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Residual gastric volumes in patients receiving chronic haemodialysis after an overnight fast- A pilot study

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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 Anaesthesia

Johannesburg, 2015

Declaration

I, Natalie Burger declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Signature

Signed at: University of the Witwatersrand, Johannesburg

On this date: 23/07/2015

Abstract

Patients with chronic renal failure are considered to be at risk of perioperative pulmonary aspiration and consequently the recommendation is to perform a rapid sequence induction on such patients. Rapid sequence induction is not without its risks and may not be necessary.

The aim of this study was to determine whether patients who are on a chronic haemodialysis program have sufficient residual gastric contents after an overnight fast, to place them at risk of pulmonary aspiration of gastric contents during anaesthesia.

The presence and volume of gastric content was ascertained by ultrasound examination of the stomachs of twenty patients. Patients were asked to fast overnight and an ultrasound was scheduled for a morning on which the patient was due to come in for a dialysis session. The appearance of the stomach and the contents were graded by the radiologist and the diameters of the gastric antrum were then measured so that the cross sectional area could be calculated.

Once the cross sectional area was known the gastric volume was calculated using a validated equation. The risk of perioperative pulmonary aspiration was then assessed according to the graded appearance as well as calculated gastric volumes. If the stomach was found to contain fluid a cut off value of 0.8ml/kg was used as a relative gastric volume that would place the patient at increased risk of perioperative pulmonary aspiration. Any patient with a gastric antrum found to be distended with fluid in both the supine and lateral positions or seen to contain solid contents was assessed as being at increased risk of perioperative pulmonary aspiration.

Gastrointestinal symptoms were assessed and compared to residual gastric volumes. Urea and creatinine concentrations were also correlated to residual gastric volumes.

In this study none of the patients with chronic renal failure on a chronic haemodialysis program were considered to be increased risk of perioperative pulmonary aspiration, after an overnight fast.

Gastrointestinal symptoms were found in 60% of patients. There was no association between gastrointestinal symptoms and residual gastric volumes. There was no correlation between either urea or creatinine levels and residual gastric volumes.

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List of abbreviations

CRF	Chronic renal failure
PPA	Perioperative pulmonary aspiration
ASA	American Society of Anesthesiologists
RSI	Rapid sequence induction
RGVs	Residual gastric volumes
CSA	Cross sectional area
CCK	Cholecystokinin
ESRD	End stage renal disease
GFR	Glomerular filtration rate

Chapter 1 – Overview of the Study

1.1 Introduction

In this chapter an overview of the study is given and will include: the background to the study, the problem statement, aim and objectives, research assumptions, research methodology, significance of the study, study outline and a summary.

1.2 Background to the study

Perioperative pulmonary aspiration (PPA) of gastric contents is a feared and potentially devastating complication in anaesthesia. The reported incidence of PPA varies greatly with ranges from as low as 1 in 9 229 in ASA I patients undergoing elective surgery to 1 in 343 in ASA IV and V patients having emergency procedures. Mortality after PPA was found to be 4.5% in the Mayo clinic study (1) and 3.5% in the AIMS study (2). PPA is presumed to be largely avoidable with proper management strategies and by identifying high risk groups preoperatively (3, 4). The primary method for reducing the risk of PPA is to ensure that the patient has an empty stomach prior to induction of anaesthesia. This is the basis for the preoperative fasting of elective surgical patients. Patients with chronic renal failure (CRF) are believed to have delayed gastric emptying, therefore current practice in anaesthesia is that such patients presenting for surgery undergo a rapid sequence induction (RSI), regardless of the period of preoperative fasting. In order to avoid PPA, RSI or modified RSI should be performed where a patient is considered to have a full stomach (5).

Patients with CRF commonly present with dyspeptic symptoms such as anorexia, nausea, vomiting, bloating, early satiety and abdominal pain (6). There may be a correlation between dyspeptic symptoms and delayed gastric emptying (7). Delayed gastric empting secondary to autonomic neuropathy, uraemia or gastric dysmotility in patients with CRF can predispose them to high residual gastric volumes (RGVs) and consequently they are at risk of regurgitation and PPA of gastric contents.

A number of reports evaluating gastric emptying in patients with CRF have yielded conflicting results. Possible reasons for this are multiple variables across the studies, including several different methods of assessing gastric emptying and some studies including patients with diabetes. There may be an association with autonomic neuropathy which often develops during the course of renal failure.

A study done by McNammee (8) in 1985 showed delayed gastric emptying in patients with uraemia not being haemodialysed but normal gastric emptying in

patients receiving regular haemodialysis. In 2000 Van Vlem (6) concluded that patients who were receiving chronic haemodialysis and had dyspepsia had significantly delayed gastric emptying. Wright (9) found in 1984 that patients with CRF receiving haemodialysis showed no demonstrable abnormality in gastric emptying whether experiencing dyspeptic symptoms or not. In 2004 Strid (10) demonstrated delayed gastric emptying in patients with CRF, the gastric emptying times were further prolonged in the patients who were on a dialysis program. He found no correlation between gastric emptying times and dyspeptic symptoms in these patients.

The greater the volume of gastric contents the greater the risk of regurgitation and aspiration during anaesthesia. Once gastric contents are aspirated, subsequent morbidity is related to the volume of contents that are aspirated. Reference is made to a critical gastric volume of between 25 and 50 ml or 0.4 - 0.8 ml/kg (11, 12).

The use of ultrasound to assess gastric volumes has been found to be highly reproducible and accurate (13-17). The results of a recent study concluded that estimation of gastric volumes by measuring cross sectional area (CSA) of the antrum by ultrasound could be used in clinical practice to identify the patient at risk of PPA during the perioperative period (18).

Previous studies on gastric emptying in patients with CRF have focused on the gastric volumes for a period of up to 6 hours postprandially (8, 10, 19-21). For the renal patient presenting for elective surgery it is important to know if there is sufficient gastric volume after an overnight fast of eight hours, which would put them at risk of PPA of gastric contents.

According to the reviewed literature no study could be identified that specifically focuses on the use of ultrasound to assess gastric volumes in patients with CRF who had been fasted overnight.

1.3 Problem statement

Patients with CRF are considered to be at risk of PPA and consequently the recommendation is to perform a RSI on such patients. RSI is not without its risks and may not be necessary.

1.4 Aim of the study

The aim of this study was to determine whether patients who are on a chronic haemodialysis program have sufficient residual gastric contents after an overnight fast, to place them at risk of pulmonary aspiration of gastric contents during anaesthesia.

1.5 Objectives of the study

Objectives of the study

The primary objective of this study was to quantify the RGVs, after an overnight fast, of patients who are on a haemodialysis program by means of ultrasound assessment of the gastric antrum.

The secondary objectives of this study were to:

- describe the gastrointestinal symptoms of the patients
- compare the RGVs in patients with and without gastrointestinal symptoms
- correlate RGVs with the urea concentrations
- correlate RGVs with the creatinine concentrations.

1.6 Research assumptions

The following definitions were used in this study.

Chronic haemodialysis patient: in this study refers to patients who had been on a haemodialysis program for a minimum of six months. The patients were dialysed three times weekly for a period of four hours per day.

Dyspepsia: in this study refers to any of the following symptoms: heartburn or acid reflux, nausea, vomiting, abdominal bloating and early satiety.

Residual gastric volume: in this study refers to the gastric volume in the fasted state. This volume will be described in mls.

Relative gastric volume: in this study refers to the gastric volume that was calculated from the ultrasound measurements of the gastric antrums divided by the patient's weight. This volume will be described in mls/kg.

Qualitative assessment: The sonographic appearance of the gastric antrum made using a three point grading system (22):

- **Grade 0**: The antrum is assumed to be empty. The anterior and posterior walls are adjacent to one another and no fluid can be visualised in either the supine or the lateral decubitus position.
- **Grade 1**: The antrum is assumed to contain a volume of fluid within the "safe" range (less than 0.8ml/kg). The fluid can only be visualized in the lateral decubitus position and not in the supine position.
- **Grade 2**: These patients may be considered at risk of perioperative pulmonary aspiration (volume greater than 0.8ml/kg). The gastric antrum is distended in both the supine and the lateral positions. If the distended lumen

is hypoechoic it contains fluid. If it has a frosted glass appearance it contains solid contents.

Empty Stomach:

- volume of gastric contents not exceeding 0.4 ml/kg body weight, or
- Grade 0 appearance on ultrasound

Not at increased risk of PPA:

- volume of gastric contents greater than 0.4 ml/kg but less than 0.8 ml/kg and
- Grade 1 appearance on ultrasound.

At risk of PPA:

- gastric contents which exceed 0.8 ml/kg, or
- Grade 2 appearance on ultrasound

1.7 Research methodology

1.7.1 Research design

A prospective, cross sectional, descriptive research design was used.

1.7.2 Study population

The study population comprised patients who were treated in a haemodialysis unit in a private hospital in Johannesburg.

1.7.3 Study sample

A convenience sample was used in this study. The sample size was realised by the number of patients that met the criteria for this study.

Inclusion and exclusion criteria

The following inclusion criteria were used in the study:

- patients with CRF who were 18 years or older
- patients who had been on haemodialysis for at least six months, and
- patients who consented to take part in the study.

Patients with the following were excluded from the study:

- diabetes mellitus

- a history of previous surgery which could distort the anatomy of the stomach and oesophagus
- a history of hiatus hernia
- those patients on medications which may affect gastric emptying such as erythromycin or metoclopramide
- a BMI> 35 kg/m^2
- patients who were pregnant.

1.7.4 Data collection

All patients attending the dialysis unit who met inclusion criteria were identified. They were then approached, the study was explained to them by the researcher and an information sheet detailing the study was provided to them. If they agreed to participate they were asked to sign consent. They were then asked about gastrointestinal symptoms, and blood results for urea and creatinine concentrations were taken from their files.

An ultrasound was scheduled for a morning on which the patient was due to come in for a dialysis session. The patient was asked to take nothing by mouth from bedtime or midnight from the night before the ultrasound.

The appearance of the stomach contents was assessed visually on ultrasound by the radiologist and the area of the gastric antrum was measured so that gastric volumes could be calculated. Once the ultrasounds were completed patients proceeded to the dialysis unit where they received breakfast and their haemodialysis was commenced.

1.7.5 Statistical analysis

Raw data was captured using Excel 2013 (Microsoft USA). Data was analysed using StatCalc version 7.3.3, a program by AcaStat software. A Fisher's exact test was performed to check for any association between presence of gastrointestinal symptoms and gastric volumes which were divided into those above 0.4 ml/kg and those below. Continuous variables such as plasma concentrations of urea and creatinine, as well as gastric volumes, were compared using Pearson correlation coefficient.

1.8 Significance of the study

This study may help identify whether the patient who has CRF and is being treated with haemodialysis is at risk of PPA after an overnight fast. If these patients are found to have raised residual gastric content then measures to minimize the risks of PPA need to be taken. This may reinforce current practice. If however the findings are that such patients have insignificant residual gastric contents then these measures may not be necessary. One of the measures taken to reduce the risk of PPA is the performance of RSI. There are risks associated with the performance of RSI, amongst which are haemodynamic instability, airway damage, hypoxia and failed intubation (23, 24).

1.9 Study report outline

The outline of the study report is as follows.

- Chapter 1: Overview of the study
- Chapter 2: Literature review
- Chapter 3: Research methodology
- Chapter 4: Results and discussion
- Chapter 5: Summary, limitations, recommendations and conclusions.

1.10 Summary

This chapter provided an overview of this study. It included the background to the study, the problem statement, aim and objectives, research assumptions, research methodology, significance of the study, and study outline.

In the next chapter a review of the relevant literature is presented.

Chapter 2 – Literature review

2.1 Introduction

Patients presenting for surgery are divided by the anaesthetist into two groups. The first group comprises those patients with potentially ‘full stomachs’, which means that they are at risk of PPA. The second group of patients are those who are fasted with no reason to expect delayed gastric emptying; these patients are not considered to be at risk of PPA. These two groups of patients are managed differently. Currently patients with CRF are put into the first group. There have been many studies done to measure gastric emptying in patients with CRF and there is currently no clear consensus between studies. The literature will be reviewed with regard to the normal physiology of gastric emptying, methods of assessing gastric emptying, CRF, dialysis and PPA.

2.2 Physiology of gastric motility and emptying

Gastric motility is controlled by an intrinsic and an extrinsic nervous system as well as by numerous hormones and neurotransmitters. Gastric emptying is the process of transferring food from the stomach to the duodenum. When food enters the stomach, the fundus and upper portion of the body of the stomach relax to accommodate the food; this is known as receptive relaxation. Peristalsis begins and the food is mixed with acid, mucus and pepsin. The chyme produced is then passed through the pylorus to the duodenum. Gastric emptying is promoted by intense peristaltic contractions, which generates pressure in the antrum, and is opposed by tonic contractions of the pyloric sphincter, which creates resistance to emptying of gastric contents. Liquids empty much faster than solids. Pyloric sphincter tone is under the control of the nervous system as well as humoral signals. (25)

2.2.1 Neural control of gastric motility

The intrinsic nervous system, which lies in the wall of the gut, is known as the enteric nervous system. It is composed of two plexuses, the myenteric plexus and the submucosal plexus. The myenteric plexus controls the motility of the gastrointestinal system. The submucosal plexus controls the local blood flow and gastrointestinal secretion of various enzymes, hydrochloric acid and mucus. The enteric nervous system is stimulated by stretch receptors in the stomach in response to food, which increases gastric motility as well as increasing pyloric tone, thus preventing emptying. The enteric nerve endings secrete many neurotransmitter substances including acetylcholine, noradrenalin, serotonin, cholecystokinin (CCK), vasoactive intestinal polypeptide, somatostatin and substance P. Noradrenalin inhibits

gastrointestinal activity and acetylcholine stimulates it. There is still uncertainty about the major functions of most of the other gastrointestinal neurotransmitters. (25)

The gastrointestinal system is also controlled by the autonomic, or extrinsic system. Sympathetic and parasympathetic nerve fibres connect with the enteric nervous system and can further activate or inhibit gastrointestinal functions. Parasympathetic impulses are transmitted via the vagus nerve. Activation of the parasympathetic system stimulates the enteric system which causes a general increase in gastrointestinal activity. Injury to the vagus nerve will impair gastric emptying (26). Vagal activity results in increased gastrin secretion, as well as decreased somatostatin secretion (27).

Sympathetic activation inhibits gastrointestinal functions by release of noradrenalin, which inhibits smooth muscle. Sensory neurons in the gut wall send afferent impulses back to the myenteric and submucosal plexuses as well as to the sympathetic nervous system and the brain stem via the vagus nerve. Afferent parasympathetic innervation from the vagus nerve regulates receptive relaxation, antral contractions and pyloric relaxation (28).

The presence of food in the duodenum acts to inhibit gastric emptying through inhibitory nervous reflexes via the enteric nervous system as well as the extrinsic nervous system. Gastric contractions are slowed and pyloric tone is increased. (25)

2.2.2 Hormonal control of gastric motility and emptying

Inhibition of gastric motility and emptying is largely due to duodenal factors. Distention of the duodenum, high acidity and fat content in the duodenum, and irritation of the duodenum all prevent further gastric emptying, thus preventing the small intestine from becoming overwhelmed by a sudden influx of food. Hormones responsible for this inhibition include CCK, secretin and gastric inhibitory peptide. (25) The presence of food in the duodenum acts to slow gastric emptying by inhibitory feedback mechanisms involving gastrointestinal hormones as well as nervous reflexes. CCK is released by cells in the duodenum and is then carried in the blood back to the stomach where it acts to inhibit the action of increased motility produced by gastrin, hence decreasing gastric emptying. (27) CCK also increases the contractile function of the pyloric sphincter, blocking the passage of food from the stomach to the duodenum (26). Gastric inhibitory polypeptide is secreted by the mucosa of the small intestine in response to fatty acids, amino acids and carbohydrates. Secretin which is secreted in response to increased acidity in the gastric contents has a direct inhibitory effect on the gastric smooth muscle. (25, 27)

Gastric emptying is promoted by the presence of food in the stomach and stretching of the stomach wall. Hormones involved include gastrin which is released from the gastric mucosa in response to the presence of food in the stomach. It is released directly by neural stimulation by the vagus nerve (27). The effects are release of gastric hydrochloric acid as well as increased motility and promotion of gastric

emptying (25). Nitric oxide mediates pyloric relaxation as a result of interactions with both intrinsic and vagal pathways and thus facilitates passage of gastric contents into the duodenum. (26)

2.3 Methods of assessing gastric emptying

There are many techniques for assessing gastric emptying; all have their advantages and disadvantages. As ultrasound is the method chosen for this study it will be discussed in greater detail.

2.3.1 Ultrasound

Ultrasound has numerous advantages over the other commonly used techniques for assessment of gastric volumes and emptying, amongst which are portability, non-invasiveness and cost effectiveness (22). Numerous studies have confirmed ultrasound as a valid method of assessing both gastric content and gastric emptying (13, 14, 16, 18, 29, 30). This method has also been found to be highly reproducible with inter observer measurement error of 0.3% (31). According to calculations performed by Bouvet et al, (18) measurements of the CSA of the gastric antrum are sensitive enough to detect the presence of fluid volumes of as little as 25ml.

In 2009 in Toronto, Perlas et al (15) evaluated the feasibility of bedside ultrasound to assess gastric content and volume. Eighteen volunteers were assessed by means of ultrasound in the fasting state as well as after ingestion of 250mls of water, 500mls of water, 500mls of effervescent water and a solid meal. A complete cross sectional view of the antrum was obtained 100% of the time at baseline and after fluid intake, but it was only visualized 72% of the time after a solid meal. The antral CSA increased proportionally to the intragastric fluid volumes within the range studied. The gastric antrum also had a distinct sonographic appearance when empty, after fluid intake, effervescent water and after a solid meal.

In 2011 Perlas et al (22) did a prospective descriptive study on the use of ultrasound as a diagnostic tool to assess gastric volumes in 200 adult, fasted, surgical patients. A three point grading system was proposed based on qualitative sonographic appearance of the gastric antrum. In this grading system Grade 0 corresponded to a completely empty stomach. Grade 1 corresponded to negligible fluid volumes (16 ± 36ml) which are within the normal ranges expected for fasted surgical patients. Grade 2 corresponded to significantly higher gastric volumes (180 ± 83ml) which would place the patient at risk of PPA. (22)

In 2013 Perlas et al (17) proposed a new mathematical model to assess gastric volumes using bedside ultrasound. In this study 108 fasted patients were randomised to receive 6 different quantities of apple juice ranging from nothing to 400mls. An ultrasound was performed prior to drinking the juice to confirm that the

stomachs were empty. After consumption of the apple juice another ultrasound was performed and the sonographer graded the stomach and the CSA was determined. The patients then underwent light sedation and upper gastrointestinal endoscopy was performed with observed volumes suctioned under direct vision. The study confirmed accuracy of the grading system by the sonographer as well as the model proposed for determination of the gastric volumes. Volume = 27 + 14.6 × right lateral CSA - 1.28 × age.

In 2014 a review article on the use of ultrasound to assess gastric content and volume was published which proposed an algorithm for the use of ultrasound in clinical practice (30). The suggestion according to the algorithm is that first a qualitative assessment of the gastric antrum is performed by scanning the patient in the supine and right lateral decubitus position. If the stomach is found to be empty (Grade 0) there is low aspiration risk and no further action is necessary. If there is fluid seen then the volume of fluid is calculated using the mathematical model proposed by Perlas in the equation above. Any solid content seen automatically places the patient at high risk for aspiration.

Ultrasonography offers an imaging technique which measures the rate and pattern of gastric emptying (32). The use of ultrasound is particularly useful to the anaesthetist in assessing gastric content and volume preoperatively so as to identify those patients at risk of PPA. Bouvet et al did a study in 2011, in France, of 183 patients. In this study a preoperative ultrasound measurement of the antral CSA was performed for each patient and then gastric contents were aspirated after tracheal intubation. The relationship between the measured antral area and the volumes aspirated were then analysed. Ultrasonographic measurement of antral CSA increased in proportion to the aspirated volume of gastric contents (18).

A study by Koenig et al in 2011 aimed to detect gastric contents by means of ultrasound prior to emergency endotracheal intubation. Ultrasound was performed on 80 patients presenting for emergency intubation in order to assess gastric fluid content. Fluid was identified in 24% of patients and in 16% there was sufficient content to necessitate insertion of a gastric tube to evacuate the stomach. Repeat ultrasound preformed after removal of the gastric contents confirmed the absence of fluid in the stomach. The performance of the ultrasound took less than two minutes. (33)

There are some limitations to the use of ultrasound for assessment of gastric volumes. It is operator dependent and there is the need for an appropriate soft tissue window and therefore there may be limitations in obese patients. Very large volumes in the antrum may not be fully visualized. A significant amount of air in the antrum may also invalidate the results. (15, 22)

2.3.2 MRI

Through multiple transaxial abdominal scans, 3D images of the stomach and any contents within can be constructed. Single shot images can also give a measurement of the gastric contents at a specific point in time. This method is however limited by the cost, specialized equipment and supine position that the patient would have to maintain during the study. (32, 34)

2.3.3 Gamma Scintigraphy

Considered the gold standard of gastric emptying studies (32), this method of assessing gastric emptying involves ingestion of a radiolabeled meal. The radioactivity in the stomach is then measured at successive intervals and is directly proportional to the volume of meal remaining in the stomach. It is widely available, validated and reproducible. Unfortunately there is a small amount of radiation exposure and a lack of uniform methodology across centres. (34)

2.3.4 Breath tests

This technique involves using ^{14}(C) octanoic acid as a marker to assess solid gastric emptying. There is no radiation exposure, the test is simple and does not require special equipment on site and can be done at the office or at home (34). It was concluded in a study that compared breath tests to gamma scintigraphy that the breath test is a reliable non-invasive test to assess gastric emptying rates of solids (35). Octanoic acid dissolves in and is bound to egg when baked. After ingestion it is broken down by pancreatic enzymes in the duodenum. ^{14}(C) Octanoic acid is absorbed and transported to the liver where it is preferentially oxidized to $^{14}CO_2$ (32). There are limitations to the use of breath tests in renal failure and particularly in patients who are on haemodialysis (36).

2.3.5 Nasogastric aspiration of gastric contents

Although previously widely used this technique has been largely abandoned in clinical practice due to its invasive nature. The other disadvantage of this method of assessing gastric contents is that it only measures liquid contents and thus is not an accurate reflection of solid contents (32).

2.4 Chronic Renal Failure

The kidneys are responsible for filtering toxins, adjusting body fluid composition, electrolyte homeostasis and acid-base balance. They are also responsible for many neurohumoral and hormonal functions. CRF results in progressive decline in the glomerular filtration rate (GFR) with accumulation of toxins and blood nitrogenous wastes, mainly urea. Fluid and electrolytes are also retained as urine production diminishes. End stage renal disease (ESRD) occurs when there is a complete or

almost complete failure of the kidneys to function. Clinical evidence of uraemia occurs when the GFR falls below 15ml/min (37).

2.4.1 Pathophysiology of gastric emptying in CRF

Gastroparesis is a chronic motility disorder of the stomach which involves delayed emptying of both liquids and solids, without evidence of mechanical obstruction (38). It is generally believed that gastroparesis involves abnormalities at three levels: the autonomic nervous system, the enteric neurons and the smooth muscle (39).

In the patient with CRF there are multiple potential mechanisms for delayed gastric emptying amongst which are gastric mucosal oedema, electrolyte disturbances, chronic uraemic toxicity, autonomic neuropathy and altered gastrointestinal peptide levels (40, 41).

Autonomic involvement is common in metabolic disorders characterized by small-fiber damage, such as ESRD. The pathophysiology of the axonal damage is probably due to the action of as yet unknown uraemic toxins to nerve fiber (42).

In 1995 Dumitrascu et al (19) studied 15 patients with CRF. The gastric antrum was assessed by means of ultrasound. Autonomic dysfunction was assessed clinically. The subgroup of patients with both sympathetic and parasympathetic dysfunction had delayed gastric emptying. Patients with only parasympathetic dysfunction had normal gastric emptying and patients without autonomic dysfunction had accelerated gastric emptying.

Gastrointestinal hormones are secreted by the cells in the gastrointestinal system. These hormones are inactivated and cleared by the kidneys and it has been found that their levels increase significantly as a consequence of uraemia (43-45). Serum levels of several polypeptide hormones involved in the modulation of gastrointestinal motility (e.g. gastrin, CCK, neurotensin) are significantly raised as a consequence of renal insufficiency. Furthermore, several other electrolyte abnormalities such as hypercalcaemia and hyperkalaemia are common in CRF, as are acid base disturbances. These abnormalities may play an important role in gastrointestinal dysmotility observed in CRF by directly affecting the smooth muscle of the gut or stimulating particular areas within the central nervous system (46).

Standard teaching is that there is delayed gastric emptying in chronic uraemia (5). The concept of delayed gastric emptying is critically important to the anaesthetist. Delays in gastric emptying result in stasis of gastric contents and consequently risks of regurgitation, vomiting and pulmonary aspiration of gastric contents during anaesthesia.

Multiple studies on gastric emptying in CRF have yielded conflicting results. Some of the studies have small sample sizes, and some include patients with diabetes, who are known to have delayed gastric emptying (47). Another possible explanation for the differing results are the different methods of assessing gastric emptying. Other

areas of debate are the effects of haemodialysis on gastric emptying and the possible relationship between dyspepsia and gastric emptying.

In 1984 Wright et al (9) performed a radionucleotide study of gastric emptying times in a group of 20 haemodialysis patients. Ten of the patients had symptoms of nausea and vomiting and the other ten did not. No abnormality in gastric emptying was found in any of the patients. Soffer et al (20) did a study in 1987 in Israel in which 18 patients who were controlled with haemodialysis were assessed for delayed gastric emptying. Nine of these patients described nausea, vomiting and postprandial bloating. The 18 patients were compared to a control group of healthy subjects. A radionucleotide method was used and retention of isotope after two and a half hours was assessed. No delayed gastric emptying was found in any of the patients.

In 1985 McNammee et al (8) studied 14 patients with CRF, using a radionucleotide technique to assess gastric emptying. The group was split into four patients who had been receiving regular haemodialysis for six to twelve months, and ten patients who had not yet been haemodialysed. No reference was made as to the diabetic status of any of the patients. Eleven healthy volunteers were used as control subjects. The results showed a significant retention of isotope in the stomachs of the patients not receiving haemodialysis as compared to the control subjects, with a $p < 0.05$ at 90 minutes. Three of the four patients on haemodialysis had normal gastric emptying although no comment was made as to the degree of the delay in gastric emptying in the fourth patient.

In 1996 Kao et al (21) used a radionucleotide technique to assess gastric emptying in Chinese patients with CRF. There was a sample size of 40 patients in this study. Diabetic patients were excluded from the trial as were any patients who had peptic ulcer disease, previous abdominal surgery or any other factor which could influence gastric emptying. Twenty of the patients were receiving regular haemodialysis and the other 20 were not yet receiving haemodialysis. There was a control group of 25 healthy volunteers. Of the 40 patients, 35 patients (88%) had delayed gastric emptying as defined by two standard deviations above the mean of the control group. There was no statistical difference in gastric emptying in the patients receiving haemodialysis. Thus it was concluded that there is a high incidence of delayed gastric emptying in the Chinese population with CRF whether they are dialysed or not. (21)

A more recent study by Strid et al (10) in 2004 in Sweden assessed gastric emptying in 39 patients with CRF. Gastric emptying was assessed by radionucleotide method. The gastric emptying results were compared to reference values previously obtained from 131 healthy control subjects. Seventeen of the patients were receiving haemodialysis, 9 were on peritoneal dialysis and 13 patients were not yet on dialysis. No diabetic patients were included. Eighteen of the patients had gastrointestinal symptoms. Delayed gastric emptying was found in 14 (36%) of the patients. There

was delayed gastric emptying in six of the 17 patients on HD (35%), six of the nine patients on PD (66%) and only two of the 13 predialysis patients (15%). The degree of uraemia in the predialysis patients was not discussed, nor was the duration of the CRF. There was no association between delayed gastric emptying and gastrointestinal symptoms.

In 2001, in Belgium, De Schoenmakere et al (48) studied gastric emptying in 56 haemodialysis patients which were compared to a healthy control group. Gastric emptying was assessed using radionucleotide evaluation. Gastric emptying was also compared to biochemical indicators of nutritional status and the conduction velocity of the fibular nerve. Results showed significant delays in gastric emptying ($p<0.05$) in the CRF group compared with the control group. In 20 patients gastric emptying time was more than double that of the control group. Further findings were that the patients with the greatest delays in gastric emptying had lower prealbumin levels and mean fibular nerve conduction velocity was slower ($p<0.05$) than those patients with normal gastric emptying. As prealbumin is considered an indicator of nutritional status the authors concluded that delayed gastric emptying in end stage renal failure could lead to malnutrition.

2.4.2 Gastric Motility in chronic renal failure

Gastric myoelectrical activity is a non-invasive method of assessing the motility of the gastrum of the stomach using surface electrodes on the abdomen which record an electrogastrogram (EGG). An abnormal EGG may predict delayed gastric emptying (49). Patients with CRF are found to have abnormal gastric myoelectrical activity. (50, 51)

In a study done in 2005 by Hirako (52) in Japan, gastric motility was assessed by means of an EGG. The aim of this study was to try and correlate a relationship between gastric motility, gastric emptying and gastrointestinal symptoms. Gastric emptying was assessed by means of a ^{14}(C) octanoic acid breath test. There were 21 patients included in the study who were matched with 21 healthy controls. Diabetic patients were not excluded. All of the patients had end stage renal failure but were not yet on haemodialysis. The patients with CRF had a higher percentage of fasting bradygastria compared to controls in the fasting state ($P<0.05$) and the postprandial state ($p<0.01$). Gastric emptying time was significantly slower in the group of patients with CRF compared with the controls ($p<0.01$). The study confirmed a high percentage of patients with both abnormal gastric motility and delayed gastric emptying which correlated with an increased incidence of gastrointestinal symptoms ($p<0.05$). (52)

2.4.3 Effect of dialysis on gastric emptying

Dialysis therapy is known to remove uraemic toxins and prevent or delay uraemic complications.

In a study by Ko et al (53) in Taiwan aimed at ascertaining whether haemodialysis alters gastric myoelectrical activity, 21 uraemic patients on haemodialysis with dyspeptic complaints were studied. Diabetic patients were excluded. Myoelectric activity was assessed using EGG as previously described. The patients were split into two subgroups: a chronic dialysis group comprised seven patients who had been on dialysis for more than five years and a new dialysis group comprised fourteen patients who had been on dialysis for less than a month. They found a low percentage of normal waves in all the patients both before and after dialysis ($p<0.01$), confirming abnormal myoelectrical activity in uraemia. However they found that there was a higher percentage of bradygastria ($p < 0.05$), in both the fasting and fed state, in the patients immediately after haemodialysis compared to before dialysis, concluding that haemodialysis itself compromises gastric myoelectrical activity in the period directly after dialysis. However haemodialysis was found to have no long term effect on gastric motility. (53) It is suggested that dialysis-associated hypotension causing periods of poor perfusion to the stomach may be a reason for the reversible gastric dysrhythmia noted (54).

Haemodialysis does not appear to remove the circulating gastrointestinal hormones involved in gastric emptying. In 1984 Sirinek et al (44) studied a group of 15 patients with CRF requiring haemodialysis. “Blood samples before and after 4 hours of haemodialysis were assayed for creatinine, blood urea nitrogen, potassium, calcium, glucose, insulin, gastrin, gastric inhibitory polypeptide, vasoactive intestinal polypeptide, pancreatic polypeptide, somatostatin, motilin, and neurotensin levels. Before dialysis, serum gastrin was minimally increased whereas gastric inhibitory polypeptide and pancreatic polypeptide were grossly increased compared with normal fasting values. Haemodialysis produced no changes in serum gastric inhibitory polypeptide, vasoactive intestinal polypeptide, pancreatic polypeptide, somatostatin, motilin, and neurotensin. Slight increases in serum insulin and gastrin levels may have occurred secondary to a dialysis-induced increase in the serum calcium level. The kidneys appear to be a major site of inactivation of insulin, gastrin, gastric inhibitory polypeptide, and pancreatic polypeptide. Dialysis does not seem to remove these hormones. Gastrin levels, although elevated in renal failure, may be suppressed by very high circulating levels of gastric inhibitory polypeptide.” (44)

A study in 2007 in Japan by Adachi (55) found improvement in the gastric emptying times and gastric motility in patients being dialysed compared with those who were predialysis.

2.4.4 Dyspepsia and gastric emptying

Renal patients often have dyspeptic symptoms. Common complaints include nausea, vomiting, postprandial bloating, early satiety, and anorexia. These dyspeptic complaints have formed the basis for many of the studies on gastric emptying that have been done on patients with CRF.

In 2000 Van Vlem et al (6) did a study in Belgium on 54 patients with CRF who were receiving chronic haemodialysis. The aim of the study was to determine whether delayed gastric emptying was related to dyspeptic symptoms. Seventeen patients (31%) were graded as dyspeptic, using specific symptoms such as nausea, vomiting, abdominal distension and early satiety. Gastric emptying was assessed by means of the ^{14}(C) octanoic acid breath test. There was a significant delay in the gastric emptying times in the haemodialysis patients compared with the healthy controls ($p<0.01$) as well as in the dyspeptic haemodialysis patients compared with the nondyspeptic haemodialysis patients ($P<0.01$). The effect of haemodialysis on gastric emptying times was also assessed by checking gastric emptying times before and after a dialysis session, and although the gastric emptying times were slightly longer after dialysis it was not statistically significant. Gastric hypomotility with associated delays in gastric emptying appear to contribute significantly to the generation of dyspepsia in patients with CRF (52).

2.5 Pulmonary aspiration

Pulmonary aspiration is a well-recognized complication in anaesthesia. In a landmark study in 1946, Mendelson (56) described pulmonary aspiration among obstetric patients, with significant morbidity and mortality. Certain high risk groups of patients, such as the obstetric patient, the patient with hiatus hernia, the patient with bowel obstruction or the trauma patient have since been identified. Patients with large gastric volumes are at risk of regurgitation and aspiration of gastric contents during anaesthesia and as such the concept of the preoperative fast came about.

Included in the traditionally accepted groups of patients at high risk of PPA are those with CRF.

According to Miller's Anesthesia; "all patients presenting for kidney transplantation should be considered to have full stomachs, regardless of the period of preoperative fasting." Patients with uraemia and other comorbid conditions (e.g., diabetes) should be considered at risk of aspiration during induction of anaesthesia. To prevent reflux and aspiration, RSI while maintaining cricoid pressure should be considered (5).

PPA involves the inhalation of oropharyngeal or gastric contents into the respiratory tract. These aspirations may include large food fragments which can occlude the

airway and lead to rapid asphyxiation, smaller particles which can produce a severe granulomatous inflammation, gastric acid which can induce a chemical pneumonitis and faeculent material which can cause an infectious pneumonia. (57)

Once pulmonary aspiration has occurred the consequences can vary from benign to lethal. Studies have found that in the majority of aspirations no complications resulted (2, 3, 58, 59). However, where patients developed signs of aspiration (crepitations, wheezing, hypoxemia, tachycardia, dyspnoea and infiltrates on chest X-ray) within two hours of the aspiration, the majority then required respiratory support and intensive care management (1). The mortality rates after aspiration as seen in the Mayo clinic study (1) and the AIMS study (2) approximates one in 20 patients.

The Mayo clinic study evaluated patients over a six year period from 1985 through to 1991. A total of 215 488 patients were reviewed. PPA occurred in 67 patients (1:3216). The rate for emergency surgery was 1:895 and for elective surgery was 1:3886. Sixty-six of the patients survived the surgery. Of these, 42 had no sequelae, 24 had signs and symptoms of aspiration within two hours and 13 required mechanical ventilation, 6 of whom required ventilation for greater than 24 hours. Three of these patients died. The total mortality was 1 in 22. (1)

The AIMS study done in New Zealand by Kluger and Short (2) reviewed 133 cases of reported PPA in which five patients died. All of these patients however were believed to have significant co-morbidities. In a computer aided study of the incidence of PPA in 185 358 anaesthetics 83 cases of aspiration were retrieved. In 83% of these cases there was a preoperative factor which indicated an increased risk of aspiration, with 61% having a history suggestive of delayed gastric emptying (peptic ulcer, pregnancy, obesity, stress, pain, increased intracranial pressure). (60)

In another retrospective study on the incidence and outcome of PPA done in Pennsylvania in 2006 by Sakai et al, the incidence of PPA was found to be low (1:7103) and of mortality especially low (1:99 441). Seventy percent of the incidents were associated with anaesthetic management that could have been improved, which suggests that in the majority of cases PPA can be prevented (3).

2.5.1 Risk factors for pulmonary aspiration

Multiple factors have been identified which place the patient at increased risk of PPA, specifically increased volume of gastric contents for whatever reason. Studies of PPA have found that in most cases a risk factor had been identified preoperatively. (3, 59)

Gastrointestinal obstruction is the factor most often associated with PPA (57). Emergency surgery, extremes of age, patients with severe pain, obstetric patients and patients with impaired gastric emptying or a history of gastroesophageal reflux would be considered at increased risk of PPA. Difficult intubation, especially with

inadequate muscle relaxation is another risk factor (11). A study by Olsson in 1986 found a six fold increased incidence of PPA at night compared to the day, perhaps due to greater number of emergency cases and a less experienced team (60).

Once rendered unconscious under general anaesthesia protective airway reflexes are lost, lower oesophageal sphincter tone is reduced and passive regurgitation of gastric contents can occur (11). Passive regurgitation is promoted by increased intragastric volume or pressure. The nature of the gastric contents aspirated may have further consequences in terms of the severity of subsequent lung damage. (4, 57)

A critical volume which when aspirated produces aspiration pneumonitis of 0.4ml/kg or 25 ml has been quoted (61). However there is evidence to suggest that volumes of up to 0.8ml/kg are well tolerated (12). Volumes of up to 1.5 ml/kg have been considered safe (30).

2.5.2 Prevention of pulmonary aspiration

Preoperative fasting

According to the ASA task force report on preoperative fasting guidelines (62) a preoperative interview should include pertinent assessment of gastrointestinal symptoms such as reflux, dysphagia and motility disorders. The potential for difficult airway management should be assessed. A history of any metabolic disorders which may place the patient at increased risk of regurgitation and pulmonary aspiration, should also be taken.

Minimum fasting periods are two hours for clear liquids, four hours for breast milk, six hours for formula milk, cow’s milk and a light meal (such as toast and liquids) and eight hours for a meal containing fried or fatty foods (62).

Rapid sequence induction

Patients who are deemed to be at high risk of pulmonary aspiration of gastric contents during general anaesthesia should have their airways secured with an endotracheal tube. Furthermore the use of a RSI is recommended (11). The primary goal of RSI is to minimize the time between loss of consciousness and tracheal intubation (23), thus minimizing the risk of PPA. RSI requires good preparation. Adequate intravenous access should be established and the patient should be monitored. The technique includes preoxygenation, rapid administration of a predetermined dose of induction agent and paralytic drug, concurrent use of cricoid pressure, avoidance of bag mask ventilation, direct laryngoscopy and endotracheal intubation. (11, 24)

The use of RSI should however be reserved for those patients where the risk of aspiration outweighs the potential risks associated with RSI. The most frightening of

these is the possible inability to secure the airway or ventilate the patient leading to hypoxia, hypercarbia and airway trauma (23).

RSI involves the rapid administration of a predetermined dose of an induction agent. This may result in drug over or under-dosing, precipitating severe haemodynamic changes (24). The patient with renal failure often has multiple co-morbidities such as cardiomyopathy, hypertension, ischaemic heart disease, central nervous system disturbances and anaemia. Sudden hemodynamic changes, such as tachycardia, hypotension and hypertension can result in serious morbidity, including myocardial ischemia, strokes and renal hypo-perfusion further compromising renal function. (5)

Succinylcholine is traditionally considered the muscle relaxant of choice for RSI due to its fast onset, providing excellent intubating conditions, and its short duration of action (63). There are however potential adverse effects associated with the administration of succinylcholine. Its use is contraindicated, due to the possibility of life threatening hyperkalaemia, in certain situations, such as CRF associated with a raised serum potassium, spinal cord injury and in patients with burns (23). It is a potential trigger for malignant hyperthermia, it can cause increases in intracranial and intraocular pressure, it can cause bradycardias, particularly in children or with repeated doses and the fasciculations can cause postoperative myalgia.

In situations where succinylcholine is contraindicated a non-depolarizing muscle relaxant such as rocuronium can be used. The onset of action can equate to succinylcholine but only if a larger dose is used, resulting in a much longer duration of action. If there are difficulties intubating and ventilating the patient the effects could be disastrous. Rocuronium would also not be the muscle relaxant of choice in a patient with CRF due to its renal excretion.

The use of an endotracheal tube is also not without its risks. Although providing a secure airway, thus minimizing the risk of aspiration and allowing for controlled ventilation, there are numerous potential complications. There can be complications from the laryngoscope blade itself, which may cause trauma to the teeth, lips, tongue or pharynx. Largyngoscopy if not performed under a sufficiently deep level of anaesthesia may induce a sympathetic response, resulting in tachycardia and hypertension which is especially undesirable in patients at risk of myocardial ischemia, such as those with CRF. It may also trigger laryngospasm or bronchospasm in susceptible individuals. The tube itself can cause trauma to the airway and vocal cords or may be misplaced either into the oesophagus or endobronchially. (64)

Gastric stimulants

The routine preoperative use of gastrointestinal stimulants such as metoclopramide, which accelerates gastric emptying, to decrease the risk of PPA in patients who have no apparent increased risk for PPA is not recommended (62). However in cases

where there is a known risk for PPA, such as in pregnancy, these agents are routinely used often in combination with an agent to raise the gastric pH. (58)

2.5.3 Pharmacological agents used to attenuate risks of PPA

Pharmacological blockade of gastric acid secretion

Proton pump inhibitors and histamine-2 receptor antagonists decrease the acidity of gastric contents. They may be useful in a high risk patient with history of reflux or PUD; however ASA guidelines do not support their routine use in patients who are not considered to be at risk of PPA (62).

Preoperative antacids

The literature does not show any relationship between reduced gastric acidity and volume secondary to the use of these drugs and improved clinical outcome (62).

The routine preoperative use of antacids to decrease the risk of PPA in patients who are not at increased risk for PPA is not recommended (62).

2.6 Summary

This chapter described the physiology of gastric motility and emptying, methods of assessing gastric emptying, the impact of CRF on gastric emptying, the effects of dialysis on gastric emptying and the relationship between dyspepsia and gastric emptying. Pulmonary aspiration was also discussed with regard to risk factors as well as methods to prevent it.

In the next chapter the research design and methodology will be reviewed.

Chapter 3: Research design and methodology

3.1 Introduction

In this chapter the research methodology will be discussed with regard to the problem statement, aim and objectives, demarcation of study field, ethical considerations, data collection, data analysis, validity and reliability of the study and a summary.

3.2 Problem statement

Patients with CRF are considered to be at risk of pulmonary aspiration of gastric contents during anaesthesia and consequently the recommendation is to perform a RSI on such patients. RSI is not without its risks and may not be necessary.

3.3 Aim of the study

The aim of this study was to determine whether patients who are on a chronic haemodialysis program have sufficient residual gastric contents after an overnight fast, to place them at risk of pulmonary aspiration of gastric contents during anaesthesia.

3.4 Objectives of the study

Objectives of the study

The primary objective of this study was to quantify the RGVs, after an overnight fast, of patients who are on a haemodialysis program by means of ultrasound assessment of the gastric antrum.

The secondary objectives of this study were to:

- describe the gastrointestinal symptoms of the patients
- compare the RGVs in patients with and without gastrointestinal symptoms
- correlate RGVs with the urea concentrations
- correlate RGVs with the creatinine concentrations.

3.5 Demarcation of study field

The study was conducted at a private hospital in Johannesburg. The study was done in the renal dialysis unit and the radiology department. The dialysis unit serves around 70 patients on chronic haemodialysis with varied aetiologies for their CRF.

3.6 Ethical considerations

Approval to conduct the study was obtained from the Human Research Ethics committee (Medical) (Appendix 1) and the Post Graduate Committee (Appendix 2) of the University of the Witwatersrand. Approval was also obtained from the Research Ethics Committee of the private hospital group (Appendix 3) and verbal consent from the head of the renal dialysis unit. The nursing staff were informed of the study.

The researcher approached the patients, explained the study and invited them to take part. Those patients who agreed received a patient information letter (Appendix 4) and signed a consent form (Appendix 5).

Anonymity and confidentiality was ensured as there was no identifiable information on the data collection forms (Appendix 6) and patients were allocated a study number. Patients' names and corresponding study number were kept on a list kept separately from the data. Only the researcher and supervisors had access to the raw data. The data will be stored securely for a period of six years following completion of the study.

The study was conducted in accordance with the declaration of Helsinki (65) and the South African Good Clinical Practice Guidelines.

3.7 Research methodology

3.7.1 Research design

A prospective, cross sectional descriptive research design was used.

Prospective study: a study in which variables are measured at the time in which the study takes place (66). In this study patients were recruited, signed consent, and data was collected thereafter.

Cross-sectional study: A research study that collects data on participants at one point in time (66). In this study data was collected on each patient on the day of the ultrasound.

Descriptive study: "Research study in which phenomena are described, or the relationship between variables is examined; no attempt is made to determine cause and effect relationships." (66) A descriptive study design best served the purpose of this study.

3.7.2 Study population

The study population comprised patients who were treated in a private haemodialysis unit in a hospital in Johannesburg.

3.7.3 Study sample

Sampling method

A convenience sample was used in this study due to the nature of the study and in order to obtain an adequate sample size. Convenience sampling is a form of non-random sampling where the most readily accessible individuals are used in obtaining an estimate of a particular element of interest (67).

Sample size

The sample size was realised by the number of patients that met the criteria for this study.

Inclusion and exclusion criteria

The following inclusion criteria were used in the study:

- patients with CRF who were 18 years or older
- who had been on haemodialysis for at least six months
- and who consented to take part in the study.

Patients with the following were excluded from the study:

- diabetes mellitus
- a history of previous surgery which could distort the anatomy of the stomach and oesophagus
- a history of hiatus hernia
- those on medications which may affect gastric emptying specifically erythromycin or metoclopramide
- a BMI > 35 kg/m^2
- patients who were pregnant.

3.7.4 Data collection

The data was collected during the period from June 2013 to May 2014.

A list was composed with all the eligible patients who regularly attended the haemodialysis unit. The patients were approached on one of their dialysis days and the study was explained to them. An information letter (Appendix 4) was provided, detailing the purpose and methods of the study. If they agreed to participate in the study they were asked to sign consent (Appendix 5).

Once the patients were recruited they were interviewed about gastrointestinal symptoms and results were recorded on the data collection sheet (Appendix 6). Urea and creatinine concentrations were obtained from their files and written on the data collection sheet. The patient was then asked to come in on a morning between 8 and 9 am before their dialysis session and after an overnight fast for an ultrasound examination of their stomach.

The ultrasounds were performed in the radiology department of the hospital by a radiologist experienced in sonography. All patients were fasted as per general hospital protocol, i.e. nil per os after going to bed or midnight, whichever was earlier.

Patients were scanned in the supine position followed by the right lateral decubitus position. The transducer was placed in the sagittal plane in the epigastric region. The antrum was visualized in the parasagittal plane in the epigastric region using the left lobe of the liver, the inferior vena cava and the superior mesenteric vein as landmarks. Once these landmarks were identified the transducer was rotated to visualize the best view of the antrum. The anterioposterior and craniocaudal diameters of the antrum were then marked out from serosa to serosa and care was taken to do measurements with the antrum at rest between peristaltic movements.

CSA of the antrum was then calculated using the formula described by Bolondi (16) in which the two maximum perpendicular diameters are used. This formula represents the surface area of an ellipse.

$$\mathrm{CSA} = \frac{\mathrm{AP} \times \mathrm{CC} \times \pi}{4}$$

Where AP is the anterioposterior diameter and CC is the craniocaudal diameter.

Once the CSA was known the gastric volumes were calculated using the following equation: Volume = 27.0 + 14.6 **×** Right lateral CSA – 1.28 **×** age.

The mathematical model for the above equation was developed by Perlas et al in 2013 and can be used to estimate gastric volumes of between 0 and 500 mls, in non-pregnant adults with a BMI < 40kg/m^2 (17).

Based on the results of the interview on gastrointestinal symptoms, patients were grouped as dyspeptic or not. The interview elicited symptoms of heartburn or acid reflux, nausea, vomiting, abdominal bloating and early satiety.

Once the ultrasound examination had been performed the patients returned to the dialysis unit where they were provided with a meal.

3.8 Data analysis

Raw data was captured using Excel 2013 (Microsoft USA). Data was analysed using StatCalc version 7.3.3, a program by AcaStat software. A Fisher's exact test was performed to check for any association between the presence of gastrointestinal symptoms and gastric volumes which were divided into those above 0.4ml/kg and those below. Continuous variables such as plasma levels of urea and creatinine and gastric volumes were correlated using Pearson correlation coefficient. A statistical significant association was taken as $p < 0.05$.

3.9 Validity and reliability of the study

According to Botma et al (68) validity "indicates whether the conclusions of the study are justified based on the design and interpretation" and reliability represents "the consistency of the measure achieved".

The validity and reliability in this study were ensured by the following:

- using an appropriate study design
- using the same ultrasound machine on all the patients
- the ultrasounds being performed by a single expert radiologist
- the remaining data was collected by the researcher only ensuring consistency
- the formula used to calculate gastric volumes was a validated formula
- all data entry on the excel spreadsheet was double checked.

3.10 Summary

This chapter provided a discussion of the problem statement, the aim and objectives, demarcation of the study field, ethical considerations, research design and methodology, data analysis and validity and reliability.

In the next chapter the results and a discussion thereof will be presented.

Chapter 4: Results and discussion

4.1 Introduction

This chapter describes the results of the study according to the objectives, followed by a discussion.

The primary objective of this study was to quantify the RGVs, after an overnight fast, of patients who are on a haemodialysis program by means of ultrasound assessment of the gastric antrum.

The secondary objectives of this study were to:

- describe the gastrointestinal symptoms of the patients
- compare the RGVs in patients with and without gastrointestinal symptoms
- correlate RGVs with the urea concentrations
- correlate RGVs with the creatinine concentrations.

4.2 Results

Data was collected during the period from June 2013 to May 2014. The dialysis unit treats around 70 patients at any given time. Twenty patients met the inclusion criteria and consented to participate in the study. The majority of the patients in the unit were diabetic (around 30 patients) and the balance refused to consent to participate in the study. Reported results have been rounded off to two decimal places.

4.2.1 Patient demographics

Demographics of the 20 patients included in the study are shown in Table 4.1.

Table 4.1 Patient demographics

Demographic	Mean (SD)	Min	Max
Age (years)	48 (19)	20	80
Height (cm)	167 (10)	150	178
Weight (kg)	72 (14)	43	103
Body Mass Index (kg/cm^2)	26 (4)	19	31
Urea concentration (mmol/L)	23 (6)	14	38

Creatinine concentration (µmol/L)	858 (256)	421	1277

4.2.2 Gastric volumes

To aid understanding of the results to follow, a few definitions used in this study have been repeated.

Qualitative assessment: The sonographic appearance of the gastric antrum made using a three point grading system (22).

- **Grade 0**: The antrum is assumed to be empty. The anterior and posterior walls are adjacent to one another and no fluid can be visualised in either the supine or the lateral decubitus position.
- **Grade 1**: The antrum is assumed to contain a volume of fluid within the "safe" range (less than 0.8ml/kg). The fluid can only be visualized in the lateral decubitus position and not in the supine position.
- **Grade 2**: These patients may be considered at risk of perioperative pulmonary aspiration (volume greater than 0.8ml/kg). The gastric antrum is distended in both the supine and the lateral positions. If the distended lumen is hypoechoic it contains fluid. If it has a frosted glass appearance it contains solid contents.

Empty Stomach:

- volume of gastric contents not exceeding 0.4 ml/kg body weight or
- Grade 0 appearance on ultrasound

Not at increased risk of PPA:

- volume of gastric contents greater than 0.4 ml/kg but less than 0.8 ml/kg and
- Grade 1 appearance on ultrasound.

At risk of PPA:

- gastric contents which exceed 0.8 ml/kg or
- Grade 2 appearance on ultrasound

Once the CSA was known the gastric volumes were calculated using the following equation: Volume = 27.0 + 14.6 × Right lateral CSA – 1.28 × age.

The primary objective of this study was to quantify the RGVs, after an overnight fast, of patients who are on a haemodialysis program by means of ultrasound assessment of the gastric antrum.

The RGVs will be quantified by:

1. Calculating the total volume of the stomach in mls.
2. Calculating the relative volume of the stomach in ml/kg.
3. Qualitative assessment using the grading system.

The calculated gastric volumes are presented in Table 4.2

Table 4.2 Calculated gastric volumes

	Mean (SD)	Min	Max	95% Confidence interval
Right lateral CSA of the gastric antrum (cm^2)	4.04 (1.25)	2.23	6.91	3.45 – 4.63
Total volume (ml)	25.91 (13.78)	0	52.65	19.46 – 32.36
Relative volume (ml/kg)	0.37 (0.21)	0	0.88	0.28 – 0.47

The total gastric volumes for the 20 participants are shown in Figure 4.1

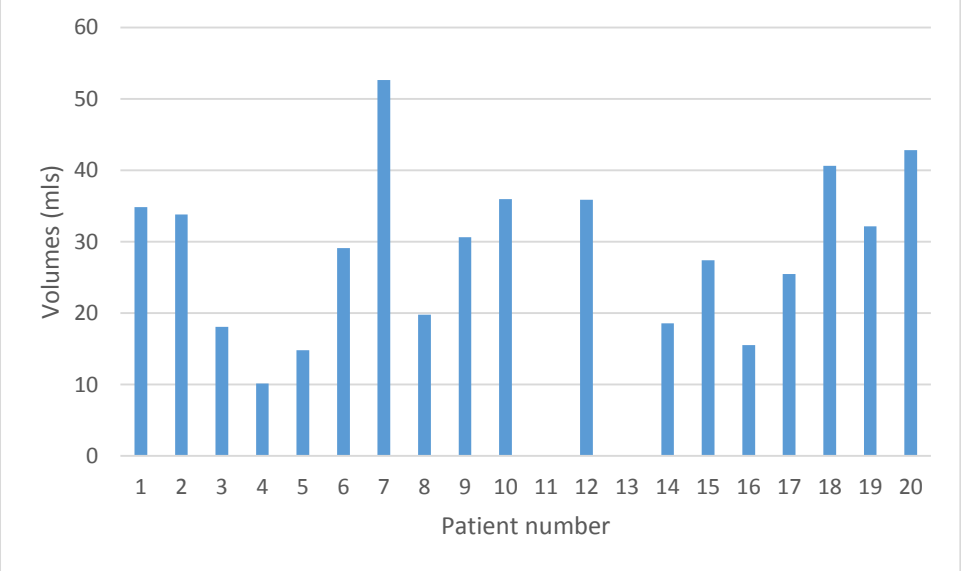


Figure 4.1 Total gastric volumes

The relative gastric volumes of the 20 patients are shown in Figure 4.2

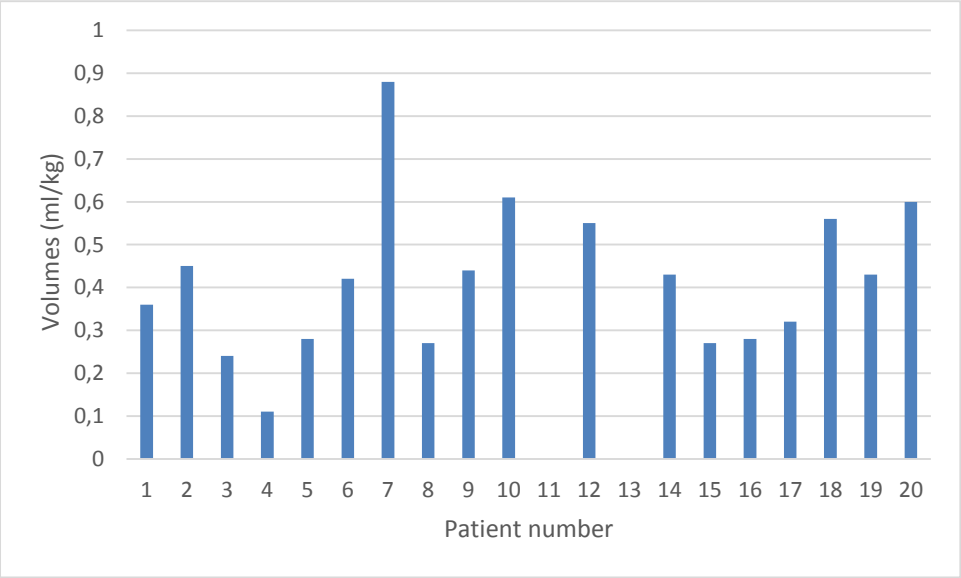


Figure 4.2 Relative gastric volumes

In order to further group the patient risk of PPA, relative gastric volumes were divided into

- those less than 0.4 ml/kg
- those between 0.4 and 0.8 ml/kg
- those greater than 0.8 ml/kg

Ten patients had volumes less than 0.4 ml/kg. Nine patients had volumes greater than 0.4ml/kg and less than 0.8 ml/kg. One patient had a volume greater than 0.8ml/kg

Qualitative assessment of gastric volumes:

Three of the patients (15%) were assessed as Grade 1. The other 17 patients (85%) were assessed as Grade 0. None of the patients were assessed as Grade 2.

The calculated gastric volumes of the three patients assessed as Grade 1 were 0.60 ml/kg; 0.56 ml/kg and 0.27 ml/kg.

The one patient that had a calculated gastric volume of 0.88 ml/kg was graded qualitatively as grade 0.

Once the volumes of the gastric antrums were known and the appearance graded, patients are grouped into one of the three categories:

- Empty stomach
- Not at increased risk of PPA
- At risk of PPA

Seventeen patients (85%) were grouped as empty stomachs. Three patients (15%) were grouped as not at risk of PPA. No patient was at risk of PPA.

4.2.3 Gastrointestinal symptoms

The first secondary objective was to describe the gastrointestinal symptoms of the patients.

A history of gastrointestinal symptoms was obtained as would be done on a routine anaesthetic preoperative interview. Patients were asked about heartburn, nausea and vomiting, abdominal bloating and early satiety. Twelve patients (60%) were found to have gastrointestinal symptoms.

Heartburn

Two (10%) patients experienced frequent episodes of heartburn. Four (20%) patients experienced occasional mild discomfort. The other fourteen patients (70%) had no symptoms. See Figure 4.3.

Nausea and vomiting

Two (10%) patients experienced frequent nausea with vomiting. Five patients (25%) had occasional nausea. Thirteen patients (65%) had no symptoms. See Figure 4.3.

Abdominal Bloating

Two patients (10%) experienced frequent bloating. Four patients (20%) had occasional bloating. Fourteen patients (70%) did not experience bloating. See Figure 4.3.

Early Satiety

One patient (5%) frequently had early satiety. Four patients (20%) sometimes had early satiety. Fifteen (75%) never experienced this. See figure 4.3.

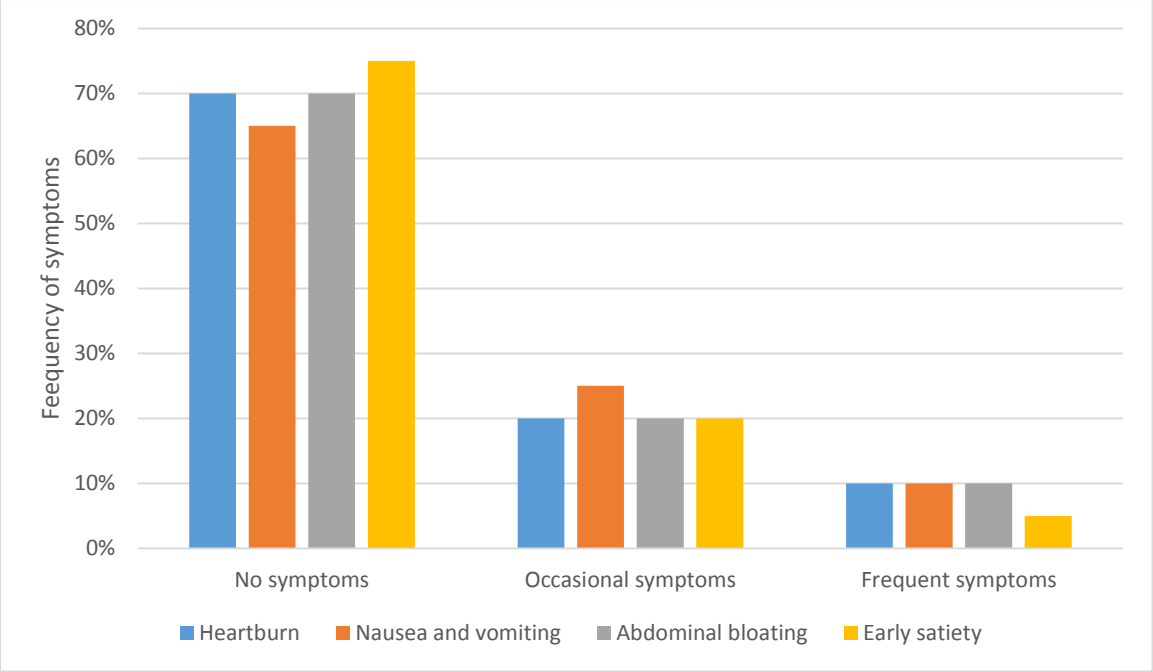


Figure 4.3 Frequency of gastrointestinal symptoms

The second secondary objective was to compare the RGVs in patients with and without gastrointestinal symptoms.

Gastric volumes were divided up into those greater than 0.4ml/kg and those less than 0.4ml/kg.

A Fisher's exact test was then performed to check for any association between gastrointestinal symptoms and gastric volumes. The two sided p value was 0.65 which is not considered significant. See Table 4.4

Table 4.3 Fisher's exact test

	Less than 0.4 ml/kg	More than 0.4ml/kg	Total
Gastrointestinal symptoms present	7 (35%)	5 (25%)	12 (60%)
Gastrointestinal symptoms absent	3 (15%)	5 (25%)	8 (40%)
Total	10 (50%)	10 (50%)	20 (100%)

P = 0.65

4.2.4 Correlation between RGVs and urea concentrations

The third secondary objective addressed was the correlation between RGVs and the urea concentrations.

This was done using Pearson Correlation Coefficient. See Figure 4.4

There was no correlation. (p = 0.43).

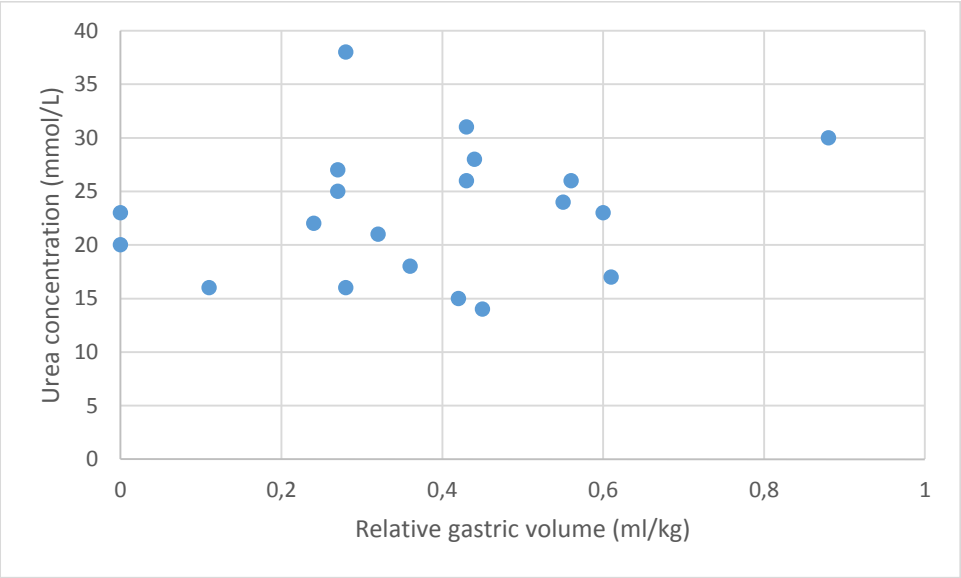


Figure 4.4 Correlation between RGVs and urea concentrations

Pearson Correlation Coefficient (r): 0.19 meaning no correlation was found.

p = 0.43 which is not significant.

4.2.5 Correlation between RGVs and creatinine concentrations

The fourth secondary objective was to correlate RGVs with creatinine concentrations.

This was done using Pearson Correlation Coefficient. See Figure 4.5

There was no correlation. (p = 0.08)

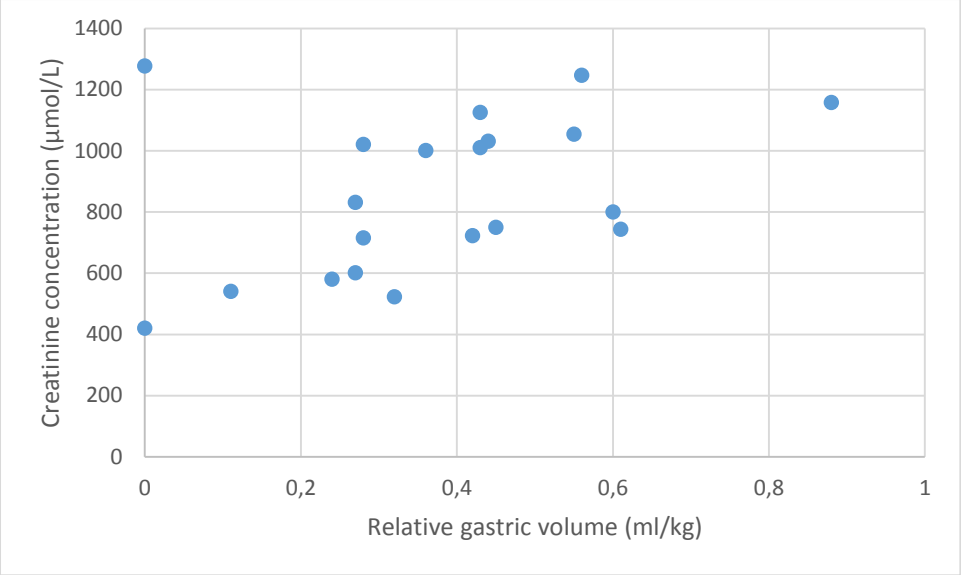


Figure 4.5 Correlation between RGVs and creatinine concentrations

Pearson Correlation Coefficient (r): 0.40 showing a weak positive relationship

p = 0.08 which is not significant

4.3 Discussion

In this study patients with CRF receiving chronic haemodialysis were assessed for the presence of gastric content after an overnight fast. A visual assessment of the sonographic appearance of the gastric contents was performed and a grade was given. The volume of gastric content was calculated and the risk of PPA was evaluated.

All 20 patients included in the study were not considered to be at an increased risk of PPA. These finding are consistent with those of previous studies in which patients receiving haemodialysis were shown to have normal gastric emptying. (9, 20)

Patients with CRF, not on dialysis, have been found to have delayed gastric emptying and decreased gastric motility (52). There is a study showing that patients not yet receiving haemodialysis have delayed gastric emptying compared with those who were receiving haemodialysis (8). An improvement in gastric emptying and gastric motility has been found in patients being dialysed (55). There is however conflicting evidence which suggests that both subgroups have delayed gastric emptying (21). One study included 56 patients all receiving haemodialysis and compared them to a healthy control group; they found gastric emptying to be significantly delayed in the CRF group (48).

Delays in gastric emptying associated with CRF are believed to be due to a multitude of aetiologies. (40, 41) Through the correction of some of the electrolyte

abnormalities and removal of uraemic toxins, haemodialysis may improve gastric emptying and motility. Haemodialysis does not however appear to remove gastrointestinal hormones involved in gastric emptying (44).

The patients in this study were all fasted for a minimum of eight hours prior to assessment of their gastric contents. In the literature reviewed, gastric emptying times were assessed and although prolonged in some studies the actual fasting volume does not seem to have been evaluated (8, 9, 21, 48).

In our study, when the appearance of the gastric antrum was assessed by the radiologist, seventeen patients were considered Grade 0, three were Grade 1 and none of the patients were considered as Grade 2. Thus no patients were at risk of PPA. This is in conflict with current teaching. (5)

The gastric volumes were calculated based on the equation validated by Perlas et al (17). Ten patients (50%) had gastric volumes less than 0.4ml/kg, nine patients (45%) had gastric volumes of between 0.4 ml/kg and 0.8 ml/kg, one patient (5%) had a gastric volume of greater than 0.8 ml/kg. The patient with the gastric volume of 0.88 ml/kg (52 mls) was 20 years old and the equation which calculated the gastric volume has age as a co-variant, calculating higher gastric volumes in younger patients. A patient with the same CSA of the gastric antrum who was 70 years old would have had a calculated volume of less than 10 mls. (30) In this particular case the radiologist graded the gastric antrum as Grade 0, having visualized no fluid within the stomach. This discrepancy may be due to small amounts of air in the stomach or a thicker antral wall. The diameters of the gastric antrum are measured from serosa to serosa, therefore an antrum that is totally empty is expected to have a CSA that is more than 0, corresponding to the thickness of the gastric wall (usually in the order of 2–5 cm^2). (17)

Patients were questioned about specific gastrointestinal symptoms and the frequency thereof. In total twelve patients reported experiencing at least one of the symptoms asked about. There was no association between gastric volumes and gastrointestinal symptoms. This is consistent with the findings of Strid (10). However there are conflicting finding in Van Vlems' study which reflected significant delays in gastric emptying in patients with dyspeptic symptoms. (7) We were not however measuring the gastric emptying times in our study, so it is possible that while there may be delays in gastric emptying, once fasted, the gastric volumes of the patients in our study were not high enough to place patients at risk of PPA. An overnight fast may provide sufficient time for the stomach to empty despite the delays in gastric emptying described in the literature. (21, 48) Since, in the fasted state, none of the patients had gastric volumes that were considered raised it was difficult to say whether raised gastric volumes were associated with dyspeptic symptoms.

The final objectives in our study were to correlate the RGVs with both the urea and the creatinine levels. The mean urea concentration was 23 mmol/l with a range from

14 to 38 mmol/l. No correlation was found between RGVs and urea concentrations. Similarly no correlation was found between RGVs and creatinine concentrations. When the literature was reviewed no reference to correlations between RGVs and urea or creatinine levels could be identified.

4.4 Summary

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

The final chapter will provide a summary of the study, including its limitations recommendations and conclusions.

Chapter 5: Summary, limitations, recommendations and conclusion

5.1 Introduction

In this chapter a summary of the study will be provided followed by a discussion of the limitations of the study. The clinical recommendation and recommendations for future research that became apparent during the course of this study will be discussed. Lastly the conclusion of the study will be presented.

5.2 Summary of the study

Aim of the study

The aim of this study was to determine whether patients who are on a chronic haemodialysis program have sufficient residual gastric contents after an overnight fast, to place them at risk of pulmonary aspiration of gastric contents during anaesthesia.

Objectives of the study

The primary objective of this study was to quantify the RGVs, after an overnight fast, of patients who are on a haemodialysis program by means of ultrasound assessment of the gastric antrum.

The secondary objectives of this study were to:

- describe the gastrointestinal symptoms of the patients
- compare the RGVs in patients with and without gastrointestinal symptoms
- correlate RGVs with the urea concentrations
- correlate RGVs with the creatinine concentrations.

Methodology of the study

All patients who met the inclusion criteria in the dialysis unit were identified. Once they had consented to participate in the study the researcher asked about gastrointestinal symptoms and blood results for urea and creatinine concentrations were taken from their files.

An ultrasound was scheduled for a morning on which the patient was due to come in for a morning dialysis session and the patient was asked to take nothing by mouth

from bedtime or midnight the night before. The appearance of the stomach and the contents were graded by the radiologist and the diameters of the gastric antrum were then measured so that the CSA could be calculated.

Once the CSA was known the gastric volume was calculated using a validated equation. These volumes where then divided by the patients weight to get the relative gastric volume in ml/kg. The risk of PPA was then assessed according to the graded appearance of the stomach as well as calculated gastric volumes. A cut off value of 0.8 ml/kg was used as a relative gastric volume that would place the patient at increased risk of perioperative pulmonary aspiration. Any patient with a gastric antrum found to be distended in both the supine and lateral positions was assessed as Grade 2 placing them at increased risk of PPA. All data was then entered onto a data collection sheet.

A Fisher's exact test was performed to check for any possible associations between gastrointestinal symptoms and RGVs. A Pearson correlation was used to correlate both urea and creatinine levels with RGVs.

Main findings of the study

In our study none of the patients were assessed as being at risk of PPA. The assessment of the gastric antrum by the radiologist in which the appearance of the stomach was graded, found none of the patients to have a significant amount of fluid or any solid contents. 85% of the patients had completely empty stomachs and 15% had a small amount of fluid considered to be within the normal range. In all patients the gastric antrum was adequately visualised.

In the three patients where some fluid was visualized, the calculated gastric volumes all fell below the threshold of 0.8 ml/kg considered to place them at risk of PPA.

Gastrointestinal symptoms were found in in 60% of patients. There was no association between gastrointestinal symptoms and RGVs.

There was no correlation between either urea or creatinine concentrations and RGVs.

5.3 Limitations of the study

The generalisability of this study should be viewed with certain limitations in mind.

This study was done contextually in a single dialysis unit at a private hospital and the results may not be generalised to other hospitals.

This was a pilot study with a small number of patients, and although it provides us with valuable insight it may be underpowered. The secondary objectives should be interpreted with caution.

Due to the fact that 85% of the patients had empty stomachs, the comparisons to gastrointestinal symptoms and correlations to urea and creatinine concentrations should also be interpreted with caution.

Although RGVs were assessed, the pH of the gastric contents is considered an important contributing factor to morbidity following an episode of PPA and this was not tested due to the invasive nature of the test.

Fasting periods were not uniform amongst patients with a minimum of eight hours but some patients may have been fasted for up to 14 hours depending on when they went to bed. Exact fasting times for individual patients were not recorded.

Assessment of autonomic function is an important factor related to aspiration risk in patients with CRF. Autonomic dysfunction was not assessed in the patients in our study.

There is controversy as to the value for residual gastric volumes that would place a patient at increased risk for PPA, with values of 0.8ml/kg quoted in the literature (61) as well as values of 1.5ml/kg (29). The threshold value for aspiration risk used in our study was chosen as 0.8ml/kg and not 1.5ml/kg due to the fact all patients our study had a calculated value for RGV's that was less than 1.5ml/kg.

5.4 Recommendations from this study

5.4.1 Recommendations for clinical practice

Anaesthetists should not make assumptions about the risk of PPA in patients with CRF. A patient with CRF on chronic haemodialysis presenting for anaesthesia following a fast of greater than 8 hours does not necessarily have RGVs that would place them at risk of PPA. There are other risk factors for PPA and each patient should be assessed individually. Although the airway should still be protected during most surgical procedures RSI may not be necessary. When in doubt about the risk of PPA in a particular patient bedside ultrasound by an experienced operator may provide a quick, easy and reliable assessment of the gastric contents.

The presence of gastrointestinal symptoms does not correspond to a raised RGV after an overnight fast. The urea and creatinine levels also show no correlation to RGVs.

The use of ultrasound to assess the gastric contents and therefore the risk of PPA should be considered in the perioperative setting, particularly in the emergency situation where fasting times have not been adhered to, as well as in patients

considered to be at high risk of PPA. Ultrasound evaluation of gastric contents may lead to prevention of unnecessary delays and cancellations of cases where there is doubt about fasting status of a patient. Where a full stomach is found preoperatively the risk/benefit of preceding can be assessed and methods of reducing the risk of PPA can be put into place. Training in the use of ultrasound to assess the gastric antrum by anaesthesiologists would be invaluable.

5.4.2 Recommendations for further research

A similar study in patients not yet receiving haemodialysis in order to assess whether the RGVs are greater than those on our study.

Evaluation of gastric contents using bedside ultrasound prior to induction of anaesthesia in the elective and emergency situation in order to assess risk of PPA in all patients.

Since this is a pilot study, a larger sample size would yield more powerful results, especially with regard to the secondary objectives. A future well designed multicentre study investigating the same parameters as our study in patients with ESRD. This study would need to be well powered and would need collaboration from different centers nationally and internationally.

A similar study which included the assessment of autonomic function would be valuable.

5.5 Conclusion

In this study patients with CRF on a haemodialysis program were not found to have RGVs, once fasted, that would place them at increased risk of PPA.

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Appendices

Appendix 1: Permission from Ethics Committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Natalie Burger

CLEARANCE CERTIFICATE	**M120115**
PROJECT	Residual Gastric Volumes in Patients Receiving Chronic Haemodialysis After an Overnight Fast
INVESTIGATORS	Dr Natalie Burger.
DEPARTMENT	Department of Anaethesiology
DATE CONSIDERED	27/01/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 27/01/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Ms Helen Perrie

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix 2: Permission from Postgraduate Committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

04 March 2015

Dr N Burger
Postnet Suite 182
P/Bag X19
Gardenview
2047
South Africa

Person No: 9904454J
TAA

Dear Dr Burger

Master of Medicine: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Medicine** has been approved:

From:

To: **Residual gastric volumes in patients receiving chronic haemodialysis after an overnight fast -A pilot study**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 3: Permission from private hospital

RESEARCH OPERATIONAL COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2013-0006

Dr Natalie Burger

E mail: natalieburger@hotmail.com

Dear Dr Burger

RE: RESIDUAL GASTRIC VOLUMES IN PATIENTS RECEIVING CHRONIC HEMODIALYSIS AFTER AN OVERNIGHT FAST

The above-mentioned research was reviewed by the Research Operational Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Private Hospital, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Committee.

ii) All information with regards to Company will be treated as confidential.

iii) Company's name will not be mentioned without written consent from the Committee.

iv) All legal requirements with regards to patient rights and confidentiality will be complied with.

v) Insurance will be provided and maintained for the duration of the research. This cover provided to the researcher must also protect both the staff and the hospital facility from potential liability

vi) In accordance with MCC approval, that medicine will be administered by or under direction of the authorised Trialist

vii) The research will be conducted in compliance with the GUIDELINES FOR GOOD PRACTICE IN THE CONDUCT OF CLINICAL TRIALS IN HUMAN PARTICIPANTS IN SOUTH AFRICA (2000)

viii) Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

ix) A copy of the research report will be provided to Company once it is finally approved by the tertiary institution, or once complete.

x) Company has the right to implement any Best Practice recommendations from the research.

xi) Company reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/Netcare or should the researcher not comply with the conditions of approval.

xii) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER.

We wish you success in your research.

Yours faithfully

Prof Dion du Plessis
Full member: Research Operational Committee & Medical Practitioner evaluating research applications as per Company Policy

Shannon Nell
Chairperson: Research Operational Committee
Date: 15/3/2013

This letter has been anonymised to ensure confidentiality in the research report. The original letter is available with author of research

Appendix 4: Patient information letter

Hello.
My name is Dr Natalie Burger. I am an anaesthetic doctor currently training at the Charlotte Maxeke Johannesburg Academic Hospital.

I would like to invite you to be part of a study that I will be conducting over the next few months at the xxx hospital haemodialysis unit.

The reason for the study is that many patients who have got chronic renal failure experience some stomach symptoms such as nausea or heartburn. One of the possible reasons for this is that the stomach does not empty as quickly as it should, after eating a meal.

I am interested in whether the stomach is empty in the morning after around ten hours without food. As an anaesthetic doctor this is an important question. Patients who come to theatre for an operation usually are told not to eat anything after they go to bed at night so that their stomachs are empty on the morning of their operation. If the stomach is not empty the patient might vomit during or after the anaesthetic, which could be dangerous for the patient. If the anaesthetic doctor knows that the stomach is full they will change the way that the put the patient to sleep for the operation.

I would like to know if after a night without food (an overnight fast) there is anything left in your stomach.

If you would like to be part of this study, we will arrange for a radiologist to do an ultrasound on your stomach when you come in for one of your dialysis sessions. This will be free of charge. I will ask you please not to have anything to eat or drink in the morning before you come to the hospital so that the results are accurate. After the ultrasound you will be provided with a meal in the dialysis unit.

The ultrasound will take place in the radiology department before your dialysis session. It involves putting some special jelly on your abdomen and then the radiologist will put a probe on your abdomen which will show a picture of your stomach. The ultrasound should not take more than ten minutes and is completely safe.

I will also perform ask you a few questions to find out if you experience any nausea, heartburn or bloating of the stomach.

Lastly I would ask your permission to look at your most recent kidney function blood tests, which should be on record at the hospital.

All information gathered during the study will be kept in a safe place and only the people working on the research will have access to it. Your name will not appear anywhere.
If you would like to be part of my study I will ask you to sign a consent form. You may withdraw at any point if you wish.
If you have any questions please contact myself or Prof Cleaton Jones.
My cell number is 084 226 3334 and you can contact Prof Cleaton-Jones on 011 717 2301
Prof Cleaton- Jones is Chairperson of the Wits university Human research ethics committee.

Thank you for taking the time to hear about my study.
Dr Natalie Burger

Appendix 5: Consent form

Informed consent

I,_____, agree to participate in the study that Dr Burger has explained to me.

Dr Burger has provided me with an information sheet, detailing the purpose of the study and how the study will be performed.

I understand that I will be asked to fast overnight.

I understand that I will have an ultrasound of my stomach.

I understand that Dr Burger will ask me some questions and examine me clinically.

I give Dr Burger permission to take blood results from my file.

I understand that I may withdraw from the study at any point and I have a contact number for Dr Burger.

_____

Participant Signature Date

_____

Researcher Signature Date

Appendix 6: Data collection Sheet

Data collection sheet

1. Patient Information

Patient study Number

Age

Weight

Height

2. Interview on Gastrointestinal symptoms

2.1 Heartburn or acid reflux

Heartburn occurs when the lower oesophageal sphincter (the muscular ring that acts as a valve between the stomach and the oesophagus) relaxes and allows stomach contents and acid to flow back from the stomach into the oesophagus.

This may be felt as a burning sensation in the chest or the upper abdomen. The burning sometimes radiated to the back. If the acid reaches the mouth it may taste sour or burn the throat.

0 Never experience Heartburn

1 Occasional mild discomfort, relieved by over the counter medications such as Rennies or other antacids. Occurs less than once a week.

2 Frequent episodes, very uncomfortable. More than once a week. Only some relief from over the counter medications. May be on prescription medications for high acid levels (reflux).

2.2 Nausea and vomiting

Nausea is the feeling that you want to vomit.

0 No symptoms of nausea

1 Occasional nausea, generally does not lead to vomiting

2 Frequent nausea. Sometimes vomiting

2.3 Abdominal Bloating

Abdominal bloating may occur normally after a large meal. The abdomen feels full and tense and may be distended and painful.

0 Never feel bloated

1 Occasional bloating, less than once a week

2 Frequent bloating, more than once a week

2.4 Early Satiety

Satiety is the feeling of being fed or gratified to or beyond the point of capacity (overfull).

During a meal, as the food reaches the stomach, there is a feeling of fullness in the stomach. The question here is does that feeling comes earlier than it should. Does this feeling of fullness prevent you from completing your meal?

0 Never

1 Sometimes

2 Always

3. Blood results

Urea

Creatinine

4.Ultrasound Findings

4.1 Qualitative findings

Gastric antrum Supine	**Grade 0**	**Grade 1**	**Grade 2**
Gastric antrum lateral	**Grade 0**	**Grade 1**	**Grade 2**

4.2 Quantitative findings

Gastric antrum supine	**AP diameter____mm**	**CC diameter____mm**	**CSA_____cm^2**
Gastric antrum lateral	**AP diameter____mm**	**CC diameter____mm**	**CSA_____cm^2**

4.3 Estimated gastric volume

Total volume_____ml

Relative volume_____ml/kg

Risk stomach **Yes** **No**