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Herbst, Julie-Ann Melissa Elizabeth

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PREOPERATIVE FASTING PRACTICES IN ADULT ELECTIVE SURGERY PATIENTS AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Julie-Ann Melissa Elizabeth Herbst

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the

degree

of

Master of Medicine in the branch of Anaesthesiology

Johannesburg, 2016

Declaration

I, Julie-Ann Melissa Elizabeth Herbst, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

.....

Julie-Ann Melissa Elizabeth Herbst

Signed on this 4th day of February at Johannesburg

Dedication

To my husband, my mother and my sister for their endless support.

Acknowledgements

I would like to thank the following people for their advice and assistance:

Mrs Helen Perrie

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Abstract

The literature describing the implementation of the latest preoperative fasting guidelines by South African health care professionals is limited. Preoperative fasting of adult patients in the health care system has been observed to be unnecessarily long. Prolonged preoperative fasting may result in detrimental effects such as hypovolaemia, dehydration, headache and hypoglycaemia. These effects impact upon patient wellbeing and satisfaction with healthcare.

The aim of this study was to describe preoperative fasting practices in adult elective surgery patients at CMJAH.

A prospective, contextual, descriptive study design was used in this study. A sample size of 62 adult patients who required anaesthesia for elective surgery estimated the mean instructed and actual fasting times to an accuracy of within 0.5%. The researcher collected data on the day of surgery using a standardised data collection sheet.

The study included 64 patients from four surgical disciplines. The median instructed fasting time was 10 hours with a minimum of 8 hours and a maximum of 12 hours. The mean actual fasting time was 14.92 (S.D. 2.50) hours. The difference between the actual and instructed fasting times was statistically significant. There was however no difference in fasting times between the four surgical disciplines.

The mean instructed and actual fasting times for adult elective surgery patients at CMJAH were longer than the recommended guidelines. The mean actual fasting time compared closely with local paediatric and international adult studies suggesting that prolonged preoperative fasting is a widespread problem.

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List of abbreviations

ASA	American Society of Anesthesiologists
ESA	European Society of Anaesthesiology
CAS	Canadian Anesthesiologists' Society
SASA	South African Society of Anaesthesiologists
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital

Chapter 1

Overview of the study

1.1 Introduction

In this chapter the practice and history of preoperative fasting is introduced. This is followed by the problem statement, the aim and the objectives of this study. The research assumptions, the study field and ethical considerations of the study are outlined. This is followed by a brief discussion of the research methodology, the significance, the validity and reliability of the study. An outline of the research report is also given.

1.2 Background

Preoperative fasting is medically required prior to the administration of an anaesthetic except for those administered for emergency surgery. The primary purpose of fasting is to avoid the potentially fatal consequences of pulmonary aspiration of gastric contents. (1)

Preoperative fasting guidelines for adult patients undergoing elective surgery have been published by various societies including the American Society of Anesthesiologists (ASA), the European Society of Anaesthesiology (ESA) and the Canadian Anesthesiologists' Society (CAS). (2-4)

Fasting guidelines were published by the ASA in 1999 (5) and updated in 2011 (6) and form the foundation of the South African fasting guidelines recommended by the South African Society of Anaesthesiologists (SASA) (7, 8). In the Practice Guidelines outlined by SASA, there are no formal recommendations for fasting (8). However, the SASA Practice Guidelines (8) and SASA Sedation Guidelines (7) refer the reader to the ASA Practice Guidelines for Preoperative Fasting, but do not specifically clarify the actual fasting guidelines. The guidelines described by the ASA are intended for healthy patients of all age groups, scheduled for elective procedures requiring anaesthesia. No specific recommendations are made for patients with comorbidities that may affect gastric emptying. The 1999 Task Force appointed by

the ASA recommended a preoperative fasting time for solids of six hours and clear fluids of two hours but stated there was insufficient evidence regarding the safety of any fasting time for solids preoperatively (5). The updated fasting guidelines published in 2011 provided further evidence to support a fasting time of two hours for clear fluids and six hours for a light meal of tea and toast (6).

Despite evidence that shorter fasting times do not pose any greater risk for pulmonary aspiration (1, 9), patients are still being fasted for prolonged periods (10, 11). A study of 155 adult patients undergoing elective surgery was conducted in Texas in the United States of America (USA) from November 1999 to May 2000 by Crenshaw et al. (10). This study was conducted from eight months after the new preoperative fasting guidelines were published in 1999. These guidelines were accepted by the ASA in 1998 prior to their publication. It was found that a large proportion of patients had been instructed to fast from midnight even after the ASA had published the new guidelines. On average, patients' fasting duration for clear liquids and solids were over 12 hours and 14 hours, respectively. Some patients fasted from clear liquids for 20 hours and solids for 37 hours.

Crenshaw et al. (12) carried out a subsequent study at the same hospital two years after implementation of a policy and education programme reinforcing the shorter preoperative fasting times outlined in the 1999 ASA guidelines. This study was conducted five years after the ASA guidelines were published in 1999 and showed little improvement in fasting practices. Breuer et al. (13) concluded in a study in Germany that some reasons for the poor adoption of shorter fasting times include concern for higher risk of pulmonary aspiration and causing confusion within the institution.

Shorter fasting times allow less flexibility in theatre list rearrangements as some patients may not have fasted long enough if they are unexpectedly shifted to an earlier theatre slot. Other reasons for inconsistency between actual fasting practices and current guidelines include:

- the difficulty of changing from the traditional routine
- the idea that longer fasts are superior

- the challenge of individual fasting instructions
- litigation concerns
- the lack of knowledge about possible adverse effects of prolonged fasting
- the limited and outdated knowledge of the risks of aspiration. (10)

There are important barriers which may inhibit doctors' adherence to practice guidelines by affecting their knowledge, attitudes and behaviour. Lack of awareness of the vast amount of research available limits doctors' knowledge of the latest applicable guidelines. Doctors' disagreement with a particular guideline and their disbelief that a behaviour can be changed may affect their attitude towards new guidelines. A new guideline may not be adhered to if it is not expected to lead to improved outcomes. Attitudes may not change if there is not enough motivation to change. Reluctance to change previous practice due to the "inertia of previous practice" may be another potential barrier that affects attitudes. The degree of convenience related to a particular guideline's use and the difficulty in merging patient preferences with that guideline may be potential external barriers. These barriers affect adherence to new guidelines (14). Nursing staff play a pivotal role in the implementation of guidelines and are essential in changing practice (15).

The adverse effects of prolonged preoperative fasting include headache, dehydration, hypovolaemia, and hypoglycaemia (9). There is evidence that shorter preoperative fasting reduces postoperative nausea and vomiting (9) and improves postoperative insulin resistance which occurs as a response to surgery (16). Adverse effects add to patient discomfort and potentiate adverse psychological effects such as irritability and anxiety (17).

A non-randomised case-control study of preoperative fasting times amongst adult surgical patients undergoing elective procedures was conducted in 2009 in Dublin, Ireland. It was found that a shorter fast resulted in fewer adverse symptoms preoperatively, which included headache, thirst and nausea. (18)

A large study of 3715 adult patients conducted in Brazil from August 2011 until September 2012 reported an actual preoperative fasting time of 12 hours (19). A

smaller study of 43 adult and paediatric patients in Ethiopia in 2013 reported an actual preoperative fasting time of 19.60 hours for solids and 12.72 hours for liquids (20). These studies show that prolonged preoperative fasting is a significant problem in developing countries.

No South African literature regarding adult preoperative fasting practices could be identified. However, one study conducted in 2010 revealed the prevalence of prolonged preoperative fasting times in children at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in Gauteng, South Africa. The mean fasting time in paediatric patients undergoing elective surgery at CMJAH was found to be 14 hours. (21)

If preoperative fasting is prolonged in children at CMJAH, it is reasonable to expect a similar situation in adult patients. The risk of hypoglycaemia in children subjected to long preoperative fasts has been well established. The need for stricter fasting regimens in paediatric wards has already been highlighted. (21)

Although the side effects of prolonged fasting are more severe in children, there are significant effects related to prolonged preoperative fasting in adults. These include reduced patient comfort, increased insulin resistance and prolonged postoperative recovery (16, 22-24). Patient comfort contributes to overall satisfaction with care (25), therefore there is a need to quantify adult preoperative fasting times to improve perioperative patient care.

1.3. Problem statement

No literature had been identified describing how well South African health care professionals were implementing the latest fasting guidelines in adult patients. It had been observed that fasting practices in public hospitals may not have been in accordance with the fasting guidelines published by the ASA as patients were being starved for unnecessarily long periods. Patients had been known to complain about the length of time they were required to fast preoperatively.

Of concern were the patients who only had their surgery in the early afternoon. These patients, according to the guidelines, would have been permitted a light breakfast at 05:00 or 06:00 the morning before surgery. Instead, it appeared patients fasted from the night before. This unnecessarily prolonged the preoperative fasting duration and potentially resulted in detrimental effects such as hypovolaemia, dehydration, headache and hypoglycaemia (9). Likewise, all patients scheduled for theatre could have been permitted clear fluids at 06:00 and they would still have been appropriately fasted by 08:00, in time for the first scheduled surgery. This did not appear to be routine at CMJAH at the time of this study.

1.4 Aim and objectives

1.4.1 Aim

The aim of this study was to describe preoperative fasting practices in adult elective surgery patients at CMJAH.

1.4.2 Objectives

The primary objectives were to:

- describe the instructed preoperative fasting times in adult elective surgery patients
- estimate the actual fasting times in adult elective surgery patients.

The secondary objectives were to:

- compare the actual and instructed fasting times in adult elective surgery patients
- describe and compare the fasting times across various disciplines within the hospital.

1.5 Research assumptions

The following definitions were applied to this study.

- **Adult:** a patient 18 years of age and over.
- **Elective surgery:** a surgical procedure which is scheduled in advance and is not considered an emergency.
- **Fasting:** the act of abstaining from food, drink or both for a period of time.
- **Fasting practice:** how patients were fasted prior to surgery.
- **Instructed fasting time:** the time from when the patient was instructed to begin fasting until the time that surgery was scheduled to commence. At CMJAH, if patients were not given a specific starting time for their surgery, this was assumed to be 08:00. The aim was that all patients on the theatre list were adequately fasted for surgery to commence at 08:00.
- **Actual fasting time:** the time from the most recent consumption of any liquid or solid, excluding sips of water taken with morning medication until the surgery starting time.

1.6 Demarcation of study field

CMJAH is a central hospital in Johannesburg, Gauteng Province, South Africa. It is affiliated to the University of the Witwatersrand and is a referral centre for smaller regional hospitals. It contains 1088 beds with 4000 staff members and approximately 28000 surgeries are performed each year. (26)

The study took place in the adult general surgery, orthopaedic, urology and gynaecology wards and theatres of CMJAH.

1.7 Ethical considerations

The proposal for this study was submitted to the relevant authorities to obtain permission to conduct the study (Appendix 1,2 and 3).

Research was conducted according to the principles of the Declaration of Helsinki (27) and the South African Good Clinical Practice Guidelines (28).

1.8 Research methodology

1.8.1 Research design

A prospective, contextual, descriptive study design was used in this study.

1.8.2 Study population

The study population consisted of adult patients who required anaesthesia for elective surgery in the general surgery, orthopaedic, urology and gynaecology departments at CMJAH.

1.8.3 Study sample

Sample size

This study aimed to estimate the mean instructed and actual fasting times in adult elective surgery patients.

The sample size was determined in consultation with a biostatistician. A sample size of 62 patients was determined to be sufficient to estimate the mean instructed and actual fasting times to an accuracy of 0.5%. This calculation assumed a standard deviation of 2 hours and a confidence interval of 95%.

Sampling method

A stratified sampling method was used in this study to select an equal number of patients from each of the four disciplines. Sixteen patients were selected from each discipline.

Inclusion and exclusion criteria were applied to this study.

1.8.4 Data collection

Data was collected from June to December 2014.

The researcher explained the study to the patients and invited them to take part in the study on the day of surgery. An information letter (Appendix 4) was given to patients to read. Consent (Appendix 5) was obtained if they agreed to participate in the study.

The researcher collected data at different times on the day of surgery using a standardised data collection sheet (Appendix 6).

The data was entered onto a Microsoft Excel® spreadsheet.

1.8.5 Data analysis

Data was analysed in consultation with a biostatistician and the use of Microsoft Excel® and GraphPad InStat® version 3.10. Descriptive and inferential statistics were used to analyse the data obtained during the study.

1.9 Significance of the study

Fasting times were found to be prolonged in paediatric patients undergoing elective surgery at CMJAH (21). It was likely that fasting times in adults undergoing elective surgery were just as long. Prolonged fasting is associated with several perioperative adverse effects which impact on patients' health, experience of and satisfaction with the health care system (16, 22, 24). Patient satisfaction is an important determinant of quality of care and contributes to the patient's perception of their own health status (25). This highlights the importance of avoiding prolonged preoperative fasting.

There was a need to evaluate preoperative fasting times to be able to assess the extent of prolonged fasting amongst adult elective surgery patients at CMJAH. With this information, the need for intervention and factors influencing preoperative fasting times could be identified. The implementation of a solution would contribute to improved patient comfort, satisfaction and perception of health care delivery in South Africa.

1.10 Validity and reliability of the study

Measures were taken to ensure the validity and reliability of the study.

1.11 Outline of research report

Chapter	Title
Chapter 1	Overview of study
Chapter 2	Literature review
Chapter 3	Methodology
Chapter 4	Results and discussion
Chapter 5	Study summary, limitations, recommendations and conclusion

1.12 Summary

In this chapter an overview of the study was given. In the following chapter a review of the literature is presented.

Chapter 2

Literature Review

2.1 Introduction

In this literature review, the history and evolution of fasting guidelines are discussed. This is followed by a description of the physiology of gastric emptying and pulmonary aspiration. Thereafter, the principles behind the need to fast patients preoperatively, the physiology of fasting and the adverse effects are presented. The benefits of shorter fasting times are explored. The current fasting guidelines are reviewed followed by the reasons for the reluctance to adopt them. In conclusion, international and South African current fasting practices are discussed.

2.2 The history of preoperative fasting and the evolution of fasting guidelines

The practice of fasting patients preoperatively began in 1883 when Joseph Lister, a British surgeon who was a forerunner in asepsis, made some recommendations to decrease vomiting linked to the anaesthetic agent chloroform. Joseph Lister wrote what were possibly the initial fasting guidelines from observations that he made during his work as a surgeon. He advised that patients could drink clear fluids up until two hours before surgery and that there should be no solid matter in the stomach at the time of surgery. Lister highlighted the different effects that solids and liquids have on patients anaesthetised with chloroform. He advocated tea or beef tea, a calorie containing drink, as the clear fluids of choice (29, 30). Calorie containing fluids are still recommended today (24).

For years since Lister's recommendation, the standard fasting regimen of 2 to 3 hours for clear liquids and 4 to 6 hours for an easily digested light meal was used by health professionals throughout the world (29).

In 1946, Mendelson noted that obstetric patients had a significant occurrence of pulmonary aspiration. He conducted a survey of New York Lying-In Hospital records. He noted that out of 44016 pregnant women, including those who needed operative intervention and those who delivered spontaneously, there were 66 cases of

aspiration of stomach contents from 1932 to 1945 in obstetric patients. It was understood, at that time, that if gastric volume increased, the risk of pulmonary aspiration increased. Additionally, lung damage was found to increase with decreasing pH. (31)

Mendelson described two separate syndromes which he observed to follow aspiration. He noted that aspiration of solid food produced laryngeal or bronchial obstruction. This obstruction was either complete or incomplete. Complete obstruction was observed to cause suffocation. Incomplete obstruction was found to produce massive lung collapse with cyanosis, increased heart rate, shortness of breath, shift of the mediastinum and consolidation over the collapsed portion of the lung. Aspiration of liquid was found to produce a syndrome similar to asthma with cyanosis, increased heart rate and shortness of breath but with no lung collapse or shift of the mediastinum. Wheezes were noted where the lungs were affected, indicating bronchospasm. Mendelson also included evidence from animal experiments on rabbits which indicated that hydrochloric acid was responsible for the bronchospasm noted in aspiration. (31)

Based on this new found evidence, stricter fasting routines were then implemented and fasting times were extended. Separate times were no longer recommended for liquids and solids for convenience. The term “NPO after midnight” was used in American textbooks from the 1960s to describe this practice (32). This tradition of fasting was widespread as it was convenient to administer, permitted rearrangement of the surgical list and was rarely challenged by health care professionals and patients (2).

Maltby et al. (22) in 1986 showed that healthy adult patients who drank 150 ml of water 2 to 3 hours before surgery had a lower mean gastric fluid volume than those who fasted from midnight. Later, it was found that an even larger amount of 150 to 450 ml of clear fluid two and a half hours prior to surgery did not raise gastric fluid volume when compared with those who fasted from midnight. There was no correlation between the amount of clear fluid that patients drank 2 to 3 hours preoperatively and residual gastric volume (33).

The idea of shorter fasting times evolved from the late 1980s and 1990s as more evidence was revealed about the adverse effects of prolonged fasting. The trend towards shorter fasting times has continued since then (2). Recently it has been found that more lenient guidelines can be used without increasing the risk of pulmonary aspiration (22, 34). Carbohydrate containing fluids are now seen to be safe to drink preoperatively and this could also diminish the catabolic stress response that occurs during surgery (35). The emptying of liquid gastric contents depends on the total amount of calories in the liquid. It has recently been shown that the rate of emptying of 250 ml of tea with 50 ml of milk was equivalent to that of 300 ml of plain black tea, as 50 ml of milk contains only approximately 33 kcal (36). Therefore tea with a small amount of milk can be consumed without prolonging the fasting time. Fasting guidelines have not been modified as yet despite this new evidence.

Although prolonged preoperative fasting times are unnecessary, studies show that they are still being prescribed for adult and paediatric patients. (37)

2.3 Physiology of gastric emptying and pulmonary aspiration

Gastric emptying is a consequence of strong peristaltic waves, which originate in the stomach antrum, overriding the resistance at the pylorus. The contractions in the antrum are initially weak and mix food with stomach secretions to form chyme. These contractions increase in intensity and spread towards the pylorus. A maximum pressure of 50 to 70 cmH_2O can be achieved at the pylorus. With normal pyloric tone, a small amount of chyme is pushed into the duodenum with each forceful peristaltic wave. Gastric emptying is controlled by the stomach and duodenum. The rate of emptying is largely determined by the rate at which the chyme can be digested and absorbed by the small intestine. (38)

There is a fine balance between promotion and inhibition of gastric emptying. Myenteric reflexes brought on by stomach wall stretch increase peristalsis and reduce pyloric tone. Gastrin, a hormone released in response to stomach wall stretch and the presence of food in the stomach, promotes secretion of acidic gastric fluid

and promotes gastric emptying. If the amount of chyme in the duodenum reaches excessive levels, multiple reflexes feedback via the enteric nervous system, the sympathetic ganglia and the vagus nerves to the stomach and brainstem. The hormones cholecystokinin, secretin and gastric inhibitory peptide are released from the small intestine in response to the presence of fats in chyme and feedback to the stomach. These negative feedback systems inhibit peristaltic contractions within the stomach and increase the tone of the pyloric sphincter, reducing gastric emptying. The constant contraction of the lower oesophageal sphincter prevents reflux of gastric contents into the oesophagus under normal conditions. (38)

The acidity, amino acid content, fat content and osmolarity of gastric contents influence gastric emptying. Neutral solutions such as isotonic saline are emptied from the stomach rapidly. An amount of 500 ml of isotonic saline is emptied from the human stomach in 12 minutes. Hypertonic solutions such as those containing acid, fat and some amino acids slow down gastric emptying. (39)

Solids that are digestible, are emptied from the stomach once they have been liquefied and are less than 2 mm in diameter. Solids that cannot be broken down into particles of this size, are broken down by an electromechanical process that occurs in cycles and migrate from the proximal stomach to the small bowel. (39)

A light meal is removed from the stomach after 1.5 to 3 hours and clear fluids exit almost immediately. This shows that the conventional fast from midnight may be stricter than necessary. (34)

The primary factor in determining gastric emptying of liquids from the stomach is gastric volume. The amount of fluid emptied from the stomach over time is directly proportional to the volume within the stomach (39). Approximately 200 ml of gastric fluid must be present for passive regurgitation to occur during anaesthesia, which is far more than the mean gastric volume in normal starved patients (33, 34, 40). Gastric volumes in normal patients who have been starved range between 10 to 30 ml with 120 ml only being exceeded rarely (34, 40, 41). Gastric volumes closer to 200 ml are usually only found in patients who have gastric disorders (42).

The incidence of pulmonary aspiration of gastric contents has declined from 0.15% in 1946 to 0.006% in 2002, but when it does occur it is potentially life-threatening (31, 43). One of the hallmarks of anaesthesia care is to avoid this potential complication. The incidence of aspiration is higher in patients who undergo emergency surgery and the mortality increases with the severity of the illness requiring surgery (44).

The type and amount of gastric contents aspirated has an effect on the severity and outcome of pulmonary aspiration. If the particles in the gastric contents aspirated are sufficiently large, airway obstruction and even death may result as a consequence. The severity of bronchoconstriction and aspiration pneumonitis increases as the pH of the gastric contents aspirated decreases. Aspiration pneumonitis, also known as Mendelson's syndrome, includes milder symptoms such as coughing and wheezing and more severe consequences such as hypoxia, dyspnoea and respiratory failure. (31, 42, 45-47)

The likelihood of pulmonary aspiration is not affected by gastric volume alone. Clear fluids are cleared from the stomach extremely quickly and follow an exponential curve. Inadequate anaesthetic depth, improper airway protection and whether the operation is an emergency place the patient at a higher risk of aspiration than the degree to which the patient has fasted (13, 45). Other factors that may increase the risk of aspiration include abdominal surgery, delayed gastric emptying, pregnancy, obesity, pain, stress, sepsis and shock (48).

Gastric emptying may be delayed by electrolyte disturbances, obesity, advanced age, hyperglycaemia, opioids, anticholinergics, disorders of the vagus nerve and increased levels of oestrogen and progesterone. These factors confound the evidence to precisely determine the exact amount of time necessary for preoperative fasting. (49, 50)

Emphasis is placed on fluid fasting for at least two hours because patients may aspirate from airway manipulation. Forcing air into the stomach during bag mask ventilation and coughing, which causes reflux of gastric contents, may result in pulmonary aspiration. The severity of the subsequent lung injury will depend on the acidity of the gastric fluid aspirated. (45-47)

2.4 The principles behind fasting

Fasting preoperatively is necessary to ensure that the gastric volume is sufficiently reduced at the initiation of an anaesthetic. The laryngeal and pharyngeal reflexes that prevent pulmonary aspiration of gastric contents are depressed during general anaesthesia. When regurgitation or vomiting occurs, the gag, cough and swallow reflexes are unable to prevent gastric contents from flowing into the lungs. (2, 31)

It is unclear which gastric volumes and pH levels, if exceeded, are associated with an increased risk of aspiration (2). The controversial study by Roberts and Shirley (51), which was published in 1980, was based on a single experiment in the rhesus monkey. They concluded that if the gastric pH value is less than 2.5 and the gastric volume is greater than 0.4 ml/kg, there is an increased risk of pulmonary aspiration. The results of this study have been questioned as it was a single experiment and 0.4 ml/kg of gastric contents was introduced into the right main bronchus only, not into the trachea as would occur in a patient who had aspirated gastric contents. Thus the conclusions that Robert and Shirley had made, were not based on a realistic situation in humans (51-53).

A study published in 1990 describing the critical volume for pulmonary aspiration revealed that, in the monkey, severe pneumonitis and mortality occurs at a gastric aspirate volume of at least 0.8 ml/kg with a pH of 1. Additionally, aspirates up to 0.6 ml/kg did not cause severe pneumonitis. In this study, significant measures were taken to ensure that aspirate had not been lost from the trachea. Certain limitations to this study were also identified, including the need to extrapolate the evidence to humans, the lack of precision in measuring clinical observations of heart rate and dyspnoea and the subjective nature of the observations. They concluded that the critical volume for acid aspiration could be increased to at least 50 ml of gastric aspirate with a pH of 1. This would lower the percentage of patients at risk of pulmonary aspiration considerably. (52)

A study in cats, whose lower oesophageal sphincter tone is similar to that in humans, demonstrated that an average intragastric volume of 21 ml/kg is necessary to override the barrier pressure of the sphincter to produce regurgitation of water into

the pharynx. This volume is 20 times in excess of the volume of 0.4 ml/kg which is required to produce pulmonary damage by injection into the trachea. (54)

The studies required to accurately define the volume of gastric contents and the pH at which the aspiration risk is elevated, are difficult to perform from an ethical perspective. Therefore, measures of gastric content are used in anaesthetised patients as “proxy outcome measures” in studies investigating fasting preoperatively. Gastric volume and pH can only be considered substitute measures of overall aspiration risk as more reliable measures are not available. (2)

Outcome measures used as indicators of risk of aspiration include gastric volume and pH. Non absorbable marker dyes are used to measure the gastric volume and degree of gastric emptying. Bromosulphthalein (BSP) or phenol red are consumed prior to surgery and they are diluted by the volume of fluid present in the stomach at the time of surgery. The gastric contents are usually collected after induction of anaesthesia. The degree of gastric emptying can be determined by comparing the amount of concentration of the dye ingested with the amount that is remaining in the stomach. This is expressed as a percentage of the initial amount of dye ingested. Cyanocobalamin, another dye, is used to calculate intra-operative gastric fluid volume. It is added to the stomach of the patient in a specific concentration during the operation. The concentration of dye in a 5 ml sample of gastric contents is measured after 10 minutes and thus the intra-operative gastric fluid volume can be calculated. The gastric content pH can be determined using a variety of methods including a pH radiometer, an indicator strip, pH paper, electrodes or a Corning pH meter. (2, 55)

Gastric volume may be non-invasively assessed at the bedside by ultrasonographic measurement of the cross-sectional area of the antrum of the stomach. Mathematical models have been generated which can accurately predict gastric volumes up to 300 ml (56). There is a linear correlation between the cross-sectional area of the antrum and the volume of gastric contents. The gastric volume can be calculated using a mathematical model. Further research is required to formulate accurate models to determine gastric volume in pregnant women and children (57, 58).

In addition to the gastric volume, the quality of the gastric contents (solid, liquid or gas) may also be determined by the use of ultrasound. Clear fluids appear hypoechoic, milk and thicker fluids have increased echogenicity and solids blur the posterior wall of the antrum. Ultrasonographic assessment of gastric content and volume is useful in patients with altered gastric emptying such as diabetics with gastroparesis, patients with renal disease or those in the intensive care unit. Ultrasonographic assessment may also be useful to assess gastric volume and contents in patients who did not follow fasting instructions or who are unreliable. (42, 57)

The administration of histamine 2-receptor antagonists, antacids and antiemetic drugs preoperatively further complicates the evidence from studies of preoperative fasting. (2)

2.5 The physiology of fasting

Fasting brings about some significant metabolic changes. Fasting overnight may result in dehydration, ranging from mild to severe, which is dependent on the total fasting time (23). Urine becomes concentrated, fluid losses due to evaporation are reduced as blood vessels constrict in the periphery and overall energy consumption is reduced (59).

One to two days of fasting results in the breakdown of glycogen stores, supplying glucose to the tissues. This is mediated by increased levels of glucagon and reduced insulin. Gluconeogenesis results in increased glucose production. Catecholamine and cortisol levels increase, regulating glucose levels to avoid hypoglycaemia. Catecholamines stimulate B- adrenergic receptors to increase free fatty acid levels by breaking down triglycerides in adipose tissue. Some free fatty acids are converted to ketones which are also used as a source of energy. Gluconeogenesis delivers most of the glucose as the duration of fasting approaches 42 hours and glycogen stores decline. Fasting beyond 48 hours results in skeletal and smooth muscle protein breakdown to amino acids. These amino acids are used in gluconeogenesis in the liver and kidneys. The rate of gluconeogenesis and muscle breakdown is

reduced as starvation continues and the body adapts by decreasing catecholamine levels. Prolonged starvation leads to fatigue, weakness and reduced immune function. (60)

Surgery increases metabolic rate. The oxidation of substrates is increased, catabolism occurs and there is breakdown of fat, protein and glycogen. Insulin resistance occurs as a result of prolonged preoperative fasting. It develops immediately after surgery and may last as long as four weeks in uncomplicated abdominal surgery. The extent of the abdominal surgery influences the change in metabolism and the severity of the insulin resistance. There is a positive correlation between postoperative insulin resistance and length of stay in hospital. Increased gluconeogenesis occurs because the ratio of insulin to glucagon is reduced. Because fasts may be as long as 10 to 16 hours, insulin resistance may be augmented and blood glucose levels increase. (23)

2.6 Adverse effects of prolonged fasting on physical and psychological wellbeing

The adverse effects of prolonged preoperative fasting include thirst, hunger, anxiety, and increased insulin resistance. (2)

In a 2001 study of fasting times among 51 women who were postpartum in a hospital in Texas, USA, patients rated their thirst and hunger on a scale. Zero on the scale represented no thirst or hunger and 10 represented the worst possible thirst or hunger. The average score for thirst was five and for hunger was four. Although the researcher did not believe that a hunger level of four was important from a clinical perspective, in their opinion a thirst score greater than five, present in two thirds of the patients, was clinically significant. The researchers concluded that the degree of discomfort associated with a thirst score of five was unnecessary as clear liquids are known to be removed from the stomach after two hours. (11)

It has been shown that a longer preoperative fast leads to higher ratings of anxiety (40, 55, 61). A study of 53 adult elective surgery patients in a hospital in Wales,

reported anxiety to be markedly higher in patients who had a standard fast when compared to those who received water up to 180 minutes preoperatively (61).

A prolonged preoperative fast has recently been shown to worsen insulin resistance postoperatively and lead to increased duration of hospital stay (62). Sutherland et al. (59), in 1986, concluded that metabolic and physiological changes occur in the body as a result of starvation. In states of prolonged fasting, as occurs in preparation for major abdominal surgery due to the need for bowel preparation, glycogen stores become depleted. Amino acids, which are required for tissue repair, are used for gluconeogenesis instead. Overall protein synthesis is reduced due to prolonged fasting and protein catabolism is increased (35, 55). Studies of physiology have shown that in patients who receive an anaesthetic after fasting for more than 12 hours, gluconeogenesis has already commenced, resulting in impaired mitochondrial function and decreased generation of adenosine triphosphate (19, 63).

Patients who are subjected to prolonged preoperative fasting periods may experience one or more of the following: dehydration, hypoglycaemia, ketosis, hypovolaemia, confusion, headache and low urine output (64).

2.7 The benefits of a shorter fast

Fluid intake prior to surgery leads to improved patient comfort as it reduces thirst, mouth dryness and anxiety (22, 34, 40, 61, 65). Allowing a patient to have their regular cup of coffee the morning before surgery will reduce the symptoms of caffeine withdrawal in regular coffee drinkers (66).

A non-randomised case-control study of preoperative fasting times among adult surgical patients undergoing elective procedures was conducted in Dublin, Ireland between October 2009 and March 2010. The 21 participants were compared to 29 patients in a previous study of preoperative fasting times in 2007 who underwent what was termed a ‘traditional fast’ by the researchers involved in the 2009 study. The control patients from the previous study, who underwent the traditional fast, abstained from fluids and solids from midnight during the night before surgery. The

patients in the 2009 study fasted for a shorter period according to a new protocol implemented over the same period as that in which the study was conducted. (18)

The patients undergoing the shorter fast were assigned to a morning or afternoon list. The group assigned to the morning list could drink fluids up until two hours before the start of the morning list and avoided solid food from midnight. Those patients assigned to the afternoon list, which started after 13:00, were encouraged to eat a light breakfast before 07:00 and to drink clear fluid until 11:00. Only 9.5% of the patients in the shorter fast group reported any adverse preoperative symptoms compared with 86.2% in the group who underwent the traditional fast. Thirst, headache and nausea were significantly less in the shortened fast group. A third of patients who underwent the shorter fast reported that they experienced reduced anxiety as a result of being permitted to drink and eat for a longer period prior to surgery. Diminished dry mouth was reported by 14% of these patients and 26.5% of them reported satisfaction. (18)

Patient satisfaction with their hospital care is a routine marker of the “quality of care” a patient receives during their hospital stay (25). As a shorter preoperative fast improves patient satisfaction by reducing immediate postoperative complications such as nausea and vomiting, it therefore also leads to improved quality of care. If a patient is dissatisfied perioperatively, this may negatively impact the patient’s perception of their own well-being and they may perceive their treatment as suboptimal despite the surgery being a success (67, 68).

The aim of successful fluid management in accordance with the Enhanced Recovery After Surgery (ERAS) guidelines for perioperative patients is for patients to be in fluid balance prior to being induced in the operating room. A lengthy preoperative fast is discouraged prior to major abdominal surgery and clear fluids and a carbohydrate drink are advised up to two hours before surgery (69).

In 2013, Imbelloni et al. (68) found that 200 ml of a carbohydrate drink 2 to 4 hours before an operation reduced discomfort preoperatively in addition to having improved satisfaction with anaesthesia in elderly patients who underwent anaesthesia for repair of hip fractures.

A study on fasting times and postoperative vomiting revealed that patients who were instructed to drink clear fluids up until three hours preoperatively experienced less postoperative thirst, did not attempt to drink excessively after surgery and therefore experienced less vomiting. Also, if patients were nauseated preoperatively due to prolonged fasting, this was more likely to continue into the postoperative period (9). Preoperative thirst is significantly decreased in patients allowed to drink 2 to 3 hours prior to surgery. Clear fluids a few hours before surgery may stimulate gastric emptying, reducing gastric volume. (22)

Oral carbohydrate-rich fluid intake on the morning of surgery has been found to mimic the effect of a good breakfast by decreasing the response to stress and improving glucose metabolism. Additionally, it reduces postoperative insulin resistance and promotes an anabolic state. This reduces the surgical stress response. (70, 71)

In animal studies, the stress response to surgery was diminished in those who fasted for less than six hours, glucose metabolism was altered favourably, insulin resistance was reduced and muscle strength improved. (16, 35)

Adult women undergoing elective laparoscopic cholecystectomy were given 200 ml of a carbohydrate drink containing 12.5% maltodextrin two hours preoperatively and were compared with a group of patients who fasted for eight hours. It was concluded that shortening the fast with a carbohydrate beverage reduced insulin resistance and the stress response to surgery. Postoperative insulin resistance may be reduced by approximately 50% when preoperative fasting is avoided. A carbohydrate drink two hours before surgery is limited to certain patients. Patients with gastro-oesophageal reflux, obstruction of the gastrointestinal tract, gastroparesis or those who are morbidly obese may have delayed gastric emptying and may possibly be at risk of regurgitation and aspiration. These patients should not receive a carbohydrate beverage two hours preoperatively. (22)

The provision of a carbohydrate-rich drink two hours pre-operatively reduces the preoperative fasting period, decreases insulin resistance and prevents depletion of glycogen stores. Less endogenous protein breakdown is necessary as less gluconeogenesis is necessary. This results in a positive protein balance. Amino

acids are then used for tissue repair instead of gluconeogenesis. Glucose control postoperatively has been shown to decrease morbidity and mortality. (23, 35)

A study of 150 adult elective surgery patients in India, found that 150 ml of water given two hours preoperatively produced a lower residual gastric volume and a higher pH than an overnight fast did. This may result in a reduced risk of pulmonary aspiration of gastric contents. (65)

2.8 Fasting guidelines

The aims of the ASA Practice Guidelines, as stated in the 2011 Updated Report, are to: “enhance the quality and efficiency of anaesthesia care, stimulate evaluation of clinical practices and reduce the severity of complications related to the perioperative pulmonary aspiration of gastric contents”. (5)

The ASA and Norwegian Clinical Guidelines recommend that adults fast from solids for a minimum of six hours and fast for two hours from clear fluids prior to elective procedures requiring general anaesthesia, regional anaesthesia or sedation. Clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea and black coffee, as defined by the ASA guidelines. Solids, like toast, require a six hour fast from the time of ingestion and are considered to be part of a light meal. Fried or fatty foods and meat are not considered a light meal as these may prolong gastric emptying and require a fast of eight hours or more from the time of ingestion. (6, 72)

The SASA Practice Guidelines recommend the ASA guidelines as a reference for fasting guidelines. No specific fasting protocol is outlined for South African anaesthesiologists by SASA. (7)

The above guidelines are for healthy patients. The term “healthy” not only refers to the physical health of the patient, which is described by the ASA status, but also to the condition of the gastrointestinal system (73). Some patient populations are more likely to suffer from regurgitation and subsequently may aspirate gastric contents. Patients who have a history of illnesses affecting the gastrointestinal system and autonomic nervous system abnormalities as in those who have diabetic neuropathy

may have delayed gastric emptying and have unique preoperative fasting needs. It is recommended that the preoperative fasting period for diabetics should be as short as possible and regular blood glucose checks should done. Intravenous fluids and insulin should be administered to maintain normoglycaemia during the fasting period (74, 75). Those patients who are obese, pregnant or elderly may also require a tailored preoperative fasting regimen to prevent regurgitation and possible aspiration. This further complicates the evidence for preoperative fasting (2).

Obese patients have been considered to be at increased risk of pulmonary aspiration since an observation was made in a study by Vaughan et al. (76) in 1975. It was found that a higher proportion of morbidly obese patients who fasted from midnight had a residual gastric volume greater than 25 ml and a pH less than 2.5 compared to non-obese patients. Warner et al. (46), in a study published in 1993, did not find obesity to be a risk factor for pulmonary aspiration in the 67 cases they studied. It was later determined in another study of 126 adult patients, that obese patients who did not have any comorbid conditions could follow the fasting guidelines for non-obese patients (44). No definite guidelines can be found regarding the inclusion or exclusion of obese patients in the above guidelines. The anaesthesiologist may currently decide whether to include obese patients in the ASA guidelines (6, 44).

The ESA is one of the few societies that considers whether milk in tea or coffee is considered a clear fluid or not and also addresses the issue of patients with delayed gastric emptying. The ESA advocates clear fluids up to two hours before elective surgery. Every member of the ESA, except one, considered tea or coffee with milk up to one fifth of total volume to be clear fluids. They also recommend that solid food should be withheld for six hours before elective surgery in adults. (3)

The ESA considers their recommendations to also be applicable to obese patients and patients with gastro-oesophageal reflux disease, diabetes and pregnant women not in labour. Milk in large quantities has the ability to curdle in the stomach and will behave like a solid, but smaller quantities are similar to clear liquids. Although no randomised studies have investigated whether aspiration is more likely to occur, the ESA considers anecdotal evidence to be sufficient to allow a small quantity of milk in tea or coffee to be considered a clear liquid. The absence of evidence in humans

and the difficulty to define and regulate a small amount of milk has resulted in the majority of guidelines advocating tea or coffee without milk. The ESA considers that patients may refuse to drink anything if they are not permitted to have their beverage with milk and therefore permit a small amount. The ESA states that there is no definitive evidence regarding preoperative fasting in patients with delayed gastric emptying, including pregnant women not in labour. The evidence which is available suggests that the effect of delayed gastric empting is not severe enough to warrant different guidelines to healthy patients with normal gastric emptying. (3)

The CAS guidelines advise a fast from solids and liquids of five hours duration and suggest that individual departments draft their own policies. The Association of Anaesthetists of Great Britain and Ireland and the Clinical Standards Board of Scotland follow the ASA guidelines. (2)

Prolonged fasting periods are now considered to be associated with higher gastric volumes and lower pH values which increase the risk and severity of pulmonary aspiration respectively (22). Since the early 1990s, fasting guidelines designed by national societies (5, 6, 77) throughout the world have been revised on a regular basis taking into account recent research on fasting, the risk of pulmonary aspiration and the adverse effects associated with prolonged fasting (33, 40).

Because the volume and pH of gastric fluid together with the presence of particulate matter contribute to the overall risk of gastric regurgitation and pulmonary aspiration, the fasting time for solids remains six hours. This allows enough time for all particulate matter to be removed from the stomach. It could take between four and six hours for the gastric emptying to occur in normal patients and patients with prolonged gastric emptying times, respectively. (39)

2.9 Reasons for prolonged fasting

Nurses, anaesthesiologists, surgeons and patients all play an important role in the implementation of fasting guidelines (15). Although health care professionals are aware of the rationale behind fasting, a lack of knowledge regarding the most recent studies on the subject has been shown (1, 66). Instructed fasting times from doctors

and nurses are known to differ within and between the two groups (78). Even though the negative consequences of preoperative fasting have been established (1), concern regarding the adverse effects of prolonged fasting is lacking amongst health care professionals (66). Patients are thus deprived of adequate nutrition for prolonged periods preoperatively.

Individual health care professionals find difficulty in evaluating the evidence of fasting studies and interventions as there are vast differences between the trials. There may be reluctance to change existing policies as they guarantee patient safety albeit at the expense of patient comfort. (2)

A common reason for the reluctance to adapt the fasting instructions given is that shorter preoperative fasts may prevent patients from moving up on the surgical schedule if the need arises. A study of 155 adult elective surgical patients in a hospital in Texas in the USA however, found that only 5% of operations were early whereas 36% were late and when they were early, the average was only by 33 minutes. This is insufficient to affect the risk of aspiration if the patient fasts for 2 to 4 hours (10). Surgical schedule variability and unpredictability of the surgical schedule is overestimated by health care professionals. Allowing clear fluids until three hours before surgery does not increase cancellations or delays and does allow more flexibility in the schedule than a two hour fast. (33, 73)

Nurses and doctors also find it more convenient for all patients to be fasted from the same time irrespective of their scheduled surgical time. Tradition is a powerful factor and health care professionals are reluctant to change longstanding fasting practices (66). Fasting times should be determined by guidelines and hospital routines should be adapted (73, 79).

Some institutions only set a starting time for the first case of the day, leaving the remaining patients without a set time for theatre. Due to this uncertainty, all patients are starved from the same time as the first, resulting in unnecessarily prolonged fasting times for the ones booked later on the list. With organisation, it is possible to tailor each patient’s fasting instructions to a pre-set theatre time, thereby reducing fasting times. (66)

In a nationwide survey of Anaesthesiology Society members in Germany in 2007, 7% of respondents still recommended traditional fasting from midnight, 45% practiced reduced preoperative fasting, 34% reported that they adhered to the new guidelines completely and 15% did not follow any specific policy or guidelines. The reduced preoperative fasting is shorter than the traditional fasting from midnight but longer than six hours for solids and two hours for fluids. This is despite the German Society of Anaesthesiology and Intensive care and the Alliance of German Anaesthesiologists officially recommending a fast of two hours for clear fluids and six hours for solid food for elective surgery since October 2004. The reasons against implementing the new guidelines included decreased flexibility in surgical list management and an increased risk of aspiration. The reasons for using the new guidelines included improved patient comfort preoperatively and improved patient satisfaction. It was also found that anaesthesiologists who conduct preoperative assessments in an outpatient department prior to admission of their patients comply with the guidelines for preoperative fasting better than those who perform preoperative assessments on patients already admitted in hospital. (13)

Patients' understanding of fasting is poor and results in poor compliance (78). This can contribute to prolonged fasting times.

Doctors and nurses have conflicting opinions regarding preoperative fasting times due to teaching prior to the change in the fasting guidelines published by the ASA in 1999 (79).It is complicated to change a clinical practice that is used widely. Compliance by doctors and nurses could be encouraged by providing new recommendations that are supported by evidence (13).

2.10 Current international preoperative fasting practices

A systematic review in 2003 entitled "Preoperative fasting for adults to prevent perioperative complications" found there was no evidence that patients who ingested fluids 2 to 3 hours preoperatively were more likely to aspirate and subsequently regurgitate gastric contents when compared with patients who had fasted from solids and liquids from midnight. The gastric volume and pH of the gastric contents was

used as a measurement of the likelihood of aspiration. Clear fluids given at 90 and 180 minutes preoperatively resulted in a reduction in thirst at induction. It was found that the type of clear fluid and duration of fast made no difference to the overall risk of aspiration. No difference was found in gastric volume and gastric pH between patients who were permitted fluid 2 to 3 hours prior to surgery and solid food six hours prior to surgery and those who fasted from midnight. The volume of gastric contents was lower after water was administered 2 to 3 hours preoperatively than in those who fasted from midnight but this difference was only 6 ml and therefore was not clinically significant. (2)

The recommendations in the available guidelines are only applicable to patients of sound health and those who do not have any conditions which result in them being more likely to aspirate. As the number and methodological quality of studies based on patients with an increased likelihood of aspirating is limited, guidelines for these patients have been difficult to establish. (2)

National clinical guidelines are needed to implement evidence-based practice (13). In an attempt to investigate whether a national consensus led to a change in fasting policies in Norway, a study was conducted in Norwegian anaesthesia departments in hospitals in 1993 and 1996. A total of 69% of the hospitals reported changes in fasting policy after implementation of the new national guidelines recommending shorter fasting times of two hours for liquids and six hours for solids. In 1993, 63% of hospitals allowed the shorter fasting duration in adults. This improved to 79% by 1996. (80)

The delay between dissemination and implementation of practice guidelines is well described (14). A study of 155 adult elective surgery patients at a hospital in Texas, USA, was conducted from November 1999 to May 2008. The purpose was to assess if the publication of the ASA guidelines, prior to the study in 1999, had altered preoperative fasting practices. Patients fasted for an average of 12 and 14 hours from liquids and solids, respectively. This study clearly demonstrated that the publication of the new guidelines had not changed preoperative fasting practices and that more collaboration was needed between nurses and doctors. (10)

Another study of preoperative fasting practices among 51 postpartum women was conducted in a hospital in Texas, USA in 2001. The participants fasted for an average of 11 hours for liquids and 13 hours for solids. These fasting times were unnecessarily long. (11)

As part of a study of preoperative fasting practices in Ireland, in 2009, a new fasting protocol was introduced and compared to the old one. The new protocol recommended fluids up to two hours and solids up to six hours prior to surgery. Twenty one patients in the new protocol group were compared with the 29 patients from a previous study in which the traditional fasting regimen from midnight was used. Although the shorter fasting protocol did reduce the mean fasting time from 14.5 hours to 6.3 hours for fluids and from 24.2 hours to 16.3 hours for solids, these fasting times were still longer than best practice guidelines. (18)

Literature regarding fasting times in developing countries has been limited until recently. Actual fasting times were measured in a study of 3715 adult patients who underwent elective surgery from August 2011 until September 2012 throughout multiple hospitals in Brazil. The study was termed the “BIGFAST multicentre study”. This study is important as it is a large study in a developing country and found that the median preoperative fasting time was 12 hours. (19)

A smaller study of preoperative fasting times in 43 patients was conducted in Ethiopia in 2013. Patients fasted from solids for 19.60 hours and from fluids for 12.72 hours. The fasting times were significantly prolonged in this study revealing an important problem of prolonged preoperative fasting in developing countries. (20)

2.11 Current South African preoperative fasting practices

No literature could be identified regarding fasting practices in South African adults. The SASA Practice Guidelines refer the reader to the ASA Practice Guidelines for Preoperative Fasting (7). The ASA guidelines are based on studies from Europe and the USA. These populations are not necessarily similar to the South African population. This shows that South Africa does not have a well-defined preoperative fasting protocol tailored to the specific needs of the South African population.

A study was conducted by Fitchat (21) in 2010 on preoperative glucose and fasting duration in children undergoing elective surgery at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in South Africa. The study found fasting times to be prolonged in elective paediatric patients, despite there being evidence highlighting the adverse effects of prolonged fasting in children. The mean fasting time was found to be 14 hours for children undergoing elective surgery. A follow up study later in 2010 at CMJAH found that the fasting times were still prolonged (81).

If paediatric preoperative fasting times are prolonged, it is possible that this may also be true for adult patients at CMJAH. Children who are subjected to prolonged preoperative fasts are at risk of hypoglycaemia. As a result, the need for stricter fasting regimens for children has been highlighted (21). The effects of prolonged preoperative fasting in adults may be less dramatic than in children but they are still significant. These effects in adults include reduced patient comfort, increased insulin resistance, prolonged postoperative recovery and reduced patient satisfaction (16, 22-24). There is a need to quantify adult preoperative fasting times at CMJAH to improve perioperative patient care and satisfaction.

2.12 Summary

In this chapter a review of the literature was presented. In the following chapter the methodology is discussed.

Chapter 3

Methodology

3.1 Introduction

In this chapter the problem statement, the aim and the objectives of the study are discussed. The ethical considerations of the study are considered. A detailed description of the research methodology is given. Lastly, the validity and reliability of the study are discussed in depth.

3.2 Problem statement

Limited literature had been identified describing how well South African health care professionals in the government health care system were implementing the latest fasting guidelines in adult patients. It had been observed that fasting practices in public hospitals may not have been in accordance with the published fasting guidelines as patients were being starved for unnecessarily long periods. Patients had been known to complain about the length of time they were required to fast preoperatively.

Of concern were the patients who only had their surgery in the early afternoon. These patients, according to the guidelines, would have been permitted a light breakfast at 05:00 or 06:00 the morning before surgery. Instead, it appeared patients fasted from the night before which unnecessarily prolonged the preoperative fasting duration and possibly lead to adverse effects such as hypovolaemia, dehydration, headache and hypoglycaemia. Likewise, all patients scheduled for theatre could have been permitted clear fluids at 06:00 and they would still all have been appropriately fasted by 08:00, in time for the first scheduled surgery. This did not appear to be routine at CMJAH at the time of this study.

3.3 Aim and objectives

3.3.1 Aim

The aim of this study was to describe preoperative fasting practices in adult elective surgery patients at CMJAH.

3.3.2 Objectives

The primary objectives were to:

- describe the instructed preoperative fasting times in adult elective surgery patients
- estimate the actual fasting times in adult elective surgery patients.

The secondary objectives were to:

- compare the actual and instructed fasting times in adult elective surgery patients
- describe and compare the fasting times across various disciplines within the hospital.

3.4 Ethical considerations

The proposal for this study was submitted to the Human Research Ethics Committee (Medical) (Appendix 1) and the Postgraduate Committee, Faculty of Health Sciences of the University of the Witwatersrand (Appendix 2) for approval. Permission was obtained from the Chief Executive Officer of CMJAH to conduct research in the hospital and access patient records (Appendix 3).

An information letter detailing the purpose and methods of the study was provided (Appendix 4). Written informed consent was obtained from each patient participating in the study (Appendix 5).

Patients were not obliged to take part in the study and it was explained to them that refusing or withdrawing would carry no consequences. Patient anonymity and

confidentiality was ensured at all times. A study number was used for each patient and no patient names or identification numbers were recorded on the data collection sheet.

The raw data will be stored securely for six years following completion of the study.

Research was conducted according to the principles of the Declaration of Helsinki (27) and Good Clinical Practice Guidelines (28).

3.5. Research methodology

3.5.1 Research design

Burns and Grove (82) describe a research design as a “blueprint for conducting a study”. It determines the methods that researchers use to obtain participants, perform data collection and interpret results.

A prospective, contextual, descriptive study design was used in this study.

A prospective study is defined as a study in which the researcher chooses a population and tracks it over time to establish results (83), as in this study.

A contextual study does not involve all patients but rather a select group e.g. inpatients (84). This study was contextual as it was conducted in patients undergoing elective surgery at a hospital in Gauteng.

A descriptive study design gathers information about characteristics in a specific study field. It is a research study in which phenomena are described or the relationship between variables is examined and cause-and-effect relationships are not identified (82). This study described fasting times in patients who were undergoing elective surgery at CMJAH.

3.5.2 Study population

The study population comprised adult patients who presented for elective procedures in the general surgery, orthopaedic, urology and gynaecology wards who required anaesthesia at CMJAH.

3.5.3 Study sample

Sample size

The sample size was based on a previous study of children undergoing elective surgery at CMJAH which reported a mean fasting time of 14 hours (21). Another study of adult elective surgery patients at a hospital in Texas, USA in 2001, also reported a mean fasting time of 14 hours (10).

The sample size was determined in consultation with a biostatistician. A sample size of 62 participants estimated the mean instructed and actual fasting times to an accuracy within 0.5%. This calculation assumed a standard deviation of 2 hours and a confidence interval of 95%.

Sampling method

A stratified sampling method was used in this study. Stratified sampling involves the selection of patients from two or more groups of the population independently (82). Sixteen patients from each discipline were included.

Inclusion and exclusion criteria

The following patients were included in this study:

- patients who could communicate in English
- patients who were undergoing elective surgical procedures
- adult patients who were18 years of age and older.

The following patients were excluded from the study:

- patients who were given premedication and attained a score more than two on the Ramsay sedation scale (85) (Appendix 7)
- patients who did not follow the routine fasting regime e.g. those patients who received total parenteral nutrition and those who were undergoing bowel preparation for colorectal surgery
- patients who had their surgical procedure cancelled.

3.5.4 Data collection

Data was collected from June to December 2014.

The researcher explained the study to the patients and invited them to take part in the study on the day of surgery. An information letter was given to patients to read (Appendix 4). Consent was obtained if they agreed to participate in the study (Appendix 5).

The researcher collected data at different times on the day of surgery using a data collection sheet (Appendix 6). In the morning, prior to surgery, information was collected from the patient. Post-surgery, the time that surgery commenced was collected from the anaesthetic chart.

The data collection sheet (Appendix 6) contained information collected from the patients:

- age
- type of surgery (general, orthopaedic, gynaecology, urology)
- gender
- ASA score
- premedication given
- Ramsay score
- presence of diabetes
- presence of intravenous line
- was a surgery starting time given to patient
- source of fasting instructions (nurse, doctor, both, none)
- instructed starting time of fast
- actual starting time of fast

- actual starting time of surgery.

The data was entered onto a Microsoft Excel® Spreadsheet.

3.5.5 Data analysis

Data was analysed in consultation with a biostatistician and the use of Microsoft Excel® and GraphPad InStat® version 3.10. Descriptive and inferential statistics were used to analyse the data obtained during the study.

Actual and instructed fasting times were summarised using means and standard deviations.

Subgroup comparisons employed one way analysis of variance. A p value of less than 0.05 was considered statistically significant. Data was summarised using means, standard deviations, medians and ranges. Groups were compared to each other using an ANOVA if the data was normally distributed or the Kruskal- Wallis test was used if the data was not normally distributed.

3.5.6 Validity and reliability of the study

Botma et al. (86) refers to validity as “the degree to which a measurement represents a true value” and reliability as the “consistency of the measure achieved.”

The validity and reliability of this study was ensured by:

- using an appropriate study design
- calculating the sample size with the assistance of a biostatistician
- one researcher collecting the data to ensure consistency
- using data collection sheets standardised the data collection process
- the researcher only making contact with the patient after the routine preoperative visit to ensure that the attending anaesthetist’s practice was not influenced
- every data entry entered into the Microsoft Excel® Spreadsheet being checked

- analysing the data with the assistance of a biostatistician.

3.6 Summary

In this chapter the methodology of the study was described.

In the following chapter the results are presented as per the research objectives. This is followed by a discussion of the results.

Chapter 4

Results and discussion

4.1 Introduction

In this chapter the results of the study are presented according to the objectives. This is followed by a discussion of the results.

The primary objectives were to:

- describe the instructed preoperative fasting times in adult elective surgery patients at CMJAH
- estimate the actual fasting times in adult elective surgery patients.

The secondary objectives were to:

- compare the actual and instructed fasting times in adult elective surgery patients
- describe and compare the fasting times across various disciplines within the hospital.

4.2 Sample realisation

A patient sample size of 62 was determined to be sufficient to estimate the mean instructed and actual fasting times to an accuracy of 0.5%. A total of 70 patients were interviewed. Six patients were excluded from the study. Of these, four patients were excluded as their surgery was postponed or cancelled and two patients received bowel preparation. Therefore 64 patients were included in the study.

4.3 Results

This study was conducted at CMJAH from June to December 2014.

The instructed fasting time was the time from when the patient was instructed to begin fasting until the time that surgery was scheduled to commence. At CMJAH, if patients were not given an estimated starting time for their surgery, this was assumed to be 08:00.

The actual fasting time was the time from the most recent consumption of any liquid or solid, excluding sips of water taken with morning medication, until the surgery starting time. All the patients included in the study did not ingest any liquid after their last intake of solids.

Percentages were reported as whole numbers. Means, standard deviations, medians, ranges and p values were rounded off to two decimal places.

4.3.1 Demographic data

There were 64 adult patients between the ages of 18 and 84 with a mean age of 50.14 (S.D. 15.24) years included in the study.

Two patients were given premedication and had a Ramsay score of 2 at the time of data collection. The remaining 62 patients were not given premedication and therefore did not require a Ramsay score.

The demographic data including the number of patients in each discipline, the ASA status, the gender, the presence or absence of diabetes, the presence or absence of an intravenous line in diabetic patients, whether an estimated starting time for surgery was given to the patient and who gave the patient the instructed fasting time is presented in Table 4.1.

Table 4.1 Demographic data

Demographic	Category	Number	Percentage
Discipline	General surgery	16	25
	Orthopaedics	16	25
	Urology	16	25
	Gynaecology	16	25
ASA status	1	30	47
	2	30	47
	3	4	6
Gender	Male	23	36
	Female	41	64
Diabetic	Yes	10	16
	No	54	84
IV line if diabetic	Yes	8	80
	No	2	20
Estimated surgery starting time given	Yes	17	27
	No	47	73
Instructions given by	Nurse and doctor	37	58
	Doctor	21	33
	Nurse	6	9

4.3.2 Primary objective: to describe the instructed preoperative fasting times in adult elective surgery patients

The median instructed fasting time was 10.00 hours with a minimum of 8.00 hours and a maximum of 12.00 hours. This result was not normally distributed as is shown in Figure 4.1. On average patients were instructed to fast for 4 hours longer than the 6 hours recommended by the guidelines.

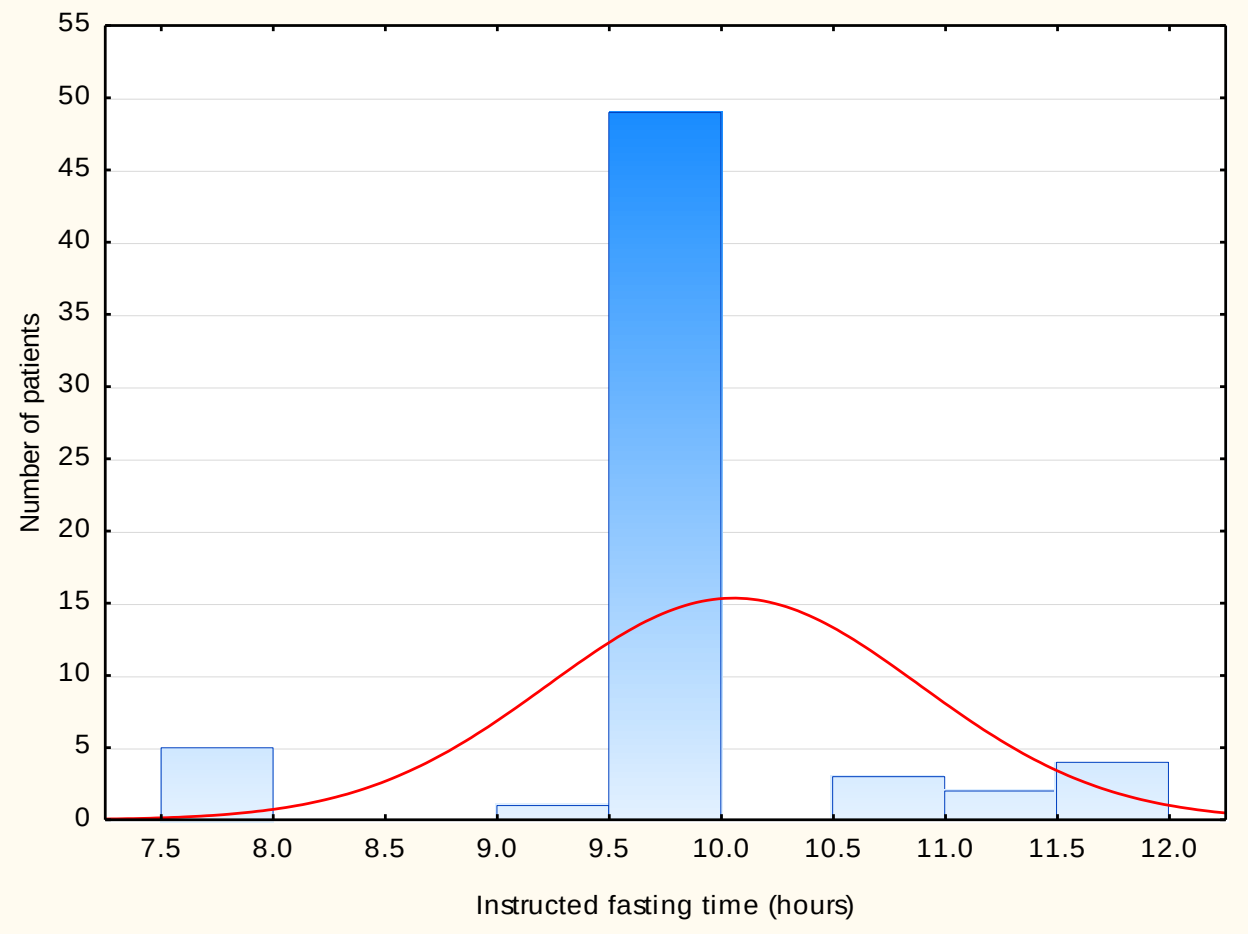

Figure 4.1 Instructed fasting times

4.3.3 Primary objective: to estimate the actual fasting times in adult elective surgery patients

The mean actual fasting time was 14.92 (S.D. 2.50) hours. The result was normally distributed as shown in Figure 4.2. On average, patients fasted for 8.92 hours longer than the recommended guideline of 6 hours.

The mean actual fasting time for the diabetic patients was 14.99 (S.D. 2.43) hours.

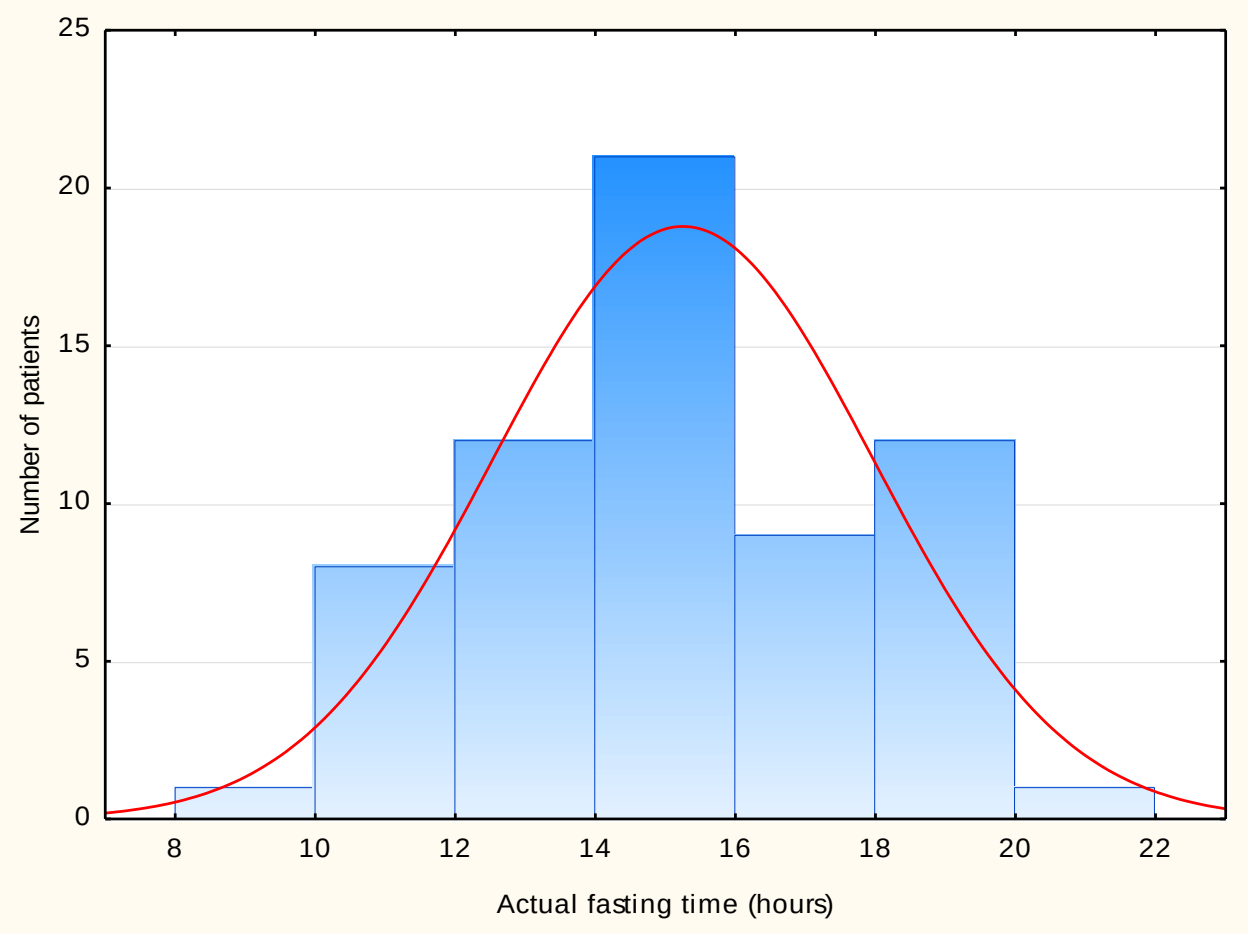

Figure 4.2 Actual fasting times

4.3.4 Secondary objective: to compare the actual and instructed fasting times in adult elective surgery patients

A two tailed Wilcoxon matched pairs test was used to compare the instructed and actual fasting times which showed a statistically significant difference between the two fasting times ($p < 0.0001$). This comparison is shown in Table 4.2.

Table 4.2 Comparison of actual and instructed fasting times

Fasting time	Instructed (hours)	Actual(hours)
Mean	9.99	14.92
Standard deviation	0.91	2.50
Median	10.00	15.00
Minimum	8.00	10.00
Maximum	12.00	20.00

4.3.5 Secondary objective: to describe and compare the fasting times across various disciplines within the hospital

Table 4.3 shows the instructed and actual fasting times per discipline.

Table 4.3 Instructed and actual fasting times per discipline

Discipline	General	Orthopaedic	Urology	Gynaecology
Instructed fasting time (hours)				
Median	10.00	10.00	10.00	10.00
Minimum	8.00	8.00	8.00	8.00
Maximum	12.00	12.00	11.50	12.00
Actual fasting time (hours)				
Mean	15.41	14.69	15.17	14.40
Standard deviation	2.81	3.07	2.44	1.56
Minimum	11.50	10.00	12.00	12.00
Maximum	19.33	19.25	20.00	16.83

As the instructed fasting times per discipline were not normally distributed, a Kruskal-Wallis test was used which indicated that there was no statistically significant difference in the instructed fasting times between disciplines ($p = 0.7089$). As the instructed fasting times were not widely distributed, the first and third quartiles for all instructed fasting times across all disciplines were 10.00 hours and were therefore not reported in Table 4.2.

The actual fasting times per discipline were normally distributed therefore an ANOVA was used. There was no significant difference in the actual fasting times between disciplines ($p = 0.6702$).

4.4 Discussion

Preoperative fasting is medically required prior to the administration of an anaesthetic except for those administered for emergency surgery. The primary purpose of fasting is to avoid the potentially fatal consequences of pulmonary aspiration of gastric contents (1).

Fasting guidelines were published by the ASA in 1999 (5) and updated in 2011 (6) and form the foundation of the South African fasting guidelines recommended by SASA (7). These guidelines recommend that patients should fast from solids for at least six hours and from liquids for at least two hours prior to surgery (5, 6) This was considerable change from the tradition of fasting patients from midnight prior to the publication of the guidelines in 1999. Despite evidence that shorter fasting times do not pose any greater risk for pulmonary aspiration (1, 9), patients are still being fasted for prolonged periods (10, 11).

The mean instructed and actual fasting times at CMJAH are still longer than recommended. This is in keeping with the literature which shows that clinical routine is slow to change despite clear guidelines (13, 66). The median instructed preoperative fasting time for adult patients at CMJAH was 10 hours. On average, patients were instructed to fast for four hours longer than the six hours that the 2011 ASA fasting guidelines advise (6).

Prolonged preoperative fasting is a widespread problem throughout the world. Studies have been conducted in the USA, Europe, Brazil and Africa which provide evidence of prolonged preoperative fasting times (10, 13, 19, 20). Limited studies of preoperative fasting times had been performed in South Africa prior to this study.

The use of universal fasting instructions for all patients instead of fasting instructions tailored to each patient's surgery starting time may have contributed to longer instructed and actual fasting times at CMJAH. This was also seen in a study of preoperative fasting in adult patients undergoing elective and general surgery in the Royal Infirmary of Edinburgh in 2011. Preoperative instructed fasting times in elective patients were 10 hours for solids and 6.25 hours for clear fluids. Doctors and nurses did not adhere to the ASA guidelines but rather instructed patients to fast from 22:00 or 24:00. The longer instructed fasting times contributed to prolonged actual fasting times (87). This is also seen at CMJAH.

A mean preoperative instructed fasting time of 10 hours was also found in a study conducted in Texas, USA in 1999 shortly after the initial shortening of preoperative fasting guidelines to six hours for solids (10). This instructed fasting time is comparable to that seen at CMJAH.

The mean actual fasting time was 14.92 (SD 2.50) hours at CMJAH. Patients fasted for 8.92 hours longer than the guidelines advise. Fasting times in adults at CMJAH were in keeping with the results from studies conducted in both developed and developing countries. The mean actual fasting time found in this study at CMJAH was similar to the mean actual fasting time of 14 hours in adult patients in Texas, USA in 1999 (10) and 13.50 hours in patients in the Royal Infirmary of Edinburgh in 2011 (87). Similarly, postpartum women in Texas, USA in 2010 had a mean actual fasting duration of 13 hours for solids (11).

Literature regarding fasting times in developing countries has been limited until recently. The large “BIGFAST multicentre study” of 3715 patients in Brazil conducted from 2011 to 2012 found that the median actual preoperative fasting time was 12 hours (19). A smaller study of preoperative fasting times in 43 patients conducted in Ethiopia in 2013 found that patients fasted from solids for 19.60 hours. The fasting times were significantly prolonged in this study revealing an important problem of prolonged preoperative fasting in developing countries (20). Patients at CMJAH were fasting for a similar length of time.

In comparing the instructed and actual fasting times at CMJAH, patients fasted an average of 4.93 hours longer than they had been instructed to. This was statistically significant ($p< 0.05$) and was similar to the average of 4.7 hours that patients fasted beyond the instructed fasting time for solids in a study conducted in Texas, in the USA in 1999 (10).

Although the assessment of fasting times in diabetic patients was not an objective, when analysing the data it was found that the diabetic patients also fasted for prolonged periods of time. It is recommended that diabetic patients should fast for a period that is as short as possible prior to surgery to avoid hypoglycaemia (75). Sixteen percent of patients were diabetic and of those, 80% had intravenous lines. This is good practice for the care of preoperative diabetic patients and especially if patients are fasting for longer periods than the guidelines recommend. The diabetic patients in this study had a mean instructed fasting time of 9.40 (S.D. 0.97) hours and a mean actual fasting time of 14.99 (S.D. 2.43) hours. Therefore diabetic patients fasted for almost 9 hours longer than the recommended guidelines.

Prolonged instructed fasting times may have been a result of patients not being allocated a specific theatre timeslot and therefore the starting time of surgery could not be estimated in order to calculate an instructed fasting time closer to the recommended six hours. The absence of a system to divide patients into a morning and an afternoon list could have contributed to the prolonged instructed fasting times as all patients were fasted as if their surgery was beginning at 08:00.

Some doctors may have believed that the shorter fasting times allowed less flexibility in theatre list rearrangements as patients may not have fasted for a long enough period if they were unexpectedly shifted to an earlier theatre slot. However, the earliest theatre slot at CMJAH was 08:00 therefore doctors and nurses were only required to fast patients from solids from 02:00 to ensure a six hour fast. Interestingly, not one patient was instructed to fast from 02:00. The nurses and doctors may have been adhering to the old doctrine of “NPO from 22:00” despite the new guidelines recommending a shorter fast.

Several studies on fasting times suggest many reasons for this reluctance to adopt the new guidelines. These reasons may explain why preoperative fasting times are prolonged at CMJAH. One particular study by Crenshaw et al. (10) provided the following as possible causes for staff prescribing prolonged preoperative fasting instructions:

- the difficulty of changing from the traditional routine
- the idea that longer fasts are superior
- the challenge of individual fasting instructions
- litigation concerns
- the lack of knowledge about possible adverse effects of prolonged fasting
- the limited and outdated knowledge of the risks of aspiration.

These reasons are areas where change can occur through staff education and collaboration.

Another possible reason for the reluctance to change the fasting routine is that the majority of patients were fasted overnight and staff may have been reluctant to wake patients to offer them a meal in the early hours of the morning or late at night. In addition, patients received their evening meal around 17:00 depending on the routine of the kitchen staff. Thereafter food was not available until the following morning. Therefore several patients starved from 17:00 on the day prior to surgery, despite being instructed to fast from 22:00. Preoperative fasting practices at CMJAH were centred around the routines of the hospital, kitchen staff, nursing staff and doctors instead of being structured to suit the individual patient.

The actual and instructed fasting times were prolonged at CMJAH during this study. Prolonged preoperative fasting has been associated with adverse effects including thirst, hunger, anxiety and increased insulin resistance (2). In addition, patients subjected to prolonged preoperative fasting periods may experience one or more of the following effects including: dehydration, hypoglycaemia, ketosis, hypovolaemia, confusion, headache or low urine output (64).

These effects impact on the patient's overall feeling of well-being. Patient satisfaction with treatment has been associated with their general feeling of health thus if patients experience these adverse effects they may be dissatisfied with the quality of their treatment despite the surgery being a success (25). A shorter preoperative fast also improves patient satisfaction by reducing postoperative complications such as nausea and vomiting. This improves the patient's perception of well-being perioperatively and satisfaction with care (67, 68).

The goal of optimal fluid management in accordance with the ERAS guidelines for perioperative patients is for the patient to be in a state of fluid balance or 'euvolaemia' prior to induction in theatre. Prolonged preoperative fasting does not aid the achievement of this goal but rather results in the patient being in a state of fluid depletion at the time surgery commences before potential fluid shifts and blood loss have even occurred. Maintaining a state of euvolaemia is vital in ensuring optimal recovery from surgery (69). Shorter preoperative fasts are associated with a decrease in the length of time patients spend in hospital and patients are more comfortable postoperatively (88).

There were an equal number of patients from each discipline in the study. There was no statistically significant difference in fasting times between disciplines for either the instructed ($p = 0.7089$) or the actual ($p = 0.6702$) fasting times.

The specialty of doctor who prescribed the fasting time was not specified in this study as patients had difficulty identifying the discipline of the prescribing doctor. If the anaesthetist was the main doctor who prescribed the fasting times, the results may have reflected the consistency of fasting time prescription by the doctors in the anaesthetic department. Another contributing factor may have been that the anaesthetists work in a different discipline every day therefore there was no dedicated group of anaesthetists per discipline. As a result, the anaesthetists may not have developed a specific fasting time for each discipline based on the theatre routine for that particular discipline.

4.5 Summary

In this chapter the results of the study were presented and discussed.

In the final chapter which follows, the summary, limitations, recommendations and conclusion of the study are presented.

Chapter 5

Study summary, limitations, recommendations and conclusion

5.1 Introduction

In this chapter a summary of the study is presented. Thereafter, the limitations, recommendations and conclusion of the study are discussed.

5.2 Study summary

5.2.1 Aim and objectives

The aim of this study was to describe preoperative fasting practices in adult elective surgery patients at CMJAH.

The primary objectives were to:

- describe the instructed preoperative fasting times in adult elective surgery patients
- estimate the actual fasting times in adult elective surgery patients.

The secondary objectives were to:

- compare the actual and instructed fasting times in adult elective surgery patients
- describe and compare the fasting times across various disciplines within the hospital.

5.2.2 Methodology

The sample size was determined in consultation with a biostatistician. A sample size of 62 participants estimated the mean instructed and actual fasting times to an accuracy of within 0.5%. This calculation assumed a standard deviation of 2 hours and a confidence interval of 95%.

A stratified sampling method was used in this study. Sixteen patients from each discipline were included to ensure equal representation from the four disciplines. As a result, a total of 64 patients were included.

A prospective, contextual, descriptive study design was used.

The researcher collected data at different times on the day of surgery using a data collection sheet. The demographic data was recorded on the data collection sheet including age, gender, discipline, presence of diabetes and an intravenous line. The fasting data including the time the patient was instructed to commence fasting, the time the patient commenced fasting, the time surgery commenced, who prescribed the instructed fasting time and whether or not a surgery starting time was given to the patient were recorded on the data collection sheet.

5.2.3 Main findings

The median instructed fasting time was 10.00 hours with a minimum of 8.00 hours and a maximum of 12.00 hours. This result was not normally distributed. On average patients were instructed to fast for 4 hours longer than the 6 hours recommended by the guidelines.

The mean actual fasting time was 14.92 (S.D. 2.50) hours. The result was normally distributed. On average, patients fasted for 8.92 hours longer than the recommended guideline of 6 hours.

A two tailed Wilcoxon matched pairs test was used to compare the instructed and actual fasting time which showed a statistically significant difference between the two fasting times ($p < 0.0001$).

As the instructed fasting times per discipline were not normally distributed, a Kruskal-Wallis test was used which indicated that there was no statistically significant difference in the instructed fasting times between disciplines ($p = 0.7089$).

The actual fasting times per discipline were normally distributed therefore an ANOVA was used. There was no significant difference in the actual fasting times between disciplines ($p = 0.6702$).

5.3 Limitations

Limitations are defined by Burns and Grove as “restrictions or problems in a study that may decrease the generalisability of the findings” (82).

This study was a contextual descriptive study conducted in adult patients from four surgical disciplines in one hospital in Johannesburg. The ability to extrapolate the results to other disciplines within the hospital and to other hospitals may therefore be limited.

This study measured the fasting time since the last ingestion of solid or liquid and did not specify the time of solid and liquid ingestion individually. None of the patients reported ingesting a liquid after their last meal and it was assumed that this meal was the last ingestion of a solid. This reflects the inadequate fasting instructions which do not specify individual times for solids and liquids. Nonetheless, separate fasting times for solids and liquids could not be calculated from this study.

The results of the comparison of fasting times between the different disciplines should be interpreted with caution as this was a secondary objective and the sample size was not calculated to fulfil this objective.

5.4 Recommendations

5.4.1 Recommendations for clinical practice

The general surgery, orthopaedic, urology and gynaecology units at CMJAH should revise their current fasting regimen and implement fasting guidelines in line with the latest fasting guidelines. The units should construct a fasting protocol tailored to the specific theatre routine for each discipline. The nursing staff, surgeons and anaesthetists prescribing fasting times in that unit should be trained to use the same protocol.

Specific fasting times should be prescribed for solids and liquids. A fasting time of six hours for solids and two hours for liquids is recommended. These instructions should not only be given to the patient verbally, but also reinforced by means of a patient

information sheet which the doctor or nurse could fill in at the time of preoperative assessment.

It is recommended that patients on each theatre list are divided into two groups. The first group would consist of patients having surgery in the morning and the patients in the second group would have their surgery in the afternoon.

The group of patients going to theatre in the morning could be given a light snack at 02:00 if they are awake and willing to eat and they could have a cup of black tea with sugar, water or clear apple juice at 06:00. These patients would still be adequately fasted by 08:00. Those patients going to theatre from midday onwards could have a light meal consisting of tea with milk and bread shortly before 06:00 as their breakfast and they would still be adequately starved for 12:00. This would require cooperation from the nurses and kitchen staff to ensure a patient receives their appropriate solid or liquid at the appropriate time.

A standardised preoperative form could be devised to attach to the front of a patients file for rapid, accessible and standardised fasting time prescription, morning or afternoon theatre slot allocation and accurate recording of actual fasting time commencement which could be used by doctors and nurses.

5.4.2 Recommendations for further research

It is recommended that a study evaluating doctors' and nurses' knowledge of preoperative fasting guidelines at CMJAH should be performed. This may highlight the need for further training on fasting time prescription.

If a standardised preoperative form for fasting time prescription and theatre slot allocation is used, a follow up study could be performed to assess the effectiveness of the form.

A study specifically evaluating the preoperative fasting protocol for diabetics, their glycaemic control and fluid therapy should be performed to assess the preoperative management of diabetics.

5.5 Conclusion

Despite the ASA Preoperative Fasting Guidelines being available since 1999 and updated in 2011, prolonged preoperative fasting at CMJAH was ongoing at the time of this study. Patients at CMJAH were instructed to fast longer than the recommended guidelines. In addition to this, patients at CMJAH fasted longer than they were instructed to, which resulted in particularly long actual fasting times.

Prolonged preoperative fasting leads to several adverse effects which not only affect the patients overall health and recovery postoperatively but also impact negatively upon the patients' perception of their own well-being and quality of care. This results in patient dissatisfaction with treatment.

Preoperative fasting practices at CMJAH were centred around the routines of the staff and were not structured to suit the needs of the individual patient.

The mean actual fasting time compared closely with other local and international studies suggesting that prolonged preoperative fasting was a worldwide problem at the time of this study.

Appendices

Appendix 1: Ethics approval

R14/49 Dr Julie-Ann Herbst et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130308

NAME: (Principal Investigator)	Dr Julie-Ann Herbst et al
DEPARTMENT:	Department of Anaesthesiology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Preoperative Fasting Practices in Adult Elective Surgery Patients at Charlotte Maxeke Johannesburg Academic Hospital
DATE CONSIDERED:	05/04/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Estie Mostert
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	05/04/2013

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 Secretary in Room 10004, 10th floor, Senate House, University.
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**.

J. Herbst — 12/08/13

Principal Investigator Signature — Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Postgraduate Committee approval

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 0117172119
Tel: 011 7172040

Reference: Ms Mpumi Mnqapu
E-mail: mpumi.mnqapu@wits.ac.za

23 August 2013
Person No: 0202032F
PAG

Dr JME Herbst
Po Box 335
Glenvista
Johannesburg
2058
South Africa

Dear Dr Herbst

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Preoperative fasting practices in adult elective surgery patients at Charlotte Maxeke Johannesburg Academic 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 3: CEO approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. M. Ndlovu
Office of the Chief Executive Officer
(011): 488-3792
(011) 488-3753
21rd January 2014

Dr. Julie-Ann Herbst
Department of Anaesthesiology
University of Witwatersrand

Dear Dr. J. Herbst

RE: "Preoperative Fasting Practices in Adult Elective Surgery Patients at Charlotte Maxeke Johannesburg Academic Hospital"

Permission is granted for you to conduct the above research as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Approved / ~~not approved~~

Ms. G. Bogoshi
Chief Executive Officer
24/01/2013

Appendix 4: Information letter

PREOPERATIVE FASTING PRACTICES IN ADULT ELECTIVE SURGERY AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Hello, my name is Dr Julie-Ann Herbst and I am a doctor who is studying to become an anaesthetist at the University of the Witwatersrand. An anaesthetist is a doctor who gives patients special medicine to make them sleep and for pain during an operation.

As part of my studies, I would like to invite you to take part in a research study because I am trying to learn more about how long adult patients do not eat or drink for before an operation.

If you agree to be in this study, it will only take ten minutes to take part in it. I will ask you some questions about the length of time you were not allowed to drink or eat before your operation. I will write the answers down on a sheet of paper. I will not record your name on the sheet of paper.

I do not think that you will be hurt or upset by taking part in this study. If you take part in the study and think that you have been hurt or upset at all, you do not have to continue. You can do this anytime before I combine your answer sheet with the ones from other patients. I will not be able to remove it from the pile once they are combined as your name will not be on it.

You will not gain anything from taking part in this study, but it will help us to find out more information about a possible problem in our hospital and lead to a change in the Charlotte Maxeke Johannesburg Academic Hospital. I will not tell anyone else anything you tell me unless that information could threaten your life if not passed on to another person.

If you do not want to be part of this study, you do not have to take part. It is your choice to be part of this study. No one will be upset with you if you do not take part in the study and your doctors will continue to treat you as usual. Please make sure you have read and understood all of the above information before taking part in the study.

You can ask me any questions that you might have about the study. If you have a question later on, you can call me on 0834872489 or Professor Cleaton-Jones (chairperson of the Human Research and Ethics Committee) on (011) 717-1234.

Please sign the consent from on the following page if you agree to take part in the study. Thank you for taking the time to read this letter.

Yours sincerely

Julie-Ann Herbst

Appendix 5: Consent form

I, ... agree to participate in the study of preoperative fasting practices in adult elective surgery at Charlotte Maxeke Johannesburg Academic Hospital.

I have read and understood the information letter provided to me by Dr Julie-Ann Herbst. I understand that I may withdraw from the study if I do not wish to take part in it.

I have had an opportunity to ask questions that I may have had regarding the study and my participation in it.

Participant name

Participant signature

Date

Appendix 6: Data collection sheet

Study number ☐ Age ☐

Type of procedure

General Surgery Orthopaedics Urology Gynaecology

ASA Score Gender

I II III IV M F

Premedication Ramsay Score

YES NO YES NO

Diabetic Intravenous line (if diabetic)

YES NO YES NO

Source of fasting instructions Nurse Doctor Both None

Fasting times (hh:mm)

Was an estimated surgery starting time given to the patient?

YES NO

If yes, what time ☐

Instructed starting time of fast ☐

Actual starting time of fast ☐

Actual starting time of surgery ☐

Appendix 7: Ramsay sedation scale (85)

Level of sedation	Clinical description of patient
Awake	
1	Patient is anxious and agitated or restless or both
2	Patient is cooperative, orientated and tranquil
3	Patient responds to command only
Asleep	
4	Patient exhibits a brisk response to light glabellar tap or loud auditory stimulus
5	Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6	Patient exhibits no response

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