in 30 days after surgery was 1:11 273 (37).

However, minor complications may be relatively common and may have economic implications as well as affect patient satisfaction as they may result in unanticipated admissions or delay in discharge as well as possible returns to the hospital after discharge (37).

Bleeding is a common surgical complaint but from an anaesthetic point of view, inadequate analgesia and post-operative nausea and vomiting are important complications (37).

Post-operative pain is the most commonly reported complication of ambulatory anaesthesia with as many as 50% of patients experiencing wound pain 24 hours after laparoscopic surgery. The management of pain for day-case surgery poses a unique challenge to the anaesthetist as inadequate pain control can delay discharge, is inhumane, may reduce patient satisfaction, may result in development of chronic pain and may even contribute to post-operative nausea and vomiting. However, over-zealous treatment with opiates may result in side effects of the opiates such as nausea and vomiting, sedation and pruritus, all of which may also reduce patient satisfaction and delay hospital discharge (37).

Headaches (12%), dizziness (10%) and drowsiness (13%) may all also be reported after day-case surgery. These symptoms are proposed to be caused by dehydration in most instances and adequate hydration intra- and post-operatively may reduce the symptoms, but they may still be distressing for the patient and reduce the patient's level of function (37).

2.4.2 Anaesthesia for Day-Case Surgery

When selecting an anaesthetic technique and surgical procedure for day-case surgery, it is imperative to consider safety, rapid recovery and minimal complications post-operatively (7). The aim is to discharge the patient home on the day of the procedure. It is important to consider that the choice of anaesthetic technique may affect post-operative morbidity at home (7).

With advances in general anaesthetic techniques, recovery post-surgery is enhanced and more complete (7) and may allow for an expedited, safer hospital discharge. This is particularly important for laparoscopic procedures where much of the literature still advocates a general anaesthetic as the preferred option. However, in many day-case surgeries, regional anaesthetic techniques may be preferable. Ideal agents to use when considering a general anaesthetic for day-case surgery would be drugs that have a rapid onset, provide adequate analgesia with few side-effects, provide amnesia, allow for adequate surgical conditions and result in earlier recovery.

It is possible to perform most gynaecological surgeries that are amenable to laparoscopic surgery with such an anaesthetic.

The use of regional blocks, local wound infiltration and drugs such as non-steroidal anti-inflammatory drugs during anaesthesia reduces the need for post-operative opiates. Therefore, the above-mentioned techniques are not only valuable in improving pain control but also in the reduction of post-operative nausea and vomiting (7).

The appeal of regional techniques for day-case surgery is the analgesia without sedation, a more prolonged course of post-operative analgesia with minimal or no use of opiates and an earlier discharge (7). The benefit of reducing opiates use allows for reduced levels of drowsiness, nausea, vomiting and pruritus all of which may delay discharge (7).

The advantages of local/ regional anaesthesia are tabulated below.

Table 9: Advantage of local/ regional anaesthesia (7)

Advantages to patient • Avoids Related complications of a general anaesthetic • Lower incidence of nausea and vomiting • Improved post-operative pain scores • Shorter recovery room time • Able to communicate during surgery • Able to observe the procedure • Earlier mobilisation • Immediate physiotherapy
Advantages to surgeon • Enables accurate assessment of function before end of surgery • Allows discussion of operative findings and treatment options at time of surgery
Advantages for health care facility • Shorter recovery room time • Reduced post-operative nursing requirements • Fewer hospital admissions • Overall reduction in costs to the facility

The disadvantages of local/ regional anaesthesia are tabulated below.

Table 10: Disadvantages of local or regional anaesthesia (7)

More time required because: Time is required to do the procedure, the onset time of the regional or local procedure may be prolonged, the procedure needs to be explained to the patient, the block may be incomplete and require supplementation or conversion to a general anaesthetic
Surgeon and patient co-operation required
Risks associated with post Dural puncture headaches
Prolonged regional block may result in urinary retention and delayed discharge

2.5 Analgesia / Pain

Pain, as defined by the International Association for the Study of Pain is an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in terms of such damage (31).

2.5.1 Physiology of Pain and Pain Pathways

The perception and expression of pain involves a myriad of factors that interact at a complex level. These factors may include sensory, emotional and behavioral factors and responses. Pain may be classified as acute or chronic pain. Acute pain is primarily caused by nociception from a noxious stimulus due to injury, a disease process or muscular or visceral dysfunction (58).

There are four described processes of pain. Nociceptor activation by a stimulus resulting in tissue damage is referred to as Transduction. Transmission refers to the process which results in a message being relayed to and perceived in certain brain regions. The message originates at the site of tissue damage. A reduction in activity in the process of transmission is referred to as Modulation. Perception involves the integration of many sensory messages into a meaningful and coherent whole. It is produced by sensory signals and is a subjective awareness. Perception is a function of several processes, including, expectation, attention and interpretation (59).

The fibre diameter or conduction velocity of nociceptors forms the basis of their classification. Group III (A δ) myelinated fibres are of two types. In general, these fibres mediate well localised, acute, sharp pain. Type I fibres respond to mechanical,

chemical and heat stimuli. Type II fibres have a higher mechanical but a lower heat threshold than type I fibres. Activity of A δ type II fibres mediates the “first” acute pain response to noxious heat. Type C unmyelinated fibres convey poorly localized dull, burning. They are slow to respond and are also known as group IV (60).

Mechanical, heat and chemical stimuli can activate pain receptors (nociceptors) in peripheral tissue. In addition, a number of various analgesia-producing substances may sensitize afferent nociceptors. These substances are released upon tissue damage or from blood cells that circulate at the site of tissue damage. They include substances such as serotonin, histamine and potassium. Tissue damage also activates enzymes which release leukotrienes, prostaglandins and bradykinin amongst other chemicals (59).

Nociceptive messages are transmitted from the site of tissue damage to the brain by the primary afferent nociceptor. In the dorsal root ganglion (cell body) the axon sends a branch out to the spinal cord and another branch to the periphery. The response to the stimulus characterises the nociceptor. The frequency of nociceptor discharge is directly related to the intensity of the stimulus. In order to block pain, transmission in small-diameter axons should be blocked. Blocking activity of the larger-diameter axons in a peripheral nerve does not block pain (59).

Impulses are transmitted from primary afferent nociceptors into the spinal cord or brain stem (depending on where they originate from). The dorsal horn of the grey matter is the termination point of these nociceptors. Chemical transmitter substances such as somatostatin, substance P, aspartic and glutamic acid are released from the nociceptors to activate pain transmission cells (59).

The axons of these second-order cells cross over at the level of the spinal cord and ascend to the thalamus and the brain stem (medial reticular formation) (59).

The lateral spinothalamic pathway (direct) and medial spinoreticulothalamic pathway (indirect) are ascending pain pathways. The lateral pathway from the spinal cord to the ventrocaudal thalamus and to the cortex is responsible for pain that originates in surface structures. This pain is described as well-localised and sharp. Pain originating from visceral and deeper somatic structures are interpreted in the medial spinoreticulothalamic pathway (59).

Referred pain occurs when a pain sensation produced in one part of the body is felt in another structure away from the organ of pain. This occurs in deep and some visceral pain. A relatable example would be diaphragmatic pain that is felt at the shoulder tip (58).

Following a prolonged, noxious stimulus changes take place within the nervous system. The changes influence the subsequent responses to the sensory input (58).

Pain may either be described as physiological pain or pathophysiological / clinical pain. With physiological pain, a noxious stimulus activates peripheral nociceptors which then transmits sensory information through several relays to the brain and is recognized as a potentially harmful stimulus. In addition, inflammation and tissue or nerve injury may occur (58).

Pathophysiological or clinical pain is used to describe processes taking place following injury that result in a stimulus-response pattern that is different from physiological pain (58)

2.5.2 Pain After Laparoscopy

When compared with a laparotomy, the pain associated with laparoscopy is less severe and of shorter duration (9). An important concept to understand when reviewing post-surgical pain is that various stimuli may initiate nociceptive responses and can cause tissue trauma at various levels. These may include thermal, mechanical, electrical and chemical stimuli which may cause superficial damage at the skin surface; ischaemia, stretch or distension and inflammation which may cause damage in deeper tissues; and ischaemia and chemical stimuli that may damage nerves.

It is evident from the proposed mechanisms of pain following laparoscopic gynaecological procedures that a variety of these noxious stimuli may act at every level; the skin surface, deeper tissue levels as well as at the level of the nerves to cause pain (58).

The greatest incidence of pain following laparoscopy is in the upper abdomen. However, pain may also occur in the lower abdomen, back and shoulders (9).

The incidence of shoulder tip pain is relatively high following laparoscopy and is quoted to be between 35% and 63% (9, 61). In an article by Dobbs et al. (2008) (62) where it was proposed that pain after laparoscopic sterilisations may be related to posture as

well as the method of sterilization, shoulder tip pain is reported to occur in up to 63% of case. Phelps et al. (1991, USA) (63) described a maneuver to reduce shoulder tip pain after laparoscopic procedures. The incidence of shoulder tip pain among their patient population varied from 35% to as much as 80%. The pain ranged from mild to severe.

Pain is reported to be the greatest immediately after the operation and decreases to a lower level within 24 hours following the surgery. However, in certain instances patients may experience a second or even third peak in the level of their pain later on (9). Dobbs et al. (62) reviewed pain in a total of 131 women following laparoscopic sterilisations. They found a reduction in the frequency of upper abdominal pain during the first post-operative night from 53% to 25%. This was followed by a rise in the frequency of pain to about 60% following a return home on the first post-operative day with a slow fall in the frequency of pain over the next 2 days.

As a result, patients may meet discharge criteria with regard to analgesia but experience pain and resulted consequences thereof on their return home. This should be anticipated and prepared for and the patient should be counselled on the possibility of a second or third peak of pain.

The pain initially is said to be visceral in nature whereas later on in the time course, shoulder pain becomes more significant (9).

During laparoscopic procedures, the peritoneum is rapidly distended. The rapid distension may be associated with neural traction and release of mediators of inflammation as well as vascular shearing (9).

The phrenic nerve may also be excited during insufflation of the abdomen with Carbon Dioxide and may explain the persistence of shoulder pain. Evidence reveals that the degree of pain correlates with the size of the gas bubble created under diaphragm and may be reduced by aspirating gas under the diaphragm or by applying local anesthetic agents under the diaphragm (64).

Pain in the upper abdomen after diagnostic laparoscopic procedures (or even lower abdominal procedures) may also be explained by residual gas under the diaphragm or peritoneal inflammation (64). This type of pain, much like shoulder tip pain may also persist for as many as three days post procedure (64).

2.5.3 Pain After Laparoscopic Tubal Ligation Surgery

Laparoscopic sterilisation is probably one of the most common operations performed laparoscopically in the UK (9). Pain after tubal ligation surgery may be viewed as unique. Post-operative analgesia may be especially challenging after laparoscopic tubal ligation surgery (2).

Laparoscopic sterilisations have been noted to cause worse pain than laparoscopies for diagnostic procedures (2, 9, 12). In a study conducted by Edwards et al. (1998) (2) a total of 80 patients undergoing diagnostic laparoscopies or laparoscopic tubal ligation surgery were recruited to a study to contrast the levels of post-operative pain (and other side effects) experienced by patients. All procedures were carried out as day-case procedures. The findings of the study revealed that immediately after the procedures, patients undergoing laparoscopic sterilisations experienced worse pain than patients who had laparoscopies performed as a means of diagnosis. However, there was no discrepancy in the level of pain experienced in the two groups after they had been out of a hospital environment for 24 hours.

Initial higher pain scores after laparoscopic tubal ligation surgery was attributed possibly to clips on the Fallopian tubes causing either a direct pressure effect or spasms of the Fallopian tube (2).

Similar rates of pain between the two groups at 24 hours suggests that pain at this stage was either due to a head down position or by irritation and stretching of the diaphragm caused by insufflation of the abdomen. Patients also complained of shoulder tip pain which would substantiate this theory (2).

Interestingly, in the study mentioned above, patients were asked if they would be prepared to have the procedure done as a day-case again. Seventy – eight percent (78%) of the patients who had diagnostic laparoscopic procedures and 70% of patients who had laparoscopic sterilisations were prepared to undergo the procedure as a day-case again (2). In addition, 17.5% (7 out of 40) of patients who had a laparoscopic tubal ligation procedure required admission overnight for analgesia. No patients who had undergone a diagnostic laparoscopic procedure required overnight admission (2).

In the article by Davis and Miller, ischaemia or damage to the fallopian tubes during sterilisation procedures have been postulated as a reason for the higher pain levels.

Davis and Miller (1988, England) (12) also noted the pain was worse for up to four hours after the laparoscopic sterilisation procedure but was not significantly greater post discharge from hospital. The surgeries were done as day-cases. It was also noted that the severity of lower abdominal pain experienced also depends on the method of sterilisation employed (12). For instance, electrosurgical sterilisation results in less post-operative pain when compared to occlusive techniques (35).

From the above, it is evident that the method of sterilization has a significant impact on the incidence, severity and timing of the pain experienced.

Alexander (9) noted that ring or loop occlusion and clips as well as use of a diathermy, were the three methods of tubal ligation most commonly used. Alexander reviewed articles of different authors and noted that there was a significant variance in the severity of pain experienced in the lower abdomen amongst the three methods.

Intra-operative (under local anaesthetic) and post-operative pain is increased when rings are used when compared with spring-loaded clips. The occurrence and severity of pain in the lower abdomen were both comparably lower after Hulka clip sterilisation than after ring sterilisation. In fact, pain after clip sterilisation did not significantly differ when compared with the pain experienced after laparoscopy performed for diagnostic purposes (9).

The greatest variance was in pain experienced in the lower abdomen in the first six hours post-surgery. Interestingly, it was found that the pain experienced after diathermy was worse than the pain associated with ring sterilisation during the procedure but that after 4 hours the pain associated with the rings was worse (9).

Patients who had Falope rings inserted had higher analgesic requirements than surgeries where diathermy (electrocoagulation) was used. The pain of clips also exceeds that of diathermy (9).

Tubal manipulation is thought to cause pain similar to dysmenorrhea. In a study by Huang et al. 67% of patient who complained of pain after tubal sterilisation described the pain as abdominal cramping. Dysmenorrhea is associated with an elevation in the level of peritoneal prostaglandins which may explain why NSAIDS provide pain relief. With tubal ligation surgery, painful uterine contractions may occur. This is as a result of prostaglandin synthesis in the injured fallopian tubes. It may be predicted that NSAIDS may assist with pain associated with this surgery (35).

2.5.4 Analgesic Options for Laparoscopic Gynaecological Surgery

Analgesia for laparoscopic gynaecological procedures poses a unique challenge especially when the procedure is amenable to and planned as a day-case procedure. Analgesia provided should be sufficient for patients to mobilise by the night of surgery and allow for analgesia for several days following the surgical procedure. However, side effects should be avoided or kept to a minimum, tolerable level. In addition, the nature of pain may vary over this period. Pain in various sites may become worse or better during the time course of recovery (65).

Postoperative analgesia combining intra-operative opiates, local anaesthesia and Non-Steroidal Anti-Inflammatory drugs (NSAIDS) may be referred to as balanced or multi-modal analgesia. The combination of the approaches has numerous advantages including significantly shorter discharge times, lower pain scores, lower incidences of post-operative nausea and vomiting when compared with more traditionally opiate based anaesthetic options (37).

Pre-emptive analgesia i.e. providing analgesia before the surgical stimulus, should theoretically reduce the amount of pain experienced after the procedure (65). With pre-emptive analgesia, drug absorption and distribution to the effect site may be optimised by the time the surgery is complete (65).

Paracetamol

Paracetamol is on the lowest rung of the World Health Organisation's pain ladder. It assists with mild to moderate pain and has an opiate – sparing effect of up to 20% when used as an adjunct to manage more severe pain (65, 66). It may be given orally as premedication (pre – emptive analgesia) or intravenously at induction of anaesthesia (65).

Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)

As described above, pain experienced after tubal manipulation may be related to prostaglandin concentrations. During laparoscopic tubal manipulation and ligation prostaglandins are released and this may aggravate pain by escalating the frequency of nociceptive impulses. NSAIDS may assist with reducing pain after laparoscopic tubal manipulation and ligation by acting as prostaglandin synthase inhibitors (9).

Numerous randomized controlled studies show NSAIDS to be more effective at

reducing pain after laparoscopy than a placebo. These include studies by Davie et al. (1982) (67) where Fenopufen was used, Brodie and Casper (1985, Canada) (68) where Indomethacin rectally was used, Huang et al. (1986, USA) (69) where oral paracetamol was used, DeLucia and White (70) where Ketorolac was used via an intramuscular route, to mention a few. Studies have also been conducted with Diclofenac both rectally as well as intravenously and intramuscularly as well as Naproxen via the rectal route (9).

However, there are also randomized controlled trials where NSAIDS failed to show more effect than a placebo at reducing pain after laparoscopy. These include studies by McLennen et al. (1990) (71) and Crocker and Paech (1992, USA) (72) both of whom used 100mg Indomethacin preoperatively via the rectal route. The pain intensity of the NSAID group was lower but the p values were greater than 0.05 and 0.07 respectively. Studies by Edwards et al. (2) where diclofenac was used via an intramuscular route post-induction echoed these findings where pain intensity was less but the p value was greater than 0.05 (9).

NSAIDS, either as the sole agent for analgesia or in combination with paracetamol are not sufficient for analgesia in the early post-operative period. However, they are said to be opiate sparing (9).

Opiates

Opiates are on the top rung of the World Health Organisation's pain ladder. They may be given pre -, peri - and post - operatively and may be either long or short acting. Pre-operative opiates have been studied in day-case laparoscopic gynaecological surgery. Morphine (73) and controlled release oxycodone (74) given before induction of anaesthesia does not reduce pain scores when compared to controls (65).

Analgesic adjuncts

Jokela et al. (2007) (75) found that Pregabalin (a GABA analogue) was used for post-operative pain control in day-case laparoscopic gynaecological surgery. There was no advantage in reducing morphine requirements post-procedure when compared with diazepam.

Ketamine pre-operatively affords an analgesic benefit over ketamine given post-operatively (76). The study was done particularly in the subsect of gynaecological

laparoscopic surgery. There is no evidence comparing ketamine and conventional opiate or NSAID based regimens (65).

Smith et al (1988, England) (77) looking at Rectus Sheath blocks for diagnostic laparoscopy it was noted that pain post diagnostic laparoscopic procedures is reduced by Rectus Sheath blocks performed bilaterally, above the umbilicus with approximately 15ml of 0.25% bupivacaine on either side.

Narchi et al. (1992) (78) and Smith et al. (1991) (79) both looked into mesosalpinx infiltrations after laparoscopic sterilisations. They concluded that injection of local anaesthetic agents into the mesosalpinx or application of local anaesthesia directly into the fallopian tube at the time of surgery reduces pain post-operatively. McKenzie and colleagues (1989, Canada) (80) echoed these findings and in addition added that application of local anesthesia to the fallopian tube or mesosalpinx reduces postoperative opiate use and results in fewer admissions to hospital overnight as a result of pain.

Narchi et al. (61) in 1991 described the use of intraperitoneal local anaesthetics for shoulder pain after day-case surgery. They reviewed 80 female out-patients who had undergone laparoscopic gynaecological procedures for various reasons. The patients were randomized to receive nothing intraperitoneally (control), 80 mls saline in the right sub diaphragmatic area under direct vision, 80 mls 0.5% lignocaine with adrenaline or 80 mls 0.125% bupivacaine with adrenaline in the right sub diaphragmatic area. The study concluded that both local anaesthetics were more effective in reducing postoperative shoulder pain than in either the control or the saline groups. They also found the duration of action of both local anaesthetic agents was about 48 hours which was much longer than expected and that by attempting to reduce post-operative pain, analgesic requirements after surgery are substantially reduced.

Alternate methods to reduce pain scores

Gas drains left in postoperatively to allow for drainage of Carbon Dioxide has been demonstrated by Alexander and Hull to reduce pain after laparoscopy (64). Phelps et al (63) described that by placing women in the Trendelenburg position and giving them five manual inflation breaths post-procedure, gas is actively removed from the abdominal cavity and pain scores may be reduced by half.

As revealed in a recent meta-analysis, warmed and humidified carbon dioxide used for insufflation of the abdomen reduces pain significantly after laparoscopic surgery. This may be the case for up to three days following the surgery (81).

2.6 Potential Side Effects of Peri-Operative Opiate Use

2.6.1 Post-Operative Nausea and Vomiting (PONV)

The vomiting process is said to be complex. There are two main areas in the brain involved in the vomiting process. The first is the chemoreceptor trigger zone (CTZ) which is located in the area postrema of the fourth ventricle lies outside the blood brain barrier (82). Therefore, substances that do not cross the blood brain barrier may still induce vomiting by acting at this site.

The other area is the vomiting centre within the blood brain barrier in the lateral reticular formation of the medulla (82).

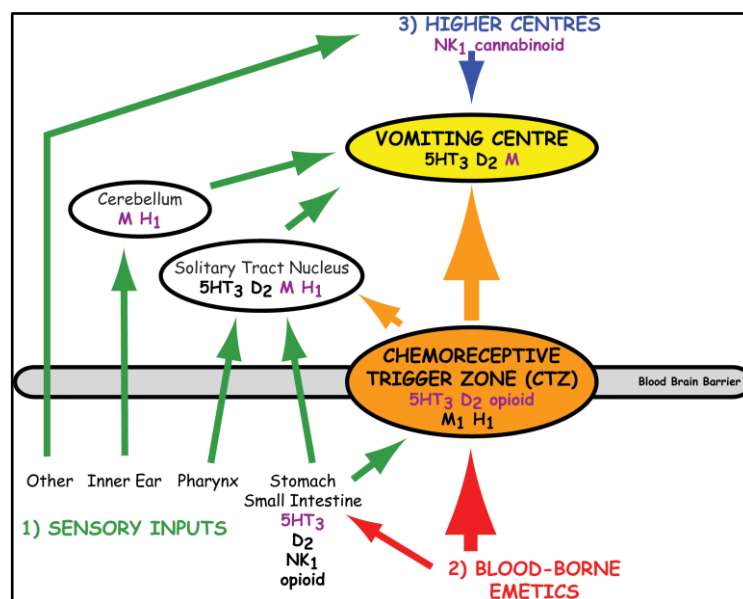


Figure 1: Key areas in the brain where nausea and vomiting are orchestrated (82)

The CTZ and vomiting centres orchestrate the sensation of nausea and initiate vomiting (82). The vomiting centre receives input from the CTZ as well as other areas in the brain and cochlear centre (82).

The CTZ is stimulated by various chemicals. These may be centrally acting agents that are emetogenic such as opiates. Oestrogens, uraemia and ketones are all chemicals which may also result in nausea and vomiting at this site (82).

As is depicted in figure 2.1 above, many neurotransmitters and their specific receptors are involved in the process of vomiting. It is therefore of benefit to employ the use of a combination of anti-emetic agents that may act at the various sites when attempting to prevent or treat post-operative nausea and vomiting (82).

Neurotransmitters and their respective receptors implicated in nausea and vomiting include:

- Dopamine – dopamine receptors
- Acetylcholine – muscarinic receptors
- Serotonin – 5-HT₃ receptors
- Substance P – Neurokinin 1 receptors

Certain patients are predisposed to developing PONV. The risk factors may be related to patient factors, surgical factors or anaesthetic related factors and the type of surgery.

Table 11: Risk factors for post-operative nausea and vomiting (PONV) (17, 37, 83)

Patient -specific	Anaesthetic related	Surgical factors	Type of surgery
Female gender	Use of volatile anaesthetics	DURATION OF surgery	Gynaecological surgery
Younger age	Use of Nitrous Oxide		Laparoscopic surgery
Non – smoking status	Use of Opiates		Strabismus surgery
History of PONV	Use of Neostigmine		ENT surgery
History of motion sickness			

Key: ENT – Ear, Nose and Throat

Laparoscopic surgery has a high incidence of PONV (8). Gharaibeh (1998) (19) observed that over 50% of patients required anti-emetics after laparoscopic surgery. In a study by Higgins et al. (1994) (35) looking into the effect of NSAIDS on recovery after out-patient laparoscopic tubal ligation, the incidence of vomiting observed in hospital and at home was as high as 40%-60% of patients and this was similar to the incidence of vomiting reported in previous studies of patients undergoing laparoscopy (13%-78%). Interestingly, they observed that the incidence was related to the phase of the

patient's menstrual cycle at the time of surgery. It was also found that patients who had received parenteral opiates in the recovery room had a higher incidence of PONV (35).

Morphine has a prolonged emetic effect and it is for this reason that shorter acting synthetic opiates are more commonly used. Claxton et al. (84) compared morphine and fentanyl in terms of post-operative nausea and vomiting and found that fentanyl was associated with less post-operative nausea and vomiting compared to morphine and that the benefit extended into the period when patients were discharged (84). However, due to the shorter duration of fentanyl, this group required two and a half times the amount of supplemental analgesia compared to the morphine group (65).

PONV is also a distressing complication of day-case anaesthesia and may worsen pain (37, 8). It may result in a delay in discharge and unanticipated hospital admissions. The incidence seems to be declining and may be attributed to newer antiemetic drugs and revised anaesthetic techniques. However, it may be difficult to assess the true incidence of PONV especially as relates to day-case surgery because as many as 35% of patients may experience PONV at home after discharge when they become more mobile. These patients may not experience symptoms prior to discharge (37).

Ondansetron, a 5HT₃ antagonist is an effective anti-emetic especially when given at the end of a procedure and 8 mg Ondansetron has been shown to be more efficacious than 10 mg of metoclopramide in reducing opiate-induced PONV (37). However, studies show that it is not more effective than small doses of Droperidol (37).

2.6.2 Pruritus

Post-operative itching is a challenge for both the anaesthesiologist and the patient.

Pruritus is a common adverse event noted after opiate use, particularly when administered into the epidural or intrathecal space (16). It is not a life-threatening complication and is often self-limiting but may be distressing for the patient and may reduce patient satisfaction. Pruritus may result in escalation of health care costs as hospital admission days may increase and there may be an increased requirement of personnel resources (16).

The incidence varies with the route of administration of the opiate analgesic (14). The reported incidence of pruritus after intravenous administration of an opiate is reported

by Biswas et al. to be as high as 50% (10%-50%) which is greater than the reported incidence after oral administration (2%-20%). Ganesh and Maxwell (2007, USA) (16) quote similar figures of 10%-50% following intravenous administration of opiates. The reported incidence of pruritus after spinal or epidural administration can range between 30% and 100% (84). Ganesh and Maxwell (16) echoed these findings with an incidence of between 20% and 100% following neuraxial opiate administration.

'Itch is an unpleasant sensation that elicits the desire or reflex to scratch' (16). It is a cutaneous sensation but is thought to be an extra-cutaneous event related to central nervous system activity. The itch felt is a neuronal projection of a sensation that is formed centrally. The pruritus may be localised when the sensation is in defined regions or generalised when the neuronal projection of the sensation is into large areas of the body surface. The afferents are thought to be C fibres (16).

The mechanism of opiate induced pruritus is not fully understood but there is increasing evidence of the important role played by the mu opiate receptor (kappa and delta opiate receptor activation does not cause pruritus). Serotonin and dopamine (D2) receptors, prostaglandins and spinal inhibitory pathways may also be involved in the genesis of pruritus (16).

Table 12: Possible receptors contributing to opiate-induced pruritus (16)

Mu opiate receptors: • Brain • Spinal Cord
Dopamine (D ₂) receptors
Serotonin (5-HT ₃) receptors
Prostaglandin system
Other: • GABA receptors • Glycine receptors

There is increasing evidence that opiate-induced pruritus is primarily mediated through central mu opiate receptors. Pruritus (scratching) was elicited by Ko et al. in monkeys by intravenous administration of mu opiate receptor agonists such as Fentanyl, Alfentanil and Remifentanil. Mu opiate receptor antagonists reversed the pruritus (16).

It is proposed that the preponderance of opiate receptors in the spinal nucleus of the trigeminal nerve explains the high incidence of pruritus in the distribution of the trigeminal nerve (16).

Dopamine receptors and serotonin receptors have also been implicated in the development of opiate-induced pruritus and dopamine receptor antagonists as well as 5-HT₃ receptor antagonists have been shown to decrease the incidence and severity of opiate-induced pruritus (16). Furthermore, it has been demonstrated where mu opiate receptors are in high concentrations, there is also a dense concentration of serotonin receptors such as the dorsal part of the spinal cord and the trigeminal nerve nucleus (16).

Release of prostaglandin E₁ and prostaglandin E₂ has been implicated in development of opiate-induced pruritus and some studies have shown that diclofenac may have an anti-pruritic effect. However, studies by Lee et al., Romsing et al. and Marret et al. have all shown that there is no significant reduction in opiate-induced pruritus with administration of certain cyclo-oxygenase 2 inhibitors (16).

The role of histamine release in the pathogenesis of opiate induced pruritus is minimal (16). GABA and Glycine receptor antagonism in the central nervous system has also been implicated in opiate-induced pruritus (16).

2.6.3 Sedation and Drowsiness

Opiates may cause sedation, especially in opiate naïve patients (10). Mild sedation is expected in patients receiving opiates. However, unintended advancing sedation may lead to respiratory depression and even death (39).

Unintended advancing sedation is defined as “sedation that occurs at increasingly higher levels along the continuum of sedation as a result of opiate administration for pain management, impairing both arousal mechanisms and content processing” by the American Society for Pain Management Nursing (ASPMN)’s (39).

The incidence of excessive or even progressive sedation associated with the use of opiates for pain management is not known. In a retrospective review of 10 511 adult in-patients who underwent surgery in 2003, it was found that 0.53% of patients received naloxone. Of these patients, 79% received the naloxone with the intention of reversing opiate induced sedation (39).

Post-operative sedation scores are the most important predictors of respiratory depression in hospitalised patients receiving intravenous opiates (39).

The consequences of severe opiate induced respiratory depression are severe and may include brain hypoxia, anoxia and eventually death (39). There are a number of risk factors for opiate induced respiratory depression which may be categorised as patient-related factors, procedural factors and analgesic technique.

Table 13 summarises risk factors for opiate induced respiratory depression

Table 13: Summary of risk factors for opiate induced respiratory depression (39)

Patient – related factors	Procedural factors	Anaesthetic / Analgesic technique
• Age > 55 years • BMI > 30kg/m² • Untreated OSA • Retrognathia • Pre-existing pulmonary or cardiac dysfunction • Smoker (> 20 pack years)	• Prolonged surgery (> 2 hrs) • Thoracic incisions • Large incisions that may impair respiratory function	• Concomitant use of sedative agents • Continuous opiate infusions • High dose opiates in a short period of time • Large single bolus opiates administration • Naloxone administration

Postoperative sedation scores are highest within the first four hours following discharge from the recovery room (39).

The anticholinergic activity of opiates is thought to result in opiate-induced sedation and drowsiness (10). Tolerance usually develops to this side-effect of opiates but dose initiation and rapid dose escalation may result in sedation (10). In the case of women presenting for laparoscopic gynaecological procedures, especially laparoscopic sterilisations, they are more likely to be opiate naïve and also more likely to require higher doses of opiates for shorter periods of time. Therefore, they are at higher risk of developing sedation or drowsiness as a side effect and are also less likely to develop tolerance to the side effect.

Methylphenidate, a psychostimulant may improve psychomotor performance scores and subjective drowsiness. It is the most common medication investigated to treat opiate induced sedation. It has been shown to improve drowsiness scores, decrease pain and reduce opiate requirements (10). However, it was studied in cancer patient who require longer term opiate use (10) and may not be a practical and viable option in the patient population under review.

2.7 PAIN – OUT

PAIN – OUT is an international pain database. The main focus of PAIN – OUT is to improve the management of post-operative pain. In order to facilitate the aim of PAIN – OUT, data about post-operative pain from medical facilities internationally was collected and pooled into one database. The database may provide feedback and benchmarking for staff in each centre about how patients are being managed especially with concern to pain patients may experience. The hope is that the information will help healthcare workers improve the management of pain for their patients.

The concept behind PAIN – OUT is relatively simple. Millions of surgical procedures are undertaken every year worldwide. According to the PAIN – OUT standard operating procedure (SOP), more than 50% of patients suffer from moderate to severe pain after a surgical procedure. The pain may last days or even weeks. It has been established that inadequate post-operative pain management does not allow for adequate recovery in a timeous fashion, it may cause distress to a patient and may reduce the patient's quality of life and impose an additional burden on the caregiver. It may also foster the development of disabling chronic pain. The added healthcare costs imposed on the patient and the healthcare facility is another important consideration. The pain may occur even after minor or moderate surgery such as laparoscopic procedures.

There are considerable differences worldwide in therapeutic outcomes between different institutions. This is largely because information is not readily available to healthcare providers. The belief is that development of new techniques for the management of acute pain is not necessary. However, it is imperative that healthcare providers learn to provide existing techniques more effectively.

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1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-dimensional reconstruction by high-resolutonal CT scanning. *Otolaryngol Head Neck Surg*. 2005 Mar;132(3):429-34.
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Section 4: Draft Article

Post-operative experiences of patients undergoing laparoscopic gynaecological surgery at an academic training hospital

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Post-operative experiences of patients undergoing laparoscopic gynaecological surgery at an academic training hospital

Abstract

Background:

There is a global trend towards performing gynaecological surgery laparoscopically. The anaesthetic technique should complement the minimally invasive nature of the surgical technique.

Developing an understanding of patients' experiences following laparoscopic gynaecological surgery is the first step toward improving the anaesthetic technique utilised for these surgeries, thereby aiming to improve the patient's peri-operative surgical experience.

Method:

We performed a retrospective descriptive study from 1 August 2014 to 31 December 2016 on all available PAIN OUT data for patients having undergone a laparoscopic gynaecological procedure at a university teaching hospital in South Africa. Data on pain experiences and side effects was captured.

Results:

Data representing 55% of cases for the period under review was available. The median age of all patients recruited to the study was 37 years old. All participants were of African descent.

The median NRS score for 'worst' and 'least' pain since surgery for all patients having undergone a laparoscopic gynaecological procedure was 5 and 3 respectively; the difference being statistically significant $p < 0.0001$.

Sixty percent of patients reported drowsiness, 48.2% of patients experienced nausea or vomiting and 22.7% of patients experienced pruritus. The median scores for drowsiness, nausea or vomiting and pruritus was 2, 0, 0 respectively.

Conclusion:

Although most patients experienced post – operative pain, and side effects experienced were higher than recommended standards of care, the severity of pain and side effects experienced may be said to be tolerable. Side effects were not related to opiate use.

Key words: Laparoscopic surgery, pain, pruritus, nausea and vomiting, drowsiness

Introduction:

Laparoscopic surgery is associated with numerous advantages over the more traditional open surgical approach. It is minimally invasive; the healing process is less painful, and recovery is expedited.¹

Statistics regarding laparoscopic gynaecological procedures in South Africa (SA) are sparse. Following international trends, anecdotal evidence suggests an increase in the number of laparoscopically performed gynaecological procedures. These procedures can generally be performed as day-case procedures.

The appeal of day-case surgery is increasing world-wide as a result of escalating health costs and buoyed by advances in anaesthetic and surgical techniques. The cost benefit of day-case surgery is well recognised.² Numerous gynaecological procedures meet requirements to be carried out as day-case laparoscopic procedures.

However, laparoscopic surgery is not without its unique risks. These risks can be due to the laparoscopic technique employed or as a result of the physiological changes associated with the creation of a pneumoperitoneum.³ The anaesthetic technique employed should be refined to anticipate and deal with these risks. Complications associated with the anaesthetic technique should also be taken into consideration.

Post-operative pain is the most commonly reported complication of day-case surgery and anaesthesia. As many as 50% of patients experience wound pain 24 hours after laparoscopic surgery.⁴ In addition, there is substantial evidence in published literature concerning side effects of opiate use such as nausea and vomiting, pruritus and sedation⁵, making management of post-operative pain more complex in these patients.

Hospitalised patients who experience opiate related adverse events have been found to have poorer clinical outcomes than patients who experienced no adverse events.⁶ Among post-surgical patients, opiate related adverse events may increase the risk of in-patient mortality by 3.4 times. In addition, opiate related adverse events have been found to increase hospital stays by 55%, health care costs by 47% and 30-day readmission rates by 36%.⁷

Tubal ligations (TL) are elective surgical procedures that are often performed on healthy women who are significant contributing members to their family structures and the country's economy. Edwards and colleagues⁸ and Higgins et al.⁹ found the mean age of women undergoing laparoscopic TL recruited to their studies was 33.2 and 32.5 years old respectively.^{8,9}

With continued feminisation of the labour force in SA¹⁰ and internationally^{11, 12}, women in this age group contribute significantly to the global economy and are often mothers to younger children who require care and nurturing. It is imperative for them to expeditiously return to a pre-surgical level of function following routine gynaecological surgery. A day-case laparoscopic technique may facilitate this aim.

Developing an understanding of patients' experiences following laparoscopic gynaecological surgery is the first step towards improving the anaesthetic technique utilised for these surgeries, thereby aiming to improve the patient's peri-operative surgical experience.

Aim and Objectives

The aim of this study was to establish pain scores after laparoscopic gynaecological surgery at an academic training facility. We also aimed to describe the incidence and severity of side effects such as nausea and vomiting, drowsiness and pruritus following these surgeries.

Describing the perioperative analgesia used for laparoscopic gynaecological surgery was an additional objective of the study. The secondary objective of this study was to compare the mentioned variables in patients presenting for laparoscopic gynaecological procedures other than laparoscopic TL to the results of patients presenting for laparoscopic TL surgery.

Methodology

This was a retrospective descriptive study.

Rahima Moosa Mother and Child hospital (RMMCH) is an academic training hospital in Johannesburg, South Africa. The hospital contributed data to the international pain data registry called PAIN OUT. Data was obtained and captured according to the Standard Operating Procedures (SOP) of the PAIN OUT study. The main focus of PAIN OUT is to improve the management of postoperative pain.

Patient data was collected and entered into the PAIN OUT registry for patients undergoing laparoscopic gynaecological surgery from 1 August 2014 to 31 December 2016. A consecutive, convenience sampling technique was utilised. The Patient Outcome Questionnaire (POQ) was completed by each patient who qualified for the study. Patients were asked to score their minimum and maximum pain experienced since surgery on a scale from 0 – 10 (Numeric Rating Scale – NRS) with 0 representing no pain and 10 representing the worst conceivable pain. The patients also rated post-operative nausea & vomiting (PONV), pruritus and sedation on a similar scale.

The Process Questionnaire (PQ) was completed by a trained investigator using data from the patient's medical records for each participant. The data was entered into the PAIN OUT database from where it was retrieved for purposes of this study.

A patient was recruited to the study if they were in the first post-operative day and were back in the ward for at least six hours after surgery. All patients were of consenting age (18 years old in SA) and informed written consent was obtained from the patient to participate in the study. All patients who fulfilled these criteria and who had undergone a laparoscopic gynaecological procedure were included as part of the study. No form of intervention was instituted. The anaesthetic technique employed at the facility for laparoscopic gynaecological surgery was fairly standard consisting of a general anaesthetic with endotracheal intubation. An opiate was used peri - operatively as a means of providing analgesia.

While there is a move internationally toward performing uncomplicated laparoscopic procedures as day cases, due to various socio-economic factors associated with our patient population, patients were admitted overnight.

The validated data collection sheets utilised in this study documented the type of drugs administered and also recorded the patients' perception of their pain and the potential side effects of their treatment.

Sample Size and Data Analysis

A minimum of 62 patients in total were required for the study based on a proportion of 50%±20% of patients experiencing pain and side effects of opiates described with a power of 90% and a significance level of 5%. A minimum of 37 patients undergoing laparoscopic TL surgery needed to be included.

However, consecutive, convenience sampling was used and all patients for which data was collected over the specified period were included in the study.

Pain and side-effect scales were expressed as medians (range and IQR). A p-value was established using the Wilcoxon matched pairs signed rank test for the difference between the pain scores for worst and least pain experienced. Data for intra-operative and post-operative analgesia was expressed as % (number) and a median with (IQR). When comparing data for laparoscopic TL surgery with laparoscopic gynaecological procedures for reasons other than TL surgery, all p-values are from the Mann – Whitney comparison for non – parametric data.

Ethical Aspects

Approval for the study was obtained from the Human Research Ethics Committee (medical) at the University of the Witwatersrand. Approval for use of the PAIN OUT database was obtained from the gatekeeper at RMMCH. Only the researcher and supervisors of the study had access to the raw data. There were no identifying patient data on the database and the data remained confidential.

Results

Data for 110 patients were available, representing 55% of cases done during the period under review. These included 37 laparoscopic TL and 73 laparoscopic procedures other than TL's. The latter included procedures such as diagnostic laparoscopic procedures (93% [n=68]), laparoscopic lysis of adhesions, laparoscopic procedures for ovarian pathology.

The median age of all patients recruited to the study was 37 (range 21 – 84) years old. The mean weight was 71.4 (SD 16.1) kg. All participants were of African descent. Ninety percent (90%) of participants were from SA. The remaining 10% of participants were from Zimbabwe (7%), Malawi (2%) and Somalia (1%).

Ninety – eight percent of all patients undergoing a laparoscopic gynaecological procedure reported pain.

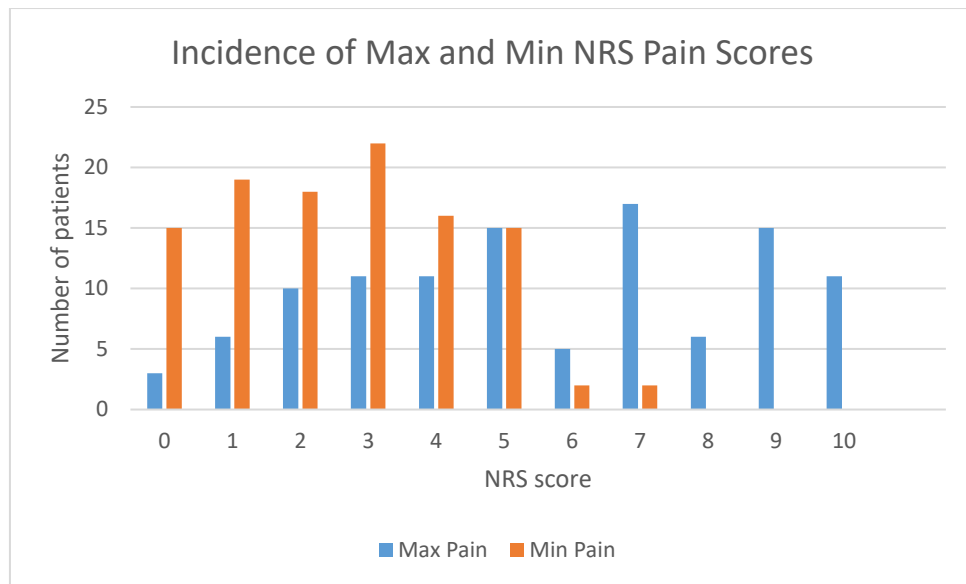


Figure 1: Incidence of maximum and minimum Numeric Rating Scale (NRS) scores reported by patients undergoing laparoscopic gynaecological procedures.

The median NRS score for 'worst' and 'least' pain since surgery for all patients having undergone a laparoscopic gynaecological procedure was 5 and 3 respectively, the difference being statistically significant $p < 0.0001$.

Sixty percent of patients reported drowsiness, 48.2% experienced PONV and 22.7% experienced pruritus. The median scores for drowsiness, PONV and pruritus was 2, 0, 0 respectively (Table I)

Table I: Descriptive data for pain scores and side effects as rated by patients after laparoscopic gynaecological procedures

Data / Variable	Median NRS (IQR)
Worst pain experienced	5 (3; 8)
Least pain experienced	3 (1; 4)
Nausea or vomiting	0 (0; 3)
Drowsiness	2 (0; 6)
Pruritus	0 (0; 0)

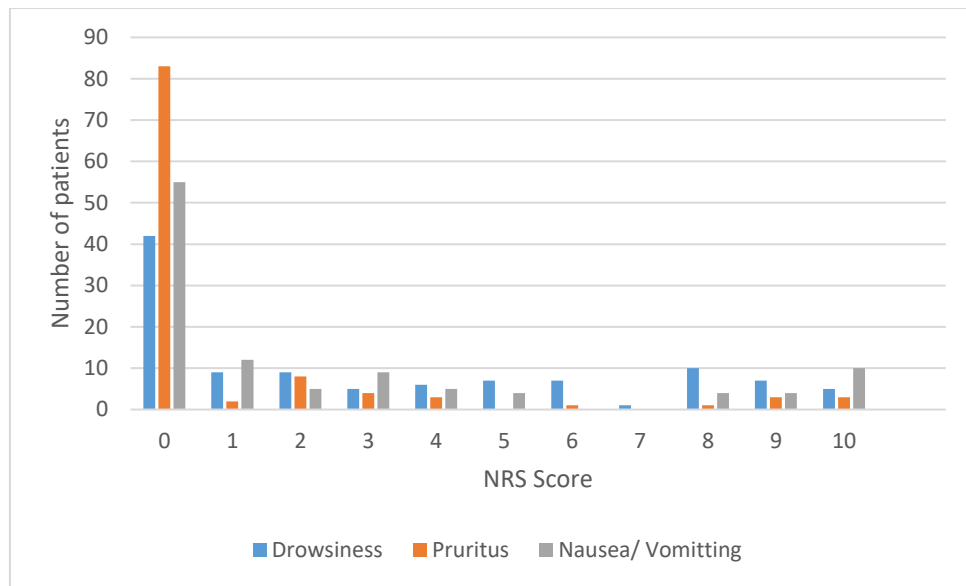


Figure 2: Numeric Rating Scale (NRS) scores of side effects of drowsiness, pruritus and nausea/ vomiting reported by patients undergoing laparoscopic gynaecological procedures.

All patient recruited to the study received an opiate intra-operatively. Morphine, the only ‘long acting’ opiate administered, was administered to 88.2% (n=97) of patients intra-operatively for analgesia; 41.2% (n = 40) of patients received Morphine as their only form of intra-operative analgesia. The mean dose of Morphine administered was 6 (SD 2.2) mg.

Where Remifentanyl was used, it was as a targeted controlled infusion (TCI). One patient received remifentanyl as their sole means of analgesia intra-operatively. Three patients received fentanyl in addition to the Remifentanyl and four patients received Morphine in addition to the Remifentanyl.

Non-Steroidal Anti-inflammatory Drugs (NSAIDS) were administered using varying routes (IM, IV and PR), Ketamine and Paracetamol were also used in various combinations as part of a multi-modal approach.

Table II: Intra-operative analgesic agents used for patients presenting for laparoscopic gynaecological procedures (Most patients received more than one analgesic agent and therefore percentages do not equal 100%)

Analgesic agent	Percentage (Number)	Mean (SD) dose
Morphine	88.2 (97)	6 (2.2) mg
Fentanyl	53.6 (59)	172.3 (41.0) mcg
Sufentanyl	22.7 (25)	16.4 (5.3) mcg
Remifentanyl	7.2 (8)	10.6 (8.2) mg
Alfentanyl	2.7 (3)	1333.3 (577.4) mcg
Paracetamol	28.1 (30.9)	1000 mg
Ketamine	30.9 (34)	19.7 (4.1) mg
Diclofenac IVI	1.8 (2)	75 mg

Diclofenac IMI	0.9 (1)	75 mg
Diclofenac suppository	3.6 (4)	100 mg
Indomethacin suppository	1.8 (2)	100 mg

Where not specified, agents were administered intravenously.

Post - operative analgesia was prescribed by the anaesthetist.

Less than ten percent (8.18%) (n=9) of patients received an opiate as their sole post-operative analgesic agent. These patients received either Morphine, Omnopon or Pethidine. The remaining 91.82% of patients received either one or the other or a combination of NSAIDS and paracetamol. Seventy five percent of patients received paracetamol post-operatively and a total of 54.5 % of patients received a NSAID post – operatively. Both these drugs are regarded as opiate sparing agents.

Table III: Post - operative analgesic agents used for patients after laparoscopic gynaecological procedures

Analgesic agent	Percentage (Number)	Dose: Median (IQR)
Diclofenac IMI	0.9 (1)	75mg
Diclofenac suppository	6.4 (7)	100mg (75; 100)
Ibuprofen	38.2 (42)	400mg (400; 800)
Naproxen	2.7 (3)	1000mg
Indomethacin	6.4 (7)	100mg
Paracetamol	75.5 (83)	1000mg (1000; 2000)
Morphine IMI	14.6 (16)	10mg (10; 13.75)
Omnopon	10 (11)	20mg
Oxycodone	0.9 (1)	150mg
Pethidine	35.5 (39)	100mg
Tramadol	4.6 (5)	50mg (50; 125)

Where not specified, agents were administered orally.

Variables for patients presenting for laparoscopic TL surgery was compared to the same variables for patients presenting for laparoscopic gynaecological surgery for various other indications (Table 4). The only statistically significantly different variables experienced between the two groups was the mean weight of the patients (p=0.0002) and the number of patients reporting drowsiness (p = 0.049).

Table IV: Comparison of laparoscopic tubal ligation surgery with laparoscopic gynaecological procedures for other indications

Variable		Laparoscopic TL (n= 37)	Other Laparoscopic gynaecological procedures (n=73)	P value
Age	Median (0, 25, 75,100)	38 (30, 35, 43, 84)	36 (21, 31, 43.5, 69)	0.1198
Weight	Mean (SD)	80.7 (16.8)	67.4 (14.0)	0.0002
Worst Pain	Median (Ranges)	5 (0, 3, 8, 10)	6 (1, 4, 8.5, 10)	0.2454
Least Pain	Median (Ranges)	2 (0, 1, 3, 6)	3 (0, 1, 5.4, 7)	0.0587
Nausea	Median (Ranges)	0 (0, 0, 2, 10)	1 (0, 0, 4.5, 10)	0.1009
Drowsiness	Median (Ranges)	0 (0, 0, 0, 9)	3 (0, 0, 6.5, 10)	0.0494
Pruritus	Median (Ranges)	0 (0, 0, 0, 9)	0 (0, 0, 0, 10)	0.9575

When comparing Morphine and other (short acting) opiates with regard to drowsiness experienced post – operatively the difference is not statistically significant $p = 0.2017$ (Mann – Whitney). There was also no statistically significant difference between patients who received an opiate as compared to patients who received no intra – operative opiates on the level of post – operative drowsiness experienced (Table V).

Table V: Comparison of the level of drowsiness patients experienced after any laparoscopic gynaecological procedure if they received Morphine as compared to other shorter acting opiates

	Morphine	Other (short acting) opiates	P value
Level of drowsiness	2 (0- 9)	3.5 (0-10)	0.2017 (Mann – Whitney)

Table VI: Comparison of the level of drowsiness patients experienced after any laparoscopic gynaecological procedure if they received opiates as compared to non - opiate analgesic agents

	Opiates	Non - opiates	P value
Level of drowsiness	3 (0- 10)	0.5 (0 – 10)	0.1464 (Mann – Whitney)

The difference in the level of drowsiness experienced between patients presenting for laparoscopic TL surgery and laparoscopic gynaecological procedures for other reasons was statistically significant ($p = 0.049$). However, from table V and VI above it seems there is a higher percentage of drowsiness with opiate use, but this was found not to be statistically significant.

Discussion

The median age for all patients presenting for a laparoscopic procedure was 37 years old. The median age for women presenting for laparoscopic TL surgery was 38 years old. Women of this age are significant contributing members to the country's economy as well as society at large and with continued feminization of the work force¹⁰, an expedited, safe recovery post – surgery is necessary.¹⁰

The difference in weight between patients presenting for laparoscopic TL surgery and other gynaecological laparoscopic procedures is statically significant with patients presenting for laparoscopic TL surgery weighing more. A higher weight may be associated with a higher incidence of post-operative local complications.¹³

Data on ethnicity of patients should be included in any assessment of pain management strategies to allow researchers to uncover and address disparities in pain management that have been shown to exist.^{14, 15}

Individuals with ethnic majority backgrounds (relative to the country in which they live) demonstrate lesser sensitivity to pain relative to groups representing ethnic minorities.^{16, 17, 18, 19}

SA studies also revealed ethnic/ cultural barriers to patient management. This may include pain and side effect management. A survey on barriers in health care delivery in Cape Town, revealed that 64% of the sample population indicated difficulties in understanding or communicating with their doctors.²⁰ Language barriers place limitations on a patient's ability to communicate with health care providers.^{21, 22} This is true in the SA context^{21, 22} especially with such cultural diversity and diversity in languages spoken. These reasons may account for the discrepancy in pain and side effects experienced in our population as compared with international studies.

Discharge of patients after day-case procedures includes consideration on recovery post anaesthesia. Most laparoscopic gynaecological procedures, especially laparoscopic TL surgeries, are amenable to day-case surgery. Certain criteria need to be met prior to allowing a patient to leave the health care facility. Excessive fatigue or sedation, nausea, vomiting or intolerable, unrelieved pain are some of the most common reasons for a delay in hospital discharge and account for unexpected hospital admissions.²

For purposes of this study, patients were questioned on day 1 post surgery about pain and side – effects of nausea/vomiting, drowsiness, or pruritus that they may have experienced at any point since the completion of the surgery. The patients were in the ward for a minimum time of 6 hours post-operatively. Of all the patients included in this study, 98% of patients reported pain at some point during this time.

The greatest incidence of pain following laparoscopy is in the upper abdomen. However, pain may also occur in the lower abdomen, back and shoulders. Pain is reported to be the greatest immediately after the operation and decreases to a lower level within 24 hours following the surgery. In certain instances patients may experience a second or even third peak in the level of their pain later on.²³ Patients were interviewed about their pain scores the day following the procedure. In most cases this would have included the period when patients were at highest risk of experiencing the 'worst' pain. Scores therefore accurately represent post – operative pain following laparoscopic procedures.

Laparoscopic TL have been noted to cause worse pain than laparoscopies for diagnostic procedures.^{8, 24, 25} Studies done internationally to compare pain and side effects experienced after laparoscopic TL surgery and diagnostic laparoscopic procedures revealed that in the immediate post-operative period, patients undergoing laparoscopic sterilisations had more severe pain than patients who had diagnostic laparoscopy. However, 24 hours after discharge there was no difference in the degree of pain experienced by the two groups.^{8, 13} In the study conducted at RMMCH, 93% of laparoscopic gynaecological procedures for reasons other than TL surgery were in fact diagnostic laparoscopic procedures. Patients were not interviewed in the immediate post-operative period. The day following the procedure, the *p* values for the difference in worst and least pain for patients undergoing laparoscopic TL surgery as opposed to laparoscopic gynaecological procedures for other reasons was not statistically significant; *p* = 0.245 and 0.058 respectively.

Dolin et al. identified over 800 original papers and reviews of publications concerned with the management of post-operative pain. Of these, data was extracted from 183 studies related to PONV, 89 related to sedation and 166 related to pruritus. The overall mean incidence of nausea was 25.2% and of emesis was 20.2%. Sedation was classified as mild or excessive. The mean for excessive sedation was only 2.6% but the mean for mild sedation was 23.9%. The overall mean incidence of pruritus was 14.7%. From a review of published data in excess of 100 000 patients, the authors stated it possible to set standards of care after surgery for vomiting (20%), nausea (25%), pruritus (14, 7%), minor sedation (24%) and excessive sedation (2, 6%). Their recommendation is that acute pain services should aim for incidences less than their stated standard of care values.⁵

Sixty percent of patients in our study reported drowsiness, 48.2% of patients experienced PONV and 22.7% of patients experienced pruritus. The median scores for drowsiness, nausea or vomiting and pruritus was 2, 0, and 0 respectively. According to the standards of care stated above, too many patients in our study experienced nausea or vomiting, drowsiness and pruritus. However, an assessment of the severity of these side effects is required. The percentage of patients experiencing the side effects are high when compared to the standards of care set by Dolin et al. However, the scores are low. The question then presents itself: is it the mere incidence of pain and side effects or rather the severity that affects the patients experience post-operatively?

Complete elimination of pain²⁶ and side effects is not possible in many cases. It is unrealistic to pose this as a treatment goal.²⁶

Improvements in treatment should strive to make pain management patient centered, effective, timely, efficient and above all, safe.²⁷ The aim should be to reduce the impact of pain and side effects on the patients function and quality of life.²⁶

A reduction in pain (and side effect) intensity represents a reasonable standard of intervention efficacy. From the patient's perspective, data from clinical trials suggest a 33% - 50% reduction in pain intensity is meaningful.^{14, 28, 29, 30}

Study Limitations

The data represented in the study included 55% of patients presenting for laparoscopic gynaecological procedures during the period under review. Reasons why patients were not included in the study include patient refusal, patients who were not able to understand a language the questionnaires were provided in, patients being discharged prior to the fulfillment of the minimum time frame required as part of the inclusion criteria and patients who were not of consenting age.

POQ and PQ were completed on the first post-operative day on patients who were back in the ward for at least six-hours but they were not necessarily completed at the same time after the procedure for each patient. The discrepancy between patients in the time elapsed between surgery and data collection may result in differences in pain scores and side effects reported.

The researcher relied on completed POQ and PQ. An assumption was made that all patients who answered the questionnaires understood what the question was asking of them and that all health care workers completed the PQ as per the SOP of the PAIN OUT study. The PAIN OUT SOP states that the questions on the POQ may not be explained to patients.

From the dose of Remifentanyl recorded, it is apparent that the reliance on accurate documentation is a limitation.

Conclusions

The proposed benefits of laparoscopic surgery, especially less associated post – operative pain and an expedited discharge is with the proviso that the anaesthetic technique adequately addresses post-operative analgesic requirements without resulting in undue, severe side effects which may delay hospital discharge and result in reduced patient satisfaction.

Analgesia for laparoscopic gynaecological procedures poses a unique challenge especially when the procedure is planned as a day-case procedure. Analgesia provided should be sufficient for patients to mobilise by the night of surgery and provide longer term analgesia as pain may persist for several days after the procedure. However, side effects should be avoided or kept to a minimum, tolerable level. In addition, the nature of pain may change over this period. Pain in various sites may become more or less severe along the time course of recovery.³¹

Postoperative analgesia combining intra-operative opiates, local anaesthesia and NSAIDS may be referred to as balanced or multi-modal analgesia. The combination of the approaches has numerous advantages including significantly shorter discharge times, lower pain scores, lower incidences of PONV when compared with more traditionally opiate based anaesthetic options.⁴

Results of this study reveal the mean age of patients presenting for laparoscopic gynaecological procedures to be among the age group of significant contributors to a countries economic and social

status. An expedited, safe, hospital discharge (particularly day case procedures) may result in improved patient satisfaction as well as economic benefits.

Although most patients experienced post – operative pain, and side effects experienced were higher than recommended standards of care, the severity of pain and side effects experienced may be said to be tolerable.

Conflicts of Interest

The authors declare that there are no conflicts of interest.

Acknowledgements

The authors would like to acknowledge the remarkable concept of the PAIN OUT study as well as thank the PAIN OUT team for use of their database.

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Section 6: Appendices

Appendix A: Post Graduate Approval



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Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

05 January 2018
Person No: 0603918W
PAG

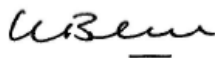
Dr M Mahomed
P O Box 85360
Emmarentia
Emmarentia
2029
South Africa

Dear Dr Mahomed

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Post-operative experiences of patients undergoing laparoscopic gynaecological surgery at an academic training hospital* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely



Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

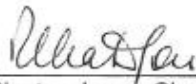
Appendix B: Ethics Approval



R14/49 Dr Mishkah Mahomed

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170285

NAME: Dr Mishkah Mahomed
(Principal Investigator)
DEPARTMENT: Anaesthesia
Rahima Moosa Mother and Child Hospital
PROJECT TITLE: Post-Operative Experiences of Patients Undergoing
Laparoscopic Gynaecological Surgery at an
Academic Training Hospital
DATE CONSIDERED: 24/02/2017
DECISION: Approved unconditionally
CONDITIONS:
SUPERVISOR: Dr Sean Chetty and Dr Adriaan Buitenweg
APPROVED BY: 
Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL: 27/02/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in February and will therefore be due in the month of February each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C: Patient Information and Consent



PATIENT OUTCOMES QUESTIONNAIRE

Dear Madam

My name is Sean Chetty and I am the head of the department of Anaesthesiology at the Rahima Moosa Mother and Child Hospital. My colleagues and I are collaborating on an international survey investigating how patients feel after surgery. The aim of the survey is to improve the management of pain after surgery in this department.

We would be grateful if you would consider participating in our survey. If you decide to join the study you will complete a questionnaire that should take approximately 5 minutes to complete. In addition, we would like permission to record some information from your hospital records. The information you provide will be made anonymous once you hand in this questionnaire. This means that your name or other form of identification will be deleted from the questionnaire after you hand it in and will not be included in any records we will hold.

Your answers in this questionnaire will not be shared with your medical or nursing team,

Your participation is voluntary and your medical team will treat you in the same way whether or not you choose to participate in our survey. Should you wish to withdraw from the study, you may do so without any problem.

CONSENT

I have had the purpose of the PAIN OUT study explained to me and have been given the opportunity to ask questions about my participation.

I agree to participate in the study

Signature Date

Version 2.6 110225

Appendix D: Patient Outcome Questionnaire

PATIENT OUTCOMES QUESTIONNAIRE																																																																																																																																																																										
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The following questions are about pain you experienced since your surgery. P1. On this scale, please indicate the worst pain you had since your surgery: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> <tr> <td colspan="3">no pain</td> <td colspan="8"></td> <td>worst pain possible</td> </tr> </table> P2. On this scale, please indicate the least pain you had since your surgery: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> <tr> <td colspan="3">no pain</td> <td colspan="8"></td> <td>worst pain possible</td> </tr> </table> P3. How often were you in severe pain since your surgery? Please circle your best estimate of the percentage of time you experienced severe pain: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0%</td><td>10%</td><td>20%</td><td>30%</td><td>40%</td><td>50%</td><td>60%</td><td>70%</td><td>80%</td><td>90%</td><td>100%</td> </tr> <tr> <td colspan="5">never in severe pain</td> <td colspan="6">always in severe pain</td> </tr> </table> P4. Circle the one number below that best describes how much, since your surgery, pain interfered with or prevented you from ... a. doing activities in bed such as turning, sitting up, changing position: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> <tr> <td colspan="3">did not interfere</td> <td colspan="8"></td> <td>completely interfered</td> </tr> </table> b. breathing deeply or coughing: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> <tr> <td colspan="3">did not interfere</td> <td colspan="8"></td> <td>completely interfered</td> </tr> </table> c. sleeping: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> <tr> <td colspan="3">did not interfere</td> <td colspan="8"></td> <td>completely interfered</td> </tr> </table> d. Have you been out of bed since your surgery? ☐ Yes ☐ No If yes, how much did pain interfere or prevent you from doing activities out of bed such as walking, sitting in a chair, standing at the sink: <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> <tr> <td colspan="3">did not interfere</td> <td colspan="8"></td> <td>completely interfered</td> </tr> </table>											0	1	2	3	4	5	6	7	8	9	10	no pain											worst pain possible	0	1	2	3	4	5	6	7	8	9	10	no pain											worst pain possible	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%	never in severe pain					always in severe pain						0	1	2	3	4	5	6	7	8	9	10	did not interfere											completely interfered	0	1	2	3	4	5	6	7	8	9	10	did not interfere											completely interfered	0	1	2	3	4	5	6	7	8	9	10	did not interfere											completely interfered	0	1	2	3	4	5	6	7	8	9	10	did not interfere											completely interfered
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PATIENT OUTCOMES QUESTIONNAIRE

P5. Pain can affect our mood and emotions.

On this scale, please circle the one number that best shows how much, since your surgery, **pain caused you to feel ...**

a. **anxious**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

not at all

extremely

b. **helpless**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

not at all

extremely

P6. Have you had any of the following **side effects** since your surgery?

Please circle "0" if no; if yes, circle the one number that best shows the severity of each:

a. **Nausea**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

none

severe

b. **Drowsiness**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

none

severe

c. **Itching**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

none

severe

d. **Dizziness**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

none

severe

P7. Since your surgery, how much **pain relief** have you received?

Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
----	-----	-----	-----	-----	-----	-----	-----	-----	-----	------

no relief

complete relief

P8. Would you have liked **MORE pain treatment** than you received?

☐ Yes ☐ No

P9. Did you receive any **information** about your **pain treatment** options?

☐ Yes ☐ No

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

not at all

very much so

P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery:

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

extremely dissatisfied

extremely satisfied

P12. Did you use or receive any **non-medicine methods** to relieve your **pain**?

☐ Yes ☐ No

If yes, **check all** that apply:

- | | | |
|--|--------------------------------------|---|
| ☐ cold pack | ☐ meditation | ☐ deep breathing |
| ☐ heat | ☐ acupuncture | ☐ prayer |
| ☐ talking to medical staff | ☐ walking | ☐ massage |
| ☐ talking to friends or relatives | ☐ relaxation | ☐ imagery or visualization |
| ☐ TENS (Transcutaneous Electrical Nerve Stimulation) | | |
| ☐ distraction (like watching TV, listening to music, reading) | | |
| ☐ other (please describe): <input type="text"/> | | |

P13. Did you have a **persistent painful condition for 3 months** or more before coming into hospital for this surgery?

☐ Yes ☐ No

a. If yes, **how severe** was the **pain** most of the time?
Please circle the number that indicates this.

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

no pain

worst pain possible

b. If yes, **where** was this **persistent pain** located?

☐ site of surgery ☐ elsewhere ☐ both (site of surgery and elsewhere)

Thank you for your time and feedback

To be filled in by the research assistant

Research assistant code:

Patient was interviewed: ☐ Yes ☐ No

If yes, please mark the reason(s):

- | | | | |
|---|--|---|--|
| ☐ Too ill / weak | ☐ Too much pain | ☐ Requested assistance | ☐ Did not understand scales |
| ☐ Technical reasons (patient has no eyeglasses / is blind; can not sit up; is illiterate; arm is in cast; etc) | | | |

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Appendix E: Process Questionnaire

DATE OF DATA COLLECTION: 2 0 1 1 1 1 1 1
TIME OF DATA COLLECTION: 1 1 1 1 1 1
WARD WHERE DATA IS COLLECTED: 1 1 1 1 1 1

RESEARCH ASSISTANT CODE: 1 1 1 1 1 1
PATIENT CODE: 1 1 1 1 1 1
ROOM NUMBER: 1 1 1 1 1 1

SCREENING - INCLUSION CRITERIA

S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward
End surgery: Date: 2 0 1 1 1 1 1 1 Time: 1 1 1 1 1 1 POD17
Back in ward: Date: 2 0 1 1 1 1 1 1 Time: 1 1 1 1 1 1 6HRS7

S2 Patient is consenting age or over

S3 Patient has given his assent (or consent) to participate
If no to S3, mark the reason(s):
☐ a. Patient is not on the ward
☐ b. Patient does not wish to participate
☐ b1. too ill
☐ b2. too much pain
☐ c. Patient is asleep
☐ d. Patient has visitors
☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
☐ f. Patient is cognitively impaired (e.g., Down's syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
☐ g. Other, specify: 1 1 1 1 1 1

DEMOGRAPHIC INFORMATION

D1 Gender ☐ Male ☐ Female
D2 Year of birth 1 9 1 1
D3 Weight 1 1 1 1 kg
D4 Height 1 1 1 1 cm
D5 Nationality (check records) 1 1 1 1
D6 Country of birth (check records) 1 1 1 1
D7 Language of Outcome questionnaire (select one)
☐ Arabic ☐ Bahasa Malaysia ☐ Danish ☐ Dutch ☐ English ☐ Finnish ☐ French
☐ German ☐ Hebrew ☐ Italian ☐ Korean ☐ Mandarin ☐ Romanian ☐ Russian
☐ Serbo-Croatian ☐ Spanish ☐ Swedish

BLANK FIELDS

Blank field 1: 1 1 1 1 1 1
Blank field 2: 1 1 1 1 1 1
Blank field 3: 1 1 1 1 1 1
Blank field 4: 1 1 1 1 1 1

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Mark medications given to patient; record cumulative doses. **PATIENT CODE:** 1 1 1 1 1 1

MEDICAL HISTORY

H1 Comorbidities
☐ yes ☐ no ☐ not possible to obtain the information
If yes, which (check all that apply):
☐ Cancer
☐ Renal insufficiency or disease without dialysis ☐ Renal disease requiring dialysis
☐ Affective disorders (depression, anxiety, phobia, PTSD, bipolar disorder) ☐ Schizophrenia
☐ Alcohol use disorder ☐ Current smoker ☐ Substance abuse of drugs (legal and illegal)
☐ Hypertension ☐ Coronary artery disease or myocardial infarction or cerebral vascular accident
☐ Sickle cell disease
☐ Liver Cirrhosis ☐ History or current upper or lower GI ulcer (peptic or duodenal ulcer disease)
☐ Irritable bowel disease (Crohn's disease, ulcerative colitis)
☐ Asthma ☐ Sleep apnea ☐ Chronic Obstructive Pulmonary Disease (COPD)
☐ Fibromyalgia
☐ Regular administration of oral or parenteral corticosteroid medications
☐ At least 1 fracture(s) / laceration(s) / tissue damage in addition to the current reason for surgery
☐ Patient has already undergone another surgery during current hospitalization
☐ Other, specify: 1 1 1 1 1 1

H2 Existing condition (check medical record)
☐ Pregnancy, Week: 1 1 ☐ not relevant ☐ not possible to obtain the information
☐ Lactation ☐ not relevant ☐ not possible to obtain the information

H3 Did the patient receive any opioid(s) before the current admission?
☐ yes ☐ no ☐ not possible to obtain the information
If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release (PO & other)
Suprenorphine	☐ mg/day	☐ µg/hr (transdermal)
Codeine	☐ mg/day	☐ mg/day
Fentanyl	☐ µg/hr (transdermal) / 1 1 1 1 1 1	☐ µg/hr (transdermal)
Hydrocodone	☐ mg/day	☐ mg/day
Hydromorphone	☐ mg/day	☐ mg/day
Morphine	☐ mg/day	☐ mg/day
Oxycodone	☐ mg/day	☐ mg/day
Oxycodone (oral, sublingual)	☐ mg/day	☐ mg/day
Peritidine (hydrocodone)	☐ mg/day	☐ mg/day
Tapentadol	☐ mg/day	☐ mg/day
Tilidin (oral, sublingual)	☐ mg/day	☐ mg/day
Tramadol	☐ mg/day	☐ mg/day
Other, specify: 1 1 1 1 1 1	☐	☐
Other, specify: 1 1 1 1 1 1	☐	☐

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Page 1

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE: _____

PRE - MEDICATION

M1 Sedatives (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.
Diazepam	☐ mg	☐ mg
Diklunthlorazepat	☐ mg	☐ mg
Haloperidol	☐ mg	☐ mg
Lorazepam	☐ mg	☐ mg
Midazolam	☐ mg	☐ mg
Promethazine	☐ mg	☐ mg
Other specify:	☐ mg	☐ mg

M2 Non-opioids (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.	i.m.	supp.
Celecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg	☐ mg
Etoricoxib	☐ mg	☐ mg	☐ mg	☐ mg
Gabapentin	☐ mg	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg	☐ mg
Nefopam	☐ mg	☐ mg	☐ mg	☐ mg
Paracetamol (acetaminophen)	☐ mg	☐ mg	☐ mg	☐ mg
Parecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Pregabalin	☐ mg	☐ mg	☐ mg	☐ mg
Other specify:	☐ mg	☐ mg	☐ mg	☐ mg
Other specify:	☐ mg	☐ mg	☐ mg	☐ mg

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Page 1

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE: _____

PRE - MEDICATION

M3 Opioids & Clonidine (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release (PO & other)	i.v.	i.m.	supp.	s.c.
Buprenorphine	☐ mg ☐ µg/hr	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Fentanyl	☐ µg	☐ µg/hr	☐ µg	☐ µg	☐ µg	☐ µg
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Morphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Nalbuphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Oxycodone (oral, Naloxone)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Pethidine (meperidine)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Piritramide	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Tapentadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Tilidin (active Naloxone)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Other specify:	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Other specify:	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Clonidine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg

SURGICAL PROCEDURE(S)

P1 Surgical procedure(s)
use ICD-9 codes link <http://icd9cm.chrisendres.com/index.php?action=proclist>

ICD-9 Procedure Code	Text
1	1
2	2
3	3
4	4

P2 Duration of surgery

Start surgery: Date: 2 0 1 1 1 1 1 1 1 1 Time: 11 11 11 11

End surgery: Date: 2 0 1 1 1 1 1 1 1 1 Time: 11 11 11 11

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Page 5

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE: _____

INTRA-OPERATIVE

M4 General anaesthesia (intra-op)
☐ yes ☐ no ☐ not possible to obtain the information
 If yes, which (multiple answers possible):
☐ Inhalational ☐ IV

M5 Regional anaesthesia (RA) (intra-op)
☐ yes ☐ no ☐ not possible to obtain the information
 If yes, which (multiple answers possible):
☐ Epidural ☐ Spinal ☐ Brachial plexus ☐ Femoral
☐ Sciatic ☐ Paravertebral ☐ Other: _____ ☐ Other: _____

In M4-M5 Mark the RA medication(s) given in the RA column

M6 Non-opioids (intra-op)
☐ yes ☐ no ☐ not possible to obtain the information
 If yes, which (multiple answers possible):

	iv.	lm.	supp.
Diclofenac	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg
Ketamine	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg
Nelopam	☐ mg	☐ mg	☐ mg
Paracetamol (Acetaminophen)	☐ mg	☐ mg	☐ mg
Parecoxib	☐ mg	☐ mg	☐ mg
Other, specify: _____	☐	☐	☐
Other, specify: _____	☐	☐	☐
	iv.	lm.	supp.

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Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE: _____

INTRA-OP

M7 Wound infiltration (intra-op)
☐ yes ☐ no ☐ not possible to obtain the information
 If yes, which (multiple answers possible; analgesic is not recorded):
☐ Single shot by surgeon ☐ Indwelling catheter ☐ Other, specify: _____ ☐ Other, specify: _____

M8 Opioids & local anaesthetics & Clonidine (intra-op)
☐ yes ☐ no ☐ not possible to obtain the information
 If yes, which (multiple answers possible):

	RA (see M5)	iv.	lm.	s.c.
Alfentanil	☐ µg	☐ µg	☐ µg	☐ µg
Buprenorphine	☐ µg	☐ µg	☐ µg	☐ µg
Codeine	☐ mg	☐ mg	☐ mg	☐ mg
Fentanyl	☐ µg	☐ µg	☐ µg	☐ µg
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg
Morphine	☐ mg	☐ mg	☐ mg	☐ mg
Nalbuphin	☐ mg	☐ mg	☐ mg	☐ mg
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg
Pethidine (Meperidine)	☐ mg	☐ mg	☐ mg	☐ mg
Piritramid	☐ mg	☐ mg	☐ mg	☐ mg
Remifentanyl	☐ µg	☐ µg	☐ µg	☐ µg
Sufentanil	☐ µg	☐ µg	☐ µg	☐ µg
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg
Bupivacaine	☐	☐	☐	☐
Levobupivacaine	☐	☐	☐	☐
Lidocaine	☐	☐	☐	☐
Prilocaine	☐	☐	☐	☐
Ropivacaine	☐	☐	☐	☐
Other, specify: _____	☐	☐	☐	☐
Other, specify: _____	☐	☐	☐	☐
Clonidine	☐ µg	☐ mg	☐ mg	☐ mg
	RA	iv.	lm.	s.c.

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Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE:

RECOVERY ROOM

M9 Non-opioids (recovery room)

☐ yes
☐ no
☐ not possible to obtain the information

if yes, which (multiple answers possible):

	p.o.	lv.	lm.	supp.
Celecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg	☐ mg
Etoricoxib	☐ mg	☐ mg	☐ mg	☐ mg
Gabapentin	☐ mg	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketamine	☐ mg	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg	☐ mg
Nefopam	☐ mg	☐ mg	☐ mg	☐ mg
Paracetamol (Acetaminophen)	☐ mg	☐ mg	☐ mg	☐ mg
Paracetamol	☐ mg	☐ mg	☐ mg	☐ mg
Pregabalin	☐ mg	☐ mg	☐ mg	☐ mg
Other, specify:				
Other, specify:				
	p.o.	lv.	lm.	supp.

M10 Regional analgesia (recovery room)

☐ yes
☐ no
☐ not possible to obtain the information

if yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Other:	☐ Other:

In M11: (1) Mark the RA medication(s) given in the RA column

(2) If the medication was given as PCA, tick appropriate box in the PCA column

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Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE:

RECOVERY ROOM

M11 Opioids & local anaesthetics & Clonidine (recovery room)

☐ yes
☐ no
☐ not possible to obtain the information

if yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release (PO & other)	RA (see M10)	lv.	lm.	supp.	s.c.	PCA (see M10)
Buprenorphine	☐ mg	☐ µg/hr	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Fentanyl	☐ µg	☐ µg/hr	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Morphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Nalbuphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Oxycodone (oral solution)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Pethidine (Meperidine)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Piritramid	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Sufentanil	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐
Tapentadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Tilidin (other, solution)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Bupivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Levobupivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Lidocaine	☐	☐	☐	☐	☐	☐	☐	☐
Prilocaine	☐	☐	☐	☐	☐	☐	☐	☐
Ropivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Other, specify:								
Other, specify:								
Clonidine	☐ µg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Naloxone (only as an antagonist for respiratory depression)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
	Immediate release (PO & other)	Controlled release (PO & other)	RA	lv.	lm.	supp.	s.c.	PCA

Version2.6.110217

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Appendix F: Data Collection Sheet

1. Have all the inclusion criteria been met?

YES		NO	
-----	--	----	--

2. Patient Demographics

Age	
Weight	

3. Nature of laparoscopic procedure

- a. Laparoscopic Tubal Ligation

OR

- b. Other Laparoscopic gynaecological procedure

Specify Procedure: _____

4. Analgesia used

Intra-operative analgesia used

Drug	Dose

Post-operative Analgesia used

Drug	Dose

5. Pain

On this scale, indicate the **worst pain** the patient had since the surgery

0	1	2	3	4	5	6	7	8	9	10
No pain possible					Worst pain					

On this scale, indicate the **least pain** the patient had since the surgery

0	1	2	3	4	5	6	7	8	9	10
No pain possible					Worst pain					

6. Average NRS Score

--

7. Side effects experienced:

a) Nausea or vomiting

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

b) Drowsiness

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

c) Pruritus

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

Appendix G: Permission from the gatekeeper of the PAIN OUT records at Rahima Moosa Mother and Child Hospital



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24 January 2017

Dr M Mahomed
Rahima Moosa Mother and Child Hospital
Cnr Fuel and Oudtshoorn Roads
Coronationville

Dear Dr Mahomed,

ACCESS TO THE PAIN OUT DATABASE

With reference to your communication on the 21st January 2017 regarding access to the PAIN OUT database that was compiled from records of patients admitted for surgery at RMMCH. As the curator of the database, I am happy to permit you to have access to the records for the purpose of completing your MMed research, provided that you are granted approval by the Human Research Ethics Committee of the University of the Witwatersrand.

Kind Regards

Dr S Chetty

Deputy Head
Department of Anaesthesiology & Critical Care

Appendix H: Letter from Supervisor re: Turnitin Report



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22 June 2018

The Chairperson
Postgraduate Committee
Department of Anaesthesiology
Faculty of Health Sciences
University of the Witwatersrand

Dear Sir,

Mmed(Anaes) : Post-operative experiences of patients undergoing laparoscopic gynaecological surgery at an academic training hospital

Dr M Mahomed (Student number: 0603918W) has submitted her research assignment to Turnitin, which returned a similarity index of 13%. These similarities appear to be due to the use of commonly used terms and phrases and not due to plagiarism.

If you have any further queries regards to this issue, please do not hesitate to contact me.

Kind Regards

Dr S Chetty (Supervisor)
Head: Clinical Department – Anaesthesiology and Critical Care, Tygerberg Hospital
Deputy Head of Department - Anaesthesiology and Critical Care, Stellenbosch University



Medicine and Health Sciences
Geneeskunde en Gesondheidswetenskappe
EzoNyango nezeeNzululwazi kwezeMpilo



Appendix I: Turnitin Report

0603918w:Mishkah_submission_4_correction_040618.docx

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PRIMARY SOURCES

1	Bajwa, Sukhminder Kulshrestha, Ashish. "Anaesthesia for laparoscopic surgery: General vs regional anaesthesia.(Review Article) (Report)", Journal of Minimal Access Surgery, Jan-March 2016 Issue Publication	1%
2	Arjunan Ganesh. "Pathophysiology and Management of Opioid-Induced Pruritus", Drugs, 2007 Publication	1%
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5	Paul Hayden, Sarah Cowman. "Anaesthesia for laparoscopic surgery", Continuing Education in Anaesthesia Critical Care & Pain, 2011 Publication	<1%
6	Submitted to University of Witwatersrand Student Paper	<1%